UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K

(Mark One)

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

For the Fiscal Year Ended December 31, 2023

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

For the transition period from_____ to _____

Commission File Number: 001-39070

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 if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☐ No ☒

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ☐ No ☒

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 and post 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 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 has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☐

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

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

State the aggregate market value of the voting and non-voting common equity held by non-affiliates computed by reference to the price at which the common equity was last sold, or the average bid and asked price of such common equity, as of the last business day of the registrant's most recently completed second fiscal quarter. The aggregate market value of the voting and non-voting common stock held by non-affiliates of the registrant as of June 30, 2023 was $4,608,643 based on the closing price reported for such date on the Nasdaq Capital Market.

The number of shares outstanding with respect to each of the classes of our common stock, as of March 8, 2024, is set forth below:

Class	**Number of shares outstanding**
Common stock, par value $0.001 per share	17,454,925

The documents incorporated by reference are as follows: None.

MONOPAR THERAPEUTICS INC.
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Forward-Looking Statements

This Annual Report on Form 10-K 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 Annual Report on Form 10-K are forward-looking statements. The words "hopes," "believes," "anticipates," "plans," "seeks," "estimates," "projects," "expects," "intends," "may," "could," "should," "would," "will," "continue," and similar expressions are intended to identify forward-looking statements. The following uncertainties and factors, among others, could affect future performance and cause actual results to differ materially from those matters expressed in or implied by forward-looking statements:

- our ability to raise sufficient funds within the next 12 months in order for us to support continued clinical development of MNPR-101 for radiopharmaceutical use in advanced cancers, and if supported by positive data from the ongoing Phase 1b dose escalation study, continue the clinical development of camsirubicin and preclinical development of MNPR-202 and related compounds; as well as our ability to further raise additional funds in the future to support any future product candidate programs through completion of clinical trials, and our current and future product candidate programs through the approval processes and, if applicable, commercialization;
- our ability to regain compliance with the Nasdaq listing standards requiring our stock closing bid price to be at least $1.00 for at least 10 consecutive trading days (and potentially up to 20) by August 26, 2024, and, in the event it is necessary to effect a reverse stock split to attempt to cure the bid price deficiency, the uncertain impact on our stock price, or if more time is needed, our ability to win an appeal to Nasdaq requesting additional time;
- 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 our 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 new radiopharmaceutical therapeutics and imaging agents;
- estimated timeframes for our clinical trials and regulatory reviews for approval to market products are uncertain;
- our ability to address the fulfillment and logistical challenges posed by the potential time-limited shelf-life of our current radiopharma 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, as such supply may be impacted by the ongoing wars between Russia-Ukraine, Israel-Hamas and other uncertain economic and market effects;
- 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;

Forward-Looking Statements (continued)

- 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 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 or the Israel-Hamas war on our clinical material manufacturing expenses and timelines, as well as on general 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 Annual Report on Form 10-K, 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 Annual Report on Form 10-K or elsewhere, including without limitation any forward-looking statements, except as required by law.

Any forward-looking statements in this Annual Report on Form 10-K 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" located elsewhere in this Annual Report on Form 10-K. These risks include, among others, the following:

- We are a clinical stage biopharmaceutical company with a history of financial losses. We expect to continue to incur significant losses for the foreseeable future and may never achieve or maintain cash self-sufficiency or profitability, which could result in a decline in the market value of our common stock.

- Funds raised to date are not sufficient to support clinical development of MNPR-101 for radiopharmaceutical use in advanced cancers beyond the planned Phase 1 clinical trial and, if supported by positive data from the ongoing Phase 1b dose escalation study, continue the clinical development of camsirubicin and preclinical development of MNPR-202 and related compounds. If we are unable to raise enough funds within the next 12 months from the sale of our common stock or other financing efforts, or conclude a strategic agreement or collaboration such as out-licensing our product candidates, or enter into a clinical or commercial partnership, we will likely have to prioritize and/or terminate one or more programs. There can be no assurance that we will be able to secure such financing or find a suitable development partner on satisfactory terms.

- The termination of our Validive clinical trial at the end of March 2023 resulted in a decrease in our stock price. The closing bid price of our stock fell below $1.00 for more than 30 consecutive trading days and on August 28, 2023, we received a notice from Nasdaq stating that we were out of compliance with Nasdaq listing standards giving us 180 days to regain compliance. On February 27, 2024, we received a notice from Nasdaq granting us an additional 180-day period to regain compliance. If we do not regain compliance by August 26, 2024 or win an appeal to extend the deadline, we would face delisting or needing to do a reverse stock split and it may have serious adverse consequences on our stock price and our ability to raise funds, which may cause us to delay, restructure or otherwise reconsider our operations. If it is necessary to effect a reverse stock split to attempt to cure the bid price deficiency, the impacts on our stock price are uncertain and could be adverse.

- 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 program.

Summary Risk Factors (continued)

- 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 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 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 effects of economic and political pressure to lower pharmaceutical prices are a major threat to the economic viability of new research-based pharmaceutical products, and any significant decrease in drug prices could materially and adversely affect the financial appeal of our products and prospects for us to raise additional 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

Item 1. Business

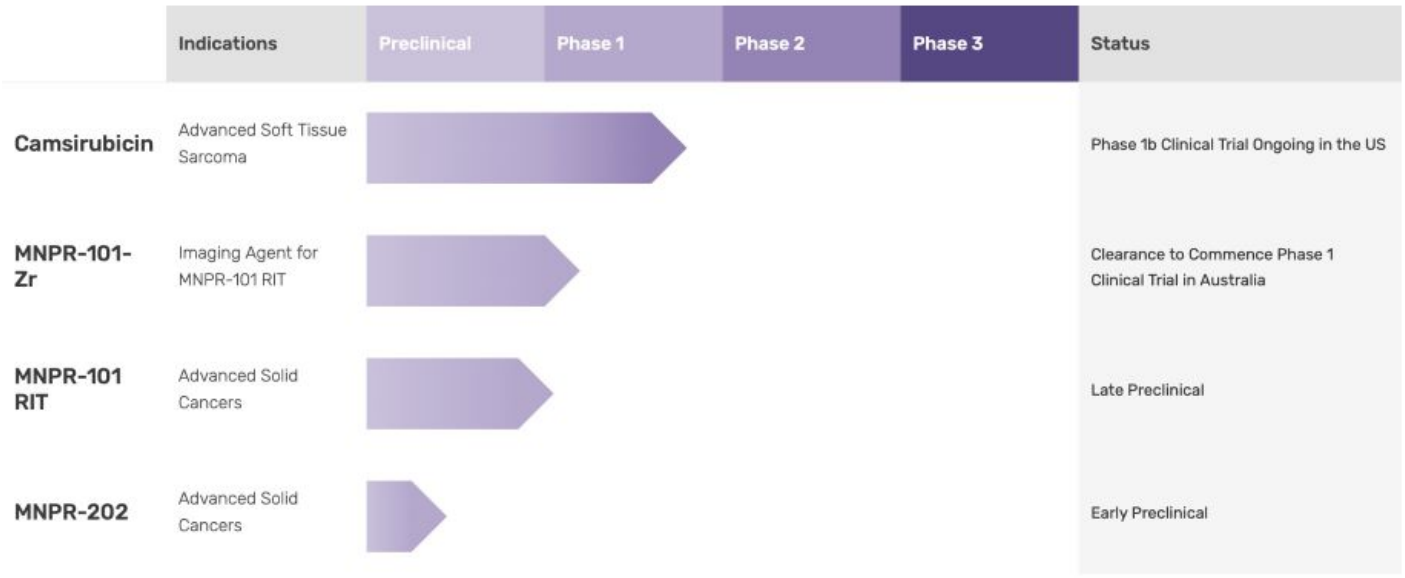
You should read the following discussion in conjunction with our financial statements as of December 31, 2023, and the notes to such financial statements included elsewhere in this Annual Report on Form 10-K.

Overview

We are a clinical stage biopharmaceutical company focused on developing innovative treatments for cancer patients. We are building a drug candidate pipeline through in-house development as well as the licensing and acquisition of therapeutics in late preclinical and in clinical development stages. We leverage our scientific and clinical experience to help reduce the risk and accelerate the clinical development of our drug product candidates.

We currently have several compounds in development: 1) MNPR-101-Zr, a clinical stage uPAR-targeted radiodiagnostic imaging agent; 2) MNPR-101-RIT, a late preclinical stage radiotherapeutic for advanced cancers; 3) camsirubicin (generic name for MNPR-201, GPX-150; 5-imino-13-deoxydoxorubicin), a Phase 1b clinical stage novel analog of doxorubicin engineered specifically to retain anticancer activity while minimizing toxic effects on the heart; and 4) an early stage camsirubicin analog, MNPR-202, for various cancers.

Our Product Pipeline



Our Product Candidates

MNPR-101 for Radiopharmaceutical Use

Our MNPR-101 radiopharmaceutical program was developed by us for advanced cancers expressing urokinase plasminogen activator receptor ("uPAR"). This proprietary, novel first-in-class radiopharmaceutical program aims to identify and selectively kill the tumors expressing uPAR, which include a majority of triple-negative breast, colorectal, and pancreatic cancers. The program uses MNPR-101, our proprietary humanized monoclonal antibody targeting uPAR, as a means to accurately deliver radioisotope payloads to the tumors. We have demonstrated promising preclinical data to-date for our MNPR-101 radiopharmaceutical program. Positron emission tomography (“PET”) imaging data of preclinical human tumor xenograft mouse models for triple-negative breast, colorectal, and pancreatic tumors expressing uPAR display high, selective and durable uptake of MNPR-101 conjugated to the imaging radioisotope zirconium-89 ("MNPR-101-Zr"). Additionally, preclinical triple-negative breast and pancreatic cancer mouse model studies with MNPR-101 conjugated to therapeutic radioisotopes ("MNPR-101-RIT") have shown promising anti-tumor activity. Overall, the preclinical imaging and therapeutic efficacy study results demonstrate the potential utility of MNPR-101 as a precision targeting radiopharmaceutical agent for both imaging and therapy in multiple cancer indications. We are actively working towards enrolling our Phase 1 dosimetry clinical trial in Australia for MNPR-101-Zr in patients with advanced cancer.

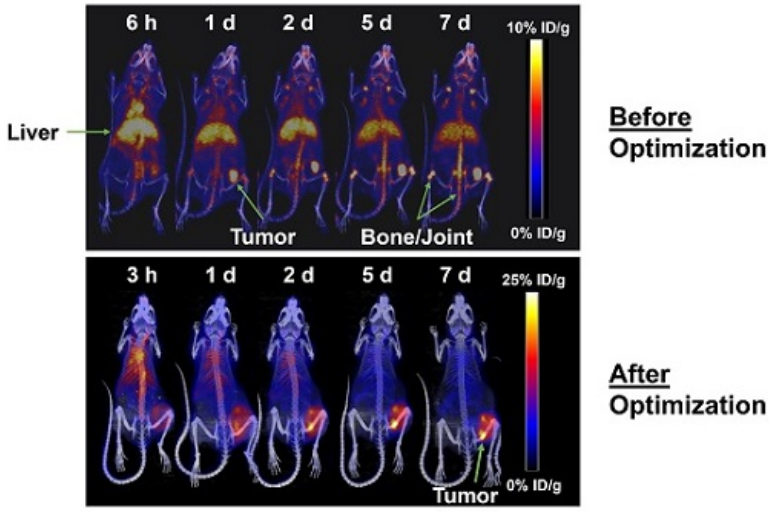
MNPR-101 is designed to selectively bind to uPAR. uPAR is highly expressed in multiple types of tumors, including breast, pancreatic, and colorectal cancers but not on most normal cells. It is estimated that the tumors and/or tumor associated cells in 97% of breast, 89% of bladder, 87% of pancreatic and 85% of colorectal cancer patients express uPAR. Moreover, several Phase 1 PET imaging studies in advanced cancer patients show that uPAR can only be detected in the tumor and not in normal tissues, making it a potentially attractive target for cancer therapies, including radiopharmaceuticals.

In February 2024, we received Human Research Ethics Committee (HREC) clearance in Australia to commence our Phase 1 dosimetry trial for MNPR-101-Zr in patients with advanced cancers. The trial will utilize total body PET/CT ("positron emission tomography–computed tomography") imaging to assess tumor uptake, normal organ biodistribution, and safety. The study will be conducted at Melbourne Theranostic Innovation Centre ("MTIC")headed by Professor Rodney Hicks, MBBS(Hons), MD, FRACP, FICIS, FAAHMS, and will use one of the world's most sensitive clinical total-body PET/CT scanners, the Siemens Biograph Vision Quadra, to image the targeting ability of MNPR-101-Zr in cancer patients. If the tumor uptake, biodistribution, and safety look encouraging in this Phase 1 clinical trial, which is anticipated to enroll approximately 12 patients, we plan to evaluate the efficacy in humans of a therapeutic version of MNPR-101 radiolabeled with an isotope such as actinium-225 ("Ac-225" or "Ac").

Overview of Preclinical Development

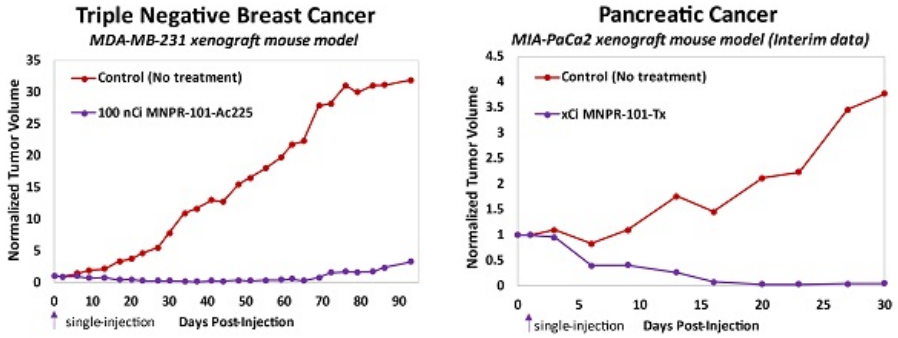
In February 2024, we announced promising preclinical data for MNPR-101 radiopharmaceutical imaging and therapeutic agents demonstrating highly selective and durable uptake in uPAR expressing tumors and potent anti-tumor effects in human tumor xenograft mouse models. Maximizing the dose delivered to the tumor relative to normal tissue is of paramount importance in radiopharmaceutical therapy. **Figure 1** below shows the before and after optimization of MNPR-101-Zr. MNPR-101-Zr is a zirconium-89 labeled version of MNPR-101 that is being developed as a radiopharmaceutical imaging agent for advanced solid tumors expressing uPAR. Monopar's in-house radiopharmaceutical development team was able to significantly increase tumor uptake of MNPR-101-Zr while minimizing uptake in healthy tissue, as shown in this preclinical PET sequential imaging time-series. The high specificity and durable tumor uptake are evident in the *After Optimization* panel below.

Figure 1. Pancreatic Cancer (MIA PaCa-2) Tumor Xenograft



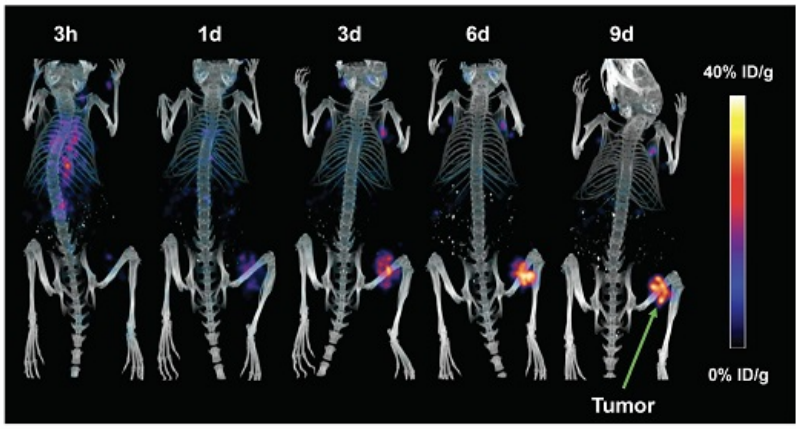
Preclinical data to date demonstrate compelling and durable anti-tumor benefits with MNPR-101 conjugated to therapeutic radioisotopes. **Figure 2** below shows preclinical efficacy data in triple negative breast cancer (left) and pancreatic cancer (right) human tumor xenograft mouse models utilizing two different therapeutic radioisotopes conjugated to MNPR-101; one of these radioisotopes has already been disclosed as being Ac-225. The results in both show near complete elimination of the tumor after a single injection of the radiopharmaceutical agent. These studies demonstrate the potential of a MNPR-101 based radiopharmaceutical to provide a very meaningful clinical benefit to cancer patients.

Figure 2. Tumor Efficacy Studies



To visualize the biodistribution of a therapeutic radioisotope conjugated to MNPR-101, lutetium-177 ("Lu-177") was used. The results of a sequential SPECT ("single-photon emission computed tomography") imaging time-series utilizing MNPR-101 conjugated to Lu-177 ("MNPR-101-Lu") can be seen in **Figure 3**. High specificity and durable uptake of MNPR-101-Lu in the tumor relative to normal tissue is readily apparent, and help explain the near complete elimination of tumors observed after a single injection of therapeutic radioisotopes bound to MNPR-101.

Figure 3. Biodistribution of Therapeutic Radioisotope Lu-177 Conjugated to MNPR-101 in Pancreatic Cancer (MIA PaCa-2) Tumor Xenograft



Camsirubicin (5-imino-13-deoxydoxorubicin; formerly MNPR-201, GPX-150)

Camsirubicin is a novel analog of doxorubicin which has been designed to reduce the cardiotoxic side effects generated by doxorubicin while retaining effective anti-cancer activity. A previous Phase 2 clinical trial for camsirubicin dosed up to 265 mg/m^2 per cycle was completed in patients with advanced (e.g., unresectable or metastatic) soft tissue sarcoma ("ASTS"). Average life expectancy for these patients is 12-15 months. In this previous study, 52.6% of patients evaluable for tumor progression demonstrated clinical benefit (partial response or stable disease), which was proportional to dose and consistently observed at higher cumulative doses of camsirubicin (>1000 mg/m^2). Camsirubicin was very well tolerated in this study and underscored the ability to potentially administer camsirubicin without restriction of cumulative dose in patients with ASTS. Although doxorubicin has been the standard of care treatment for ASTS for over 40 years, doxorubicin is limited to a lifetime cumulative dose maximum of 450 mg/m^2 due to the risk of causing irreversible cardiotoxicity. Even if a patient is responding to doxorubicin, therefore, their treatment is discontinued once this lifetime cumulative dose has been reached.

In contrast to doxorubicin, camsirubicin is selective for topoisomerase II-alpha. Doxorubicin is used to treat adult and pediatric solid and blood (hematologic) cancers, including soft tissue sarcomas, breast, gastric, ovarian and bladder cancers, leukemias and lymphomas. Despite clinical studies demonstrating the anti-cancer benefit of higher cumulative doses of doxorubicin, the clinical efficacy of doxorubicin has historically been limited by the risk of patients developing irreversible, potentially life-threatening cardiotoxicity. For example, several clinical studies completed in the 1990s demonstrated that concurrent doxorubicin (60 mg/m^2, 8 cycles) and paclitaxel gave a 94% overall response rate in patients with metastatic breast cancer but led to 18% of these patients developing congestive heart failure. Reduction of doxorubicin to 4-6 cycles of treatment decreased the incidence of congestive heart failure, but also reduced response rates to 45-55%. In a clinical study looking at dose response, sarcoma patients on the high dose (75 mg/m^2) doxorubicin had a response rate of 37% compared to just 18% in the low dose (45 mg/m^2) doxorubicin group. With the cumulative dose restriction on doxorubicin, the median progression free survival for ASTS patients is approximately 6 months, with median overall survival of 12-15 months. There is a significant unmet opportunity to develop a replacement for doxorubicin that can be dosed higher and for longer to improve anti-tumor activity.

Camsirubicin has been engineered specifically to retain the anticancer activity of doxorubicin while minimizing its toxic effects on the heart. Similar to doxorubicin, the antitumor effects of camsirubicin are mediated through the stabilization of the topoisomerase II complex after a DNA strand break and DNA intercalation leading to tumor cell apoptosis (cell death). Inhibiting the topoisomerase II-alpha isoform is desired for the anti-cancer effect, while inhibiting the topoisomerase II-beta isoform has been demonstrated to mediate, at least in part, the cardiotoxicity associated with all anthracycline drugs currently used in the clinic. Camsirubicin is substantially more selective than doxorubicin for inhibiting topoisomerase II-alpha versus topoisomerase II-beta. This selectivity may partly explain the minimal cardiotoxicity that has been observed for camsirubicin in preclinical and clinical studies to date. We believe that these attributes provide a strong rationale for developing camsirubicin as a monotherapy as well as in combination with other anticancer agents, without potential restrictions on cumulative dose, and offer the opportunity to pursue a large market opportunity for camsirubicin in a broad spectrum of cancer types.

Camsirubicin Clinical Data

Two clinical studies of camsirubicin have been completed and one is currently ongoing.

In October 2013, a Phase 1 dose escalation study conducted at the University of Iowa completed enrollment of 24 patients who received one of eight different dose levels of camsirubicin ranging from 14 to 265 mg/m^2. No evidence of irreversible cardiotoxicity was observed in any of these patients, including 4 patients who received prior anthracycline (doxorubicin or related molecules) treatment. Stable disease was observed in 55.0% of patients in this Phase 1 study, including 3 out of 4 patients with leiomyosarcoma, which is a type of soft tissue sarcoma that originates in connective tissue and smooth muscle most commonly in the uterus, stomach and small intestine. No growth factor support (G-CSF) was given to patients, and the limiting toxicity was neutropenia.

In January 2015, a multi-center open label single arm Phase 2 clinical trial was initiated in doxorubicin-naïve patients with ASTS. This Phase 2 clinical trial enrolled 22 patients and was completed in August 2016. Camsirubicin was administered intravenously at 265 mg/m^2 every 3 weeks for up to 16 doses, with all patients being given growth factor support, and there was clear indication of anticancer activity at this well-tolerated dose and schedule. The majority of patients (52.6%) evaluable for tumor progression demonstrated clinical benefit (stable disease or partial response), which was proportional to dose and consistently observed at higher cumulative doses of camsirubicin (>1000 mg/m^2). The progression-free survival at 6 months was 38%, higher than the 6-month PFS of doxorubicin in three of the more recent studies, which showed 23%, 25%, and 33% 6-month PFS for doxorubicin. Camsirubicin was very well tolerated in this study and underscored the potential ability to administer camsirubicin without restriction for cumulative dose in patients with ASTS. Under compassionate use access, one patient received 20 cycles of camsirubicin (cumulative dose 5,300 mg/m^2). Apart from one patient who developed febrile neutropenia and severe leukopenia, there were no grade 4 toxicities reported and no grade 3 side effects other than anemia. A transient decrease in left ventricular ejection fraction ("LVEF") was observed in four patients treated with camsirubicin. These decreases in LVEF in camsirubicin treated patients were not serious adverse events and were transient, with LVEF subsequently returning to normal levels in all four subjects. Despite some subjects in this study receiving camsirubicin for up to 20 cycles, effects on cardiac function were of no clinical significance and there was no evidence of irreversible heart failure in any subject.

Based on the previous clinical results, in September 2021, we commenced an open-label, Phase 1b dose escalation trial of camsirubicin plus growth factor support (pegfilgrastim/G-CSF) in the U.S. as first-line treatment for patients with ASTS. The aim is to administer camsirubicin without restricting cumulative dose, thereby potentially improving efficacy by keeping patients who are responding on treatment. These are patients who are not candidates for surgery or radiation treatment, and are largely made up of patients with metastatic disease. Doxorubicin is the current standard of care in the first-line setting for these patients. Although this Phase 1b is designed to determine the maximum tolerated dose of camsirubicin, given the historical dose-dependent anti-tumor response repeatedly demonstrated with doxorubicin, efficacy measurements are being tracked in these patients as the dose is increased. We are presently enrolling patients at the fifth dose level. The fifth dose level is over twice the highest dose reached in any prior camsirubicin clinical trial (650 mg/m^2 versus 265 mg/m^2).

MNPR-202 and Related Analogs

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

License, Development and Collaboration Agreements

XOMA Ltd.

To humanize our MNPR-101 antibody, we have taken a non-exclusive license to XOMA (US) LLC's humanization technology and know-how. Humanization involves replacing most of the non-critical parts of the mouse sequence of an antibody with the human sequence to minimize the ability of the human immune system to recognize this antibody as foreign. As such, MNPR-101 has been engineered to be 95% human sequence using the XOMA technology. Under the terms of the non-exclusive license with XOMA Ltd., we are to pay only upon clinical, regulatory and sales milestones which could reach up to $14.925 million if we achieve all milestones. The agreement does not require the payment of sales royalties. There can be no assurance that we will reach any milestones. As of March 8, 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.

Onxeo S.A.

In June 2016, we executed an agreement with Onxeo S.A., a French public company, which gave us the exclusive option to license (on a world-wide exclusive basis) Validive (clonidine hydrocholoride mucobuccal tablet; clonidine HCI MBT) a mucoadhesive tablet of clonidine based on the Lauriad mucoadhesive technology. The agreement included clinical, regulatory, developmental and sales milestones and escalating royalties on net sales. In September 2017, we exercised the option to license Validive from Onxeo for $1 million. On March 27, 2023, we discontinued our Validive Phase 2b/3 VOICE trial based upon our Data Safety Monitoring Board's determination that the trial did not meet the pre-defined threshold for efficacy of a 15% absolute difference in severe oral mucositis prevention between Validive and placebo. We have not incurred any license or royalty obligations and the license has been terminated effective January 2024.

Intellectual Property Portfolio and Exclusivity

An important part of our strategy is obtaining patent protection to help preserve the proprietary nature of our product candidates, and to prevent others from developing competitive agents that are similar. Our patent portfolio includes issued patents and pending patent applications in the U.S. and in foreign countries. Our general practice is to seek patent protection in major markets worldwide.

MNPR-101

Our patent portfolio for our MNPR-101 antibody (huATN-658), as well as its epitope, consists of two issued U.S. composition of matter and their methods of use patents and corresponding (granted and pending) patents and patent applications in multiple foreign jurisdictions, including the European Union, Japan, and other Asian countries. These patents are owned by us. The patents covering the composition of matter of MNPR-101 will expire in 2025 and the patents covering the MNPR-101 epitope will expire in 2027. Being a novel biologic, it is eligible for 12 years of exclusivity in the U.S. under the Biologics Price Competition and Innovation Act ("BPCI Act"), and it will benefit from varying durations of similar exclusivity in numerous other countries. The Radio-Immuno-Therapeutic derivative of MNPR-101 ("uPRIT") patent, if granted expires in 2041.

Patent life determination depends on the date of filing of the application and other factors as promulgated under the patent laws. In most countries, including the U.S., the patent term is generally 20 years from the earliest claimed filing date (the priority date) of a non-provisional patent application in the applicable country, not taking into consideration any potential patent term adjustment that may be filed in the future or any regulatory extensions that may be obtained. Some of our patents are currently near expiration and we may pursue patent term extensions for these where appropriate or to let patents lapse. See "Risk Factors – Risks Related to our Intellectual Property".

MNPR-101 for Radiopharmaceutical Use

In collaboration with NorthStar, we filed a provisional patent application entitled "Precision Radioimmunotherapeutic Targeting of the Urokinase Plasminogen Activator Receptor (uPAR) for Treatment of Severe COVID-19 Disease" with the USPTO on June 15, 2020. A full international application (International Application Number PCT/US2021/037416) that claims priority to the provisional filing date was filed under the Patent Cooperation Treaty ("PCT") on June 15, 2021. This application covers novel compositions and uses of cytotoxic radioisotopes attached to antibodies that bind to uPAR, thereby creating precision targeted radiotherapeutics, also known as uPRITs, for the treatment of severe COVID-19 and other respiratory diseases.

In May 2021, we and NorthStar filed a provisional patent application with the USPTO titled "Bio-Targeted Radiopharmaceutical Compositions Containing Ac-225 and Methods of Preparation." Radiopharmaceutical therapy is a promising approach to treat cancer and other diseases using radioactive isotopes bound with proteins/antibodies to target and kill cells. If validated through further evaluation, it could potentially improve efficacy and safety and enhance manufacturing efficiency of actinium-based radiopharmaceuticals, the full potential of which are presently constrained by the price and scarcity of Ac-225.

Also in May 2021, we and NorthStar filed a provisional composition of matter patent application titled "Urokinase Plasminogen Activator Receptor-Targeted Radiopharmaceutical" covering a radiotherapeutic consisting of our proprietary antibody MNPR-101 bound to Ac-225 via the isotope binding agent PCTA. This RIT demonstrated 98% radiochemical purity and high stability and has the potential to be a highly selective, potent treatment for a variety of cancers, severe COVID-19, and other diseases characterized by aberrant uPAR expression.

Camsirubicin

Camsirubicin (GPX-150) is covered by manufacturing process patents. We have a patent for chemical synthesis technology that efficiently converts cardiotoxic "13-keto" anthracyclines such as doxorubicin, daunorubicin, epirubicin, and idarubicin into novel, patentable, and potentially less-cardiotoxic "5-imino-13-deoxy" analogs. A novel chemical composition of an intermediate for this synthesis is also patented. In addition, we have a patent covering the combination of camsirubicin with paclitaxel for the treatment of cancer, plus covering the method of use of these two drugs for this purpose. Our camsirubicin patent portfolio contains eight issued U.S. patents (two of which have expired) and one U.S. pending patent application. We have certain corresponding patents and applications in twenty-nine foreign jurisdictions, including the U.S., EU, Japan, and other Asian countries. The process patents for the synthesis of camsirubicin intermediates will expire in 2024 and the patents covering the combination use of camsirubicin and its analogs with taxanes will expire in 2026. The patent covering novel, potentially more potent analogs of camsirubicin expires in 2038. We may pursue patent term extensions where appropriate or let patents lapse. We have obtained patent protection around the intermediates and process used to manufacture camsirubicin and we expect to obtain Hatch-Waxman exclusivity (applicable to new chemical entities) for 5 years that will prevent generic competition. We have also obtained U.S. and EU orphan drug status in soft tissue sarcoma.

MNPR-202

In December 2020, we announced the issuance of a U.S. patent (US 10,450,340) covering compositions of matter (2-pyrrilino camsirubicin) for a novel family of camsirubicin analogs. This patent, which expands the Company's camsirubicin intellectual property portfolio, is expected to expire in 2038 not including any patent term extensions. The patent broadens our camsirubicin portfolio and creates a pipeline that has been designed to retain the potentially favorable non-cardiotoxic chemical backbone of camsirubicin and the potent broad-spectrum antitumor activity of doxorubicin. Further, preclinical evidence suggests that this new family of 2-pyrrilino camsirubicin analogs could be active in doxorubicin-resistant tumor cells which may enable use in cancer types beyond those possible with camsirubicin.

Manufacturing

We do not currently own or operate manufacturing facilities for the production or testing of MNPR-101 radiopharmaceutical program, camsirubicin, or MNPR-202, nor do we have plans to develop our own manufacturing operations in the foreseeable future. We presently depend on third-party contract manufacturers for all our required raw materials, Active Pharmaceutical Ingredients ("API"), and finished drug products for our preclinical and clinical studies. We are having clinical batches of MNPR-101-Zr manufactured in preparation for treating patients in our Phase 1 radiopharma program in advanced cancers. Also, we have completed manufacturing of the clinical batches of drug product for camsirubicin which are being used in our ongoing Phase 1b dose-escalation camsirubicin clinical trial.

Oncology Market Competition

The pharmaceutical industry in general, and the oncology therapeutics sector in particular, are characterized by intense competition. We face competition from pharmaceutical and biotechnology companies, many of which are larger and better financed than us. We also face competition in our efforts to develop and commercialize new oncology therapeutics from academic and government laboratories. The therapeutics that we are developing, if successfully commercialized, will have to compete with existing therapeutics already on the market and novel therapeutics currently in development, as well as new therapeutics that may be discovered and developed in the future. Our product candidates will also have to compete with alternate treatment modalities, such as improvements in radiation treatments, which are also subject to continual innovation and improvement. Additional information can be found in the section entitled "Risk Factors – Risks Related to Our Business Operations and Industry."

MNPR-101 Radiopharmaceutical Program Competition

Our MNPR-101 radiopharmaceutical program, including MNPR-101-Zr and MNPR-101 conjugated to therapeutic radioisotopes, is susceptible to all of the competitive factors listed in the first paragraph of this section on Oncology Market Competition. In addition to the current standard of care for patients with advanced cancers, we consider our most direct competitors to be companies that are developing targeted radiopharmaceuticals for the treatment of cancer. There are several companies that are developing radiopharmaceuticals for cancers including, but not limited to: Bayer AG, Bristol Myers Squibb, Eli Lilly and Company, Novartis AG, Actinium Pharmaceuticals, Inc., Johnson & Johnson, Telix Pharmaceuticals Limited, Lantheus Holdings, Inc. and Genentech, as well as several early-stage companies that are developing a wide range of targeted radiopharmaceuticals for advanced cancers. For the uPAR-targeted radiopharmaceuticals, CuraSight, a Danish biotech company, is currently developing a non-antibody-based uPAR radiodiagnostic and radiotherapeutic pair which binds to a different epitope on uPAR as compared to MNPR-101.

Camsirubicin Competition

We believe our camsirubicin program, if approved, could replace doxorubicin as the first-line treatment for ASTS. In addition, we believe that camsirubicin would compete with a number of currently available anthracycline-based drugs on the market for other cancer indications. These are largely derivatives of doxorubicin, or reformulations of doxorubicin such as liposomal doxorubicin (e.g., Doxil, sold by Johnson & Johnson). All of these have the issue of cardiotoxicity. In addition to approved products, there are a number of product candidates in development, largely as new formulations or derivatives of doxorubicin.

MNPR-202 Competition

Our MNPR-202 program is in the early stages of development and as such is the most susceptible to all of the competitive factors listed in the first paragraph of this section on Oncology Market Competition.

Government Regulation and Product Approval

Government authorities in the U.S., at the federal, state and local level, and in other countries such as Australia, extensively regulate, among other things, the research, development, testing, manufacture, quality control, approval, labeling, packaging, storage, record-keeping, promotion, advertising, distribution, post-approval monitoring and reporting, marketing and export and import of products such as those we are developing. The pharmaceutical product candidates that we develop must be approved by the U.S. Food and Drug Administration ("FDA") and the Therapeutics Goods Administration ("TGA") before they may be legally marketed in the U.S. and Australia, respectively. See “Risk Factors – Risks Related to Clinical Development and Regulatory Approval”.

Regulatory Framework in Australia

The Therapeutic Goods Administration, through the Therapeutic Goods Act 1989 and the Therapeutic Goods Regulations, is responsible for the efficacy, quality, safety and timely availability of drugs and medical devices in Australia. The mission statement of the TGA is “To ensure the safety, quality and efficacy of therapeutic goods available in Australia at a standard equal to that of comparable countries, and that premarket assessment of therapeutic goods is conducted within a reasonable time." The TGA administers two pathways for clinical trials, the Clinical Trials Notification ("CTN") and Clinical Trials Approval ("CTA") schemes. These provide an avenue through which 'unapproved' therapeutic goods may be lawfully supplied for use solely for experimental purposes in humans. The choice of which route to use (CTN or CTA) lies firstly with the Australian clinical trial sponsor and then with the Human Research Ethics Committee ("HREC") that approves the protocol.

Clinical trials of medicines and biologicals typically proceed through 'phases' of development, which generally follow: Phase 1 (human pharmacology), Phase 2 (therapeutic exploratory), and Phase 3 (therapeutic confirmatory). Phase 4 may be conducted for post-marketing surveillance or resolution of treatment uncertainties. Clinical development pathways are becoming less rigid with respect to phase and seamless adaptive trial designs and other cross-phase studies exist. Under the CTN and CTA schemes the use of therapeutic goods in the trial must be in accordance with the Guideline for Good Clinical Practice, the National Statement and the protocol approved by the HREC responsible for monitoring the conduct of the trial. The trial sponsor must also comply with the requirements of any other Commonwealth and/or state and territory legislation in relation to clinical trials and the supply of therapeutic goods.

A company or organization wishing to supply a therapeutic good in Australia must apply for market authorization from the TGA. The TGA assesses the application, and if market authorization is granted, the therapeutic good is entered on the Australian Register of Therapeutic Goods ("ARTG"). The TGA uses three pathways to evaluate a prescription medicine: the standard pathway, the priority review pathway and the provisional approval pathway. The TGA is required by statute to complete its evaluation for approval of a medicine in the standard pathway within 255 working days. The priority review pathway has a target timeframe of 150 working days and allows for faster assessment of vital and life-saving prescription medicines. Sponsors of promising new prescription medicines (with only preliminary clinical data available) can seek fast-tracked registration through the provisional approval pathway. All pathways require evidence that medicines are made according to Good Manufacturing Practice ("GMP"). GMP describes principles and procedures to ensure therapeutic goods are of high quality. The TGA inspects Australian (and some overseas) manufacturers to ensure compliance with GMP standards.

The evaluation and approval process of a new medicine in Australia generally follows:

- Pre-submission: before submitting an application, potential sponsors should ensure that the proposed product meets the eligibility requirements for the assessed listed medicines pathway. Applicants can arrange a free optional pre-submission meeting with the TGA prior to submitting the application for a new assessed listed medicine;

- Application submission: applications are created and lodged through TGA Business services;

- Preliminary assessment: The TGA will conduct a preliminary assessment of the application to determine whether it meets the administrative requirements and basic technical eligibility requirements to proceed to evaluation;

- Evaluation and requests for information: Once an application has passed preliminary assessment and the evaluation fee has been paid, the application enters the evaluation phase. During this phase, the TGA assesses the application, reviews any responses to requests for information, and documents the findings. The TGA may decide to seek advice from an expert advisory committee, such as the Advisory Committee for Complementary Medicines (ACCM);

- The decision: When making the decision under section 26AE of the Therapeutics Goods Act (1989) on whether to list the medicine in the ARTG, the decision maker (the delegate of the Secretary of the Department of Health) will review all documentation associated with the application, including the dossier, evaluation reports, responses to requests for information, and advice from expert advisory committees;

- Finalization: Sponsors need to provide a patent certificate under subsection 26B(1) of the act, or notification that this is not required before the medicine can be listed in the ARTG;

- Conduct post-marketing requirements, if any: a drug may be selected for a post-market compliance review at any time. The TGA will check the assessed listed medicine's compliance against the regulatory requirements that are self-certified by the sponsor.

Therapeutic goods generally need to be entered on the ARTG before they can be sold in Australia. However, there are a number of ways that patients can gain access to products that have not been approved for use in Australia:

- The Special Access Scheme ("SAS") allows a health practitioner to access an unapproved therapeutic good for an individual patient on a case-by-case basis;
- Medical professionals can apply to the TGA to become an 'Authorised Prescriber' of a specific unapproved good to specific patients with a particular medical condition. In some instances, doctors also need to have their application approved by a human research ethics committee or endorsed by a specialist college;
- Depending on the level of risk involved, a sponsor of a clinical trial can make either a notification or application to the TGA to use an unapproved good in the trial;
- Under the Personal Importation Scheme, individuals can legally import a three-month supply of some unapproved therapeutic goods for personal use, without TGA approval. A prescription from an Australian-registered medical practitioner is required for S4 and S8 medicines;
- If a medicine included in the ARTG is in short supply, the Secretary (or delegate) can approve the import and supply of a substitute medicine that is not on the ARTG. In some instances, pharmacists are allowed to substitute medicines, including different strengths or forms of a product, without a prescribing doctor's approval where a medicine is unavailable.

U.S. Pharmaceutical Product Development Process

In the U.S., the FDA regulates pharmaceutical products under the Federal Food, Drug and Cosmetic Act ("FDCA") and implementing regulations. Pharmaceutical products are also subject to other federal, state and local statutes and regulations. The process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state, local and foreign statutes and regulations require the expenditure of substantial time and financial resources. Failure to comply with the applicable U.S. requirements at any time during the product development process, approval process or after approval, may subject an applicant to administrative or judicial enforcement. FDA enforcement could result in refusal to approve pending applications, withdrawal of an approval, a clinical hold, warning letters, product recalls, product seizures, total or partial suspension of production or distribution injunctions, fines, refusals of government contracts, restitution, disgorgement or civil or criminal penalties. Any agency or judicial enforcement action could have a material adverse effect on us. The process required by the FDA before a non-biological pharmaceutical product may be marketed in the U.S. generally involves the following:

- Completion of preclinical laboratory tests, animal studies and formulation studies according to Good Laboratory Practices ("GLP"), and other applicable regulations;
- Submission to the FDA of an Investigational New Drug application ("IND"), which must become effective before human clinical studies may begin;
- Performance of adequate and well-controlled human clinical studies according to the FDA's current Good Clinical Practices ("GCP"), to establish the safety, efficacy and optimum dose of the proposed pharmaceutical product for its intended use;
- Submission to the FDA of a New Drug Application ("NDA") or Biologics License Application ("BLA"), for a new pharmaceutical product;
- Satisfactory completion of an FDA inspection of the manufacturing facility or facilities where the pharmaceutical product is produced to assess compliance with the FDA's current Good Manufacturing Practice standards ("cGMP"), to assure that the facilities, methods and controls are adequate to preserve the pharmaceutical product's identity, strength, quality and purity;
- FDA audits of the preclinical and clinical study sites that generated the data in support of the NDA or BLA;
- FDA review and approval of the NDA; and
- Fulfillment of FDA post-marketing requirements, if any.

The lengthy process of seeking required approvals and the continuing need for compliance with applicable statutes and regulations require the expenditure of substantial resources, and approvals are inherently uncertain.

Before testing any compounds with potential therapeutic value in humans, the pharmaceutical product candidate enters the preclinical testing stage. Preclinical tests include laboratory evaluations of product chemistry, toxicity and formulation, as well as in-vitro and animal studies to assess the potential safety and activity of the pharmaceutical product candidate. These early proof-of-principle studies are done using sound scientific procedures and thorough documentation. The conduct of single and repeat dose toxicology and toxicokinetic studies in animals must comply with federal regulations and requirements including GLP. The sponsor must submit the results of the preclinical tests, together with manufacturing information, analytical data, any available clinical data or literature and a proposed clinical protocol, to the FDA as part of the IND. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA has concerns and notifies the sponsor. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical study can begin. If resolution cannot be reached within the 30-day review period, either the FDA places the IND on clinical hold, or the sponsor withdraws the application. The FDA may also impose clinical holds on a pharmaceutical product candidate at any time before or during clinical studies due to safety concerns or non-compliance. Accordingly, it is not certain that submission of an IND will result in the FDA allowing clinical studies to begin, or that, once begun, issues will not arise that suspend or terminate such clinical studies.

During the development of a new drug, sponsors are given opportunities to meet with the FDA at certain points. These points may be prior to submission of an IND, at the end of Phase 2, and before an NDA or BLA is submitted. Meetings at other times may be requested. These meetings can provide an opportunity for the sponsor to share information about the data gathered to date, for the sponsor to ask specific questions to the FDA, for the FDA to provide advice, and for the sponsor and FDA to reach agreement on the next phase of development. Sponsors typically use the end of Phase 2 meeting to discuss their Phase 2 clinical results and present their plans for the pivotal Phase 3 clinical (registration) trial(s) that they believe will support approval of the new drug. A sponsor may be able to request a Special Protocol Assessment (“SPA”), the purpose of which is to reach agreement with the FDA on the Phase 3 clinical trial protocol design and analyses that will form the primary basis of an efficacy claim.

According to FDA guidance for industry on the SPA process, a sponsor which meets the prerequisites may make a specific request for a SPA and provide information regarding the design and size of the proposed clinical trial. The FDA’s goal is to evaluate the protocol within 45 days of the request to assess whether the proposed trial is adequate, and that evaluation may result in discussions and a request for additional information. A SPA request must be made before the proposed trial begins, and all open issues must be resolved before the trial begins. If a written agreement is reached, it will be documented and made part of the IND record. The agreement will be binding on the FDA and may not be changed by the sponsor or the FDA after the trial begins except with the written agreement of the sponsor and the FDA or if the FDA determines that a substantial scientific issue essential to determining the safety or efficacy of the drug was identified after the testing began.

Clinical studies involve the administration of the pharmaceutical product candidate to healthy volunteers or patients under the supervision of qualified investigators, generally physicians not employed by or under the clinical study sponsor’s control. Clinical studies are conducted under protocols detailing, among other things, the objectives of the clinical study, dosing procedures, subject selection and exclusion criteria, how the results will be analyzed and presented and the parameters to be used to monitor subject safety. Each protocol must be submitted to the FDA as part of the IND. Clinical studies must be conducted in accordance with Good Clinical Practice (“GCP”) guidelines. Further, each clinical study must be reviewed and approved by an independent institutional review board (“IRB”), at, or servicing, each institution at which the clinical study will be conducted. An IRB is charged with protecting the welfare and rights of study participants and is tasked with considering such items as whether the risks to individuals participating in the clinical studies are minimized and are reasonable in relation to anticipated benefits. The IRB also approves the informed consent form that must be provided to each clinical study subject or his or her legal representative and must monitor the clinical study until completed.

Human clinical studies are typically conducted in three sequential phases that may overlap or be combined:

- Phase 1. The pharmaceutical product is initially introduced into healthy human subjects and tested for safety, dosage tolerance, absorption, metabolism, distribution and excretion.

- Phase 2. The pharmaceutical product is evaluated in a limited patient population to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the product for specific targeted diseases, to determine dosage tolerance, optimal dosage and dosing schedule and to identify patient populations with specific characteristics where the pharmaceutical product may be more effective.

- Phase 3. Clinical studies are undertaken to further evaluate dosage, clinical efficacy and safety in an expanded patient population at geographically dispersed clinical study sites. These clinical studies are intended to establish the overall risk/benefit ratio of the product and provide an adequate basis for product labeling. The studies must be well-controlled and usually include a control arm for comparison. One or two Phase 3 studies are required by the FDA for an NDA or BLA approval, depending on the disease severity and other available treatment options.

- Post-approval studies, or Phase 4 clinical studies, may be conducted after initial marketing approval. These studies are used to gain additional experience from the treatment of patients in the intended therapeutic indication.

- Progress reports detailing the results of the clinical studies must be submitted at least annually to the FDA and written IND safety reports must be submitted to the FDA and the investigators for serious and unexpected adverse events or any finding from tests in laboratory animals that suggests a significant risk for human subjects. Phase 1, Phase 2 and Phase 3 clinical studies may not be completed successfully within any specified period, if at all. The FDA or the sponsor or its data safety monitoring board may suspend a clinical study at any time on various grounds, including a finding that the research subjects or patients are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical study at its institution if the clinical study is not being conducted in accordance with the IRB's requirements or if the pharmaceutical product has been associated with unexpected serious harm to patients.

Concurrent with clinical studies, companies usually complete additional animal studies and must also develop additional information about the chemistry and physical characteristics of the pharmaceutical product as well as finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the pharmaceutical product candidate and, among other things, must develop methods for testing the identity, strength, quality and purity of the final pharmaceutical product. Additionally, appropriate packaging must be selected and tested, and stability studies must be conducted to demonstrate that the pharmaceutical product candidate does not undergo unacceptable deterioration over its shelf life.

U.S. Review and Approval Processes

The results of product development, preclinical studies and clinical studies, along with descriptions of the manufacturing process, analytical tests conducted on the chemistry of the pharmaceutical product, proposed labeling and other relevant information are submitted to the FDA as part of an NDA or BLA requesting approval to market the product. The submission of an NDA or BLA is subject to the payment of substantial user fees; a waiver of such fees may be obtained under certain limited circumstances.

In addition, under the Pediatric Research Equity Act ("PREA"), an NDA, BLA or a supplement thereof must contain data to assess the safety and effectiveness of the pharmaceutical product for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. The FDA may grant deferrals for submission of data or full or partial waivers. Unless otherwise required by regulation, PREA does not apply to any pharmaceutical product for an indication for which orphan designation has been granted.

The FDA reviews all NDAs and BLAs submitted before it accepts them for filing and may request additional information rather than accepting an NDA or BLA for filing. Once the submission is accepted for filing, the FDA begins an in-depth review of the NDA or BLA. Under the goals and policies agreed to by the FDA under the Prescription Drug User Fee Act ("PDUFA"), the FDA has 10 months in which to complete its initial review of a standard NDA or BLA and respond to the applicant, and six months for a priority NDA or BLA. The FDA does not always meet its PDUFA goal dates for standard and priority NDAs or BLAs. The review process and the PDUFA goal date may be extended by three months if the FDA requests or if the NDA or BLA sponsor otherwise provides additional information or clarification regarding information already provided in the submission within the last three months before the PDUFA goal date.

After the NDA or BLA submission is accepted for filing, the FDA reviews the NDA or BLA application to determine, among other things, whether the proposed product is safe and effective for its intended use, and whether the product is being manufactured in accordance with cGMP to assure and preserve the product's identity, strength, quality and purity. The FDA may refer applications for novel pharmaceutical products or pharmaceutical products which present difficult questions of safety or efficacy to an advisory committee, typically a panel that includes clinicians and other experts, for review, evaluation and a recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions. During the pharmaceutical product approval process, the FDA also will determine whether a risk evaluation and mitigation strategy ("REMS"), is necessary to assure the safe use of the pharmaceutical product. If the FDA concludes that a REMS is needed, the sponsor of the NDA or BLA must submit a proposed REMS; the FDA will not approve the NDA or BLA without a REMS, if required.

Before approving an NDA or BLA, the FDA will inspect the facilities at which the product is manufactured. The FDA will not approve the product unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. Additionally, before approving an NDA or BLA, the FDA will typically inspect one or more clinical sites as well as the site where the pharmaceutical product is manufactured to assure compliance with GCP and cGMP. If the FDA determines the application, manufacturing process or manufacturing facilities are not acceptable, it will outline the deficiencies in the submission and often will request additional testing or information. In addition, the FDA will require the review and approval of product labeling.

The NDA and BLA review and approval process is lengthy and difficult and the FDA may refuse to approve an NDA or BLA if the applicable regulatory criteria are not satisfied or may require additional clinical data or other data and information. Even if such data and information are submitted, the FDA may ultimately decide that the NDA or BLA does not satisfy the criteria for approval. Data obtained from clinical studies are not always conclusive and the FDA may interpret data differently than the sponsor interprets the same data. The FDA will issue a complete response letter if the agency decides not to approve the NDA or BLA. The complete response letter usually describes all of the specific deficiencies in the NDA or BLA identified by the FDA. The deficiencies identified may be minor, for example, requiring labeling changes, or major, for example, requiring additional clinical studies. Additionally, the complete response letter may include recommended actions that the applicant might take to place the application in a condition for approval. If a complete response letter is issued, the applicant may either resubmit the NDA or BLA, addressing all of the deficiencies identified in the letter, or withdraw the application.

If a product receives regulatory approval, the approval may be significantly limited to specific diseases and dosages or the indications for use may otherwise be limited, which could restrict the commercial value of the product. Further, the FDA may require that certain contraindications, warnings or precautions be included in the product labeling. In addition, the FDA may require Phase 4 testing which involves clinical studies designed to further assess pharmaceutical product safety and effectiveness and may require testing and surveillance programs to monitor the safety of approved products that have been commercialized.

Other International Regulation

In addition to regulations in the U.S. and Australia, there are a variety of foreign regulations governing clinical studies and commercial sales and distribution of our future product candidates. Whether or not FDA or HREC approval is obtained for a product, approval of a product must be obtained by the comparable regulatory authorities of foreign countries before clinical studies or marketing of the product can commence in those countries. The approval process varies from country to country, and the time may be longer or shorter than that required for FDA or HREC approval. The requirements governing the conduct of clinical studies, product licensing, pricing and reimbursement vary greatly from country to country. In addition, certain regulatory authorities in select countries may require us to repeat previously conducted preclinical and/or clinical studies under specific criteria for approval in their respective country which may delay and/or greatly increase the cost of approval in certain markets targeted for approval by us.

Under E.U. regulatory systems, marketing applications for pharmaceutical products are typically submitted under a centralized procedure to the EMA. The centralized procedure provides for the granting of a single marketing authorization that is valid for all E.U. member states. The EMA also has designations for Orphan Drugs, which, if applicable, can provide for faster review, lower fees and more access to advice during drug development. While the marketing authorization in the European Union is centralized, the system for clinical studies (application, review and requirements) is handled by each individual country. Approval to run a clinical study in one country does not guarantee approval in any other country. The pharmaceutical industry in Canada is regulated by Health Canada. A New Drug Submission (“NDS”) is the equivalent of a U.S. NDA and must be filed to obtain approval to market a pharmaceutical product in Canada. Marketing regulations and reimbursement are subject to national and provincial laws. In Japan, applications for approval to manufacture and market new drugs must be approved by the Ministry of Health, Labor and Welfare. Nonclinical and clinical studies must meet the requirements of Japanese laws. Results from clinical studies conducted outside of Japan must be supplemented with at least a bridging clinical study conducted in Japanese patients.

In addition to regulations in Europe, Canada, Japan, Australia and the U.S., there are a variety of foreign regulations governing clinical studies, commercial distribution and reimbursement of future product candidates which we may be subject to as we pursue regulatory approval of the MNPR-101 radiopharmaceutical program, camsirubicin, or any future product candidates internationally.

Compliance with Environmental Laws

Since we do not have our own laboratory or manufacturing facilities, we do not estimate any annual costs of compliance with environmental laws.

Employees

Our operations are currently managed by five individuals (including our executive chairman and our Acting Chief Medical Officer), of whom two have a PhD, two have an MD, two have an MBA, one has an MSc in health economics and policy, one has an MS from Stanford University, and one is a former CPA. They have worked at industry leading companies such as BioMarin Pharmaceutical Inc., Raptor Pharmaceuticals, and Onyx Pharmaceuticals. As of March 8, 2024, we had ten employees; nine of whom were full-time. We anticipate hiring additional employees in clinical operations, regulatory affairs and other departments, to help manage our clinical studies, regulatory submissions, and manufacturing to support the MNPR-101 program and camsirubicin development, business development and corporate strategy. In addition, to complement our internal expertise, we have contracts with medical and scientific consultants, manufacturers, laboratories, and contract research organizations that specialize in various aspects of drug development including clinical development, preclinical development, manufacturing, quality assurance, and regulatory affairs.

Corporate Information

We were formed as a Delaware limited liability company in December 2014, with the name Monopar Therapeutics, LLC. In December 2015, we converted to a Delaware C corporation. Our principal executive offices are located at 1000 Skokie Blvd, Suite 350, Wilmette, IL 60091. Our telephone number is (847) 388-0349. Our corporate website is located at www.monopartx.com. Any information contained in, or that can be accessed through our website, is not incorporated by reference in this Annual Report on Form 10-K.

Trademark Notice

All trademarks, service marks and trade names in this Annual Report on Form 10-K are the property of their respective owners. We have omitted the ® and ™ designations, as applicable, for the trademarks used herein.

Available Information

Our corporate website is located at www.monopartx.com. The reference to these website addresses does not constitute incorporation by reference of the information contained on the websites and should not be considered part of this Annual Report on Form 10-K.

We intend to satisfy any disclosure requirement under Item 5.05 of Form 8-K regarding an amendment to, or waiver from, a provision of our Code of Business Conduct and Ethics by posting such information on our website as specified above.

Item 1A. Risk Factors

RISK FACTORS

An investment in our common stock involves a high degree of risk. A prospective investor should carefully consider the following information about these risks, together with other information appearing elsewhere in this Annual Report on Form 10-K, before deciding to invest in our common stock. The occurrence of any of the following risks could have a material adverse effect on our business, financial condition, results of operations and future prospects and prospective investors could lose all or part of their investment. The risk factors discussed below and elsewhere in this Annual Report on Form 10-K are not exhaustive; other significant risks may exist that are not identified in this Annual Report on Form 10-K, but that might still materially and adversely affect our business, prospects, financial condition, and results of operations were any of such risks to occur.

Risks Related to Our Financial Condition and Capital Requirements

We have a limited operating history, expect to incur significant operating losses, and have a high risk of never being profitable.

We commenced operations in December 2014 and have an operating history of approximately nine years. Therefore, there is limited historical financial or operational information upon which to evaluate our performance. Our prospects must be considered in light of the uncertainties, risks, expenses, and difficulties frequently encountered by companies in their early clinical stages of operations. Many, if not most, companies in our industry at our stage of development 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 and enables profitability.

From inception in December 2014 through December 31, 2023, we have incurred losses of approximately $60.2 million, which includes $13.5 million of non-cash in-process research and development, which was incurred in connection with our 2017 acquisition of camsirubicin. We expect to continue to incur substantial operating losses over the next several years for the clinical development of our current and future licensed or purchased product candidates and will continue to incur losses for the foreseeable future. We expect that our R&D and G&A expenses will increase to enable the execution of our strategic plan. As a result, we anticipate that we will seek to raise additional capital within the next 12 months to fund our future operations. We will seek to obtain needed capital through a combination of equity offerings, including at-the-market sales programs, debt financings, strategic collaborations and grant funding. To date, we have funded our operations through net proceeds from the initial public offering of our common stock, net proceeds from sales of our common stock through at-the-market sales programs, private placements of our preferred and common stock, and the net receipt of funds related to our acquisition of camsirubicin and related assets.

The amount of future losses and when, if ever, we will become profitable are uncertain. We do not have any products that have generated revenues from commercial sales, and do not expect to generate revenues from the commercial sale of products in the near future, if ever. Our ability to generate revenue and achieve profitability will depend on, among other things, successful completion of the development of our 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 our activities. If we are unsuccessful at some or all of these undertakings, our business, financial condition, and results of operations are expected to be materially and adversely affected.

We will need to raise substantial additional funding or find one or more suitable pharmaceutical partners to continue to advance our clinical programs and support our preclinical activities.

In order to be commercially viable, we must successfully research, develop, test, obtain regulatory approval for, manufacture, introduce, market and distribute some or all MNPR-101-Zr, MNPR-101 RIT, camsirubicin, and MNPR-202, and, if applicable, any other product candidates we may develop. The estimated required capital and time-frames necessary to achieve these developmental milestones as described in this Annual Report on Form 10-K or as we may state from time to time are subject to inherent risks, which are beyond our control. Clinical development of MNPR-101-Zr, MNPR-101 RIT, camsirubicin and MNPR-202 will require significant funds. Proceeds to-date from the sales of our common stock we believe could be sufficient for us to complete our planned Phase 1 dosimetry trial of MNPR-101-Zr, continued development of MNPR-101-RIT and the ongoing open-label Phase 1b camsirubicin clinical trial, but will not be sufficient for us to support additional clinical development of MNPR-101 for radiopharmaceutical use in advanced cancers and camsirubicin clinical development beyond Phase 1b. To complete the MNPR-101 radiopharmaceutical and camsirubicin clinical programs we will need to raise additional funding in the tens of millions of dollars. Therefore, we will need to raise significant additional funds or find a suitable pharmaceutical partner within the next 12 months to support our current and any future product candidates through completion of clinical trials, approval processes and, if applicable, commercialization. If we are able to raise financing, it may be on terms that are unfavorable to us and if we are unable to raise sufficient funds or find a suitable pharmaceutical partner, we may have to discontinue or delay clinical development of our current or future product candidates.

The Russia-Ukraine war and/or the Israel-Hamas war will likely have continuing global effects on fuel costs and shipping and broader impacts on economic, trade and financial market conditions, which could delay the shipping of supplies for our clinical material manufacturing, potentially resulting in increased manufacturing expenses, delays to our clinical programs and adverse effects on our financing activities and financial condition.

The Russia-Ukraine war and the Israel-Hamas war are volatile situations, resulting in financial services and banking instability in the respective regions. The U.S. and other countries' sanctions against Russia and Russian entities, together with existing inflationary conditions and supply chain challenges arising in the wake of the Israel-Hamas war, are affecting fuel costs and shipping, resulting in higher costs and delays for various types of supplies. These cost increases and delays may affect our clinical material manufacturing which will likely have an adverse effect on our financial condition. In addition, at this stage, we are unable to predict whether the wars and resulting instability will have broader adverse impacts to European, U.S. or global economic, trade and financial market conditions, which could adversely affect our operations and financial condition in a variety of ways. In particular, financial market instability or volatility may make it more difficult to raise required financing.

If we continue to incur operating losses and fail to obtain the capital necessary to fund our operations, we will be unable to advance our development programs, complete our clinical trials, or bring products to market, or may be forced to reduce or cease operations entirely. In addition, any capital obtained by us may be obtained on terms that are unfavorable to us, our investors, or both.

While we believe adequate cash is currently available to operate at least through June 30, 2025, developing a new drug and conducting clinical trials and the regulatory review processes for one or more disease indications involves substantial costs. We have projected cash requirements for the near term based on a variety of assumptions, but some or all of such assumptions are likely to be incorrect and/or incomplete, possibly materially in an adverse direction. Our actual cash needs may deviate materially from those projections, changes in market conditions or other factors may increase our cash requirements, or we may not be successful even in raising the amount of cash we currently project will be required for the near term. We will need to raise additional capital in the future; the amount of additional capital needed will vary as a result of a number of factors, including without limitation the following:

- receiving less funding than we require;
- higher than expected costs to manufacture and ship our active pharmaceutical ingredient, radioisotopes, and our product candidates;
- higher than expected costs for preclinical testing;
- the cost and availability of radioisotopes such as Ac-225 or Zr-89, or any other medical isotope we may incorporate into our product candidates;
- an increase in the number, size, duration, and/or complexity of our clinical trials;
- slower than expected progress in developing our MNPR-101 radiopharmaceutical program, camsirubicin, and MNPR-202 or other product candidates, including without limitation, additional costs caused by program delays;
- higher than expected costs associated with attempting to obtain regulatory approvals, including without limitation additional costs caused by additional regulatory requirements or larger clinical trial requirements;
- higher than expected personnel, consulting or other costs, such as adding personnel or industry expert consultants or pursuing the licensing/acquisition of additional assets; and
- higher than expected costs to protect our intellectual property portfolio or otherwise pursue our intellectual property strategy.

When we attempt to raise additional financing, there can be no assurance that we will be able to secure such additional financing in sufficient quantities or at all. We may be unable to raise additional capital for reasons including, without limitation, our operational and/or financial performance, investor confidence in us and the biopharmaceutical industry, credit availability from banks and other financial institutions, the status of current projects, and our prospects for obtaining any necessary regulatory approvals. General economic and financial market conditions, which have recently been impacted by inflation, bank instability and other factors, can also adversely impact our ability to raise additional financing. Potential investors' capital investments may have shifted to other opportunities with perceived greater returns and/or lower risk, thereby reducing capital available to us, if available at all.

In addition, any additional financing might not be available, and even if available, may not be available on terms acceptable to us or our then-existing investors. We will seek to raise funds through public or private equity offerings, including at-the-market sales programs, debt financings, corporate collaboration or licensing arrangements, mergers, acquisitions, sales of intellectual property, or other financing vehicles or arrangements. To the extent that we raise additional capital by issuing equity securities or other securities, our then-existing investors will experience dilution. If we raise funds through debt financings or bank loans, we may become subject to restrictive covenants, our assets may be pledged as collateral for the debt, and the interests of our then-existing investors would be subordinated to the debt holders or banks. In addition, our use of and ability to exploit assets pledged as collateral for debt or loans may be restricted or forfeited. To the extent that we raise additional funds through collaboration or licensing arrangements, we may be required to relinquish significant rights (including without limitation intellectual property rights) to our technologies or product candidates, or grant licenses on terms that are not favorable to us. If we are not able to raise needed funding under acceptable terms or at all, then we will have to reduce expenses, including the possible options of curtailing operations, abandoning opportunities, licensing or selling off assets, reducing costs to a point where clinical development or other progress is impaired, or ceasing operations entirely.

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.

In the wake of the COVID-19 pandemic, the Russia-Ukraine war, the Israel-Hamas war and other geopolitical factors, economic conditions have become strained, with inflation and supply chain challenges impacting businesses worldwide. These conditions affect fuel costs and shipping, resulting in higher costs and delays for various types of supplies. These cost increases and delays may affect our clinical material manufacturing which will likely have an adverse effect on our financial condition. In addition, the effects of responses to inflationary conditions, such as significantly increased interest rates, on the economy and market conditions are difficult to predict. If U.S. or global economic, trade and financial market conditions continue to be challenged or volatile, or we do not effectively manage our response to these conditions, our operations and financial condition could be adversely affected in a variety of ways.

Unstable market and economic conditions may have serious adverse consequences on our ability to raise funds, which may cause us to delay, restructure or cease our operations.

From time to time, global and domestic credit and financial markets have experienced extreme disruptions, including severely diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, increases in unemployment rates, and uncertainty about economic stability. Recently, COVID-19, the Russia-Ukraine war and the Israel-Hamas war have created volatility and uncertainty. Recent instability in the banking industry has added to the volatility and uncertainty. Our financing strategy will be adversely affected by any such economic downturn, volatile business environment and continued unpredictable and unstable market conditions. If the equity and credit markets deteriorate, it may make a debt or equity financing more difficult to complete, costlier, and more dilutive. Failure to secure any necessary financing in a timely manner and on favorable terms will have a material adverse effect on our business strategy and financial performance, and could require us to cease or delay our operations.

Our operations and financial results could be adversely impacted by resurgences of COVID-19 or any future pandemics, which may negatively impact our ability to manufacture our product candidates for our clinical trials, our ability to accrue and conduct our clinical trials, and may delay regulatory agency responses. Any such impact will negatively impact our financial condition and could require us to delay our clinical development programs.

If there is a resurgence of COVID-19 or any future pandemics arise, we may experience disruptions that could severely impact our business, preclinical studies and clinical trials, including:

- Delays in receiving approval from the FDA, the TGA in Australia and other foreign regulatory authorities to initiate our planned clinical trials;
- Delays or difficulties in enrolling and monitoring patients in our clinical trials;
- Delays or difficulties in clinical site initiation, including difficulties in recruiting clinical site investigators and clinical site staff;
- Delays in trial drug shipments due to vaccine shipments tying up available pharmaceutical product shipping lanes and increasing their cost;
- Diversion of healthcare resources away from the conduct of clinical trials, including the diversion of hospitals serving as our clinical trial sites and hospital staff supporting the conduct of our clinical trials;
- Risk that participants enrolled in our clinical trials will acquire diseases while the clinical trial is ongoing, which could impact the results of the clinical trial, including by increasing the number of observed adverse events;

- Interruption of key clinical trial activities, such as clinical trial site data monitoring, due to limitations on travel imposed or recommended by federal or state governments, employers and others or interruption of clinical trial subject visits and study procedures, which may impact the integrity of subject data and clinical study endpoints;

- Interruption or delays in the operations of the FDA, the TGA, and other foreign regulatory agencies, which may impact approval timelines;

- Interruption of, or delays in receiving, supplies of our product candidates from our contract manufacturing organizations due to staffing or supply shortages, production slowdowns, global shipping delays or stoppages and disruptions in delivery systems;

- Limitation on employee resources that would otherwise be focused on the conduct of our preclinical studies and clinical trials, including because of sickness of our employees or their families or the desire of employees to avoid contact with large groups of people.

- Refusal of the FDA, the TGA, and other foreign regulatory authorities to accept data from clinical trials in affected geographies; and

- Impacts from prolonged remote work arrangements, such as increased cybersecurity risks.

The extent to which the long-term effects of COVID-19 or any future pandemics further impact our business, including our preclinical studies and clinical trials, results of operations and financial condition will depend on future developments which remain highly uncertain and cannot be predicted with confidence.

Risks Related to Clinical Development and Regulatory Approval

Radiopharmaceuticals are a relatively novel approach to cancer imaging and treatment, which may create significant and potentially unpredictable challenges for it.

Our future success depends on the successful development of our product candidates, including MNPR-101 for radiopharmaceutical use and any future radiopharmaceutical agent(s) that we may develop in-house, in-license or acquire, which are designed to image, identify or treat cancers by targeted delivery of radioisotopes to tumors. While radiation as a therapy for cancers has existed for decades, oncology treatment using systemic delivery of targeted radiopharmaceuticals in general is relatively new. Only a few therapies utilizing systemic delivery of radioisotopes have been approved globally, and only a limited number of clinical trials of products based on radioisotope therapies have been conducted. There are currently no approved therapies which use Ac-225, which we are exploring with MNPR-101. Global supply of Ac-225 is also currently limited and may not be capable of expanding sufficiently to provide the amounts required at commercial scale. As such, it is difficult to accurately predict the developmental challenges that the Company may incur for its product candidates as they proceed through product discovery or identification, preclinical studies and clinical trials, and, if approved, commercialization. In addition, there may be long-term effects from radiopharmaceutical treatment, including late radiation toxicity, with any of the Company's current or future product radiopharmaceutical candidates that it cannot predict at this time. It is difficult for us to predict the time and cost of the development of our product candidates. Any of these factors may prevent the Company from completing our preclinical and clinical trials that we may initiate, or from commercializing any product candidates we may develop on a timely or profitable basis, if at all. In addition, the success of the Company's current and future radiopharmaceutical programs will depend on several factors, including the following:

- sourcing clinical and, if approved for commercialization, commercial supplies for the materials, such as radioisotopes, used to manufacture our product candidates;

- sourcing or establishing manufacturing capabilities to produce adequate amounts of our product candidates;

- securing reliable supply chain for our product candidates given that isotope half-life times are limited;

- utilizing imaging agents to visualize tumor uptake in advance of administering our therapeutic candidates, which may increase the risk of adverse side effects;

- facilitating patient access to the limited number of facilities able to administer our product candidates;
- using medicines to manage adverse side effects of our drug candidates that may not adequately control the side effects or that may have detrimental impacts on the efficacy of the treatment; and
- establishing sales and marketing capabilities upon obtaining any regulatory approval to gain market acceptance of the Company's novel radiopharmaceutical imaging and therapeutics.

The lengthy process of seeking required approvals and the continuing need for compliance with applicable statutes and regulations require the expenditure of substantial resources, and approvals are inherently uncertain. If any of our radiopharmaceutical program product candidates are approved, their commercial success will depend upon competitive products, public perception of radioisotopes and the degree of their market acceptance by physicians, patients, healthcare payors and others in the medical community.

Adverse events in clinical trials of our product candidates or in clinical trials of others developing radiopharmaceuticals or similar agents and the resulting negative publicity, as well as any other adverse events in the field of radiopharmaceuticals that may occur in the future, could result in a decrease in demand for our product candidates. Also, future success of our drug candidates, if approved will depend on gaining and maintaining acceptance by physicians, patients, third-party payors and other members of the medical community as their being efficacious and cost-effective alternatives to competing products and treatments.

Due to the radioactive nature of MNPR-101-Zr and MNPR-101 therapeutic agents, as well as our future radiopharmaceutical candidates, once manufactured, our drug candidates will have time-limited stability, and as a result, we may encounter difficulties with fulfilment and logistics. If we or our manufacturers are unable to meet the challenges posed by the time-limitations inherent in the composition of our MNPR-101 radiopharmaceutical program or any of our future drug candidates, it would adversely affect our business, financial condition, results of operations and prospects.

We expect our other radiopharmaceutical drug candidates to also have time-limited stability. As such, our drug candidates, including MNPR-101 radiopharmaceutical program, must be manufactured on an as-needed basis, and shipped almost immediately thereafter. Because our drug candidates, including our MNPR-101 radiopharmaceutical program, cannot be “stockpiled” and stored for even a small number of days ahead of shipment, we or any third-party manufacturer must be able to manufacture our drug candidates on a rolling basis, and any kind of delays, even if seemingly insignificant, could result in an immediate and substantial impact on our ability to deliver the drug candidate to patients. Any significant delays in delivering drug candidates to patients could damage our reputation and result in deviations from our clinical trial protocols, which in turn could affect our ability to advance the preclinical and clinical development of our MNPR-101 radiopharmaceutical program or our other current and future radiopharmaceutical candidates on a timely basis, or at all. We do not currently maintain a manufacturing facility, and therefore we currently rely on third-party manufacturers for the production of our MNPR-101 radiopharmaceutical program in connection with our ongoing studies. We cannot be sure that such manufacturers will be able to meet our demand for our radiopharmaceutical programs on a timely basis.

In addition, once manufactured, our MNPR-101 radiopharmaceutical program and future radiopharmaceutical drug candidates in the clinic must be quickly and safely transported to the applicable clinical trial site. As we scale our operations and enroll larger clinical trials, and prepare for potential commercialization, we will need to scale our shipping capabilities. Labor disputes, government restrictions, work stoppages, pandemics, derailments, damage or loss events, adverse weather conditions, and other events beyond our control could interrupt or delay transportation, which could result in the damage to our MNPR-101 radiopharmaceutical program or any current or future drug candidate with similar shelf-life restrictions.

If we or our manufacturers are unable to meet the challenges posed by the time-limitations inherent in the composition of our MNPR-101 radiopharmaceutical program or any of our current or future drug candidates, it would adversely affect our business, financial condition, results of operations and prospects.

Perceptions of these challenges and risks in the market may adversely impact our stock price and our ability to successfully raise funding as we focus our preclinical and clinical efforts on our radiopharmaceutical program.

We do not have and may never have any approved products on the market. Our business is highly dependent upon receiving approvals from various U.S., Australian, and international governmental agencies and will be severely harmed if we are not granted approval to manufacture and sell our product candidates.

In order for us to commercialize any treatment for cancer or any other disease indication, we must obtain regulatory approvals of such treatment for that indication. Satisfying regulatory requirements is an expensive process that takes many years and involves compliance with requirements covering research and development, testing, manufacturing, quality control, labeling and promotion of drugs for human use. To obtain necessary regulatory approvals, we must, among other requirements, complete clinical trials demonstrating that our products are safe and effective for a particular indication. There can be no assurance that our products will prove to be safe and effective, that our clinical trials will demonstrate the necessary safety and effectiveness of our product candidates, or that we will succeed in obtaining regulatory approval for any treatment we develop even if such safety and effectiveness are demonstrated.

Any delays or difficulties we encounter in our clinical trials may delay or preclude regulatory approval from the FDA, or from international regulatory organizations. Any delay or preclusion of regulatory approval would be expected to delay or preclude the commercialization of our products. Examples of delays or difficulties that we may encounter in our clinical trials include, without limitation. the following:

- Clinical trials may not yield sufficiently conclusive results for regulatory agencies to approve the use of our products.
- Our products may fail to be more effective than current therapies, or to be effective at all.
- We may discover that our products have adverse side effects, which could cause our products to be delayed or precluded from receiving regulatory approval or reduce the effective size of our target patient population or otherwise expose us to significant commercial and legal risks.
- It may take longer than expected to determine whether or not a treatment is safe and effective.
- Patients involved in our clinical trials may suffer severe adverse side effects even up to death, whether as a result of treatment with our products, the withholding of such treatment, or other reasons which may not include the effects of our treatment (whether within or outside of our control).
- We may fail to be able to enroll a sufficient number of patients in our clinical trials to meet trial statistical plans and gain statistical significance, or it may take longer than expected to enroll.
- Patients enrolled in our clinical trials may not have the safety or efficacy characteristics necessary to obtain regulatory approval for a particular indication or patient population.
- We may be unable to produce sufficient quantities of product to complete the clinical trials.
- Even if we are successful in our clinical trials, required governmental approvals may still not be obtained or, if obtained, may not be maintained.
- If approval for commercialization is granted, it is possible the authorized use will be more limited than is necessary for commercial success, or that approval may be conditioned on completion of further clinical trials or other activities, which will cause a substantial increase in costs and which we might not succeed in performing or completing.
- If granted, approval may be withdrawn or limited if problems with our products emerge or are suggested by the data arising from their use or if there is a change in law or regulation.

Any success we may achieve at a given stage of our clinical trials does not guarantee that we will achieve success at any subsequent stage, including without limitation final FDA or other regulatory organizations' approval.

We may encounter delays or rejections in the regulatory approval process because of additional government regulation resulting from future legislation or administrative action, or from changes in the policies of the FDA or other regulatory bodies during the period of product development, clinical trials, or regulatory review. Failure to comply with applicable regulatory requirements may result in criminal prosecution, civil penalties, recall or seizure of products, total or partial suspension of production, or an injunction preventing certain activity, as well as other regulatory action against our product candidates or us. As a company, we have no experience in successfully obtaining regulatory approval for a product and thus may be poorly equipped to gauge, and may prove unable to manage, risks relating to obtaining such approval.

Outside the U.S., our ability to market a product is contingent upon receiving clearances from appropriate non-U.S. regulatory authorities, including the HREC in Australia. Non-U.S. regulatory approval typically includes all of the risks associated with FDA clearance discussed above as well as geopolitical uncertainties and the additional uncertainties and potential prejudices faced by U.S. pharmaceutical companies conducting business abroad. In certain cases, governmental pricing restrictions and practices can make achieving even limited profitability very difficult.

Even if we complete the clinical trials we discussed with the FDA or TGA, there is no guarantee that at the time of submission the FDA or TGA will accept our new drug application (“NDA”) or biologics license application ("BLA") based on the trials discussed.

Any future decision by the FDA and TGA will be driven largely by the data generated from our currently ongoing or any future planned trials. However, the FDA and other regulatory organizations, including the TGA, will learn from their total experience in the review of multiple drugs in multiple indications and they will apply that knowledge of broad and diverse experience even if less than a perfect match with our product. If the FDA or TGA require additional clinical trials it will increase our costs, delay our potential path to commercialization and could materially affect our financial condition.

As a company, we have never completed a clinical trial and have limited experience in completing regulatory filings and any delays in regulatory filings could materially affect our financial condition.

While members of our team have conducted numerous clinical trials at previous companies, and have launched and marketed innovative pharmaceutical products in the U.S. and internationally, as a company, we have not yet completed any clinical trials of our product candidates, nor have we demonstrated the ability to obtain marketing approvals, manufacture product candidates at a commercial scale, or conduct sales and marketing activities necessary for the successful commercialization of a product. Consequently, we have no historical basis as a company by which one can evaluate or predict reliably our future success or viability.

Additionally, while our team has experience at prior companies with regulatory filings, as a company, we have limited experience with regulatory filings with agencies such as the FDA, TGA, or EMA. Any delay in our regulatory filings for our product candidates, and any adverse development or perceived adverse development with respect to the applicable regulatory authority’s review of such filings, including, without limitation, the FDA’s issuance of a “refuse to file” letter or a request for additional information, could materially affect our financial condition.

We, or any future collaborators, may not be able to obtain and maintain orphan drug exclusivity for our product candidates in the U.S. and Europe.

Camsirubicin has been granted orphan drug designation for the treatment of soft tissue sarcoma in the U.S. and in the EU. We may seek additional orphan drug designations or regulatory incentives for our pipeline product candidates, for other indications or for future product candidates. There can be no assurances that we will be able to obtain such designations.

Even if we obtain orphan drug designation for a product candidate, we may not be able to maintain orphan drug exclusivity for that drug. For example, in certain geographies, orphan drug designation may be removed if the prevalence of an indication increases beyond the patient number limit required to maintain designation. Generally, if a drug with an orphan drug designation subsequently receives the first marketing approval for the indication for which it has such designation, the drug is entitled to a period of marketing exclusivity, which precludes the EMA or the FDA from approving another marketing application for the same product in the same indication for that time period. Orphan drug exclusivity may be lost if the FDA or EMA determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantity at the specified quality of the product to meet the needs of patients with the rare disease or condition. Moreover, even after an orphan drug is approved, the FDA can subsequently approve a different drug for the same condition if the FDA concludes that the later drug is clinically superior in that it is shown to be safer, more effective or makes a major contribution to patient care compared to our product.

The FDA may reevaluate the Orphan Drug Act and its regulations and policies, and similarly the EMA may reevaluate its policies and regulations. We do not know if, when, or how the FDA or EMA may change their orphan drug regulations and policies in the future, and it is uncertain how any changes might affect our business. Depending on what changes the FDA and/or EMA may make to their orphan drug regulations and policies, our business could be adversely impacted.

If serious adverse or undesirable side effects are identified during the development of our product candidates, we may abandon or limit our development or commercialization of such product candidates.

If our product candidates are associated with undesirable side effects or have unexpected characteristics, we may need to abandon their development or limit development to certain uses or subpopulations in which the undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective.

If we elect to or are forced to suspend or terminate any clinical trial with one of our product candidates, the commercial prospects of such product candidate will be harmed, and our ability to generate revenue from such product candidate will be delayed or eliminated. Any of these occurrences may harm our business, financial condition and prospects significantly.

If we experience delays or difficulties in the enrollment of subjects to our clinical trials, our receipt of necessary regulatory approvals could be delayed or prevented, which could materially affect our financial condition.

Identifying, screening and enrolling patients to participate in clinical trials of our product candidates is critical to our success, and we may not be able to identify, recruit, enroll and dose a sufficient number of patients with the required or desired characteristics to complete our clinical trials in a timely manner. The timing of our clinical trials depends on our ability to recruit patients to participate as well as to subsequently dose these patients and complete required follow-up periods.

In addition, we may experience enrollment delays related to increased or unforeseen regulatory, legal and logistical requirements and COVID-19-related or other future pandemic-related as well as issues related to currently ongoing or any future geopolitical risks at certain clinical trial sites. These delays could be caused by reviews by regulatory authorities and contractual discussions with individual clinical trial sites. Any delays in enrolling and/or dosing patients in our current clinical trials could result in increased costs, delays in advancing our product candidates, delays in testing the effectiveness of our product candidates or in termination of the clinical trials altogether.

Patient enrollment may be affected if our competitors have ongoing clinical trials with products for the same indications as our product candidates, and patients who would otherwise be eligible for our clinical trials instead enroll in our competitors' clinical trials. Patient enrollment may also be affected by other factors, including:

- delays in U.S., Australian or other foreign regulatory approvals to start the clinical trial;
- coordination with any clinical research organizations to enroll and administer the clinical trials;
- coordination and recruitment of collaborators and investigators at individual sites;
- size of the patient population and the effectiveness of the process for identifying patients;
- design of the clinical trial protocol;
- eligibility and exclusion criteria;
- perceived therapeutic risks and benefits of the product candidates being studied;
- availability of competing commercially available therapies and other competing products' clinical trials;
- time of year in which the trials are initiated or conducted;
- severity and prognosis of the diseases under investigation;
- ability to obtain and maintain subject consents;
- ability to enroll and treat patients in a timely manner;
- risk that enrolled subjects will drop out before completion of the trials;
- proximity and availability of clinical trial sites for prospective patients;
- ability to monitor subjects adequately during and after treatment;
- logistical challenges posed by the time-limited shelf-life of our current or future drug candidates;
- patient referral practices of physicians; and
- potential long-term effects of COVID-19, any resurgences thereof or any future pandemics.

Our inability to enroll a sufficient number of patients for clinical trials would result in significant delays and could require us to abandon one or more clinical trials altogether. Enrollment delays in these clinical trials may result in increased development costs for our product candidates, which could materially 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 and lose time to market and potential revenues.

Completion of our clinical trials and commercialization of our product candidates require access to, or development of, facilities to manufacture a sufficient supply of our product candidates. We will utilize third parties to manufacture our MNPR-101 radiopharma program and camsirubicin. We currently have manufacturing arrangements for MNPR-101-Zr and camsirubicin for clinical use. We have not yet secured manufacturing agreements for MNPR-101-RIT or MNPR-202 for clinical use.

In the future we may become unable, for various reasons, to rely on our sources for the manufacture of our product candidates, either for clinical trials or, at some future date, for commercial distribution. We may not be successful in identifying additional or replacement third-party manufacturers, or in negotiating acceptable terms with any we do identify. We may face competition for access to these manufacturers' facilities and may be subject to manufacturing delays if the manufacturers give other clients higher priority than they give to us. Even if we are able to identify an additional or replacement third-party manufacturer, the delays and costs associated with establishing and maintaining a relationship with such manufacturer may have a material adverse effect on us.

Before we can begin to commercially manufacture camsirubicin, MNPR-101-Zr, MNPR-101 RIT, MNPR-202 or any other product candidate, we must obtain regulatory approval of the manufacturing facility and process. Manufacturing of drugs for clinical and commercial purposes must comply with current Good Manufacturing Practices requirements, commonly known as "cGMP." The cGMP requirements govern quality control and documentation policies and procedures. Complying with cGMP and non-U.S. regulatory requirements will require that we expend time, money, and effort in production, recordkeeping, and quality control to ensure that the product meets applicable specifications and other requirements. We, or our contracted manufacturing facility, must also pass a pre-approval inspection prior to FDA or TGA approval. Failure to pass a pre-approval inspection will likely significantly delay or prevent FDA, TGA or other international regulatory agencies' approval of our products. If we fail to comply with these requirements, we would be subject to possible regulatory action and may be limited in the jurisdictions in which we are permitted to sell our products and will lose time to market and potential revenues.

It is uncertain whether product liability insurance will be adequate to address product liability claims, or that insurance against such claims will be affordable or available on acceptable terms in the future.

Clinical research involves the testing of new drugs on human volunteers pursuant to a clinical trial protocol. Such testing involves a risk of liability for personal injury to or death of patients due to, among other causes, adverse side effects, improper administration of the new drug, or improper volunteer behavior. Claims may arise from patients, clinical trial volunteers, consumers, physicians, hospitals, companies, institutions, researchers, or others using, selling, or buying our products, as well as from governmental bodies including a possibility in some states for product liability claims being made based on generic copies of our drugs. In addition, product liability and related risks are likely to increase over time, in particular upon the commercialization or marketing of any products by us or parties with which we enter into development, marketing, or distribution collaborations. Although we have obtained product liability insurance in connection with our clinical trials, there can be no assurance that the amount and scope of such insurance coverage will be appropriate and sufficient in the event any claims arise, that we will be able to secure additional coverage should we attempt to do so, or that our insurers would not contest or refuse any attempt by us to collect on such insurance policies. Regardless of their merit or eventual outcome, product liability claims may result in:

- withdrawal of clinical trial volunteers;
- decreased demand for our products when approved;
- injury to our reputation and significant, adverse media attention; and
- potentially significant litigation costs, including without limitation, any damages awarded to the plaintiffs if we lose or settle claims.

If the market opportunities for our current and potential future drug candidates are smaller than we believe they are, our ability to generate product revenues will be adversely affected and our business may suffer.

Our understanding of the number of patients who have advanced cancers that express uPAR and are eligible for MNPR-101-Zr and MNPR-101-RIT as well as patients who have advanced soft tissue sarcoma ("ASTS") is based upon estimates and various scientific publications from governments or academic institutions. These estimates or reports may prove to be incorrect, and new studies may demonstrate or suggest a lower estimated incidence or prevalence of patients who might be eligible or amenable to MNPR-101-Zr, MNPR-101-RIT, and camsirubicin. Also, eligible or amenable patients may become increasingly difficult to identify and access due to many different factors, such as increasing competition in the radiopharmaceutical space. Moreover, the targetable population for our MNPR-101 radiopharmaceutical program and camsirubicin may further be reduced if our estimates or addressable populations are erroneous or sub-populations of patients within the addressable populations do not benefit from our MNPR-101 radiopharmaceutical program or camsirubicin.

Risks Related to Our Reliance on Third Parties

Corporate, non-profit, and academic collaborators may take actions (including lack of effective actions) to delay, prevent, or undermine the success of our products.

Our operating and financial strategy for the development, clinical testing, manufacture, and commercialization of product candidates is heavily dependent on us entering into collaborations with corporations, non-profit organizations, academic institutions, licensors, licensees, and other parties. There can be no assurance that we will be successful in establishing such collaborations. Current and future collaborations are and may be terminable at the sole discretion of the collaborator. The activities of any collaborator will not be within our direct control and may not be in our power to influence. There can be no assurance that any collaborator will perform its obligations to our satisfaction or at all; that we will derive any revenue, profits, or benefit from such collaborations; or that any collaborator will not compete with us. If any collaboration is not pursued, we may require substantially greater capital to undertake development and commercialization of our proposed products, and may not be able to develop and commercialize such products effectively, if at all. In addition, a lack of development and commercialization collaborations may lead to significant delays in introducing proposed products into certain markets and/or reduced sales of proposed products in such markets. Furthermore, current and future collaborators may act deliberately or inadvertently in ways detrimental to our interests.

The termination of third-party licenses could adversely affect our rights to important compounds or technologies.

We rely on certain rights to MNPR-101 that we have secured through a non-exclusive license agreement with XOMA. XOMA, as licensor, has the ability to terminate the license if we breach our obligations under the license agreement and do not remedy any such breach within a set time after receiving written notice of such breach from XOMA. A termination of the license agreement might force us to cease developing and/or selling MNPR-101-Zr or MNPR-101 RIT, if either gets to market.

Data provided by collaborators and other parties upon which we rely have not been independently verified and could turn out to be inaccurate, misleading, or incomplete.

We rely on third-party vendors, scientists, and collaborators to provide us with significant data and other information related to our projects, clinical trials, and business. We do not independently verify or audit all of such data (including possibly material portions thereof). As a result, such data may be inaccurate, misleading, or incomplete.

In certain cases, we may need to rely on a single supplier for a particular manufacturing material or service, and any interruption in or termination of service by such supplier could delay or disrupt the commercialization of our products.

We rely on third-party suppliers for the materials used to manufacture our compounds. Some of these materials may at times only be available from one supplier. Any interruption in or termination of service by such single source suppliers could result in a delay or disruption in manufacturing until we locate an alternative source of supply. There can be no assurance that we would be successful in locating an alternative source of supply or in negotiating acceptable terms with such prospective supplier.

We rely on a limited number of contracted manufacturing plants. If we need to enlist new contract manufacturers, it will delay our MNPR-101 radiopharmaceutical program and our camsirubicin program and may increase the costs of our clinical trials.

Our contracted camsirubicin active pharmaceutical ingredient manufacturing plant as well as our contracted raw materials manufacturing plant are in countries in Asia and Europe, either of which may be affected by imposed tariffs and regional geopolitical factors outside of their control, including the Russia-Ukraine war and Israel-Hamas war, which may affect the supply of camsirubicin active pharmaceutical ingredient and raw materials. If we need to enlist new contract manufacturers, it will delay our camsirubicin clinical program and may increase our cost for our Phase 1b and future camsirubicin clinical trials.

Our contracted MNPR-101-Zr manufacturing plant as well as our raw material supplier are currently located in the U.S., but the Russia-Ukraine war and Israel-Hamas war may adversely affect the sourcing of radioisotopes and timely supply of MNPR-101-Zr to clinical sites. If we need to enlist new contract manufacturers, it will delay our MNPR-101-Zr clinical program and may increase our cost for the currently ongoing or future clinical trials.

We rely on third parties to conduct our non-clinical studies and our clinical trials. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may be unable to obtain regulatory approval for or commercialize our current product candidates or any future products, on a timely and efficient basis or at all, and our financial condition will be adversely affected.

We do not have the capacity to independently conduct non-clinical studies and clinical trials. We rely on medical institutions, clinical investigators, contract laboratories, collaborative partners and other third parties, such as contract research organizations or clinical research organizations, to conduct non-clinical studies and clinical trials on our product candidates. The third parties with whom we contract for execution of our non-clinical studies and clinical trials play a significant role in the conduct of these studies and trials and the subsequent collection and analysis of data. However, these third parties are not our employees, and except for contractual duties and obligations, we have limited ability to control the amount or timing of resources that they devote to our programs.

Although we rely on third parties to conduct our non-clinical studies and clinical trials, we remain responsible for ensuring that each of our non-clinical studies and clinical trials is conducted in accordance with its investigational plan and protocol. Moreover, the FDA, TGA, EMA and other foreign regulatory authorities require us to comply with regulations and standards, including some regulations commonly referred to as good clinical practices (“GCPs”), for conducting, monitoring, recording and reporting the results of clinical trials to ensure that the data and results are scientifically credible and accurate, and that the trial subjects are adequately informed of the potential risks of participating in clinical trials.

In addition, the execution of non-clinical studies and clinical trials, and the subsequent compilation and analyses of the data produced, requires coordination among various parties. In order for these functions to be carried out effectively and efficiently, it is imperative that these parties communicate and coordinate with one another. Moreover, these third parties may also have relationships with other commercial entities, some of which may compete with us. Under certain circumstances, these third parties may be able to terminate their agreements with us upon short notice. If the third parties conducting our clinical trials do not perform their contractual duties or obligations, experience work stoppages, do not meet expected deadlines, terminate their agreements with us or need to be replaced, or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical trial protocols or GCPs, or for any other reason, we may need to enter into new arrangements with alternative third parties, which could be difficult, costly or impossible, and our clinical trials may be extended, delayed or terminated or may need to be repeated. If any of the foregoing were to occur, we may not be able to obtain, on a timely and efficient basis or at all, regulatory approval for or to commercialize the product candidate being tested in such trials, and as a result, our financial condition will be adversely affected.

Risks Related to Commercialization of Our Product Candidates

We have no experience as a company in commercializing any product. If we fail to obtain commercial expertise, upon product approval by regulatory agencies, our product launch and revenues could be delayed.

As a company, we have never obtained regulatory approval for, or commercialized, any product. Accordingly, we have not yet begun to build out any sales or marketing or distribution capabilities. If we are unable to establish, or contract for, effective sales and marketing and distribution capabilities, or if we are unable to enter into agreements with third parties to commercialize our product candidates on favorable terms or on any reasonable terms at all, we may not be able to effectively generate product revenues once our product candidates are approved for marketing. If we fail to obtain commercial expertise or capabilities, upon drug approval, our product launch and subsequent revenues could be delayed and /or fail to reach their commercial potential.

Our product development efforts are at an early stage. We have not yet undertaken any marketing efforts, and there can be no assurance that future anticipated market testing and analyses will validate our marketing strategy. We may need to modify the products, or we may not be successful in either developing or marketing those products.

As a company, we have not completed the development or clinical trials of any product candidates and, accordingly, have not yet begun to market or generate revenue from the commercialization of any products. Obtaining approvals of these product candidates will require substantial additional research and development as well as costly clinical trials. There can be no assurance that we will successfully complete development of our product candidates or successfully market them. We may encounter problems and delays relating to research and development, regulatory approval, intellectual property rights of product candidates, or other factors. There can be no assurance that our development programs will be successful, that our product candidates will prove to be safe and effective in or after clinical trials, that the necessary regulatory approvals for any product candidates will be obtained, or, even if obtained, will be as broad as sought or will be maintained for any period thereafter, that patents will issue on our patent applications, that any intellectual property protections we secure will be adequate, or that our collaboration arrangements will not diminish the value of our intellectual property through licensing or other arrangements. Furthermore, there can be no assurance that any product we might market will be received favorably by customers (whether physicians, payers, patients, or all three), adequately reimbursed by third-party payers, or that competitive products will not perform better and/or be marketed more successfully. Additionally, there can be no assurances that any future market testing and analyses will validate our marketing strategies. We may need to seek to modify the product labels through additional studies in order to be able to market them successfully to reach their commercial potential.

If we are unable to establish relationships with licensees or collaborators to carry out sales, marketing, and distribution functions or to create effective marketing, sales, and distribution capabilities, we will be unable to market our products successfully.

Our business strategy may include out-licensing product candidates to or collaborating with larger firms with experience in marketing and selling pharmaceutical products. There can be no assurance that we will successfully be able to establish marketing, sales, or distribution relationships with any third-party, that such relationships, if established, will be successful, or that we will be successful in gaining market acceptance for any products we might develop. To the extent that we enter into any marketing, sales, or distribution arrangements with third parties, our product revenues per unit sold are expected to be lower than if we marketed, sold, and distributed our products directly, and any revenues we receive will depend upon the efforts of such third parties.

If we are unable to establish such third-party marketing and sales relationships, or choose not to do so, we would have to establish in-house marketing and sales capabilities. We have no experience in marketing or selling oncology pharmaceutical products, and currently have no marketing, sales, or distribution infrastructure and no experience developing or managing such infrastructure for an oncology related product. To market any products directly, we would have to establish a marketing, sales, and distribution force that has technical expertise and could support a distribution capability. Competition in the biopharmaceutical industry for technically proficient marketing, sales, and distribution personnel is intense and attracting and retaining such personnel may significantly increase our costs. There can be no assurance that we will be able to establish internal marketing, sales, or distribution capabilities or that these capabilities will be sufficient to meet our needs.

Commercial success of our product candidates will depend on the acceptance of these products by physicians, payers, and patients.

Any product candidate that we may develop may not gain market acceptance among physicians, payers and patients. Market acceptance of and demand for any product that we may develop will depend on many factors, including without limitation:

- Comparative superiority of the efficacy and safety in the treatment of the disease indication compared to alternative treatments;
- Less incidence, less prevalence and more severity of adverse side effects;
- Potential advantages over alternative treatments;
- Cost effectiveness;
- Convenience and ease of administration, stability and shelf life, for distributor, physician and patient;
- Sufficient third-party coverage and/or reimbursement;
- Strength of sales, marketing and distribution support; and
- Our ability to provide acceptable and compelling evidence of safety and efficacy.

If any product candidate developed by us receives regulatory approval but does not achieve an adequate level of market acceptance by physicians, payers, and patients, we may generate insufficient, little, or no product revenue to earn appropriate returns on the investment of product development costs and may not become profitable at sufficient product sales volumes to earn sustainable profitability.

Our products may not be accepted for reimbursement or adequately reimbursed by third-party payers.

The successful commercialization of any products we might develop will depend substantially on whether the costs of our products and related treatments are reimbursed at acceptable levels by government authorities, private healthcare insurers, and other third-party payers, such as health maintenance organizations. Reimbursement rates may vary, depending upon the third-party payer, the type of insurance plan, and other similar or dissimilar factors. If our products do not achieve adequate reimbursement, then the number of physician prescriptions of our products may not be sufficient to make our products profitable, and to earn a sufficient profit to earn a reasonable return on our investment and a provide a cash flow to finance future investments on the next generation of products and investments in new technological platforms.

Comparative effectiveness research demonstrating benefits of a competitor’s product could adversely affect the sales of our product candidates. If third-party payers do not consider our products to be cost-effective compared to other available therapies, they may not cover our products as a benefit under their plans or, if they do, the level of payment may not be sufficient to allow us to sell our products on a profitable basis sufficient for our Company to remain competitive and thrive.

Adequate third-party reimbursement may not be available to enable us to maintain price levels sufficient to realize an appropriate return on our investment in the product development of that product. In addition, in the U.S. there is a growing emphasis on comparative effectiveness research, both by private payers and by government agencies. To the extent other drugs or therapies are found to be more effective than our products, payers may elect to cover such therapies in lieu of our products or reimburse our products at a lower rate.

The effects of economic and political pressure to lower pharmaceutical prices are a major threat to the economic viability of new research-based pharmaceutical products, and any significant decrease in drug prices could materially and adversely affect our prospects.

Emphasis on managed care and government price controls in the U.S. has increased and we expect this will continue to increase the pressure on pharmaceutical pricing. Coverage policies and third-party reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained for one or more products for which we receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

Any development along these lines could materially and adversely affect our prospects. We are unable to predict what political, legislative or regulatory changes relating to the healthcare industry, including without limitation any changes affecting governmental and/or private or third-party coverage and reimbursement, may be enacted in the future, or what effect such legislative or regulatory changes would have on our business. However, if governmental price management does not provide for the very high price of pharmaceutical research, it could create very demanding challenges for our industry and our prospects or require breakthroughs in research productivity, of which there can be no assurance.

If we obtain FDA approval for any of our product candidates, we will be subject to various federal and state fraud and abuse laws; these laws may impact, among other things, our proposed sales, marketing and education programs. Fraud and abuse laws are expected to increase in breadth and in detail, which will likely increase our operating costs and the complexity of our programs to ensure compliance with such enhanced laws.

If we obtain FDA approval for any of our product candidates and begin commercializing those products in the U.S., our operations may be directly, or indirectly through our customers, distributors, or other business partners, subject to various federal and state fraud and abuse laws, including, without limitation, anti-kickback statutes and false claims statutes which may increase our operating costs. These laws may impact, among other things, our proposed sales, marketing and education programs. In addition, we may be subject to data privacy and security regulation by both the federal government and the states in which we conduct business.

If our operations are found to be in violation of any of the federal and state fraud and abuse laws or any other governmental regulations that apply to us, we may be subject to criminal actions and significant civil monetary penalties, which would adversely affect our ability to operate our business and our results of operations.

If our operations are found to be in violation, even inadvertently, of any of the federal and state fraud and abuse laws, including, without limitation, anti-kickback statutes and false claims statutes or any other governmental regulations that apply to us, we may be subject to penalties, including criminal and significant civil monetary penalties, damages, fines, imprisonment, exclusion from participation in government healthcare programs, and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations. To the extent that any of our product candidates are ultimately sold in a foreign country, we may be subject to similar foreign laws and regulations, which may include, for instance, applicable post-marketing requirements, including safety surveillance, anti-fraud and abuse laws, and implementation of corporate compliance programs and reporting of payments or transfers of value to healthcare professionals.

Negotiated prices for our products covered by a Part D prescription drug plan and other government programs will be lower than the prices we might otherwise obtain.

Government payment for some of the costs of prescription drugs may increase demand for our products for which we receive marketing approval; however, any negotiated prices for our products covered by a Part D prescription drug plan and other government programs will be lower than the prices we might otherwise obtain. We anticipate that the number and type of products that will be subject to federal pricing will increase substantially over time. There may be rules to demand that the government and medical institutions, which are in part supported by government funding, will be granted access to medicines at the same highly favorable prices given to the governmental direct medical care programs.

Risks Related to Our Intellectual Property

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 take advantage of our (and our licensors') development efforts to develop competing drugs.

Our commercial success will depend in part on obtaining patent protection for any products and other technologies we might develop, and successfully defending any patents we obtain against third-party challenges. See "Business – License, Development and Collaboration Agreements". The assignment and transfer of the camsirubicin (formerly GPX-150) patent portfolio from TacticGem, LLC ("TacticGem") to us has been completed. We filed and have been granted in the U.S. and various countries around the world patents for antibodies that target uPAR for our MNPR-101 program. We have also been granted in the U.S. and various countries around the world patents to a specific sequence of amino acids on uPAR, to which our MNPR-101 antibody binds. We are currently prosecuting this patent in other countries around the world to further protect MNPR-101. We also have jointly applied for patents with our collaborator, NorthStar, for MNPR-101-Zr and MNPR-101-RIT conjugates. The patent process is subject to numerous risks and uncertainties, and there can be no assurance that we will be successful in obtaining and defending patents. See "Business - Intellectual Property Portfolio and Exclusivity". These risks and uncertainties include without limitation the following:

- Patents that may be issued or licensed may be challenged, invalidated, or circumvented; or may not provide any competitive advantage for other reasons.
- Our licensors may terminate or breach our existing or future license agreements, thereby reducing or preventing our ability to exclude competition; termination of such license agreements may also subject us to risk of patent infringement of patents to which we no longer have a license.
- Our competitors, many of which have substantially greater resources than us and have made significant investments in competing technologies, may seek, or may already have obtained, patents that will limit, interfere with, or eliminate our ability to make, use, and sell our potential products either in the U.S. or in international markets.
- As a matter of public policy regarding worldwide health concerns, there may be significant pressure on the U.S. government and other international governmental bodies to limit the scope of domestic and international patent protection for cancer treatments that prove successful.
- Countries other than the U.S. may have less restrictive patent laws than those upheld by the U.S. courts; therefore, non-U.S. competitors could exploit these laws to create, develop, and market competing products. In some countries, the legal compliance with pharmaceutical patents, patent applications and other intellectual property regulations is very weak or actively evaded in some cases with government aid.

In addition, the U.S. Patent and Trademark Office ("USPTO") and patent offices in other jurisdictions have often required that patent applications concerning pharmaceutical and/or biotechnology-related inventions be limited or narrowed substantially to cover only the specific innovations exemplified in the patent application, thereby limiting their scope of protection against competitive challenges. Thus, even if we or our licensors are able to obtain patents, the scope of the patents may be substantially narrower than anticipated.

If we permit our patents to lapse or expire, we will not be protected and will have less of a competitive advantage. The value of our products may be greatly reduced if this occurs. Our patents expire at different times and are subject to the laws of multiple countries. Some of our patents are currently near expiration and we may pursue patent term extensions for these where appropriate or permit them to lapse. See "Business - Intellectual Property Portfolio and Exclusivity".

In addition to patents, we also rely on trade secrets and proprietary know-how. While we take measures to protect this information by entering into confidentiality and invention agreements with our employees, consultants and collaborators, we cannot provide any assurances that these agreements will be fully enforceable and will not be breached, that we will be able to protect ourselves from the harmful effects of disclosure if they are not fully enforceable or are breached, that any remedy for a breach will adequately compensate us, that these agreements will achieve their intended aims, or that our trade secrets will not otherwise become known or be independently discovered by competitors. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts inside and outside the U.S., are less willing or unwilling to protect trade secrets. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent them from using that technology or information to compete with us. If any of our trade secrets were to be disclosed to or independently developed by a competitor, our competitive position would be harmed, and the value of the trade secrets may be greatly reduced.

The patent protection we obtain and preserve for our product candidates may not be sufficient to provide us with any material competitive advantage.

We may be subject to competition despite the existence of intellectual property we license or own. We can give no assurances that our intellectual property claims will be sufficient to prevent third parties from designing around patents we own or license and developing and commercializing competitive products. The existence of competitive products that avoid our intellectual property could materially adversely affect our operating results and financial condition. Furthermore, limitations, or perceived limitations, in our intellectual property may limit the interest of third parties to partner, collaborate or otherwise transact with us, if third parties perceive a higher than acceptable risk to commercialization of our products or future products. If a competitor were able to successfully design around any method of use and formulation patents we may have now or in the future, it is highly likely that our business and competitive advantage would be adversely affected.

Patent terms may be inadequate to protect our competitive position on our product candidates for an adequate amount of time. If this occurs, our competitive position, business, financial condition, results of operations, and prospects would be materially harmed.

Patents have a limited lifespan. In the U.S., if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest U.S. non-provisional filing date. Various extensions may be available, but the life of a patent, and the protection it affords, is limited. Even if patents covering our product candidates are obtained, once the patent life has expired for a product candidate, we may be open to competition from competitive medications, including generic medications. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such product candidates might expire before or shortly after such product candidates are commercialized. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing product candidates similar or identical to ours.

Depending upon the timing, duration and conditions of any FDA marketing approval of our product candidates, one or more of our U.S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, referred to as the Hatch-Waxman Amendments, and similar legislation in the European Union. The Hatch-Waxman Amendments permit a patent term extension of up to five years for a patent covering an approved product as compensation for effective patent term lost during product development and the FDA regulatory review process. However, we may not receive an extension if we fail to exercise due diligence during the testing phase or regulatory review process, fail to apply within applicable deadlines, fail to apply prior to expiration of relevant patents or otherwise fail to satisfy applicable requirements. Moreover, the length of the extension could be less than we request. Only one patent per approved product can be extended, the extension cannot extend the total patent term beyond 14 years from approval and only those claims covering the approved drug, a method for using it or a method for manufacturing it may be extended. If we are unable to obtain patent term extension or the term of any such extension is less than we request, the period during which we can enforce our patent rights for the applicable product candidate will be shortened and our competitors may obtain approval to market competing products sooner. As a result, our revenue from applicable products could be reduced. Further, if this occurs, our competitors may take advantage of our investment in development and trials by referencing our clinical and preclinical data and launch their product earlier than might otherwise be the case, and our competitive position, business, financial condition, results of operations, and prospects would be materially harmed.

Intellectual property disputes could require us to spend time and money to address such disputes and could limit our intellectual property rights.

The biopharmaceutical industry has been characterized by extensive litigation regarding patents and other intellectual property rights, and companies have employed intellectual property litigation and USPTO post-grant proceedings to gain a competitive advantage. We may become subject to infringement claims or litigation arising out of patents and pending applications of our competitors, or additional interference proceedings declared by the USPTO to determine the priority and patentability of inventions. The defense and prosecution of intellectual property suits, USPTO proceedings, and related legal and administrative proceedings are costly and time-consuming to pursue, and their outcome is uncertain. Litigation may be necessary to enforce our issued patents, to protect our trade secrets and know-how, or to determine the enforceability, scope, and validity of the proprietary rights of others. An adverse determination in litigation or USPTO post-grant and interference proceedings to which we may become a party could subject us to significant liabilities, require us to obtain licenses from third parties, or restrict or prevent us from selling our products in certain markets. Even if a given patent or intellectual property dispute were settled through licensing or similar arrangements, our costs associated with such arrangements may be substantial and could include the payment by us of large, fixed payments and ongoing royalties. Furthermore, the necessary licenses may not be available on satisfactory terms or at all. Even where we have meritorious claims or defenses, the costs of litigation may prevent us from pursuing these claims or defenses and/or may require extensive financial and personnel resources to pursue these claims or defenses. In addition, it is possible there may be defects of form in our current and future patents that could result in our inability to defend the intended claims. Intellectual property disputes arising from the aforementioned factors, or other factors, may materially harm our business.

We may not be able to enforce our intellectual property rights throughout the world.

The laws of some foreign countries do not protect intellectual property rights to the same extent as the laws of the U.S. Companies have encountered significant problems in protecting and defending intellectual property rights in certain foreign jurisdictions. The legal systems of some countries, particularly developing countries, do not favor the enforcement of patents and other intellectual property protection, especially those relating to life sciences. This could make it difficult for us to stop the infringement of our patents or the misappropriation of our other intellectual property rights. For example, many foreign countries have compulsory licensing laws under which a patent owner must grant licenses to third parties. In addition, many countries limit the enforceability of patents against third parties, including government agencies or government contractors. In these countries, patents may provide limited or no benefit.

Proceedings to enforce our patent rights in foreign jurisdictions, whether or not successful, could result in substantial costs and divert our efforts and attention from other aspects of our business. Furthermore, while we intend to protect our intellectual property rights in our expected significant markets, we cannot ensure that we will be able to initiate or maintain similar efforts in all jurisdictions in which we may wish to market our current or any future product candidates. Accordingly, our efforts to protect our intellectual property rights in such countries may be inadequate. In addition, changes in the law and legal decisions by courts in the U.S. and foreign countries may affect our ability to obtain and enforce adequate intellectual property protection for our products and technology.

Changes to the patent law in the U.S. and other jurisdictions could diminish the value of patents in general, thereby impairing our ability to protect our product candidates.

As is the case with other biopharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biopharmaceutical industry involves both technological and legal diligence and complexity. Therefore, obtaining and enforcing biopharmaceutical patents is costly, time consuming and inherently uncertain. In addition, the U.S. has recently enacted and is currently implementing wide ranging patent reform legislation. The U.S. Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents once obtained. Depending on future actions by the U.S. Congress, the federal courts and the USPTO, as well as other jurisdictions around the world, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future.

Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other provisions during the patent process. There are situations in which noncompliance due to issues beyond our control, can result in abandonment or lapse of a patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, competitors might be able to enter the market earlier than would otherwise have been the case.

If we fail to comply with our obligations under any license, collaboration or other intellectual property-related agreements, we may be required to pay damages and could lose intellectual property rights that may be necessary for developing, commercializing and protecting our current or future technologies or drug candidates or we could lose certain rights to grant sublicenses.

Any license, collaboration or other intellectual property-related agreements impose, and any future license, collaboration or other intellectual property-related agreements we enter into are likely to impose, various development, commercialization, funding, milestone, royalty, diligence, sublicensing, insurance, patent prosecution and enforcement or other obligations on us. If we breach any of these obligations, or use the intellectual property licensed to us in an unauthorized manner, we may be required to pay damages and the licensor may have the right to terminate the license. In spite of our best efforts, any of our future licensors might conclude that we have materially breached our license agreements and might therefore terminate the license agreements, thereby removing our ability to develop and commercialize products and technologies covered by these license agreements. Any license agreements we enter into may be complex, and certain provisions in such agreements may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could narrow what we believe to be the scope our rights to the relevant intellectual property or technology, or increase what we believe to be our financial or other obligations under the relevant agreement, either of which could have a material adverse effect on our business, financial condition, results of operations, and prospects.

We may seek to obtain licenses from licensors in the future, however, we may be unable to obtain any such licenses at a reasonable cost or on reasonable terms, if at all. In addition, if any of our future licensors terminate any such license agreements, such license termination could result in our inability to develop, manufacture and sell products that are covered by the licensed technology or could enable a competitor to gain access to the licensed technology. Any of these events could have a material adverse effect on our competitive position, business, financial condition, results of operations, and ability to achieve profitability.

Furthermore, we may not have the right to control the preparation, filing, prosecution, maintenance, enforcement and defense of patents and patent applications that we license from third parties. Therefore, we cannot be certain that these patents and patent applications will be prepared, filed, prosecuted, maintained, enforced and defended in a manner consistent with the best interests of our business. If our future licensors fail to prosecute, maintain, enforce and defend patents we may in-license, or lose rights to licensed patents or patent applications, our license rights may be reduced or eliminated. In such circumstances, our right to develop and commercialize any of our products or drug candidates that is the subject of such licensed rights could be materially adversely affected. In certain circumstances, our licensed patent rights are subject to our reimbursing our licensors for their patent prosecution and maintenance costs.

Moreover, our licensors may own or control intellectual property that has not been licensed to us and, as a result, we may be subject to claims, regardless of their merit, that we are infringing, misappropriating or otherwise violating the licensor's intellectual property rights and the amount of any damages or future royalty obligations that would result, if any such claims were successful, would depend on the technology and intellectual property we use in products that we successfully develop and commercialize, if any. Therefore, even if we successfully develop and commercialize products, due to such obligations, we may be unable to achieve or maintain profitability.

Third parties may initiate legal proceedings alleging that we are infringing, misappropriating or otherwise violating their intellectual property rights, the outcome of which would be uncertain and could have a material adverse impact on the success of our business.

Our commercial success depends, in part, upon our ability or the ability of any of our future collaborators to develop, manufacture, market and sell our current or any future drug candidates and to use our proprietary technologies without infringing, misappropriating or otherwise violating the proprietary and intellectual property rights of third parties. The biotechnology and pharmaceutical industries are characterized by extensive and complex litigation regarding patents and other intellectual property rights.

We or any of our future licensors or strategic partners, may be party to, or be threatened with, adversarial proceedings or litigation regarding intellectual property rights with respect to our current or any potential future drug candidates and technologies, including derivation, reexamination, inter partes review, post-grant review or interference proceedings before the USPTO and similar proceedings in jurisdictions outside of the U.S. such as opposition proceedings. If we or our licensors or strategic partners are unsuccessful in any interference proceedings or other priority or validity disputes (including through any patent oppositions) to which we or they are subject, we may lose valuable intellectual property rights through the loss of one or more patents or our patent claims may be narrowed, invalidated, or held unenforceable. In some instances, we may be required to indemnify our licensors or strategic partners for the costs associated with any such adversarial proceedings or litigation. Third parties may also assert infringement, misappropriation or other claims against us, our licensors or our strategic partners based on existing patents or patents that may be granted in the future, as well as other intellectual property rights, regardless of their merit. There is a risk that third parties may choose to engage in litigation or other adversarial proceedings with us, our licensors or our strategic partners to enforce or otherwise assert their patent rights or other intellectual property rights. Even if we believe such claims are without merit, a court of competent jurisdiction could hold that these third-party patents and other intellectual property rights are valid, enforceable and infringed, which could have a material adverse impact on our ability to utilize our developed technologies or to commercialize our current or any future drug candidates deemed to be infringing. In order to successfully challenge the validity of any such U.S. patent in federal court, we would need to overcome a presumption of validity by presenting clear and convincing evidence of invalidity. There is no assurance that a court of competent jurisdiction, even if presented with evidence we believe to be clear and convincing, would invalidate the claims of any such U.S. patent.

Further, we cannot guarantee that we will be able to successfully settle or otherwise resolve such adversarial proceedings or litigation. If we are unable to successfully settle future claims on terms acceptable to us, we may be required to engage in or to continue costly, unpredictable and time-consuming litigation and may be prevented from or experience substantial delays in marketing our drug candidates. If we or any of our licensors or strategic partners are found to infringe, misappropriate or violate a third-party patent or other intellectual property rights, we could be required to pay damages, including treble damages and attorney's fees, if we are found to have willfully infringed. In addition, we, or any of our licensors or strategic partners may choose to seek, or be required to seek, a license from a third-party, which may not be available on commercially reasonable terms, if at all. Even if a license can be obtained on commercially reasonable terms, the rights may be non-exclusive, which could give our competitors access to the same technology or intellectual property rights licensed to us, and we could be required to make substantial licensing and royalty payments. We also could be forced, including by court order, to cease utilizing, developing, manufacturing and commercializing our developed technologies or drug candidates deemed to be infringing. We may be forced to redesign current or future technologies or products. Any of the foregoing could have a material adverse effect on our ability to generate revenue or achieve profitability and possibly prevent us from generating revenue sufficient to sustain our operations.

In addition, we or our licensors or strategic partners may find it necessary to pursue claims or to initiate lawsuits to protect or enforce our patent or other intellectual property rights. If we or our licensors or strategic partners were to initiate legal proceedings against a third-party to enforce a patent covering one of our drug candidates or our developed technology, the defendant could counterclaim that such patent is invalid or unenforceable. In patent litigation in the U.S., defendant counterclaims alleging invalidity or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, for example, claiming patent-ineligible subject matter, lack of novelty, indefiniteness, lack of written description, non-enablement, anticipation or obviousness. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO or made a misleading statement during prosecution. The outcome of such invalidity and unenforceability claims is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art of which we or our licensors or strategic partners and the patent examiner were unaware during prosecution. If a defendant were to prevail on a legal assertion of invalidity or unenforceability, we could lose at least part, and perhaps all, of the patent protection for one or more of our drug candidates. The narrowing or loss of our owned and licensed patent claims could limit our ability to stop others from using or commercializing similar or identical technologies and products. All of these events could have a material adverse effect on our business, financial condition, results of operations and prospects. Patent and other intellectual property rights also will not protect our drug candidates and technologies if competitors or third parties design around such drug candidates and technologies without legally infringing, misappropriating or violating our patent or other intellectual property rights.

The cost to us in defending or initiating any litigation or other proceedings relating to our patent or other intellectual property rights, even if resolved in our favor, could be substantial, and any litigation or other proceedings would divert our management's attention and distract our personnel from their normal responsibilities. Such litigation or proceedings could materially increase our operating losses and reduce the resources available for development activities or any future sales, marketing or distribution activities. We may not have sufficient financial or other resources to conduct such litigation or proceedings adequately. Some of our competitors may be able to more effectively sustain the costs of complex patent litigation because they have substantially greater resources. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could delay our research and development efforts and materially limit our ability to continue our operations. Furthermore, because of the substantial amount of discovery required in connection with certain such proceedings, there is a risk that some of our confidential information could be compromised by disclosure. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments and if securities analysts or investors perceive these results to be negative, such announcements could have a material adverse effect on the price of our common stock.

Intellectual property rights of third parties could adversely affect our ability to commercialize our current or future technologies or drug candidates, and we might be required to litigate or obtain licenses from third parties to develop or market our current or future technologies or drug candidates, which may not be available on commercially reasonable terms, or at all.

There are numerous companies that have pending patent applications and issued patents broadly covering immune-therapies generally or covering small molecules directed against the same targets as, or targets similar to, those we are pursuing. Our competitive position may materially suffer if patents issued to third parties or other third-party intellectual property rights cover our current or future technologies, drug candidates or elements thereof, or our manufacture or uses relevant to our development plans. In such cases, we may not be in a position to develop or commercialize current or future technologies or drug candidates unless we successfully pursue litigation to nullify or invalidate the third-party intellectual property rights concerned or enter into a license agreement with the intellectual property rights holder, if available on commercially reasonable terms. There may be issued patents of which we are not aware, held by third parties that, if found to be valid and enforceable, could be alleged to be infringed by our current or future technologies or drug candidates. There also may be pending patent applications of which we are not aware that may result in issued patents, which could be alleged to be infringed by our current or future technologies or drug candidates. Should such an infringement claim be successfully brought, we may be required to pay substantial damages or be forced to abandon our current or future technologies or drug candidates or to seek a license from any patent holders. No assurances can be given that a license will be available on commercially reasonable terms, if at all.

Third-party intellectual property rights holders may also actively bring infringement, misappropriation or other claims alleging violations of intellectual property rights against us. We cannot guarantee that we will be able to successfully settle or otherwise resolve such claims. If we are unable to successfully settle future claims on terms acceptable to us, we may be required to engage in or to continue costly, unpredictable and time-consuming litigation and may be prevented from, or experience substantial delays in, marketing our drug candidates. If we fail in any such dispute, in addition to being forced to pay damages, we may be temporarily or permanently prohibited from commercializing any of our current or future technologies or drug candidates that are held to be infringing, misappropriating or otherwise violating third-party intellectual property rights. We might, if possible, also be forced to redesign current or future technologies or drug candidates so that we no longer infringe, misappropriate or violate the third-party intellectual property rights. Any of these events, even if we were ultimately to prevail, could require us to divert substantial financial and management resources that we would otherwise be able to devote to our business, which could have a material adverse effect on our financial condition and results of operations.

Risks Related to Our Business Operations and Industry

We have a limited operating history.

To date, we have engaged exclusively in acquiring pharmaceutical product candidates, licensing rights to product candidates, entering into collaboration agreements with respect to key services or technologies for our drug product development, and conducted clinical trials, but have not yet received any governmental approvals, brought any product to market, manufactured products in commercial quantities or sold any pharmaceutical products. As a company we have limited experience in negotiating, establishing, and maintaining strategic relationships, conducting clinical trials, and managing the regulatory approval process, all of which will be necessary if we are to be successful. Our lack of experience in these critical areas makes it difficult for a prospective investor to evaluate our abilities and increases the risk that we will fail to successfully execute our strategies.

Furthermore, if our business grows rapidly, our operational, managerial, legal, and financial resources will be strained. Our development will require continued improvement and expansion of our management team and our operational, managerial, legal, and financial systems and controls.

In the normal course of business, we have evaluated and expect to evaluate potential acquisitions and/or licenses of patents, compounds, and technologies that our management believes could complement or expand our business. In the event that we identify an acquisition or license candidate we find attractive, there is no assurance that we will be successful in negotiating an agreement to acquire or license, or in financing or profitably exploiting, such patents, compounds, or technologies. Furthermore, such an acquisition or license could divert management time and resources away from other activities that would further our current business development.

If we lose key management leadership, and/or scientific personnel, and if we cannot recruit qualified employees, managers, directors, officers, or other significant personnel, it is highly likely that we will experience program delays and increases in compensation costs, and our business will be materially disrupted.

Our future success is highly dependent on the continued service of principal members of our management, leadership, and scientific personnel, who are able to terminate their employment with us at any time and may be able to compete with us. The loss of any of our key management, leadership, or scientific personnel including, in particular, Christopher M. Starr, our Executive Chairman of the Board of Directors (referred to as the "Board"), and Chandler D. Robinson, our President and CEO, could materially disrupt our business and materially delay or prevent the successful product development and commercialization of our product candidates. We have an employment agreement with Dr. Robinson which has no term but is for at-will employment, meaning the executive has the ability to terminate his employment at any time. We have a consulting agreement with Dr. Starr that is terminable with 30-days' notice by Dr. Starr or us.

Our future success will also depend on our continuing ability to identify, hire, and retain highly skilled personnel for all areas of the organization. Competition in the biopharmaceutical industry for scientifically and technically qualified personnel is intense, and we may be unsuccessful in identifying, hiring, and retaining qualified personnel. Our continued requirement to identify, hire, and retain highly competent personnel may cause our compensation costs to increase materially.

We incur costs as a result of operating as a public company, and our management is required to devote substantial time to investor relations, information and communication to the public, and related compliance initiatives and corporate governance practices.

As a public company, and particularly after we are no longer an emerging growth company after 2024, we will incur significant legal, accounting and other expenses that we did not incur as a private company. The Sarbanes-Oxley Act, the Dodd-Frank Wall Street Reform and Consumer Protection Act, the listing requirements of the Nasdaq Capital Market and other applicable securities rules and regulations impose various requirements on public companies, including establishment and maintenance of effective disclosure and financial controls and corporate governance practices. Our management and other personnel devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations increase our legal and financial compliance costs and make some activities more time-consuming and costly. For example, we expect that these rules and regulations may make it more difficult and more expensive for us to obtain director and officer liability insurance, which in turn could make it more difficult for us to attract and retain qualified members of our Board. However, these rules and regulations are often subject to varying interpretations, in many cases due to their lack of specificity, and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices.

Despite ongoing compliance training and periodic education, our employees and consultants may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements, which could result in delays or terminations of our development programs and adversely affect our business.

Although we regularly train our employees on compliance and we are aware of no misconduct or improper activities to date, we are exposed to the risk of employee or consultant fraud or other misconduct. Misconduct by our employees or consultants could include intentional failures to: comply with FDA regulations; provide accurate information to the FDA; comply with manufacturing standards; comply with federal and state healthcare fraud and abuse laws and regulations; report financial information or data accurately or disclose unauthorized activities to us. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Employee and consultant misconduct could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. It is not always possible to identify and deter such misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant fines or other sanctions. Such actions could adversely affect our business including delaying or terminating one or more of our development programs.

We are an emerging growth company and we cannot be certain if the reduced disclosure requirements applicable to emerging growth companies will make our common stock less attractive to investors.

We are an emerging growth company. Under the Jumpstart Our Business Startups Act of 2012 (the "JOBS Act"), emerging growth companies can delay adopting new or revised accounting standards until such time as those standards apply to private companies. We have irrevocably elected to opt out of this provision and, as a result, we will comply with new or revised accounting standards when they are required to be adopted by public companies that are not emerging growth companies.

For as long as we continue to be an emerging growth company, we intend to take advantage of certain other exemptions from various reporting requirements that are applicable to other public companies including, but not limited to, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements, exemptions from the requirements of holding a nonbinding advisory stockholder vote on executive compensation and any golden parachute payments not previously approved, exemption from the requirement of auditor attestation in the assessment of our internal control over financial reporting and exemption from any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements (auditor discussion and analysis). If we do take advantage of these exemptions, the information that we provide stockholders will be different than what is available with respect to other public companies. We cannot predict if investors will find our common stock less attractive because we will rely on these exemptions. If investors find our common stock less attractive as a result of our status as an emerging growth company, there may be less liquidity for our common stock and our stock price may be more volatile.

We will remain an emerging growth company until the earliest of (1) the last day of the year (a) following the fifth anniversary of the completion of our initial public offering, (b) in which we have total annual gross revenue of at least $1.235 billion or (c) in which we are deemed to be a large accelerated filer, which means the market value of our common stock that is held by non-affiliates exceeds $700 million as of the prior June 30th, and (2) the date on which we have issued more than $1.0 billion in non-convertible debt securities during the prior three-year period. We anticipate this will be December 31, 2024. Even after we no longer qualify as an emerging growth company, we may remain a "smaller reporting company" and "non-accelerated filer" and rely on certain reduced disclosure obligations and/or exemptions available to such companies.

Competition and technological change may make our product candidates less competitive or obsolete.

The biopharmaceutical industry is subject to rapid technological change. We have many potential competitors, including major drug and chemical companies, specialized biopharmaceutical firms, universities and other research institutions. These companies, firms, and other institutions may develop products that are more effective than our product candidates or that would make our product candidates less competitive or obsolete. Many of these companies, firms, and other institutions have greater financial resources than us and may be better able to withstand and respond to adverse market conditions within the biopharmaceutical industry, including without limitation the lengthy product development and regulatory approval processes for product candidates.

We face significant competition from other biotechnology and pharmaceutical companies, and our operating results will suffer if we fail to compete effectively.

The biotechnology and pharmaceutical industries are characterized by rapidly advancing technologies, intense competition and a strong emphasis on proprietary products. While we believe we have significant competitive advantages with our expertise in small molecules and biologics, and rare disease clinical development, along with a strong intellectual property portfolio, we currently face and will continue to face competition for our drug development programs from companies that are developing doxorubicin analogs/replacements, or are targeting uPAR. The competition is likely to come from multiple sources, including larger pharmaceutical companies, biotechnology companies and academia. Accordingly, our competitors may have more resources and be more successful than us in obtaining approval for treatments and achieving widespread market acceptance. For any products that we may ultimately commercialize, not only will we compete with any existing therapies and those therapies currently in development, we will have to compete with new therapies that may become available in the future.

We may engage in strategic transactions that could impact our liquidity, increase our expenses and present significant distractions to our management.

From time to time, we may consider strategic transactions, such as acquisitions of companies, asset purchases, and out-licensing or in-licensing of products, product candidates or technologies. Additional potential transactions that we may consider include a variety of different business arrangements, including spin-offs, strategic partnerships, joint ventures, restructurings, divestitures, business combinations and investments. Any such transaction will require us to incur non-recurring or other charges, may increase our near- and long-term expenditures and may pose significant integration challenges or disrupt our management or business, which could adversely affect our operations and financial results. For example, these transactions may entail numerous operational and financial risks, including:

- exposure to unknown technologies, product candidates, medical conditions and indications, product manufacturing challenges and uncertainties, and other unknown factors of potential high risk;
- disruption of our business and diversion of our management's time and attention in order to develop acquired products, product candidates or technologies;
- incurrence of substantial debt or dilutive issuances of equity securities to pay for acquisitions;
- higher-than-expected acquisition and integration costs;
- write-downs of assets, goodwill or impairment charges;
- increased amortization expenses;
- difficulty and cost in combining the operations and personnel of any acquired businesses with our operations and personnel;
- impairment of relationships with key suppliers or customers of any acquired businesses due to changes in management and ownership; and
- inability to retain key employees of any acquired businesses or for our current business based on changed circumstances.

Accordingly, although there can be no assurance that we will undertake or successfully complete any transactions of the nature described above, any transactions that we do complete may be subject to the foregoing or other risks, and could have a material adverse effect on our business, results of operations, financial condition and prospects.

Our business and operations are vulnerable to computer system failures, cyber-attacks or deficiencies in our cybersecurity, which could increase our expenses, divert the attention of our management and key personnel away from our business operations and adversely affect our results of operations.

Despite the implementation of security measures, our internal computer systems, and those of third parties on which we rely, are vulnerable to damage from: computer viruses; malware; natural disasters; terrorism; war; telecommunication and electrical failures; cyber-attacks or cyber-intrusions over the Internet; attachments to emails; persons inside our organization; or persons with access to systems inside our organization. The risk of a security breach or disruption, particularly through cyber-attacks or cyber intrusion, including by computer hackers, foreign governments, and cyber terrorists, has generally increased as the number, intensity and sophistication of attempted attacks and intrusions from around the world have increased. If such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our product development programs. For example, the loss of clinical trial data from completed or ongoing or planned clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach was to result in a loss of or damage to our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur material legal claims and liability, and damage to our reputation, and the further development of our product candidates could be delayed. We could be forced to expend significant resources in response to a cyber security breach, including repairing system damage, increasing cyber security protection costs by deploying additional personnel and protection technologies, paying regulatory fines and resolving legal claims and regulatory actions, all of which would increase our expenses, divert the attention of our management and key personnel away from our business operations and adversely affect our results of operations.

Failure to comply with health and data protection laws and regulations could lead to government enforcement actions (which could include civil or criminal penalties), private litigation or adverse publicity and could negatively affect our operating results and business.

We and our current and any of our future collaborators may be subject to federal, state and foreign data protection laws and regulations (i.e., laws and regulations that address privacy and data security). In the U.S., numerous federal and state laws and regulations, including federal health information privacy laws (e.g., the Health Insurance Portability and Accountability Act ("HIPAA"), as amended by the Health Information Technology for Economic and Clinical Health Act ("HITECH")), state data breach notification laws, state health information privacy laws and federal and state consumer protection laws (e.g., Section 5 of the Federal Trade Commission Act), that govern the collection, use, disclosure and protection of health-related and other personal information could apply to our operations or the operations of our collaborators. In addition, we may obtain health information from third parties (including research institutions from which we obtain clinical trial data) that are subject to privacy and security requirements under HIPAA, as amended by HITECH, or other privacy and data security laws. Depending on the facts and circumstances, we could be subject to criminal penalties if we knowingly obtain, use, or disclose individually identifiable health information maintained by a HIPAA-covered entity in a manner that is not authorized or permitted by HIPAA.

International data protection laws, including Regulation 2016/679, known as the General Data Protection Regulation ("GDPR") may also apply to health-related and other personal information obtained outside of the U.S. The GDPR went into effect on May 25, 2018. The GDPR introduced new data protection requirements in the EU, as well as potential fines for non-compliant companies of up to the greater of €20 million or 4% of annual global revenue. The regulation imposes numerous new requirements for the collection, use, storage and disclosure of personal information, including more stringent requirements relating to consent and the information that must be shared with data subjects about how their personal information is used, the obligation to notify regulators and affected individuals of personal data breaches, extensive new internal privacy governance obligations and obligations to honor expanded rights of individuals in relation to their personal information (e.g., the right to access, correct and delete their data). In addition, the GDPR includes restrictions on cross-border data transfers. The GDPR increased our responsibility and liability in relation to personal data that we process where such processing is subject to the GDPR, and we may be required to put in place additional mechanisms to ensure compliance with the GDPR, including as implemented by individual countries.

In Australia, they have enacted robust data protection regulations to safeguard personal information of its citizens. These laws include the Federal Privacy Act of 1988 and Privacy Legislation Amendment Act of 2022. These laws also specifically address data protection measures such data residency requirements, requirements for handling personal health records and data subject rights that detail specific rights Australian citizens have on the collection and use of their personal data.

In addition, California enacted the California Consumer Privacy Act ("CCPA"), which creates new individual privacy rights for California consumers (as defined in the law) and places increased privacy and security obligations on entities handling personal data of consumers or households. The CCPA requires covered companies to provide new disclosure to consumers about such companies' data collection, use and sharing practices, provide such consumers new ways to opt-out of certain sales or transfers of personal information, and provide consumers with additional causes of action. The CCPA went into effect on January 1, 2020, and certain amendments went into effect in 2023. Other states have adopted similar laws. The CCPA, and other state privacy laws, may impact our business activities and exemplify the vulnerability of our business to the evolving regulatory environment related to personal data and protected health information.

Compliance with U.S. and international data protection laws and regulations could require us to take on more onerous obligations in our contracts, restrict our ability to collect, use and disclose data, or in some cases, impact our ability to operate in certain jurisdictions. Failure to comply with U.S. and international data protection laws and regulations could result in government enforcement actions (which could include civil or criminal penalties), private litigation or adverse publicity and could negatively affect our operating results and business.

If we, our contract research organizations ("CROs") or our IT vendors experience security or data privacy breaches or other unauthorized or improper access to, use of, or destruction of personal data, we may face costs, significant liabilities, harm to our brand and business disruption.

In connection with our drug research and development efforts, we or our CROs may collect and use a variety of personal data, such as names, mailing addresses, email addresses, phone numbers and clinical trial information. Although we have extensive measures in place to prevent the sharing and loss of patient data in our clinical trial processes associated with our developed technologies and drug candidates, any failure to prevent or mitigate security breaches or improper access to, use of, or disclosure of our clinical data or patients' personal data could result in significant liability under state (e.g., state breach notification laws), federal (e.g., HIPAA, as amended by HITECH), and international laws (e.g., the GDPR). Any failure to prevent or mitigate security breaches or improper access to, use of, or disclosure of our clinical data or patients' personal data may cause a material adverse impact to our reputation, affect our ability to conduct new studies and potentially disrupt our business. We may also rely on third-party IT vendors to host or otherwise process some of our data and that of users, and any failure by such IT vendor to prevent or mitigate security breaches or improper access to or disclosure of such information could have similarly adverse consequences for us. If we are unable to prevent or mitigate the impact of such security or data privacy breaches, we could be exposed to litigation and governmental investigations, which could lead to a potential disruption to our business.

If we do not comply with laws regulating the protection of the environment and health and human safety, our business could be adversely affected.

Our research and development and drug candidates and future commercial manufacturing may involve the use of hazardous materials and various chemicals. We currently do not maintain a research laboratory, but we engage third-party research organizations and manufacturers to conduct our preclinical studies, clinical trials and manufacturing. These third-party laboratories and manufacturers are subject to federal, state and local laws and regulations governing the use, manufacture, storage, handling and disposal of these hazardous materials. We must rely on the third parties' procedures for storing, handling and disposing of these materials in their facilities to comply with the relevant guidelines of the states in which they operate and the Occupational Safety and Health Administration of the U.S. Department of Labor. Although we believe that their safety procedures for handling and disposing of these materials comply with the standards mandated by applicable regulations, the risk of accidental contamination or injury from these materials cannot be eliminated. If an accident occurs, this could result in significant delays in our development. We are also subject to numerous environmental, health and workplace safety laws and regulations. Although we maintain workers' compensation insurance to cover us for costs and expenses, we may incur due to injuries to our employees, this insurance may not provide adequate coverage against potential liabilities. Additional federal, state and local laws and regulations affecting our operations may be adopted in the future. We may incur substantial costs to comply with, and substantial fines or penalties if we violate, any of these laws or regulations.

We have limited the liability of and indemnified our directors and officers.

Although our directors and officers are accountable to us and must exercise good faith, good business judgement, and integrity in handling our affairs, our Second Amended and Restated Certificate of Incorporation (the "Certificate of Incorporation") and indemnification agreements executed by all of our non-employee directors and officers provides that our non-employee directors and officers will be indemnified to the fullest extent permitted under Delaware law. As a result, our stockholders may have fewer rights against our non-employee directors and officers than they would have absent such provisions in our Certificate of Incorporation and indemnification agreements, and a stockholder's ability to seek and recover damages for a breach of fiduciary duties may be reduced or restricted. Delaware law allows indemnification of our non-employee directors and officer, if they (a) have acted in good faith, in a manner the non-employee director or officer reasonably believes to be in or not opposed to our best interests, and (b) with respect to any criminal action or proceeding, if the non-employee director or officer had no reasonable cause to believe the conduct was unlawful.

Pursuant to the Certificate of Incorporation and indemnification agreement, each non-employee director and officer who is made a party to a legal proceeding because he or she is or was a non-employee director or officer, is indemnified by us from and against any and all liability, except that we may not indemnify a non-employee director or officer: (a) for any liability incurred in a proceeding in which such person is adjudged liable to Monopar or is subjected to injunctive relief in favor of Monopar; (b) for acts or omissions that involve intentional misconduct or a knowing violation of law, fraud or gross negligence; (c) for unlawful distributions; (d) for any transaction for which such non-employee director or officer received a personal benefit or as otherwise prohibited by or as may be disallowed under Delaware law; or (e) with respect to any dispute or proceeding between us and such non-employee director or officer unless such indemnification has been approved by a disinterested majority of the Board or by a majority in interest of disinterested stockholders. We are required to pay or reimburse attorney's fees and expenses of a non-employee director or officer seeking indemnification as they are incurred, provided the non-employee director or officer executes an agreement to repay the amount to be paid or reimbursed if there is a final determination by a court of competent jurisdiction that such person is not entitled to indemnification.

Future legislation or executive or private sector actions may increase the difficulty and cost for us to commercialize our products and adversely affect the prices obtained for such products.

In the U.S., there have been and continue to be a number of legislative initiatives to contain healthcare costs. For example, in March 2010, the Affordable Care Act (the "ACA"), was enacted, which substantially changed the way healthcare is financed by both governmental and private insurers, and significantly impacted the U.S. pharmaceutical industry.

Since its enactment, there have been numerous judicial, administrative, executive, and legislative challenges to certain aspects of the ACA, and we expect there will be additional challenges and amendments to the ACA in the future. If any of these developments continue the downward pressure on pharmaceutical pricing, especially under the Medicare program, or increase regulatory burdens and operating costs, it could adversely impact our business. We cannot predict what effect further changes to the ACA would have on our business.

In addition, government price reporting and payment regulations are complex, and we will be required to continually assess the methods by which we plan to calculate and report any future pricing in accordance with these obligations. Our methodologies for calculations are inherently subjective and may be subject to review and challenge by various government agencies, which may disagree with our interpretation. If the government disagrees with our reported calculations, we may need to restate the previously reported data and could be subject to additional financial and legal liability.

Further, the increasing cost of healthcare as a percentage of GDP and the massive and increasing deferred liabilities behind most governmental healthcare programs (such as Medicare and Medicaid and state and local healthcare programs especially for retirement benefits) continue to be an economic challenge which threatens the overall economic health of the U.S. High cost healthcare products and therapies that are early in their life cycle are attractive targets for parties that believe that the cost of healthcare must be better controlled and significantly reduced. Pharmaceutical prices and healthcare reform have been debated and acted upon by legislators for many years. Future legislation or executive or private sector actions related to healthcare reform could materially and adversely affect our business by reducing our ability to generate revenue at prices sufficient to reward for the risks and costs of pharmaceutical development, to raise capital, and to market our products.

There is no assurance that federal or state healthcare reform will not adversely affect our future business and financial results, and we cannot predict how future federal or state legislative, judicial or administrative changes relating to healthcare reform and third-party payers will affect the pharmaceutical industry in general and our business in particular.

Even if we are able to commercialize any drug candidate, such drug candidate may become subject to unfavorable pricing regulations or third-party coverage and reimbursement policies, which would harm our business.

Our ability to commercialize any products successfully will depend, in part, on the extent to which coverage and adequate reimbursement for these products and related treatments will be available from third-party payors, such as government authorities, private healthcare insurers and health maintenance organizations. Patients who are prescribed medications for the treatment of their conditions generally rely on third-party payors to reimburse all or part of the costs associated with their prescription drugs. Coverage and adequate reimbursement from government healthcare programs, such as Medicare and Medicaid, and private healthcare insurers are critical to new product acceptance. Patients are unlikely to use our future products, if any, unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost.

Cost-containment is a priority in the U.S. healthcare industry and elsewhere. As a result, government authorities and other third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. Increasingly, third-party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. Third-party payors also may request additional clinical evidence beyond the data required to obtain marketing approval, requiring a company to conduct expensive pharmacoeconomic studies in order to demonstrate the medical necessity and cost-effectiveness of its products. Commercial third-party payors often rely upon Medicare coverage policy and payment limitations in setting their reimbursement rates, but also have their own methods and approval process apart from Medicare determinations. Therefore, coverage and reimbursement for pharmaceutical products in the U.S. can differ significantly from payor to payor. We cannot be sure that coverage and adequate reimbursement will be available for any product that we commercialize and, if reimbursement is available, that the level of reimbursement will be adequate. Coverage and reimbursement may impact the demand for, or the price of, any drug candidate for which we obtain marketing approval. If coverage and reimbursement are not available or are available only at limited levels, we may not be able to successfully commercialize any drug candidate for which we obtain marketing approval.

Additionally, the regulations that govern regulatory approvals, pricing and reimbursement for new drugs and therapeutic biologics vary widely from country to country. Some countries require approval of the sale price of a drug or therapeutic biologic before it can be marketed. In many countries, the pricing review period begins after marketing approval is granted. In some foreign markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. As a result, we might obtain regulatory approval for a product in a particular country, but then be subject to price regulations that delay our commercial launch of the product, possibly for lengthy time periods, and negatively impact the revenues we are able to generate from the sale of the product in that country. Adverse pricing limitations may hinder our ability to recoup our investment in one or more drug candidates, even if our drug candidates obtain regulatory approval.

Politically divided governmental actions and related political actions outside of government can impact the FDA's role in the timely and effective review of new pharmaceutical products in the U.S. and our business may be adversely impacted.

In recent years, there has been significant political conflict around budgeting and governmental funding of operations in the U.S. Government. Shutdowns or threats to government shutdowns are recurring events. In the past, these events have, limited the FDA to activities necessary to address imminent threats to human life and to activities funded by carry-over user fees. Future government shutdowns or other activities which limit the financial resources available to the FDA (and in particular to the Center for Drug Evaluation and Research) will delay the processing of new product drug development submissions, reviews, and approvals and other required regulatory actions. Such delays will adversely impact our business and financial condition.

Effective collaboration with the FDA for the approval of drug candidates is a highly demanding process which can result in increased time and expense to gain approvals.

Our Company has in-house expertise and experience in the management of drug approvals. Qualified consultants and drug research organizations are also available to aid in our drug approval process; however, there is a meaningful risk that discussions and interactions inherent in the drug approval process and future developments or new improvements will result in delays, added expenses and new scientific/medical requirements which will cause adverse financial results and will likely impact the price of the Company's stock.

Future tax reform measures may negatively impact our financial position.

Tax reform measures are unpredictable and can change as the U.S. Congress and executive leadership changes. For example, on December 22, 2017, the Tax Cuts and Jobs Act of 2017 was signed into law that significantly revised the Internal Revenue Code of 1986, as amended (the "Code"). It is difficult to predict what future tax reform measures, if any, could be implemented and the extent to which they will impact our financial condition and our business.

Foreign currency exchange rates may adversely affect our consolidated financial statements.

Sales and purchases in currencies other than the U.S. Dollar expose us to fluctuations in foreign currencies relative to the U.S. Dollar and may adversely affect our consolidated financial statements. Increased strength of the U.S. Dollar increases the effective price of our future drug products sold in U.S. Dollars into other countries, which may require us to lower our prices or adversely affect sales to the extent we do not increase local currency prices. Decreased strength of the U.S. Dollar could adversely affect the cost of materials, products and services we purchase overseas. Sales and expenses of our non-U.S. businesses are also translated into U.S. Dollars for reporting purposes and the strengthening or weakening of the U.S. Dollar could result in unfavorable foreign currency translation and transaction effects. In addition, certain of our businesses may in the future invoice customers in a currency other than the business' functional currency, and movements in the invoiced currency relative to the functional currency could also result in unfavorable foreign currency translation and transaction effects. We also face exchange rate risk from our investments in subsidiaries owned and operated in foreign countries.

Our anticipated operating expenses and capital expenditures over the next year are based upon our management's estimates of possible future events. Actual amounts and the cost of new conditions could differ materially from those estimated by our management.

Development of pharmaceuticals and cancer drugs is extremely risky and unpredictable. We have estimated operating expenses and capital expenditures over the next year based on certain assumptions. Any change in the assumptions could cause the actual results to vary substantially from the anticipated expenses and expenditures and could result in material differences in actual versus forecasted expenses or expenditures. Furthermore, all of the factors are subject to the effect of unforeseeable future events. The estimates of capital expenditures and operating expenses represent forward-looking statements within the meaning of the federal securities laws. Prospective investors are cautioned that any such forward-looking statements are not guarantees of future performance and involve risks and uncertainties. Actual events or results may differ materially from those discussed in the forward-looking statements as a result of various factors, including the risk factors set forth under this "Risk Factors" section in this Annual Report on Form 10-K.

The financial and operational projections that we may make from time to time are subject to inherent risks.

The projections that we provide herein or our management may provide from time to time (including, but not limited to, our success in raising strategic and substantial financial resources, the cost and timing of our clinical trials, clinical and regulatory timelines, production and supply matters, commercial launch dates, and other financial or operational matters) reflect numerous assumptions made by our management, including assumptions with respect to our specific as well as general business, regulatory, economic, market and financial conditions and other matters, all of which are difficult to predict and many of which are beyond our control. Accordingly, there is a risk that the assumptions made in preparing the projections, or the projections themselves, will prove inaccurate. There may be differences between actual and projected results, and actual results may be materially different from those contained in the projections. The inclusion of the projections in this Annual Report on Form 10-K should not be regarded as an indication that our management considered or consider the projections to be a guaranteed prediction of future events, and the projections should not be relied upon as such. See "Cautionary Statement Concerning Forward-Looking Statements."

Our present and potential future international operations may expose us to business, political, operational, and financial risks associated with doing business outside of the U.S.

Our business is subject to risks associated with conducting business internationally. Some of our suppliers and clinical research organizations and clinical trial sites are located outside of the U.S. Furthermore, if we or any future collaborator succeeds in developing any products, we anticipate marketing them in the EU, the United Kingdom and other jurisdictions in addition to the U.S. If approved, we or our collaborator may hire sales representatives and conduct physician and patient association outreach activities outside of the U.S. Doing business internationally involves a number of risks, including but not limited to:

- multiple, conflicting and changing laws and regulations such as privacy regulations, tax laws, export and import restrictions, employment laws, regulatory requirements, and other governmental approvals, permits and licenses which can vary jurisdictions to jurisdiction with different degrees of review and enforcement;
- failure by us to obtain and maintain regulatory approvals for the use of our products in various countries;
- rejection or qualification of foreign clinical trial data by the competent authorities of other countries;
- additional potentially relevant third-party patent and other intellectual property rights that may be necessary to develop and commercialize our products and drug candidates;
- complexities and difficulties in obtaining, maintaining, enforcing and defending our patent and other intellectual property rights;
- difficulties in staffing and managing foreign operations by a small-scale organization;
- complexities associated with managing multiple payor reimbursement regimes, government payors or patient self-pay systems;
- limits, as a U.S.-based company, in our ability to penetrate international markets;
- financial risks, such as longer payment cycles, difficulty collecting accounts receivable, the impact of local and regional financial crises on demand and payment for our products and exposure to foreign currency exchange rate fluctuations;
- natural disasters, political and economic instability, including wars, terrorism and political unrest, outbreak of disease, boycotts, curtailment of trade and other business restrictions, implementation of tariffs;
- certain expenses including, among others, expenses for travel, translation and insurance; and
- regulatory and compliance risks that relate to anti-corruption compliance and record-keeping that may fall within the purview of the U.S. Foreign Corrupt Practices Act, its accounting provisions or its anti-bribery provisions or provisions of anti-corruption or anti-bribery laws in other countries.

Any of these factors could harm our ongoing international clinical operations and supply chain, as well as any future international expansion and operations and, consequently, our business, financial condition, prospects and results of operations.

We are subject to U.S. and foreign anti-corruption and anti-money laundering laws with respect to our operations and non-compliance with such laws can subject us to criminal or civil liability and harm our business.

We are subject to the U.S. Foreign Corrupt Practices Act of 1977, as amended ("the FCPA"), the U.S. domestic bribery statute contained in 18 U.S.C. § 201, the U.S. Travel Act, the USA PATRIOT Act, and possibly other state and national anti-bribery and anti-money laundering laws in countries in which we conduct activities. Anti-corruption laws are interpreted broadly and prohibit companies and their employees, agents, third-party intermediaries, joint venture partners and collaborators from authorizing, promising, offering or providing, directly or indirectly, improper payments or benefits to recipients in the public or private sector. We interact with officials and employees of government agencies and government-affiliated hospitals, universities and other organizations. In addition, we may engage third-party intermediaries to promote our clinical research activities abroad or to obtain necessary permits, licenses and other regulatory approvals. We can be held liable for the corrupt or other illegal activities of these third-party intermediaries, our employees, representatives, contractors, partners and agents, even if we do not explicitly authorize or have actual knowledge of such activities.

We have a Code of Business Conduct and Ethics which mandates compliance with the FCPA and other anti-corruption laws applicable to our business throughout the world. However, we cannot assure you that our employees and third-party intermediaries will comply with this code or such anti-corruption laws. Noncompliance with anti-corruption and anti-money laundering laws could subject us to whistleblower complaints, investigations, sanctions, settlements, prosecution, other enforcement actions, disgorgement of profits, significant fines, damages, other civil and criminal penalties or injunctions, suspension or debarment from contracting with certain persons, the loss of export privileges, reputational harm, adverse media coverage and other collateral consequences. If any subpoenas, investigations or other enforcement actions are launched, or governmental or other sanctions are imposed, or if we do not prevail in any possible civil or criminal litigation, our business, results of operations and financial condition could be materially harmed. In addition, responding to any action will likely result in a materially significant diversion of management's attention and resources and significant defense and compliance costs and other professional fees. In certain cases, enforcement authorities may even cause us to appoint an independent compliance monitor which can result in added costs and administrative burdens.

Risks Associated with our Common Stock

Existing and new investors will experience dilution as a result of future sales or issuances of our common stock and future option exercises under our 2016 Stock Incentive Plan and any amendments to the plan.

Our non-employee directors, employees, and certain of our consultants have been and will be issued equity and/or granted options that vest with the passage of time. Up to a total of 5,100,000 shares of our common stock may be issued as stock options or restricted stock units under the Amended and Restated Monopar Therapeutics Inc. 2016 Stock Incentive Plan, and stock options for the purchase of up to 2,119,001 shares of our common stock have already been granted (1,553,867 stock options are exercisable) and are outstanding along with 410,136 restricted stock units that have been granted to non-employee directors and employees as of March 8, 2024. The issuance of such equity upon vesting of restricted stock units and/or the exercise of such options, and the grant of new equity awards, will dilute both our existing and our new investors. As of March 8, 2024, 189,346 stock options have been exercised.

Our existing and our new investors will also experience substantial dilution resulting from the issuance by us of equity securities in connection with certain transactions, including without limitation, future offering of shares in future fundraising efforts, intellectual property licensing, acquisition, or commercialization arrangements.

Holders of the shares of our common stock will have no control of our operations or of decisions on major transactions.

Our business and affairs are managed by or under the direction of our Board. Our stockholders are entitled to vote only on actions that require a stockholder vote under federal or state law. Stockholder approval requires the consent and approval of holders of a majority or more of our outstanding stock. Shares of stock do not have cumulative voting rights and therefore, holders of a majority of the shares of our outstanding stock will be able to elect all Board members. TacticGem, LLC ("TacticGem") owns 7,166,667 shares of common stock (41.06%). The limited liability company agreement requires TacticGem to pass through votes (including the vote for the election of directors) to its members in proportion to their membership percentages in TacticGem (57.367% owned by Tactic Pharma and 42.633% owned by Gem). As a result, Tactic Pharma, our initial investor, holds an approximately 24.51% beneficial interest in us and together with Gem's beneficial ownership of approximately 17.50%, the two entities control a significant portion of our stock and will have substantial influence in the election of all Board members and control of our affairs. In addition, our Chief Executive Officer and director, as well as one of our other directors, are associated with Tactic Pharma.

The interim analysis for our Validive Phase 2b/3 clinical program yielded a no-go decision resulting in a reduction of our stock price. If our stock price does not increase before the Nasdaq extended deadline for regaining compliance or if we do not win an appeal for additional time, our business could be adversely impacted.

The termination of our Validive clinical trial due to the no-go decision at the end of March 2023 resulted in a decrease in our stock price. The closing bid price of our stock fell below $1.00 for more than 30 consecutive trading days and on August 28, 2023 we received a notice from Nasdaq stating that we are out of compliance with Nasdaq listing standards giving us 180 days to regain compliance. On February 27, 2024, we were granted a second 180-day period to regain compliance by August 26, 2024. However, there can be no assurance that we will regain compliance. If it is necessary to effect a reverse stock split to attempt to cure the bid price deficiency, the impacts on our stock price are uncertain and could be adverse. If we do not regain compliance, we would face delisting and it may have serious adverse consequences on our ability to raise funds, which may cause us to delay, restructure or otherwise reconsider our operations.

Our failure to meet the other continued listing requirements of The Nasdaq Capital Market could result in a de-listing of our common stock.

If we fail to satisfy other continued listing requirements of The Nasdaq Capital Market, such as, but not limited to, the corporate governance requirements, the Nasdaq Stock Market ("Nasdaq") may take steps to de-list our common stock. Such a de-listing or the announcement of such de-listing will have a negative effect on the price of our common stock and would impair your ability to sell or purchase our common stock when you wish to do so. In the event of a de-listing, we would take actions to restore our compliance with the Nasdaq listing requirements, but we can provide no assurance that any such action taken by us would allow our common stock to become listed again, stabilize the market price or improve the liquidity of our common stock, prevent our common stock from dropping below the Nasdaq minimum bid price requirement or prevent future non-compliance with the Nasdaq listing requirements.

The stock price of our common stock may be volatile or may decline regardless of our operating performance.

The market prices for securities of biotechnology and pharmaceutical companies have historically been highly volatile, and the market has from time-to-time experienced significant price and volume fluctuations that appear to be unrelated to the operating performance of particular companies. Our common stock has only been trading on the Nasdaq Capital Market since December 19, 2019, and has experienced significant volatility in market prices through March 8, 2024, ranging from a low of $0.274 to a high of $48.00. From time to time, whether in response to news releases or for uncertain reasons, our stock price has also experienced significant intraday volatility and volume changes. Our small public float and relatively low and inconsistent trading volumes exacerbate volatility.

The market price of our common stock is likely to remain highly volatile and may fluctuate substantially due to many factors, including:

- announcements concerning the progress and success of our clinical trials, our ability to obtain regulatory approval for and commercialize our product candidates, including any requests we receive from the FDA or TGA for additional studies or data that result in delays in obtaining regulatory approval or launching our product candidates, if approved;
- unstable market conditions in the pharmaceutical and biotechnology sectors or the economy as a whole;
- price and volume fluctuations in the overall stock market;
- the failure of our product candidates, if approved, to achieve anticipated commercial success; in the time projected by securities analysts and others;
- announcements of disruptions in supply and manufacturing of radioisotopes or raw materials required to manufacture radioisotopes, and any events that may disrupt the timely supply of radiopharmaceuticals to clinical sites;
- announcements of the clinical success, NDA approval or introduction of new products by us or our direct competitors;
- announcements of developments concerning product development results or intellectual property rights of others;
- litigation or public concern about the safety and/or efficacy of our potential or approved products;

- actual fluctuations in our quarterly or annual operating results, and concerns by investors that such fluctuations may occur in the future and are indicative of internal problems;
- deviations in our operating results from the estimates of securities analysts or other analyst comments;
- additions or departures of key personnel;
- healthcare reform legislation, including measures directed at controlling the pricing of pharmaceutical products, and third-party coverage and reimbursement policies;
- announcements or publicity concerning current or future strategic collaborations;
- discussion of our Company, our stock price or our potential future market value by the financial and scientific press and online investor communities; and
- market responses to the fluctuating conditions of COVID-19 or any future pandemics or to the Russia-Ukraine war or Israel-Hamas war.

We may become involved in securities class action litigation that could divert management's attention and harm our business.

The stock markets have from time-to-time experienced significant price and volume fluctuations that have affected the market prices for the common stock of biotechnology and pharmaceutical companies. Our stock price has experienced such fluctuations since our initial public offering. These broad market fluctuations may cause the market price of our stock to advance or decline. In the past, securities class action litigation has often been brought against a company following a decline in the market price of its securities. This risk is especially relevant for us because biotechnology and biopharmaceutical companies have experienced significant stock price volatility in recent years. We may become involved in this type of litigation in the future. Litigation often is expensive and diverts management's attention and resources, which could adversely affect our business.

Substantial amounts of our outstanding shares may be sold into the market. If there are substantial sales of shares of our common stock, the price of our common stock could decline.

The price of our common stock could decline if there are substantial sales of our common stock, particularly sales by our non-employee directors, executive officers and significant stockholders, or if there is a large number of shares of our common stock available for sale and the market perceives that sales will occur. We have 17,454,925 outstanding shares of our common stock as of March 8, 2024. A substantial portion of our outstanding shares of common stock are currently held by non-employee directors, executive officers and other affiliates and are subject to volume limitations under Rule 144 under the Securities Act of 1933, as amended (Securities Act).

Our largest stockholders have rights, subject to some conditions, to require us to file registration statements covering their shares or to include their shares in registration statements that we may file for ourselves or our stockholders. We have also registered shares of common stock that we have issued and may issue under our employee equity incentive plans. These shares are able to be sold freely in the public market upon issuance, subject to existing internal practices which prohibit sales under certain circumstances and volume limitations for affiliates. The market price of the shares of our common stock could decline as a result of the sale of a substantial number of our shares of common stock in the public market or the perception in the market that the holders of a large number of shares intend to sell their shares.

Our ability to use our net operating loss carry-forwards and certain other tax attributes may be limited.

Under Section 382 of the Code, if a corporation undergoes an "ownership change" (generally defined as a greater than 50% change, by value, in its equity ownership over a three-year period), the corporation's ability to use its pre-change net operating loss carry-forwards and other pre-change tax attributes (such as research tax credits) to offset its post-change income may be limited. We believe that additional fundraising efforts in the next three years, may trigger an "ownership change" limitation in the near future. As a result, if we earn net taxable income, our ability to use our pre-change net operating loss carry-forwards to offset U.S. federal taxable income will be subject to limitations, which could result in increased future tax liability to us had we not been subject to such limitations.

If securities or industry analysts do not publish research or publish inaccurate or unfavorable research about our business, our stock price and trading volume could decline.

The trading market for our common stock will depend in part on the research and reports that securities or industry analysts publish about us or our business. If one or more of the analysts who covers us downgrades our stock or publishes inaccurate or unfavorable research about our business, our stock price may decline. If one or more of these analysts ceases coverage of our Company or fails to publish reports on us regularly, demand for our stock could decrease, which might cause our stock price and trading volume to decline.

We do not intend to pay dividends for the foreseeable future and, as a result, your ability to achieve a return on your investment will depend on appreciation in the price of our common stock.

We have never declared or paid any cash dividends on our capital stock, and we do not intend to pay any cash dividends in the foreseeable future. Any determination to pay dividends in the future will be at the discretion of our Board. Accordingly, investors must rely on sales of their common stock after price appreciation, which may never occur, as the only way to realize any future gains as a return on their investments.

There can be no assurance that we will ever provide liquidity to our investors through a sale of our Company.

While acquisitions of pharmaceutical companies like ours are not uncommon, potential investors are cautioned that no assurances can be given that any form of merger, combination, or sale of our Company will take place or that any merger, combination, or sale, even if consummated, would provide liquidity or a profit for our investors. You should not invest in our Company with the expectation that we will be able to sell the business in order to provide liquidity or a profit for our investors.

Delaware law and provisions in our amended and restated bylaws could make a merger, tender offer or proxy contest difficult, thereby depressing the potential trading price of our common stock.

Anti-takeover provisions in our charter documents and under Delaware law could make an acquisition of us difficult, limit attempts by our stockholders to replace or remove our current management or Board and adversely affect our stock price.

Provisions of our amended and restated bylaws may delay or discourage transactions involving an actual or potential change in our control or change in our management, including transactions in which stockholders might otherwise receive a premium for their shares, or transactions that our stockholders might otherwise deem to be in their best interests. Therefore, these provisions could adversely affect the price of our stock. Among other things, our amended and restated bylaws:

- provide that all vacancies on our Board may only be filled by our Board and not by stockholders;
- allow the holders of a plurality of the shares of common stock entitled to vote in any election of directors to elect all of the directors standing for election, if they should so choose; and
- provide that special meetings of our stockholders may be called only by our Board.

In addition, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, which generally prohibits a Delaware corporation from engaging in any of a broad range of business combinations with any "interested" stockholder for a period of three years following the date on which the stockholder became an "interested" stockholder.

Item 1C. Cybersecurity

Like many companies, we face significant and persistent cybersecurity risks. The small size of our organization and limited resources could exacerbate these risks. However, we are committed to maintaining governance and oversight of these risks and to implementing standard operating procedures ("SOPs") and training to help us assess, identify, monitor and respond to these risks. Some examples of procedures implemented include an internal inventory of software and database exposures, a risk analysis of database vendors, review of vendor back-up, security and privacy measures. In addition, we are in the process of drafting an internal cybersecurity policy which will be the basis for SOPs and training. Our internal server includes a firewall and is scanned for malware several times a day and the data is backed up in the Cloud for ease of restoration as needed. Employees are trained to avoid phishing emails and our internal controls system is designed to mitigate the risk of payments of fraudulent invoices. While we have not, as of the date of this Form 10-K, experienced cybersecurity threats, including as a result of a prior incident, that resulted in, or that we believe is reasonably likely to result in, a material adverse impact to our business strategy, results of operations or financial condition, there can be no guarantee that we will not experience a material incident in the future. Such incidents, whether successful or not, could impair our access to critical information including confidential operational and patient records and have the potential to be costly to effect remedies. See "Risk Factors" for more information on our cybersecurity risks.

We aim to incorporate industry best practices for companies of our size and financial strength throughout our cybersecurity program. Our cybersecurity strategy focuses on implementing effective and efficient controls, technologies, and training programs to assess, identify, and manage material cybersecurity risks. Our Board of Directors has ultimate oversight of cybersecurity risk and has established a Cybersecurity committee headed by our Chief Financial Officer. As a small organization with limited resources, we do not have a dedicated cybersecurity organization or employee personnel with specific cybersecurity expertise. Our Chief Financial Officer was chosen to head our Cybersecurity committee due to more generalized management experience with financial and operating systems and oversight of third-party providers. Our Management team and our Board of Directors regularly review our cybersecurity program which generally occurs at least annually, or more frequently as determined to be necessary or advisable.

Item 2. Properties

While we are currently on a month-to-month lease for our executive headquarters at 1000 Skokie Blvd in the Village of Wilmette, Illinois for our corporate offices, we may enter into a longer-term lease in the next twelve months.

Item 3. Legal Proceedings

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

PART II

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities

Market Information

Our common stock is listed under the symbol "MNPR" on the Nasdaq Capital Market.

Holders

As of March 8, 2024, there were 17,454,925 shares of our common stock outstanding held by 30 holders of record and approximately 3,200 beneficial stockholders.

Dividends

We have never paid cash dividends on any of our capital stock and we currently intend to retain our future earnings, if any, to fund the development and growth of our business. We do not intend to pay cash dividends to holders of our common stock in the foreseeable future.

Registration Rights

We are subject to an agreement with TacticGem, LLC ("TacticGem"), our largest stockholder, which obligates us to file a Form S-3 or other appropriate form of registration statement covering the resale of any of our common stock by TacticGem, or its members Gem Pharmaceuticals, LLC, or Tactic Pharma, LLC, upon direction by TacticGem. Through the date hereof, TacticGem has not required us to file such a resale registration statement, although there can be no assurance we will not be required to do so in the future.

Recent Sales of Unregistered Securities.

There were no securities issuances that were not registered under the Securities Act during the reporting period.

Item 7. 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 financial statements and related notes appearing at the end of this Annual Report on Form 10-K. Some of the information contained in this discussion and analysis or set forth elsewhere in this Annual Report on Form 10-K, 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. You should read the "Risk Factors" section of this Annual Report on Form 10-K, Item 1A, for a discussion of important factors that could cause actual results to differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis.

Overview

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

Financial Status

Our cash, cash equivalents and investments as of December 31, 2023, were $7.3 million. As discussed further below and elsewhere in this Annual Report, we expect that our current funds will be sufficient at least through June 30, 2025 for us to: (1) conduct and conclude our first-in-human clinical trial with our MNPR-101-Zr radiopharmaceutical program; (2) continue our ongoing open-label Phase 1b camsirubicin clinical trial; and (3) continue to research MNPR-202. 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 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”). For the year ended December 31, 2023, we sold 1,793,441 shares of our common stock at an average gross price per share of $1.21 for net proceeds of $2,072,503 after fees, commissions and expenses of $98,230.

From January 1 to March 8, 2024, we sold 2,545,305 shares of our common stock at an average gross price per share of $1.29 for net proceeds of $3,194,310, after fees and commissions of $81,932.

MNPR-101 for Radiopharmaceutical Use, Development Update

Our proprietary, novel MNPR-101 radiopharmaceutical program is a first-in-class urokinase plasminogen activator receptor ("uPAR") targeting radiopharmaceutical for advanced tumors. The Company's radiopharmaceutical development team has conjugated MNPR-101, its proprietary first-in-class humanized monoclonal antibody that is highly selective against uPAR, to imaging and therapeutic radioisotopes, to develop highly precise imaging and therapeutic radiopharmaceutical agents that have the potential to image and eradicate tumors expressing uPAR while sparing healthy tissues. In February 2024, the Company announced promising preclinical data and regulatory clearance in Australia to commence a first-in-human Phase 1 clinical trial of MNPR-101-Zr for imaging tumors in patients with advanced cancers. Monopar is moving aggressively towards opening enrollment to patients in this Phase 1.

Camsirubicin Clinical Update

The Phase 1b open-label, dose-escalating clinical trial of camsirubicin in patients with advanced soft tissue sarcoma (“ASTS”) is currently ongoing and enrolling in the fifth dose-level cohort (650 mg/m^2), which is nearly 2.5x the highest dose evaluated in any prior camsirubicin clinical trial (265 mg/m^2).

MNPR-202 and Related Analogs Updates

MNPR-202, an analog of camsirubicin designed to potentially treat doxorubicin- and camsirubicin-resistant cancers, is being tested in preclinical models by our collaborator, the Cancer Science Institute of Singapore at the National University of Singapore.

Discontinuation of Validive Development

On March 27, 2023, we announced that based on Validive not meeting the pre-specified efficacy threshold in our interim clinical trial data analysis, we terminated the study, discontinued the development of Validive and subsequently terminated the license with Onxeo, SA.

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 EMA and launched multiple drugs in the U.S and the EU. Understanding the preclinical, clinical, regulatory and commercial development processes and hurdles are key factors in successful drug development and the expertise demonstrated by our management team across all of these areas increases the probability of success in advancing the product candidates in our product pipeline. Our strategic goal is to acquire, develop and commercialize promising oncology product candidates that address important unmet medical needs of cancer patients. Five key elements of our strategy to achieve this goal are to:

- **Continue the development of MNPR-101 for radiopharmaceutical use as a therapeutic as well as a diagnostic imaging agent**. Based on promising preclinical results utilizing radiolabeled MNPR-101, we have been cleared to conduct a Phase 1 dosimetry clinical trial of MNPR-101-Zr in patients with advanced cancers in Australia.

- **Advance the clinical development of camsirubicin, by pursuing indications where doxorubicin has demonstrated efficacy.** ASTS will be the first indication, which is anticipated to allow camsirubicin to go head-to-head against doxorubicin, the current first-line treatment. In this indication, camsirubicin previously demonstrated clinical benefit (stable disease or partial response) in 52.6% of patients evaluable for tumor progression in a single-arm Phase 2 study. Clinical benefit was proportional to dose and was consistently observed at higher cumulative doses of camsirubicin (>1000 mg/m^2). Camsirubicin was very well tolerated in this Phase 2 study and underscored the ability to potentially administer camsirubicin without restriction as to cumulative dose (doxorubicin is limited due to heart toxicity to 450 mg/m^2 cumulative dose). Our current ongoing Phase 1b clinical trial continues towards establishing a new, higher recommended dose for the next Phase 2 ASTS clinical trial.

- **Continue the development of MNPR-202 and related analogs in multiple types of cancers.** The 2-pyrrilino camsirubicin analog (MNPR-202) and related analogs represent proprietary compositions of matter designed to retain the non-cardiotoxic backbone of camsirubicin yet exhibit novel features in terms of antitumor activity and mechanism that distinguish these analogs from camsirubicin as well as from doxorubicin, potentially addressing camsirubicin- and doxorubicin-resistant cancers.

- **Expand our drug development pipeline through in-licensing and acquisition of product candidates.** We plan to continue the expansion of our drug development pipeline through 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.

- **Utilize the expertise and prior experience of our team in the areas of asset acquisition, drug development and commercialization to establish ourselves as a leading biopharmaceutical company.** Our senior executive team has relevant experience in biopharmaceutical in-licensing and acquisitions as well as developing product candidates through approval and commercialization. In aggregate, our team has co-founded BioMarin Pharmaceutical (Nasdaq: BMRN), Sensant Corp (acquired by Siemens), American BioOptics (assets acquired by Olympus), Raptor Pharmaceuticals ($800 million sale to Horizon Therapeutics), and Tactic Pharma, LLC (“Tactic Pharma”) (sale of lead asset, choline tetrathiomolybdate, was ultimately acquired by Alexion in June 2018 for $764 million; Alexion was subsequently acquired by AstraZeneca).

Implications of Being an Emerging Growth Company

We qualify as an "emerging growth company" as defined in the Jumpstart Our Business Startups Act of 2012 ("JOBS Act"). An emerging growth company may take advantage of specified reduced reporting burdens that are otherwise applicable generally to public companies. These provisions include, but are not limited to:

- inclusion of only two years, as compared to three years, of audited financial statements in addition to any required unaudited interim financial statements with correspondingly reduced "Management's discussion and analysis of financial condition and results of operations" disclosures;
- an exemption from the auditor attestation requirement in the assessment of our internal control over financial reporting pursuant to the Sarbanes-Oxley Act of 2002 ("Sarbanes-Oxley Act");
- an exemption from compliance with any new requirements adopted by the Public Company Accounting Oversight Board ("PCAOB") requiring mandatory audit firm rotation;
- reduced disclosure about executive compensation arrangements; and
- an exemption from the requirement to seek non-binding advisory votes on executive compensation or golden parachute arrangements.

We expect to take advantage of these provisions until we are no longer an emerging growth company. We will remain an emerging growth company until the earliest of (1) the last day of the year (a) following the fifth anniversary of the completion of our initial public offering which is December 2024, (b) in which we have total annual gross revenue of at least $1.235 billion or (c) in which we are deemed to be a large accelerated filer, which means the market value of our common stock that is held by non-affiliates exceeds $700 million as of the prior June 30th, and (2) the date on which we have issued more than $1.0 billion in non-convertible debt during the prior three-year period. We expect to no longer qualify as an emerging growth company at the end of 2024.

We have elected to take advantage of certain of the reduced disclosure obligations in this Annual Report on Form 10-K, and may elect to take advantage of other reduced reporting requirements in future filings. As a result, the information that we provide to our stockholders may be reduced and/or less detailed than what you might find from other public reporting companies.

In addition, we are also a "smaller reporting company" as defined in Rule 12b-2 of the Exchange Act and have elected to take advantage of certain of the scaled back disclosure requirements available to smaller reporting companies such as avoiding the extensive narrative disclosure required of other reporting companies, particularly in the description of executive compensation. Our status as a smaller reporting company will not be impacted by the loss of emerging growth company status at the end of 2024, so we may continue to take advantage of these scaled disclosure requirements so long as we qualify. In addition, the loss of emerging growth status will not impact our "non-accelerated filer" status, which also provides an exemption from the auditor attestation requirement with respect to internal control over financial reporting.

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, entering into collaboration agreements for testing and clinical development of our drug product candidates and providing the infrastructure to support the clinical development of our drug product candidates. We do not anticipate commercial revenues from operations until we complete testing and development of one of our drug product candidates and obtain marketing approval or we sell, enter into a collaborative marketing arrangement, or out-license one of our drug product candidates to another party. See "Liquidity and Capital Resources".

Recently Issued and Adopted Accounting Pronouncements

During the year ended December 31, 2023, there were two recently issued accounting pronouncements that are described in more detail in Note 2 of our consolidated financial statements included elsewhere in this Annual Report on Form 10-K.

Critical Accounting Policies and Use of Estimates

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

Clinical Trials Accruals

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

Stock-Based Compensation

We account for stock-based compensation arrangements with employees, non-employee directors and consultants using a fair value method, which requires the recognition of compensation expense for costs related to all stock-based 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. For options granted in 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 years ended December 31, 2023 and 2022, was estimated using the simplified method. Forfeitures only include actual forfeitures to-date as the Company accounts for forfeitures as they occur due to a limited history of forfeitures. We have not paid dividends and do not anticipate paying a cash dividend in future vesting periods and, accordingly, use an expected dividend yield of zero. The risk-free interest rate is based on the rate of U.S. Treasury securities with maturities consistent with the estimated expected term of the awards.

Results of Operations

Comparison of the Years Ended December 31, 2023, and December 31, 2022

The following table summarizes the results of our operations for the years ended December 31, 2023, and 2022:

	Year Ended December 31,		
(in thousands)	**2023**	**2022**	**Variance**
Research and development expenses	$ 5,600	$ 7,592	$ (1,992)
General and administrative expenses	3,231	2,945	286
Total operating expenses	8,831	10,537	(1,706)
Operating loss	(8,831)	(10,537)	1,706
Interest income	429	21	408
Net loss	$ (8,402)	$ (10,516)	$ 2,114

Research and Development ("R&D") Expenses

R&D expenses for the year ended December 31, 2023 were $5,600,000, compared to $7,592,000 for the year ended December 31, 2022. This represents a decrease of $1,992,000 primarily attributed to (1) a $1,375,000 decrease for Validive clinical trial and manufacturing costs as a result of the termination of that program in March 2023, (2) a $904,000 decrease for a reduction in camsirubicin clinical trial and manufacturing costs, (3) a $126,000 decrease in R&D salaries, partially offset by (1) a $408,000 increase related to MNPR-101 radiopharma activity and (2) a $5,000 net increase in other R&D expenses.

General and Administrative ("G&A") Expenses

G&A expenses for the year ended December 31, 2023, were $3,231,000, compared to $2,945,000 for the year ended December 31, 2022. This represents an increase of $286,000 primarily attributed to a $220,000 increase in G&A personnel salaries, bonuses, benefits and stock-based compensation for annual (non-cash) equity grants, and a $66,000 net increase in other G&A expenses.

Interest Income

Interest income for the year ended December 31, 2023, increased by $408,000 versus the year ended December 31, 2022. The increase is due to interest earned on treasury bills and money market accounts that yielded higher interest rates in 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 $60.2 million as of December 31, 2023. We anticipate that we will continue to incur losses for the foreseeable future. We expect that our R&D and G&A expenses will increase to enable the execution of our strategic plan. As a result, we anticipate that we will seek to raise additional capital within the next 12 months to fund our future operations. We will seek to obtain needed capital through a combination of equity offerings, including at-the-market sales programs, debt financings, strategic collaborations and grant funding. To date, we have funded our operations through net proceeds from the initial public offering of our common stock, net proceeds from sales of our common stock through at-the-market sales programs, private placements of our preferred and common stock, and the net receipt of funds related to the acquisition of camsirubicin. We anticipate that the currently available funds as of March 8, 2024, will fund our planned operations at least through June 30, 2025.

We invest our cash equivalents in two money market accounts and U.S. Treasury Bills.

Cash Flows

The following table provides information regarding our cash flows for the years ended December 31, 2023, and 2022.

	Year Ended December 31,		
(in thousands)	**2023**	**2022**	**Variance**
Net cash used in operating activities	$ (7,858)	$ (7,228)	$ (630)
Net cash provided by (used in) investing activities	4,928	(4,919)	9,847
Net cash provided by financing activities	2,027	33	1,994
Effect of exchange rates	(17)	(4)	(13)
Net decrease in cash and cash equivalents	$ (920)	$ (12,118)	$ 11,198

During the years ended December 31, 2023 and 2022, we had net cash outflows of $920,000 and $12,118,000, respectively, a decrease of $11,198,000. During 2022, we began investing our idle cash due to the rising interest rates, resulting in a significant increase in cash used in investing activities. During 2023, we had net cash provided by investing activities as some of our investments made in 2022 matured and were used in operating activities, as well as higher net cash provided by financing activities due to more funds raised from sales of our common stock under an at-the-market sales program compared to 2022.

Cash Flow Used in Operating Activities

The cash flow used in operating activities during the year ended December 31, 2023, compared to the year ended December 31, 2022 was essentially flat.

Cash Flow Used in Investing Activities

The increase to cash flow provided by investing activities during the year ended December 31, 2023, compared to cash used in investing activities during the year ended December 31, 2022, of $9,847,000 was related to the fact that our investment in U.S. Treasury Bills commenced in December 2022 with maturities reinvested or used as working capital throughout 2023.

Cash Flow Provided by Financing Activities

The increase in cash flow provided by financing activities during the year ended December 31, 2023, compared to the year ended December 31, 2022, of $1,994,000 was primarily due to higher net proceeds from sales of our common stock through an at-the-market sales program.

Future Funding Requirements

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

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

- continue the clinical and preclinical activities of MNPR-101-Zr and MNPR-101-RIT to image and treat cancer;
- advance the clinical development for camsirubicin;
- continue the preclinical activities, and potentially later-on enter clinical development, of MNPR-202 (and related analogs) for various cancer indications;

- acquire and/or license additional pipeline drug product candidates and pursue the future preclinical and/or clinical development of such drug product candidates;
- seek regulatory approvals for any of our current and future drug product candidates that successfully complete registration clinical trials;
- establish or purchase the services of a sales, marketing and distribution infrastructure to commercialize any products for which we obtain marketing approval;
- develop or contract for manufacturing/quality capabilities or establish a reliable, high quality supply chain sufficient to support our clinical requirements and to provide sufficient capacity to launch and supply the market for any product for which we obtain marketing approval; and
- add or contract for required operational, financial 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 March 8, 2024, will fund our obligations at least through June 30, 2025. We have based this estimate on assumptions that may prove to be wrong, and we could use our available capital resources sooner than we currently expect. Because of the numerous risks and uncertainties associated with the development and commercialization of our drug product candidates, and the extent to which we enter into collaborations with third parties to participate in the development and commercialization of our drug product candidates, we are unable to accurately estimate with high reliability the amounts and timing required for increased capital outlays and operating expenditures associated with our current and anticipated drug product candidate development programs.

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

- the progress of clinical development and regulatory interactions and approvals of our MNPR-101 radiopharma program;
- the progress of clinical development and regulatory interactions and approvals of camsirubicin;
- the costs, timing and outcomes of seeking, obtaining, and maintaining FDA, TGA and other international regulatory approvals;
- the progress of preclinical and potentially clinical development of MNPR-202 (and related analogs);
- the number and characteristics of other drug product candidates that we may license, acquire, invent or otherwise pursue;
- the scope, progress, timing, cost and results of research, preclinical development and clinical trials and regulatory requirements for future drug product candidates;

- the costs associated with manufacturing/quality requirements, establishing a reliable supply chain, and establishing or contracting for sales, marketing and distribution capabilities;
- our ability 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 in the future, including the timing of receipt of or payment to or from others of any license, milestone or royalty payments under these arrangements.

Expenditures are expected to increase in 2024 and onward for:

- development of our MNPR-101 radiopharma program to image and treat various advanced cancers;
- Development of our camsirubicin program if data support development beyond Phase 1b;
- development of potential new in-licensed product candidates;
- employee compensation and consulting fees to support the increased scope of activities required for the progress of our product candidate programs including MNPR-101 for radiopharmaceutical use, camsirubicin, and MNPR-202 (and related analogs)

We are working towards initiating enrollment for our MNPR-101-Zr Phase 1 dosimetry clinical trial. If the tumor uptake, biodistribution, and safety look encouraging in this Phase 1 dosimetry trial, we may proceed to evaluate the efficacy in humans of a therapeutically radio-labeled version of MNPR-101 bound to an isotope such as Ac-225, which will require additional funding or finding a suitable pharmaceutical partner. There can be no assurance that any such events will occur. We intend to continue evaluating drug product candidates for the purpose of growing our pipeline. Identifying and securing high-quality compounds usually takes time and related expenses; however, our spending could be significantly accelerated in 2024 and onward if additional drug product candidates are acquired and enter clinical development. In this event, we may be required to expand our management team, and pay higher contract manufacturing costs, contract research organization fees, other clinical development costs and insurance costs that are not currently projected. Additional long-term funding is needed to generally to support our current and future product candidates through clinical trials, approval processes and, if applicable, commercialization.

Until we can generate a sufficient amount of product revenue to finance our cash requirements, we expect to finance our future cash needs primarily through a combination of equity offerings, including at-the-market sales programs, 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

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 March 8, 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.

Onxeo S.A.

In June 2016, we executed an agreement with Onxeo S.A., a French public company, which gave us the exclusive option to license (on a world-wide exclusive basis) Validive (clonidine hydrocholoride mucobuccal tablet; clonidine HCI MBT) a mucoadhesive tablet of clonidine based on the Lauriad mucoadhesive technology. In September 2017, we exercised the option to license Validive from Onxeo for $1 million. In March 2023, we discontinued our Validive Phase 2b/3 VOICE trial based upon ours Data Safety Monitoring Board's determination that the trial did not meet the pre-defined threshold for efficacy of a 15% absolute difference in severe oral mucositis prevention between Validive and placebo. We have not incurred any license or royalty obligations and the license has been terminated effective January 2024.

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 office space on a month-to-month basis 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. See Item 1A - “Risk Factors - We have limited the liability of and indemnified our directors and officers.”

Item 8. Financial Statements and Supplementary Data

The information required to be filed in this item appears on pages F-1 to F-22 of this Annual Report on Form 10-K.

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure

None.

Item 9A. Controls and Procedures

Our Chief Executive Officer and Chief Financial Officer have provided certifications filed as Exhibits 31.1, 31.2 and 32.1. Such certifications should be read in conjunction with the information contained in this Item 9A for a more complete understanding of the matters covered by those certifications.

(a) Management's Annual Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as defined in Rule 13a15(f) of the Securities Exchange Act of 1934 (the "Exchange Act"). Our internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of the financial reporting and the preparation of financial statements for external purposes in accordance with U.S. generally accepted accounting principles. This process includes those policies and procedures (i) that pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of our assets, (ii) that receipts and expenditures are being made only in accordance with authorizations of our management and non-employee directors, (iii) that provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of our assets that could have a material effect on our financial statements, and (iv) that provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with GAAP. Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of the internal control over financial reporting to future periods are subject to risk that the internal control may become inadequate because of changes in conditions, or that the degree of compliance with policies or procedures may deteriorate.

Our management has assessed the effectiveness of our internal control over financial reporting as of December 31, 2023. Management based this assessment on the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission in Internal Control – Integrated Framework (2013). Management's assessment included an evaluation of the design of our internal control over financial reporting and testing of the operational effectiveness of our internal control over financial reporting. Based on management's assessment, management has concluded that, as of December 31, 2023, our internal control over financial reporting was effective.

(b) 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 December 31, 2023, pursuant to Rules 13a15(e) and 15d15(e) under the Exchange Act. Based on that evaluation, our Chief Executive Officer and Chief Financial Officer have concluded that our disclosure controls and procedures, as of such date, were effective.

(c) Changes in Internal Control over Financial Reporting

We have concluded that the consolidated financial statements and other financial information included in this Annual Report on Form 10-K 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 quarter ended December 31, 2023 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information

During the quarter ended December 31, 2023, 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.

PART III

Item 10. Directors, Executive Officers and Corporate Governance

Directors

The names, positions and ages of our directors as of March 28, 2024, are as follows:

Name	Age	Positions	Director Since
Christopher M. Starr, PhD	71	Executive Chairman, Director, Member of the Plan Administrator Committee	December 2014
Chandler D. Robinson, MD MBA MSc	40	Chief Executive Officer, Director	December 2014
Raymond W. Anderson, MBA	82	Director, Chair of the Audit Committee, Chair of the Compensation Committee and Member of the Corporate Governance and Nominating Committee, Member of the Plan Administrator Committee	April 2017
Michael J. Brown, MSc	67	Director, Member of the Audit Committee, Member of the Compensation Committee, Member of the Corporate Governance and Nominating Committee, Member of the Plan Administrator Committee	December 2014
Arthur J. Klausner, MBA	63	Director, Chair of the Corporate Governance and Nominating Committee, Member of the Audit Committee, Member of the Compensation Committee	August 2017
Kim R. Tsuchimoto	61	Chief Financial Officer, Director	March 2023

Background of Directors

The principal occupations for the past five years (and, in some instances, for prior years) of each of our directors are as follows:

Christopher M. Starr, PhD - Executive Chairman and Board Member

Dr. Starr is a co-founder and has been our Executive Chairman and a Board Member of ours and our predecessor, Monopar Therapeutics, LLC, since its inception in December 2014. Dr. Starr was the co-founder and served as the chief executive officer ("CEO") at Raptor Pharmaceuticals ("Raptor") (Nasdaq: RPTP), from its inception in 2006 through December 2014 and continued to serve Raptor as a member of its board of directors until Raptor was sold to Horizon Pharma plc in October 2016. The principal business of Raptor was the development and commercialization of treatments for rare diseases. Dr. Starr was also a co-founder of BioMarin Pharmaceutical ("BioMarin") (Nasdaq: BMRN) in 1997 where he last served as Vice President of Research and Development until 2006. BioMarin is a fully-integrated multinational biopharmaceutical company. Dr. Starr earned a B.S. from Syracuse University and a Ph.D. in Biochemistry and Molecular Biology from the State University of New York Health Science Center, in Syracuse, New York. Dr. Starr also currently serves on the boards of privately held Glycomine Inc. and Thiogenesis Therapeutics Corp., a Canadian public start-up biotech company.

Dr. Starr's board qualifications include over 25 years of executive experience in funding and operating public and private biopharmaceutical companies. We believe Dr. Starr's experience qualifies him to serve as the executive chairman of our Board.

Chandler D. Robinson, MD MBA MSc - Chief Executive Officer and Board Member

Dr. Robinson is a co-founder and has been our CEO and a Board Member of ours and our predecessor, Monopar Therapeutics, LLC, since its inception in December 2014. Since 2010, Dr. Robinson has been, and continues to be, a manager of Tactic Pharma, which he co-founded and led as CEO until it became a holding company in April 2014. Tactic Pharma acquired and developed preclinical and clinical stage biopharmaceutical compounds. From 2003 to 2006, Dr. Robinson conducted research at Northwestern University on a drug candidate currently being developed to treat Wilson's disease, which was acquired by Tactic Pharma in 2010 and sold in 2014. Among his previous experiences, Dr. Robinson in 2008 worked at Onyx Pharmaceuticals, an oncology biopharmaceutical company, in their Nexavar marketing division, from 2008 to 2009 as a co-manager of a healthcare clinic in San Jose CA, from 2004 to present as Founder and President of an undergraduate research focused non-profit now in its 20th year, and from 2006 to 2007 as part of a quantitative internal hedge-fund style team at Bear Stearns investment bank. He also previously co-founded and was on the board of Wilson Therapeutics (acquired by Alexion Pharmaceuticals Inc., now a part of AstraZeneca), a biopharmaceutical company, and is currently on the board of Northwestern University's Chemistry of Life Processes Institute. Dr. Robinson graduated summa cum laude from Northwestern University, earned a master's degree in International Health Policy and Health Economics from the London School of Economics on a Fulbright Scholarship, an MBA from Cambridge University on a Gates Scholarship through Bill Gates' Trust, and an MD from Stanford University.

Dr. Robinson's extensive leadership and management experience along with his medical and business degrees, his entrepreneurial and strategic vision and knowledge of Monopar's product candidates and operations led to the conclusion that he should serve as a member of our Board.

Michael J. Brown, MSc – Board Member

Mr. Brown has been a Board Member of ours and our predecessor, Monopar Therapeutics, LLC since its inception in December 2014. Since 1994, Mr. Brown has served as Chairman, and since 1996 as CEO, of Euronet Worldwide Inc. ("Euronet") (Nasdaq: EEFT) which offers payment and transaction processing and distribution solutions to financial institutions, retailers, service providers and individual consumers. Mr. Brown has been President of Euronet since December 2014. Mr. Brown has also served on the boards of Euronet's predecessor companies. He has an M.S. in molecular and cellular biology.

Mr. Brown's extensive leadership and management experience, including strategic planning, business development, and financing strategies led to the conclusion that he should serve as a member of our Board.

Raymond W. Anderson, MBA, MS – Board Member

Mr. Anderson has been a Board Member of ours since April 2017. Mr. Anderson served as a board member, chair of the audit committee and member of the compensation committee at Raptor, a biopharmaceutical company, from its founding in 2006 to its acquisition in 2016. Mr. Anderson worked at Dow Pharmaceutical Sciences, Inc., a dermatological prescription drug formulation company, from July 2003 until he retired in June 2010. He most recently served as Dow's Managing Director from January 2009 to June 2010, and previously served as Dow's Chief Financial Officer and Vice President, Finance and Administration. Prior to joining Dow in 2003, Mr. Anderson was Chief Financial Officer for Transurgical, Inc., a private ultrasound surgical system company. Prior to that, Mr. Anderson served as Chief Operating Officer and Chief Financial Officer at BioMarin, a biopharmaceutical company, from June 1998 to January 2002. Mr. Anderson holds an M.B.A. from Harvard University, an M.S. in administration from George Washington University and a B.S. in engineering from the U.S. Military Academy.

Mr. Anderson's background and experience as a finance executive in the biopharmaceutical industry and his qualification as an "audit committee financial expert" under SEC and Nasdaq rules led to the conclusion that he should serve as a member of our Board.

Arthur J. Klausner, MBA – Board Member

Mr. Klausner has been a Board Member of ours since August 2017. He has been a consultant to the biopharmaceutical industry since 2009 and currently serves as Executive Chairman of the oncology drug development company Concarlo Therapeutics, Inc. From 2018 to 2022, Mr. Klausner served as President, CEO, and a director of the nephrology drug development company Goldilocks Therapeutics, Inc. He served as CEO of Gem Pharmaceuticals, LLC ("Gem") from September 2012 until Gem's drug development assets were acquired by us in 2017. In addition to his role at Gem, Mr. Klausner served as CEO of the ophthalmology therapeutics company Jade Therapeutics Inc. from 2012 until 2015. Previously, Mr. Klausner spent a total of 18 years at the life science venture capital firms Domain Associates and Pappas Ventures (now Pappas Capital). Mr. Klausner currently serves on venture capital investment review boards for the New York University ("NYU") Innovation Venture Fund and NYU Langone Health. He received his M.B.A. from the Stanford University Graduate School of Business and his B.A. in biology from Princeton University.

Mr. Klausner's extensive leadership and management experience in the biopharmaceutical industry led to the conclusion that he should serve as a member of our Board.

Kim R. Tsuchimoto – Chief Financial Officer and Board Member

Ms. Tsuchimoto has been our Chief Financial Officer since June 2015 and has been a Board Member of ours since March 2023. Ms. Tsuchimoto spent over nine years at Raptor, a biopharmaceutical company, as its Chief Financial Officer from Raptor's inception in May 2006 until September 2012, as Raptor's Vice President of International Finance, Tax & Treasury from September 2012 to February 2015, and lastly as Raptor's Vice President, Financial Planning & Analysis and Internal Controls from February to May 2015. Prior to Raptor, Ms. Tsuchimoto spent eight years at BioMarin, a biopharmaceutical company, and its predecessor, Glyko, Inc., where she held the positions of Vice President-Treasurer, Vice President-Controller and Controller. Ms. Tsuchimoto received a B.S. in Business Administration from San Francisco State University. She holds an inactive California Certified Public Accountant license. Ms. Tsuchimoto also currently serves on the board of Thiogenesis Therapeutics Corp., a Canadian public start-up biotech company.

Ms. Tsuchimoto's over 25 years of experience in the biopharma industry including her strong financial management, corporate governance and financial strategy experience led to the conclusion that she should serve as a member of our Board.

Executive Officers

Our current executive officers, their respective ages as of the date of March 28, 2024 and positions are set forth in the following table. Biographical information regarding each executive officer (other than Dr. Robinson and Ms. Tsuchimoto) is set forth following the table. Biographical information for Dr. Robinson and Ms. Tsuchimoto is set forth above under Directors.

Name	*Age*	*Positions*
Chandler D. Robinson, MD MBA MSc	40	Chief Executive Officer, Director
Kim R. Tsuchimoto	61	Chief Financial Officer, Secretary, Treasurer, Director
Andrew J. Cittadine	52	Chief Operating Officer
Patrice Rioux, MD, Ph.D.	73	Acting Chief Medical Officer

Andrew J. Cittadine – Chief Operating Officer

Mr. Cittadine has been our Chief Operating Officer since June 2021. Mr. Cittadine is an experienced healthcare executive and serial entrepreneur with a successful track record of identifying, founding, and building healthcare businesses from concept to commercialization to acquisition by Fortune Global 1000 firms. From 2020 to 2021, Mr. Cittadine was the principal of Alatri Group, a consulting company, advising Monopar along with other life sciences companies. From 2011 to 2020, Mr. Cittadine was the Chief Executive Officer of Diagnostic Photonics, Inc., a VC-backed developer and manufacturer of advanced imaging systems for oncology surgery and diagnostics. Prior to that he was the co-founder and Chief Executive Officer of American BioOptics, a developer of advanced oncology diagnostic test and screening systems for GI cancers, which was acquired by Olympus Medical. Prior to that, Mr. Cittadine was interim Chief Executive Officer of Sonarmed Inc., an angel and venture-backed critical care company developing neonatal respiratory monitoring systems which was acquired by Medtronic and was a co-founder and Vice President of Marketing at Sensant Corp., a Silicon Valley, angel-backed oncology imaging startup developing 3D ultrasound imaging systems, which was acquired by Siemens Medical. Mr. Cittadine received his BA, BS, and MS from Stanford and an MBA from Northwestern's Kellogg School of Management.

Patrice Rioux, MD, Ph.D. – Acting Chief Medical Officer

Dr. Rioux has been our Acting Chief Medical Officer since December 2016. He is the co-founder, Director and Chief Executive Officer of Thiogenesis Therapeutics Corp. Dr. Rioux has been performing development, medical/regulatory, and clinical consulting services through his consulting company, pRx Consulting, LLC from June 2004 to the present. Dr. Rioux received his medical education at Faculté de Médecine Pitié-Salpetriere, Université Paris VI, Paris, France, his Ph.D. in Mathematical Statistics at Faculté des Sciences, Université Paris VII, France and his Degree of Pharmacology (pharmacokinetics and clinical pharmacology) at Faculté de Médecine Pitié-Salpetriere.

Code of Business Conduct and Ethics

We have adopted a Code of Business Conduct and Ethics that is applicable to our principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions. It also applies to all of our employees and our non-employee directors. Our Code of Business Conduct and Ethics is available on our website at www.monopartx.com and will be provided to any person without charge upon request.

Audit Committee

Our Audit Committee consists of Mr. Anderson, Mr. Klausner and Mr. Brown, who are independent members as defined by Nasdaq rules applicable to audit committees and the SEC under Rule 10A-3 under the Exchange Act. Mr. Anderson serves as chair of the Audit Committee and is an "audit committee financial expert" as defined by Nasdaq and the SEC.

Item 11. Executive and Director Compensation

Summary Executive Compensation Table

The following table provides information regarding the compensation earned during the years ended December 31, 2023 and 2022 for our named executive officers, which include our Chief Executive Officer and the two highest compensated executive officers whose compensation exceeded $100,000 during our last fiscal year.

Name and Positions	*Fiscal Year*	*Salary ($)*	*Bonus ($)*	*Stock Awards ($) (1)(2)*	*Option Awards ($) (1) (2)*	*Non-Equity Incentive Plan ($) (3)*	*All Other Compensation*	*Total ($)*
Chandler D. Robinson, MD	2023	580,000	-	534,078	534,077	130,500	-	1,778,655
Chief Executive Officer and Director	2022	550,000	-	446,662	446,662	158,125	-	1,601,448
Kim R. Tsuchimoto	2023	300,000	-	247,219	247,221	54,000	-	848,441
Chief Financial Officer, Secretary, Treasurer and Director	2022	285,000	-	172,290	172,289	65,550	-	695,128
Andrew Cittadine	2023	360,000	-	247,219	247,221	56,700	-	911,141
Chief Operating Officer	2022	325,000	-	182,000	179,920	65,406	-	752,326

(1) The amounts in these columns represent the aggregate grant date fair value of restricted stock units and stock options awarded, respectively, during the applicable year to the named executive officers, computed in accordance with FASB ASC Topic 718. The fair value of restricted stock units reflected in the Stock Awards column is based upon the closing price on the date of grant. The fair value of stock options in the Option Awards column is estimated on the date of grant using the Black-Scholes option pricing model. For a discussion of valuation assumptions, see Note 5 to our consolidated financial statements included in this Annual Report on Form 10-K.

(2) In 2023, Dr. Robinson, Ms. Tsuchimoto and Mr. Cittadine were granted stock options to purchase up to 221,839, 102,688 and 102,688 shares of our common stock, respectively, at an exercise price of $3.16 per share, as discussed below in the section “Outstanding Equity Awards at Fiscal Year End”. Based upon the Black-Scholes valuation model for stock option compensation expense, the value of Dr. Robinson’s, Ms. Tsuchimoto’s and Mr. Cittadine’s stock options was $534,077, $247,221 and $247,221, respectively. The stock options vested 6/48ths on June 30, 2023, and 1/48th per month thereafter.

In 2023, Dr. Robinson, Ms. Tsuchimoto and Mr. Cittadine were granted 169,012, 78,234 and 78,234 restricted stock units which vested 6/48ths on June 30, 2023, and 3/48ths per quarter thereafter. Based upon the closing price on the date of grant, the value of Dr. Robinson’s, Ms. Tsuchimoto’s and Mr. Cittadine’s restricted stock units was $534,078, $247,219, and $247,219, respectively.

In 2022, Dr. Robinson, Ms. Tsuchimoto and Mr. Cittadine were granted stock options to purchase up to 211,018, 81,395 and 85,000 shares of our common stock, respectively, at an exercise price of $2.80 per share, as discussed below in the section “Outstanding Equity Awards at Fiscal Year End”. Based upon the Black-Scholes valuation model for stock option compensation expense, the value of Dr. Robinson’s, Ms. Tsuchimoto’s and Mr. Cittadine’s stock options was $446,662, $172,289 and $179,920, respectively. The stock options vested 6/48ths on June 30, 2022, and 1/48th per month thereafter.

In 2022, Dr. Robinson, Ms. Tsuchimoto and Mr. Cittadine were granted 159,522, 61,532 and 65,000 restricted stock units which vested 6/48ths on June 30, 2022, and 3/48ths per quarter thereafter. Based upon the closing price on the date of grant, the value of Dr. Robinson's, Ms. Tsuchimoto's and Mr. Cittadine's restricted stock units was $446,662, $172,290, and $182,000, respectively.

(3) In 2023 and 2022, Non-equity Incentive Plan represents payments based on partial fulfillment of pre-set 2023 and 2022 corporate goals, respectively.

Chief Executive Officer Compensation

In December 2016, we entered into an employment agreement with Dr. Robinson for his role as our chief executive officer. Although we have been paying Dr. Robinson as our employee since January 1, 2016, we did not enter into a formal employment agreement until December 2016. Dr. Robinson's employment agreement is for an indefinite term (for at-will employment). The agreement was amended and restated on November 1, 2017.

Under his 2017 employment agreement, Dr. Robinson received a specified base salary, which may be adjusted from time to time in accordance with normal business practice and in our sole discretion. In addition, Dr. Robinson is eligible for an annual non-equity incentive plan performance bonus, of up to 50% of his base salary, based on achieving pre-set, written goals as recommended by management and reviewed by our Compensation Committee and our Executive Chair and approved by our Board. In February 2023, the Board awarded Dr. Robinson a bonus of $158,125 related to the partial achievement of pre-set 2022 non-equity incentive plan goals and approved a new base salary for Dr. Robinson of $580,000. In February 2024, the Board awarded Dr. Robinson a bonus of $130,500 related to the partial achievement of pre-set 2023 non-equity incentive plan goals.

Chief Financial Officer Compensation

On November 1, 2017, we entered into an employment agreement with Ms. Tsuchimoto for her role as our Chief Financial Officer. Ms. Tsuchimoto's employment agreement is for an indefinite term (for at-will employment). The agreement was amended on March 1, 2018. Under her employment agreement, Ms. Tsuchimoto received a specified base salary, which may be adjusted from time to time in accordance with normal business practice and in our sole discretion. In addition, Ms. Tsuchimoto is eligible for an annual non-equity incentive plan performance bonus, of up to 40% of her base salary, based on achieving pre-set, written goals as recommended by management and reviewed by our Compensation Committee and our Executive Chair and approved by our Board. In February 2023, the Board awarded Ms. Tsuchimoto a bonus of $65,550 related to the partial achievement of pre-set 2022 non-equity incentive plan goals and approved a new base salary for Ms. Tsuchimoto of $300,000. In February 2024, the Board awarded Ms. Tsuchimoto a bonus of $54,000 related to the partial achievement of pre-set 2023 non-equity incentive plan goals.

Chief Operating Officer Compensation

On June 1, 2021, we entered into an employment agreement with Mr. Cittadine for his role as our Chief Operating Officer. Mr. Cittadine's employment agreement is for an indefinite term (for at-will employment). Under his employment agreement, Mr. Cittadine received a specified base salary, which may be adjusted from time to time in accordance with normal business practice and in our sole discretion. In addition, Mr. Cittadine is eligible for an annual non-equity incentive plan performance bonus, of up to 35% of his base salary, based on achieving pre-set, written goals as recommended by management and reviewed by our Compensation Committee and our Executive Chair and approved by our Board. In February 2023, the Board awarded Mr. Cittadine a bonus of $65,406 related to the partial achievement of pre-set 2022 non-equity incentive plan goals and approved a new base salary for Mr. Cittadine of $360,000. In February 2024, the Board awarded Mr. Cittadine a bonus of $56,700 related to the partial achievement of pre-set 2023 non-equity incentive plan goals.

Outstanding Equity Awards at December 31, 2023

The following table sets forth outstanding stock option awards held by named executive officers as of December 31, 2023.

Name	*Number of Securities Underlying Unexercised Options (#) Exercisable*		*Number of Securities Underlying Unexercised Options (#) Unexercisable*		*Option Exercise Price ($)*	*Option Expiration Date*	*Number of Shares or Units of Stock That Have Not Vested (#)*	*Market Value of Shares or Units of Stock That Have Not Vested ($)(8)*
Chandler D. Robinson, M.D.,	55,460	(1)	166,379	(1)	$ 3.16	February 1, 2033		
Chief Executive Officer and Director	105,509	(2)	105,509	(2)	$ 2.80	February 2, 2032		
	52,500	(3)	17,500	(3)	$ 6.81	January 26, 2031		
	70,000	(4)	-	(4)	$ 14.35	February 11, 2030		
	145,500	(5)	-	(5)	$ 6.00	August 27, 2028		
	84,000	(6)	-	(6)	$ 0.001	February 19, 2027		
	84,000	(7)	-	(7)	$ 0.001	April 3, 2026		
							229,009	77,909
Kim R. Tsuchimoto,	25,672	(1)	77,016	(1)	$ 3.16	February 1, 2033		
Chief Financial Officer, Secretary and Treasurer	40,698	(2)	40,697	(2)	$ 2.80	February 2, 2032		
	20,570	(3)	6,857	(3)	$ 6.81	January 26, 2031		
	20,455	(4)	-	(4)	$ 14.35	February 11, 2030		
	41,100	(5)	-	(5)	$ 6.00	August 27, 2028		
	23,520	(6)	-	(6)	$ 0.001	February 19, 2027		
	21,000	(7)	-	(7)	$ 0.001	April 3, 2026		
							95,556	32,508
Andrew J. Cittadine,	25,672	(1)	77,016	(1)	$ 3.16	February 1, 2033		
Chief Operating Officer	42,500	(2)	42,500	(2)	$ 2.80	February 2, 2032		
	18,750	(9)	11,250	(9)	$ 5.89	June 30, 2031		
	45,208	(10)	24,792	(10)	$ 5.76	June 1, 2031		
							91,175	31,018

(1) Dr. Robinson, Ms. Tsuchimoto and Mr. Cittadine were granted stock option awards on February 1, 2023, which commenced vesting on January 1, 2023, and vested 6/48ths on the six-month anniversary of vesting commencement date (June 30, 2023) and vested 1/48th per month thereafter.

(2) Dr. Robinson, Ms. Tsuchimoto and Mr. Cittadine were granted stock option awards on February 2, 2022, which commenced vesting on January 1, 2022, and vested 6/48ths on the six-month anniversary of vesting commencement date (June 30, 2022) and vested 1/48th per month thereafter.

(3) Dr. Robinson and Ms. Tsuchimoto were granted stock option awards on January 26, 2021, which commenced vesting on January 1, 2021, and vested 6/48ths on the six-month anniversary of vesting commencement date (June 30, 2021) and vested 1/48th per month thereafter.

(4) Dr. Robinson and Ms. Tsuchimoto were granted stock option awards on February 11, 2020, which commenced vesting on January 1, 2020, and vested 6/48ths on the six-month anniversary of vesting commencement date (June 30, 2020) and vested 1/48th per month thereafter.

(5) Dr. Robinson and Ms. Tsuchimoto were granted stock option awards on August 28, 2018, which commenced vesting on October 1, 2018, and vested 6/51 on the six-month anniversary of vesting commencement date (March 31, 2019) and vested 1/51 per month thereafter.

(6) Dr. Robinson and Ms. Tsuchimoto were granted stock option awards on February 20, 2017, which vested 6/48ths on the six-month anniversary of grant date (August 20, 2017) and 1/48th per month thereafter.

(7) Dr. Robinson and Ms. Tsuchimoto were granted stock option awards on April 4, 2016, which vested 50% on the grant date (April 4, 2016), 25% on the six-month anniversary of the grant date (October 4, 2016) and 25% on the one-year anniversary of the grant date (April 3, 2017).

(8) The value of RSUs shown in the table that have not yet vested was calculated using $0.3402, the closing price of our common stock on December 31, 2023.

In 2023, Dr. Robinson, Ms. Tsuchimoto and Mr. Cittadine were granted 169,012, 78,234 and 78,234 restricted stock units which vested 6/48ths on June 30, 2023, and 3/48ths per quarter thereafter.

In 2022, Dr. Robinson, Ms. Tsuchimoto and Mr. Cittadine were granted 159,522, 61,532 and 65,000 restricted stock units which vested 6/48ths on June 30, 2022, and 3/48ths per quarter thereafter.

In 2021, Dr. Robinson and Ms. Tsuchimoto were granted 63,060 and 19,536 restricted stock units which vested 6/48ths on June 30, 2021, and 3/48ths per quarter thereafter.

In 2020, Dr. Robinson and Ms. Tsuchimoto were granted 26,895 and 4,923 restricted stock units which vest 25% on January 1, 2021, January 1, 2022, January 1, 2023 and January 1, 2024

(9) Mr. Cittadine was granted stock option awards on June 30, 2021, which vested 6/48ths on the six-month anniversary of employment commencement (November 30, 2021) and 1/48th per month thereafter.

(10) Mr. Cittadine was granted stock option awards on June 1, 2021, which vested 6/48ths on the six-month anniversary of grant date (November 30, 2021) and 1/48th per month thereafter.

Potential Payments upon Termination or Change in Control

Each of Dr. Robinson's, Ms. Tsuchimoto's, and Mr. Cittadine's employment agreements provides that upon execution and effectiveness of a release of claims, Dr. Robinson, Ms. Tsuchimoto and Mr. Cittadine will be entitled to severance payments if their employment with us terminates under certain circumstances. If we terminate their employment without "cause," or if Dr. Robinson or Ms. Tsuchimoto resigns for "good reason," in each case absent a "change in control," Dr. Robinson would receive, (1) base salary continuation for 12 months, (2) any vested equity awards will continue to be exercisable for 12 months, and (3) payment of or reimbursement for COBRA continuation coverage until the earlier of 12 months following termination or the date the executive becomes eligible for coverage under an employer's plan. Ms. Tsuchimoto would receive, (1) base salary continuation for 3 months, (2) any vested equity awards will continue to be exercisable for 12 months, and (3) if Ms. Tsuchimoto is full-time, payment of or reimbursement for COBRA continuation coverage until the earlier of 12 months following termination or the date the executive become eligible for coverage under an employer's plan. Mr. Cittadine would receive, (1) base salary continuation for 3 months, (2) any vested equity awards will continue to be exercisable for 6 months, and (3) payment of or reimbursement for COBRA continuation coverage until the earlier of 6 months following termination or the date the executive become eligible for coverage under an employer's plan.

If Dr. Robinson's employment is terminated without cause or for good reason within 12 months following a change in control, he would be entitled to (1) a lump sum payment in an amount equal to 1.5 times his respective base salary plus target annual bonus for the year in which the termination occurs, (2) payment of or reimbursement for COBRA continuation coverage until the earlier of 18 months following termination or the date the executive becomes eligible for coverage under an employer's plan and (3) full vesting acceleration of all outstanding equity awards. If Dr. Robinson's employment is terminated because of death or permanent disability, we will be obligated to provide base salary continuation and COBRA payment or reimbursement for a period of three months.

If Ms. Tsuchimoto's employment is terminated without cause or for good reason within 12 months following a change in control, she would be entitled to (1) a lump sum payment in an amount equal to .25 times her base salary plus target annual bonus for the year in which the termination occurs, (2) if Ms. Tsuchimoto is full-time, payment of or reimbursement for COBRA continuation coverage until the earlier of three months following termination or the date the executive becomes eligible for coverage under an employer's plan and (3) full vesting acceleration of all outstanding equity awards. If Ms. Tsuchimoto's employment is terminated because of death or permanent disability, we will be obligated to provide base salary continuation and COBRA payment or reimbursement for a period of three months.

If Mr. Cittadine's employment is terminated without cause or for good reason within 12 months following a change in control, he would be entitled to (1) a lump sum payment in an amount equal to .75 times his base salary plus target annual bonus for the year in which the termination occurs, (2) payment of or reimbursement for COBRA continuation coverage until the earlier of six months following termination or the date the executive becomes eligible for coverage under an employer's plan and (3) full vesting acceleration of all outstanding equity awards. If Mr. Cittadine's employment is terminated because of death or permanent disability, we will be obligated to provide base salary continuation and COBRA payment or reimbursement for a period of three months.

Upon any termination of employment, Dr. Robinson, Ms. Tsuchimoto and Mr. Cittadine are entitled to receive any accrued but unpaid base salary and any earned but unpaid annual bonus.

The employment agreements with Dr. Robinson, Ms. Tsuchimoto and Mr. Cittadine provide that, in the event that any payments the executives received in connection with a change in control of our Company are subject to the excise tax under Section 4999 of the Internal Revenue Code of 1986, as amended, such payments will be reduced to the greatest amount payable that would not result in no such tax owed, but only if it is determined that such reduction would cause the executive to be better off, on a net after-tax basis, than without such reduction and payment of the excise tax under Section 4999 of the Code.

Pension Benefits

We do not have a defined benefit pension plan. Our named executive officers did not participate in, or otherwise receive any special benefits under, any pension or defined benefit retirement plan sponsored by us during the year ended December 31, 2023.

401(k) Plan

We maintain a defined contribution employee retirement plan for our employees. The plan is intended to qualify as a tax-qualified plan under Section 401(k) of the Code so that contributions to the 401(k) plan, and income earned on such contributions, are not taxable to participants until withdrawn or distributed from the 401(k) plan.

The 401(k) plan provides that each participant may contribute up to 100% of his or her pre-tax compensation, up to a statutory limit, which is $22,500 for 2023. Participants who are at least 50 years old can also make "catch-up" contributions, which in 2023 may be up to an additional $7,500 above the statutory limit. Employees become eligible to participate in the 401(k) plan after four months of active employment with the Company.

Under the 401(k) plan, each employee is fully vested in his or her deferred salary contributions. Employee contributions are held and invested by the plan's trustee. The 401(k) plan also permits us to make discretionary profit-sharing contributions and discretionary matching contributions, subject to established limits and a vesting schedule.

Nonqualified Deferred Compensation

During the year ended December 31, 2023, our named executive officers did not contribute to, or earn any amount with respect to, any defined contribution or other plan sponsored by us that provides for the deferral of compensation on a basis that is not tax-qualified.

Hedging Policy

Our Insider Trading Policy prohibits short sales of our stock and short-swing transactions by our officers and non-employee directors. We have not adopted any other practices or policies regarding the ability of our employees (including officers) or non-employee directors to purchase financial instruments (including prepaid variable forward contracts, equity swaps, collars, and exchange funds), or otherwise engage in transactions, that hedge or offset, or are designed to hedge or offset, any decrease in the market value of our securities that are held by them.

Director Compensation for the Year Ended December 31, 2023

The following table sets forth the compensation of our non-employee directors during the year ended December 31, 2023.

Name	*Fees Earned or Paid in Cash ($)*	*Stock Awards ($) (1)*	*Option Awards ($) (2)*	*All Other Compensation ($)*	*Total ($)*
Christopher M. Starr, Ph.D.	80,000	32,020	32,021	120,000	264,041
Michael J. Brown	62,000	32,020	32,021	0	126,041
Raymond W. Anderson	72,500	32,020	32,021	0	136,541
Arthur J. Klausner	64,500	32,020	32,021	0	128,541

(1) The amounts in this column represent the aggregate grant date fair value of stock-based awards granted during the year ended December 31, 2023, to the non-employee directors, computed in accordance with FASB ASC Topic 718. The fair value of restricted stock units is based upon the closing price on the date of grant. For a discussion of valuation assumptions, see Note 5 to our consolidated financial statements included elsewhere in this Annual Report on Form 10-K.

(2) The amounts in this column represent the aggregate grant date fair value of option awards granted during the year ended December 31, 2023, to the non-employee directors, computed in accordance with FASB ASC Topic 718. The fair value of stock options is estimated on the date of grant using the Black-Scholes option pricing model. For a discussion of valuation assumptions, see Note 5 to our consolidated financial statements included elsewhere in this Annual Report on Form 10-K.

(3) Commencing on January 1, 2022, Dr. Starr executed a consulting agreement to provide to us advisory services in the areas of clinical development, regulatory strategy and manufacturing based upon his expertise in those areas at $10,000 per month. The agreement renews annually unless terminated by either party.

As of December 31, 2023, our non-employee directors held the following number of stock options, all of which were fully vested:

Name	*Aggregate Number of Shares Subject to Stock Awards*	*Aggregate Number of Shares Subject to Stock Options*
Christopher M. Starr, Ph.D.	-	233,247
Michael J. Brown	-	86,271
Raymond W. Anderson	-	86,271
Arthur J. Klausner	-	86,271

There were no unvested restricted stock units as of December 31, 2023.

The table below reflects the non-equity fee schedule for non-employee directors for 2023. Long-term equity compensation is determined annually utilizing the Black-Scholes valuation model along with review of peer group companies.

Position	2023 Annual Fees ($)*
Board Member	
Independent Board Member Base Fee	40,000
Additional Fee for Executive Chairman of the Board	40,000
Committees	
Committee fees are in addition to the base Board Member fee.	
Audit Committee	
Audit Committee Chair	15,000
Audit Committee Member	10,000
Compensation Committee	
Compensation Committee Chair	12,500
Compensation Committee Member	7,000
Corporate Governance and Nomination Committee (CG&N)	
CG&N Committee Chair	7,500
CG&N Committee Member	5,000

*Paid quarterly in arrears.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters

The following table and the related notes present information on the beneficial ownership of shares of our common stock, our only outstanding class of stock, as of March 8, 2024, by:

- each of our non-employee directors;
- each of our named executive officers;
- all of our current non-employee directors and executive officers as a group; and
- each person known by us to beneficially own more than five percent of our common stock.

Beneficial ownership is determined in accordance with the rules of the SEC and includes voting or investment power with respect to the securities. Shares of our common stock that may be acquired by an individual or group within 60 days of March 8, 2024, pursuant to the exercise of options, are deemed to be outstanding for the purpose of computing the percentage ownership of such individual or group, but are not deemed to be outstanding for the purpose of computing the percentage ownership of any other person shown in the table. Beneficial ownership percentage is based upon 17,454,925 shares of our common stock outstanding as of March 8, 2024.

Except as indicated in footnotes to this table, we believe that the stockholders named in this table have sole voting and investment power with respect to all shares of common stock shown to be beneficially owned by them, based on information provided to us by such stockholders.

Name and Address of Beneficial Owner *Unless otherwise noted, addresses are: 1000 Skokie Blvd., Suite 350, Wilmette, IL 60091	**Common Stock Beneficially Owned**	**Percent of Class Held**
TacticGem, LLC (1)	7,166,667	41.1%
Tactic Pharma LLC (1)	4,277,940	24.5%
Gem Pharmaceutical LLC (1) 941 Lake Forest Cir., Birmingham, AL 35244	3,055,394	17.5%
Diane Hendricks (1)	3,524,144	20.2%
Chandler D. Robinson, Chief Executive Officer and Director (2)	787,702	4.4%
Christopher M. Starr, Executive Chairman (3)	308,510	1.7%
Michael J. Brown, Director (4)	322,134	1.8%
Raymond W. Anderson, Director(5)	113,134	*
Arthur Klausner, Director (6)	117,134	*
Kim R. Tsuchimoto, Chief Financial Officer and Director (7)	255,236	1.4%
Andrew J. Cittadine, Chief Operating Officer (8)	208,499	1.2%
Executive officers and directors as a group (8) persons (9)	6,488,751	34.1%

(1) Tactic Pharma shares voting and investment power over 4,111,273 shares of our common stock owned by TacticGem, and Gem shares voting and investment power over 3,055,394 shares of our common stock owned by TacticGem, because pursuant to the TacticGem limited liability company agreement all votes of our common stock are passed through to Tactic Pharma and Gem in proportion to their percentage interests in TacticGem. After an initial holding period, which ended after we were subject to the reporting requirements of the Exchange Act and filed all required reports for a period of at least 12 months, either member of TacticGem can cause up to its proportionate shares of our common stock to be distributed to it. Tactic Pharma holds 166,667 shares of stock in its own name. Dr. Robinson is a manager of Tactic Pharma; because of this, he may be deemed to share voting and dispositive power over 4,111,273 shares of our common stock owned by TacticGem, and over our common stock owned by Tactic Pharma. Gem is controlled by Pharma Investments, LLC, which is in turn controlled by Diane M. Hendricks. DMH Business LLC, controlled by Ms. Hendricks, purchased 468,750 shares in our initial public offering. The amount controlled by Ms. Hendricks includes Gem’s ownership and DMH Business LLC’s ownership.

(2) Includes 638,873 common stock options that are vested or vest within 60 days after March 8, 2024.

(3) Includes 233,247 common stock options that are vested or vest within 60 days after March 8, 2024.

(4) Includes 86,271 common stock options that are vested or vest within 60 days after March 8, 2024.

(5) Includes 86,271 common stock options that are vested or vest within 60 days after March 8, 2024.

(6) Includes 86,271 common stock options that are vested or vest within 60 days after March 8, 2024.

(7) Includes 210,640 common stock options that are vested or vest within 60 days after March 8, 2024.

(8) Includes 156,729 common stock options that are vested or vest within 60 days after March 8, 2024.

(9) Includes 4,277,940 shares beneficially owned by Tactic Pharma. Refer to footnote (1) above.

* Less than 1%

Securities Authorized for Issuance Under Equity Compensation Plans

The following table provides information as of December 31, 2023, with respect to shares of our common stock that may be issued under existing equity compensation plans.

Plan Category	*Number of Securities to be Issued Upon Exercise of Outstanding Options, Warrants and Rights*	*Weighted-Average Exercise Price of Outstanding Options, Warrants and Rights*	*Number of Securities Remaining Available for Future Issuance under Equity Compensation Plans*
Equity compensation plans approved by security holders (1)	2,109,001	$4.01	1,956,038

(1) The Monopar Therapeutics Inc. 2016 Stock Incentive Plan.

All of our equity compensation plans have been approved by our security holders.

Item 13. Certain Relationships and Related Transactions and Director Independence

Relationships and Related-Person Transactions

Since January 2023, we have not engaged reportable transactions with our co-founders, non-employee directors, executive officers, holders of more than 5% of our voting securities, and affiliates or immediate family members of our non-employee directors, executive officers and holders of more than 5% of our voting securities, and our co-founders.

Registration Rights

We are subject to an agreement with TacticGem, LLC ("TacticGem"), our largest stockholder, which obligates us to file a Form S-3 or other appropriate form of registration statement covering the resale of any of our common stock by TacticGem, or its members Gem Pharmaceuticals, LLC, or Tactic Pharma, LLC, upon direction by TacticGem. Through the date hereof, TacticGem has not required us to file such a resale registration statement, although there can be no assurance we will not be required to do so in the future.

Procedures for Related-Person Transactions

A "related person" includes any non-employee director, nominee for director or executive officer of the Company; a beneficial owner of more than five percent of any class of our voting securities; and a person who is an immediate family member of any such non-employee director, nominee for director, executive officer or more-than-five percent beneficial owner (the term "immediate family member" shall include any child, stepchild, parent, stepparent, spouse, sibling, mother-in-law, father-in-law, son-in-law, daughter-in-law, brother-in-law or sister-in-law and any person (other than a tenant or employee) sharing the household of any such non-employee director, nominee for director, executive officer or more-than-five percent beneficial owner).

Our Board has adopted our Audit Committee Charter which delegates the review and approval of related-person transactions to the Audit Committee. The Audit Committee reviews and approves or disapproves any transaction required to be disclosed according to SEC Regulation S-K, Item 404 between the Company and any related party on an on-going basis and oversees policies and procedures for the Audit Committee's judgments as to related party transactions as required by Nasdaq. Our Audit Committee will discuss with our management the business rationale for the transactions and whether appropriate disclosures have been made.

Director Independence

We believe it is important to have independent directors on our Board who can make decisions without being influenced by personal interests. Consistent with these considerations, after review of all relevant identified transactions or relationships between each Director, or any of their family members, and us, our senior management and our independent registered public accounting firm, our Board has affirmatively determined that the following directors are independent Directors within the meaning of the applicable Nasdaq listing standards: Dr. Starr, Mr. Brown, Mr. Anderson and Mr. Klausner. In making this determination, our Board found that none of the Directors had a material or other disqualifying relationship with us. With respect to Dr. Starr, the Board considered that he receives compensation for consulting services, as disclosed elsewhere in this Annual Report on Form 10-K, which does not exceed the applicable Nasdaq independence threshold. Dr. Robinson, our President and Chief Executive Officer, and Ms. Tsuchimoto, our Chief Financial Officer, Secretary and Treasurer, are not independent Directors by virtue of their employment relationship with us.

Our Audit Committee consists of Mr. Anderson, Mr. Klausner and Mr. Brown, who are independent members as defined by Nasdaq rules applicable to audit committees and the SEC under Rule 10A-3 under the Exchange Act. Mr. Anderson serves as chair of the Audit Committee and is a financial expert as defined by Nasdaq and the SEC.

Our CG&N Committee consists of Mr. Klausner, Mr. Brown and Mr. Anderson who are independent members. Mr. Klausner serves as the chair of the CG&N Committee.

Our Compensation Committee consists of Mr. Anderson, Mr. Brown and Mr. Klausner who are independent members defined by Nasdaq rules applicable to compensation committee members. Mr. Anderson serves as the chair of the Compensation Committee.

Our Plan Administrator Committee consists of Dr. Starr, Mr. Brown and Mr. Anderson who are independent members.

There are no other arrangements or understanding between any of our directors and any other persons pursuant to which they were selected as a director.

Item 14. Principal Accounting Fees and Services

All audit, audit-related, tax and other services rendered by BPM LLP have been and will be reviewed, pre-approved and performance monitored by the Audit Committee. Audit and permissible non-audit services may be pre-approved by the Audit Committee delegate represented by Mr. Anderson, its chair, or Mr. Klausner, an Audit Committee member, if Mr. Anderson is not available. Pre-approval decisions are reported by the chair/delegate to the Audit Committee promptly but not later than the next scheduled Audit Committee meeting.

Fees for Independent Registered Public Accounting Firm

The following is a summary of the aggregate fees recorded by us on a generally accepted accounting principles basis for the audit and other services rendered by BPM LLP, our independent registered public accounting firm, for the years ended December 31, 2023, and 2022.

	For the Year Ended December 31,	
Description of Services Provided by BPM LLP	**2023**	**2022**
Audit Fees: These services relate to review or audit of our financial statements*.	$ 310,500	$ 279,000
Audit-Related Fees: These services relate to assurance and services reasonably related to or derivative from the performance of the audit or review of our financial statements.	$ 15,000	$ 32,477
Tax Compliance Fees: These services relate to the preparation of our Federal, state and foreign tax returns and other filings.	-	-
Tax Consulting and Advisory Services: These services primarily relate to the area of tax strategy and minimizing our Federal, state, local and foreign taxes.	-	-
All Other Fees	-	-

*Includes audit fees related to the audit of the prior year-end financial statements and the current year's quarterly reviews.

PART IV

Item 15. Exhibits, Financial Statement Schedule

1. Financial Statements

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2. Financial Statements Schedules

Other financial statements schedules are not included because they are not required, or the information is otherwise shown in the Consolidated Financial Statements or notes thereto.

(b) Exhibits

The following exhibits are filed as part of this Annual Report on Form 10-K.

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	Amended and Restated Bylaws	Form 10-Q filed on May 12, 2022
4.1	Description of Registered Securities	Filed herewith as Exhibit 4.1
10.1*	License Agreement with XOMA Ltd.	Form 10-K filed on March 26, 2018
10.2*	Contribution Agreement (351) – Containing Registration Rights with TacticGem	Form 10-K filed on March 26, 2018
10.3	2016 Stock Incentive Plan, as amended	Form DEF14A filed on April 29, 2022
10.4	Form of Incentive Stock Option Agreement	Form 10-K filed on March 24, 2022
10.5	Form of Non-qualified Stock Option Agreement	Form 10-K filed on March 24, 2022
10.6	Form of Restricted Stock Unit Grant Notice	Form 10-K filed on March 24, 2022
10.7	Employment Agreement of Chandler D. Robinson – effective November 1, 2017	Form 10-K filed on March 26, 2018
10.8	Employment Agreement of Kim R. Tsuchimoto – effective November 1, 2017	Form 10-K filed on March 26, 2018
10.9	Amendment One to Employment Agreement of Kim R. Tsuchimoto – effective March 1, 2018	Form 10-K filed on March 26, 2018
10.10	Consulting Agreement of pRx Consulting (Patrice Rioux) – effective January 1, 2023	Filed herewith as Exhibit 10.1
10.11	Consulting Agreement of Christopher M. Starr – effective January 1, 2022	Form 10-K filed on March 24, 2022
10.12	Capital on Demand™ Sales Agreement with JonesTrading Institutional Services, LLC	Form 8-K filed on April 20, 2022
21.1	Subsidiaries of Monopar Therapeutics Inc. as of December 31, 2023	Filed herewith as Exhibit 21.1
23.1	Consent of Independent Registered Public Accounting Firm	Filed herewith as Exhibit 23.1
24.1	Power of Attorney (included in the signature page hereto)	
31.1	Certification of Chandler D. Robinson, Chief Executive Officer	Filed herewith as Exhibit 31.1
31.2	Certification of Kim R. Tsuchimoto, Chief Financial Officer	Filed herewith as Exhibit 31.2
32.1	Certification of Chandler D. Robinson, Chief Executive Officer and Kim R. Tsuchimoto, Chief Financial Officer	Filed herewith as Exhibit 32.1
97	Compensation Recoupment Policy	Filed herewith as Exhibit 97
101.INS	Inline XBRL Taxonomy Extension Schema	
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)	

Confidential Information has been omitted and filed separately with the SEC on exhibits marked with (*). Confidential treatment has been approved with respect to the omitted information, pursuant to an Order dated January 8, 2018.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) 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: March 28, 2024

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

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Chandler D. Robinson and Kim R. Tsuchimoto, his attorney-in-fact, with the power of substitution, for him in any and all capacities, to sign any amendments to this Annual Report on Form 10K and to file the same, with exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, hereby ratifying and confirming all that each of said attorneys-in-fact, or his substitute or substitutes, may do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated:

Signatures	Title	Date
/s/ Chandler D. Robinson Chandler D. Robinson	Chief Executive Officer and Director (Principal Executive Officer)	March 28, 2024
/s/ Kim R. Tsuchimoto Kim R. Tsuchimoto	Chief Financial Officer and Director (Principal Financial Officer and Principal Accounting Officer)	March 28, 2024
/s/ Christopher M. Starr Christopher Starr	Executive Chairman of the Board and Director	March 28, 2024
/s/ Raymond W. Anderson Raymond W. Anderson	Director	March 28, 2024
/s/ Michael J. Brown Michael Brown	Director	March 28, 2024
/s/ Arthur J. Klausner Arthur Klausner	Director	March 28, 2024

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Stockholders and Board of Directors of Monopar Therapeutics Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Monopar Therapeutics Inc. and its subsidiaries as of December 31, 2023 and 2022, and the related consolidated statements of operations and comprehensive loss, stockholders' equity, and cash flows for each of the two years in the period ended December 31, 2023, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of Monopar Therapeutics Inc as of December 31, 2023 and 2022, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2023, in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

These financial statements are the responsibility of the entity's management. Our responsibility is to express an opinion on these financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) ("PCAOB") and are required to be independent with respect to Monopar Therapeutics Inc. in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. Monopar Therapeutics Inc is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the entity's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ BPM LLP

We have served as Monopar Therapeutics Inc.'s auditor since 2015.

Walnut Creek, California
March 27, 2024

Monopar Therapeutics Inc.

Consolidated Balance Sheets

	December 31, 2023	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	$ 7,266,080	$ 8,186,194
Investments	—	4,933,550
Other current assets	66,433	45,982
Total current assets	7,332,513	13,165,726
Operating lease right-of-use asset	12,646	61,228
Total assets	$ 7,345,159	$ 13,226,954
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable, accrued expenses and other current liabilities	$ 1,757,393	$ 3,128,894
Total current liabilities	1,757,393	3,128,894
Non-current operating lease liability	—	8,408
Total liabilities	1,757,393	3,137,302
Commitments and contingencies (Note 9)		
Stockholders' equity:		
Common stock, par value of $0.001 per share, 40,000,000 shares authorized, 14,904,497 and 12,946,573 shares issued and outstanding as of December 31, 2023, and December 31, 2022, respectively	14,905	12,947
Additional paid-in capital	65,793,210	61,871,784
Accumulated other comprehensive income (loss)	(14,132)	8,942
Accumulated deficit	(60,206,217)	(51,804,021)
Total stockholders' equity	5,587,766	10,089,652
Total liabilities and stockholders' equity	$ 7,345,159	$ 13,226,954

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

Monopar Therapeutics Inc.

Consolidated Statements of Operations and Comprehensive Loss

	For the Years Ended December 31,	
	2023	**2022**
Operating expenses:		
Research and development	$ 5,600,193	$ 7,591,601
General and administrative	3,231,042	2,945,276
Total operating expenses	8,831,235	10,536,877
Loss from operations	(8,831,235)	(10,536,877)
Interest income	429,039	21,239
Net loss	(8,402,196)	(10,515,638)
Other comprehensive income (loss):		
Foreign currency translation loss	(17,272)	(2,937)
Unrealized (loss) gain on investments	(5,802)	15,039
Comprehensive loss	$ (8,425,270)	$ (10,503,536)
Net loss per share:		
Basic and diluted	$ (0.61)	$ (0.83)
Weighted average shares outstanding:		
Basic and diluted	13,823,951	12,718,166

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

Monopar Therapeutics Inc.
Consolidated Statements of Stockholders' Equity
Years Ended December 31, 2023 and 2022

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balance at January 1, 2022	12,598,125	$ 12,598	$ 60,220,016	$ (3,160)	$ (41,288,383)	$ 18,941,071
Issuance of common stock under a Capital on Demand™ Sales Agreement with JonesTrading Institutional Services LLC, net of commissions, fees and expenses of $87,611	64,573	65	87,253	—	—	87,318
Issuance of common stock to non-employee directors pursuant to vested restricted stock units	45,744	45	(45)	—	—	—
Issuance of common stock to employees pursuant to vested restricted stock units, net of taxes	70,131	70	(76,703)	—	—	(76,633)
Issuance of common stock upon exercise of stock options	168,000	169	—	—	—	169
Stock-based compensation (non-cash)	—	—	1,641,263	—	—	1,641,263
Net loss	—	—	—	—	(10,515,638)	(10,515,638)
Other comprehensive income	—	—	—	12,102	—	12,102
Balance at December 31, 2022	12,946,573	12,947	61,871,784	8,942	(51,804,021)	10,089,652
Issuance of common stock under a Capital on DemandTM Sales Agreement with JonesTrading Institutional Services LLC, net of commissions, fees and expenses of $98,230	1,793,441	1,794	2,070,710	—	—	2,072,504
Issuance of common stock to non-employee directors pursuant to vested restricted stock units	40,532	40	(40)	—	—	—
Issuance of common stock to employees pursuant to vested restricted stock units, net of taxes	123,951	124	(47,093)	—	—	(46,969)
Issuance of common stock upon exercise of stock options	—	—	—	—	—	—
Stock-based compensation (non-cash)	—	—	1,897,849	—	—	1,897,849
Net loss	—	—	—	—	(8,402,196)	(8,402,196)
Other comprehensive loss	—	—	—	(23,074)	—	(23,074)
Balance at December 31, 2023	14,904,497	$ 14,905	$ 65,793,210	$ (14,132)	$ (60,206,217)	$ 5,587,766

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

Monopar Therapeutics Inc.

Consolidated Statements of Cash Flows

	For the Years Ended December 31,	
	2023	**2022**
Cash flows from operating activities:		
Net loss	$ (8,402,196)	$ (10,515,638)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense (non-cash)	1,897,849	1,641,263
Changes in operating assets and liabilities, net		
Other current assets	(20,410)	171,755
Accounts payable, accrued expenses and other current liabilities	(1,333,536)	1,478,299
Operating lease right-of-use assets and liabilities, net	—	(4,238)
Net cash used in operating activities	(7,858,293)	(7,228,559)
Cash flows from investing activities:		
Purchase of short-term investments	(7,882,094)	(4,918,511)
Maturities of short-term investments	12,809,842	—
Net cash provided by (used in) investing activities	4,927,748	(4,918,511)
Cash flows from financing activities:		
Cash proceeds from the sales of common stock under a Capital on Demand™ Sales Agreement	2,074,196	109,337
Taxes paid related to net share settlement of vested restricted stock units	(46,969)	(76,633)
Cash proceeds from the issuance of stock upon exercise of stock options	—	169
Net cash provided by financing activities	2,027,227	32,873
Effect of exchange rates	(16,796)	(3,478)
Net decrease in cash and cash equivalents	(920,114)	(12,117,675)
Cash and cash equivalents at beginning of period	8,186,194	20,303,869
Cash and cash equivalents at end of period	$ 7,266,080	$ 8,186,194
Supplemental disclosure of non-cash investing and financing activities		
Accrued financing fees	$ 1,692	$ 22,018

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

MONOPAR THERAPEUTICS INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

December 31, 2023

Note 1 - Nature of Business and Liquidity

Nature of Business

Monopar Therapeutics Inc. ("Monopar" or the "Company") is a clinical-stage biopharmaceutical company focused on developing innovative treatments for cancer patients. Monopar currently has several compounds in development: 1) MNPR-101-Zr, a clinical stage uPAR-targeted radiodiagnostic imaging agent; 2) MNPR-101-RIT, a late preclinical stage radiotherapeutic for advanced cancers; 3) camsirubicin (generic name for MNPR-201, GPX-150; 5-imino-13-deoxydoxorubicin), a Phase 1b clinical stage novel analog of doxorubicin engineered specifically to retain anticancer activity while minimizing toxic effects on the heart; and 4) an early stage camsirubicin analog, MNPR-202, for various cancers. On March 27, 2023, the Company discontinued its Validive Phase 2b/3 VOICE trial based upon its Data Safety Monitoring Board's determination that the trial did not meet the pre-defined threshold for efficacy of a 15% absolute difference in severe oral mucositis prevention between Validive and placebo. The Company continued to record clinical site close-out related expenses for Validive throughout 2023. The Company is not anticipating incurring any license or royalty obligations or incurring any significant expenses beyond 2023 related to Validive.

Liquidity

The Company has incurred an accumulated deficit of approximately $60.2 million as of December 31, 2023 and since inception has not generated any revenue. 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. Management estimates that currently available cash will provide sufficient funds to enable the Company to meet its obligations at least through June 30, 2025. The Company's ability to fund its future operations, including the continued clinical development of its MNPR-101 radiopharma program and camsirubicin, is dependent upon its ability to execute its business strategy, to obtain additional funding and/or to execute collaborative research agreements. There can be no certainty that future financing or collaborative research agreements will occur in the amounts required or at a time needed to maintain operations, if at all.

Risks and Uncertainties

The termination of the Company's Validive clinical trial at the end of March 2023 resulted in a decrease in the Company's stock price. The closing bid price of the Company's stock fell below $1.00 for more than 30 consecutive trading days, and on August 28, 2023, the Company received a notice from Nasdaq stating that it is out of compliance with Nasdaq listing standards giving the Company 180 days to regain compliance. On February 27, 2024, the Company was granted a second 180-day period to regain compliance; there can be no assurance that the Company will regain compliance within Nasdaq's extended time limits and requirements. If the Company does not regain compliance, the Company would face delisting and it may have serious adverse consequences on the Company's ability to raise funds, which may cause Monopar to delay, restructure or otherwise reconsider its operations. If it is necessary to effect a reverse stock split to attempt to cure the bid price deficiency, the impacts on the Company's stock price are uncertain and could be adverse.

Market variables over which the Company has no control, such as inflation of product costs, higher capital costs, labor rates and fuel, freight and energy costs, as well as geopolitical events could cause the Company to suffer significant increases in its operating and administrative expenses.

The Russia-Ukraine war, and resulting sanctions against Russia and Russian entities or allies, have increased fuel costs and may cause shipping delays. In addition, the Israel-Hamas war has created additional uncertainties. The broader economic, trade and financial market consequences of these events are uncertain at this time, which may increase the cost of supplies for the Company's clinical materials, may delay the manufacture of its clinical materials, may increase costs of other goods and services, or make it more difficult or costly to raise additional financing, any of which could cause an adverse effect on the Company's clinical and development program and on the Company's financial condition.

There remains uncertainties as to the long-term impacts of COVID-19 or any potential resurgences thereof. The Company is unable to estimate COVID-19's or any future pandemic disease's financial impact or duration in light of treatment options and potential surges of new cases from current or future COVID-19 variants or a future pandemic or its potential impact on the Company's current clinical trial and development programs, including COVID-19's or a future pandemic's effect on drug candidate manufacturing, shipping, patient recruitment at clinical sites and regulatory agencies around the globe.

MONOPAR THERAPEUTICS INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

December 31, 2023

Note 2 - Significant Accounting Policies

Basis of Presentation

These 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 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 consolidated financial statements contain all normal, recurring adjustments necessary to present fairly the Company's consolidated financial position as of December 31, 2023 and 2022, the Company's consolidated results of operations and comprehensive loss and the Company's consolidated cash flows for the years ended December 31, 2023 and 2022.

Functional Currency

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

Comprehensive Loss

Comprehensive loss represents net loss plus any income or losses not reported in the consolidated statements of operations and comprehensive loss, such as foreign currency translation gains and losses and unrealized gains and losses on debt security investments that are reflected on the Company's 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 consolidated financial statements and accompanying notes. Actual results could differ from those estimates.

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 March 2024, the Company analyzed its cash requirements at least through June 30, 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.

MONOPAR THERAPEUTICS INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

December 31, 2023

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 December 31, 2023 and 2022 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 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 consolidated balance sheets. Realized gains and losses from the sale of investments, if any, are determined are recorded net in the 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 December 31, 2022 consisted of U.S. Treasury Bills with maturities of over three months to one year.

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 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 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 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 December 31, 2023, 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 years ended December 31, 2023, and 2022. The following table presents the assets and liabilities recorded that are reported at fair value on the Company's consolidated balance sheets on a recurring basis. No values were recorded in Level 2 or Level 3 at December 31, 2023, and 2022.

Assets and Liabilities Measured at Fair Value on a Recurring Basis

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

December 31, 2022	**Level 1**	**Total**
Assets:		
Cash equivalents(1)	$ 7,248,946	$ 7,248,946
Investments(2)	4,933,550	4,933,550
Total	$ 12,182,496	$ 12,182,496

(1) Cash equivalents as of December 31, 2023 and 2022 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.

(2) Investments represents the fair value of the Company's investment in U.S. Treasury Bills with maturities at the date of purchase from three months to one year.

Net Loss per Share

Net loss per share for the years ended December 31, 2023, and 2022, is calculated by dividing net loss by the weighted-average shares of common stock outstanding during the period. Diluted net loss per share for the years ended December 31, 2023, and 2022 is calculated by dividing net loss by the weighted-average shares of the sum of a) weighted average common stock outstanding (13,823,951 and 12,718,166 shares for the years ended December 31, 2023, and 2022, respectively) and b) potentially dilutive shares of common stock (such as stock options and restricted stock units) outstanding during the period. As of December 31, 2023, and 2022, potentially dilutive securities included stock-based awards to purchase up to 2,527,092 and 1,915,600 shares of the Company's common stock, respectively. For the years ended December 31, 2023 and 2022, potentially dilutive securities are excluded from the computation of fully diluted net loss per share as their effect is anti-dilutive.

Research and Development Expenses

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

Clinical Trials Accruals

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

Collaborative Agreements

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

During the years ended December 31, 2023, and 2022, 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 years ended December 31, 2023, and 2022, no milestones were met, and no royalties were earned, therefore, the Company did not pay or accrue/expense any license or royalty payments under any of its license agreements.

Patent Costs

The Company expenses costs relating to issued patents and patent applications, including costs relating to legal, renewal and application fees, as a component of general and administrative expenses in its 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 December 31, 2023, and 2022. 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 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 years ended December 31, 2023, and 2022, 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 2022. The Company does not anticipate significant changes to its current uncertain tax positions through December 31, 2023. The Company plans on filing its U.S. Federal and state tax returns for the year ended December 31, 2023, prior to the extended filing deadlines in all jurisdictions.

Stock-Based Compensation

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

Stock-based compensation expense for awards granted to employees, non-employee directors and consultants are based on the fair value of the underlying instrument calculated using the Black-Scholes option-pricing model on the date of grant for stock options and using the closing stock price on the date of grant for RSUs and recognized as expense on a straight-line basis over the requisite service period, which is the vesting period. Determining the appropriate fair value model and related assumptions requires judgment, including estimating the future stock price volatility and expected terms. For stock options granted in 2022, the expected volatility rates are estimated based on the Company's historical actual volatility over the two-year period from its initial public offering on December 18, 2019 through December 31, 2021. 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. Forfeitures only include known forfeitures to-date as the Company accounts for forfeitures as they occur due to a limited history of forfeitures. The expected term for options granted to date is estimated using the simplified method. 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 8 - Loss per Share.

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 consolidated financial statements and related disclosures. The Company does not expect a material impact to its financial statements based on adoption of this ASU.

Note 3 - Investments

As of December 31, 2023 the Company had two money market accounts and available-for-sale investments with contractual maturities of 90 days or less categorized as 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 consolidated balance sheet as of December 31, 2023.

As of December 31, 2022	Cost Basis	Unrealized Gains	Aggregate Fair Value
U.S. Treasury Bills	$ 6,905,171	$ 15,039	$ 6,920,210
Money Market Accounts	5,262,286	—	5,262,286
Total	**$ 12,167,457**	**$ 15,039**	**$ 12,182,496**

As of December 31, 2022 there were no available-for-sale securities in an unrealized-loss position and there were no sales of available-for-sale securities made during 2022. U.S. Treasury Bills classified as Investments on the consolidated balance sheet as of December 31, 2022 were $4.9 million.

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.

Sales of Common Stock

On April 20, 2022, the Company executed a new Capital on Demand™ Sales Agreement with JonesTrading, pursuant to which Monopar may offer and sell, from time to time, through or to JonesTrading, as sales agent or principal, shares of Monopar's common stock. On April 20, 2022, the Company filed a prospectus supplement with the U.S. Securities and Exchange Commission relating to the offer and sale of its common stock from time to time pursuant to the agreement up to an aggregate amount of $4,870,000. Subsequently, the Company filed a new Form S-3, which included therein a prospectus to increase the aggregate amount offered under this agreement to $6,505,642. The Form S-3 was declared effective by the Securities and Exchange Commission on January 4, 2023, at which time the prospectus included therein replaced the prior prospectus supplement. Expenses related to these financing activities were recorded as offering costs (a reduction of additional paid in capital) on the Company's consolidated statement of stockholders' equity for the period. During the years ended December 31, 2023, and 2022, the Company sold 1,793,441 and 64,573 shares of its common stock at an average gross price per share of $1.21 and $2.71 for net proceeds of $2,116,435 and $170,552, after fees and commissions of $54,298 and $4,377, respectively. In addition, for the year ended December 31, 2023, the Company incurred legal, accounting and other fees totaling $43,932 for net proceeds after fees, commissions and expenses of $2,072,503. For the year ended December 31, 2022, the Company incurred legal, accounting and other fees totaling $83,234 for net proceeds after fees, commissions and expenses of $87,318.

As of December 31, 2023, the Company had 14,904,497 shares of common stock issued and outstanding.

MONOPAR THERAPEUTICS INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

December 31, 2023

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 700,000 shares of stock-based awards in the form of stock options, restricted stock units, stock appreciation rights and other stock-based awards to employees, non-employee directors and consultants. In October 2017, the Company's Board of Directors voted to increase the stock award pool to 1,600,000 shares of common stock, which subsequently was approved by the Company's stockholders. In April 2020, the Company's Board of Directors voted to increase the stock award pool to 3,100,000 (an increase of 1,500,000 shares of common stock), which was approved by the Company's stockholders in June 2020. In April 2021, the Company's Board of Directors voted to approve an amendment to the 2016 Stock Incentive Plan to remove certain individual award limits and other provisions related to I.R.C. Section 162(m) and to update the limit on Incentive Stock Options to no more that 100% of the maximum aggregate number of shares which may be granted under the plan, which was approved by the Company's stockholders in June 2021. In March 2022, the Company's Board of Directors voted to increase the stock award pool to 5,100,000 (an increase of 2,000,000 shares of common stock), which was approved by the Company's stockholders in June 2022.

During the year ended December 31, 2023, the Company's Plan Administrator Committee (with regards to non-officer employees and consultants) and the Company's Compensation Committee, as ratified by the Board of Directors (in the case of executive officers and non-employee directors), granted to executive officers, non-officer employees, non-employee directors and consultants aggregate stock options for the purchase of 508,902 shares of the Company's common stock with exercise prices ranging from $2.37 to $3.16 per share which vest over 1 to 4 years. All stock option grants have a 10-year term. In addition, during the year ended December 31, 2023, an aggregate 368,345 restricted stock units were granted to executive officers, non-officer employees and non-employee directors which vest over 1 to 4 years.

Under the Plan, the per share exercise price for the shares to be issued upon exercise of an option shall be determined by the Plan Administrator, except that the per share exercise price shall be no less than 100% of the fair market value per share on the grant date. Fair market value is the Company's closing price on 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**
Balance at January 1, 2022	**1,543,989**	$ **4.78**
Granted	604,064	2.83
Forfeited	(337,103)	6.13
Exercised	(168,000)	0.001
Balance at December 31, 2022	**1,642,950**	**4.28**
Granted(1)	508,902	3.14
Forfeited(2)	(42,851)	3.93
Exercised	—	—
Balance at December 31, 2023	**2,109,001**	**4.01**
Unvested options outstanding expected to vest(3)	601,746	**3.37**

(1) 508,902 options vest as follows: options to purchase 443,182 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; options to purchase 55,720 shares of the Company's common stock vest quarterly over one year; and options to purchase 10,000 shares of the Company's common stock vest monthly over one year. Exercise prices range from $2.37 to $3.16 per share.

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

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

A summary of options outstanding as of December 31, 2023, is shown below:

Exercise Prices	Number of Shares Subject to Options Outstanding	Weighted-Average Remaining Contractual Term in Years	Number of Shares Subject to Options Fully Vested and Exercisable	Weighted-Average Remaining Contractual Term in Years
$0.001 - $5.00	1,371,895	6.95	832,423	5.80
$5.01 - $10.00	617,942	5.50	555,668	5.30
$10.01 - $15.00	113,039	6.09	113,039	6.09
$15.01 - $20.00	6,125	6.09	6,125	6.09
	2,109,001	**6.48**	**1,507,255**	**5.64**

Restricted stock unit activity under the Plan was as follows:

	Restricted Stock Units	Weighted-Average Grant Date Fair Value per Unit
Unvested balance at December 31, 2021	**111,462**	$ **8.44**
Granted	403,522	2.80
Vested	(149,706)	4.07
Forfeited	(92,628)	4.01
Unvested balance at December 31, 2022	**272,650**	**4.00**
Granted	368,345	3.16
Vested	(222,904)	3.73
Forfeited	—	—
Unvested Balance at December 31, 2023	**418,091**	**3.40**

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

	Years Ended December 31,	
	2023	2022
Stock options granted	508,902	604,064
Fair value of shares vested	$ 980,455	$ 970,451

At December 31, 2023, the aggregate intrinsic value of outstanding vested stock options was $131,413 (there were no outstanding unvested stock options that had intrinsic value) and the weighted-average exercise price in aggregate was $4.01 which includes $4.27 for fully vested stock options and $3.37 for stock options expected to vest. At December 31, 2023, unamortized balance of stock-based compensation was $2.8 million, to be amortized over the following 2.5 years.

During the years ended December 31, 2023, and 2022, the Company recognized $1,014,046 and $818,164 of employee, non-employee director and consultant stock-based compensation expense as general and administrative expenses, respectively, and $883,803 and $823,099 as research and development expenses, respectively. The stock-based compensation expense is allocated on a departmental basis, based on the classification of the stock-based award holder. No income tax benefits have been recognized in the consolidated statements of operations and comprehensive loss for stock-based compensation arrangements.

MONOPAR THERAPEUTICS INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

December 31, 2023

Note 6 - Related Party Transactions

As of December 31, 2023, Tactic Pharma, LLC ("Tactic Pharma"), the Company's initial investor, beneficially owned 29% of Monopar's common stock and during the year ended December 31, 2023, 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 December 31, 2023. 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 – Income Taxes

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. The valuation allowance increased by approximately $2,124,000 and $3,421,000 during the years ended December 31, 2023, and 2022, respectively.

The provision for income taxes for December 31, 2023, and 2022, consists of the following:

	As of December 31,	
	2023	**2022**
Current:		
Federal	$ -	$ -
State	800	800
Foreign	-	-
Total current:	800	800
Deferred:		
Federal	-	-
State	-	-
Foreign	-	-
Total deferred:	-	-
Total provision*	$ 800	$ 800

*Total provision for income taxes of $800 for each of the years ended December 31, 2023 and 2022, is recorded in general and administrative expenses on the Company's consolidated statements of operations and comprehensive loss as it is not considered a material amount.

The difference between the effective tax rate and the U.S. federal tax rate is as follows (in %):

	As of December 31,	
	2023	2022
Federal income tax	21.00	21.00
State income taxes, less federal benefit	6.03	6.39
Tax credits	3.12	5.57
Permanent differences	(2.81)	(2.45)
Change in valuation allowances	(25.33)	(32.58)
Other	(2.02)	2.06
Effective tax rate benefit (expense)	(0.01)	(0.01)

Deferred tax assets and liabilities consist of the following:

	As of December 31,	
	2023	2022
Deferred tax assets:		
Net operating loss carryforwards	$ 3,871,391	$ 3,548,494
Tax credits carryforwards	1,322,457	1,254,678
Stock-based compensation	800,998	630,113
Intangible asset basis differences	4,417,201	3,824,482
Accrued liabilities & allowances	76,403	96,478
Capitalized research and development	2,777,414	1,787,350
Gross deferred tax assets	13,265,864	11,141,595
Valuation allowance	(13,265,864)	(11,141,595)
Net deferred tax assets	$ —	$ —

As of December 31, 2023, Company had total federal net operating loss carryforwards of approximately $13,548,000, which will begin to expire in 2035. Losses generated after 2017 will be carried forward indefinitely. At December 31, 2023, the Company had state net operating loss carryforwards of approximately $13,578,000 which will begin to expire in 2035.

As of December 31, 2023, the Company had federal and state tax credits of $1,554,000 and $125,000, respectively. The federal credits expire beginning after the year 2035 and the state credits begin to expire in 2024.

The Tax Reform Act of 1986 limits the use of net operating carryforwards and R&D credits in certain situations where changes occur in the stock ownership of a company. In the event the Company has had a change in ownership, utilization of the carryforwards and R&D credits could be limited. The Company has not performed a net operating loss or R&D credit utilization study to date.

The Company accounts for uncertain tax positions in accordance with ASC 740-10, "*Accounting for Uncertainty in Income Taxes*." ASC 740-10 prescribes a comprehensive model for the recognition, measurement, presentation and disclosure in financial statements of any uncertain tax positions that have been taken or are expected to be taken on a tax return. It is Company's policy to include penalties and interest expense related to income taxes as an income tax expense.

A reconciliation of the beginning and ending amount of unrecognized tax benefits is as follows:

	2023	2022
Beginning uncertain tax benefits	$ 321,175	$ 103,104
Current year - increases	65,389	150,701
Prior year - increases (decreases)	(50,742)	67,370
Ending uncertain tax benefits	$ 335,822	$ 321,175

Included in the balance of uncertain tax benefits at December 31, 2023 are $335,822 of tax benefits that, if recognized, would not impact the effective tax rate as it would be offset by the reversal of related deferred tax assets which are subject to a full valuation allowance. The Company anticipates that no material amounts of unrecognized tax benefits will be settled within 12 months of the reporting date. As of December 31, 2023, the Company had no accrued interest or penalties recorded related to uncertain tax positions.

The Company files U.S. federal, California and Illinois state tax returns. The Company is subject to California state minimum franchise taxes. All tax returns will remain open for examination by the federal and state taxing authorities for three and four years, respectively, from the date of utilization of any net operating loss carryforwards or R&D credits. In addition, due to the operations in certain foreign countries, the Company became subject to local tax laws of such countries. Nonetheless, as of December 31, 2023, due to the insignificant expenditures in such countries, there was no material tax effect to the Company's 2023 consolidated financial statements.

On December 22, 2017, the Tax Cuts and Jobs Act of 2017 ("TCJA") was enacted. On January 1, 2022, a provision of the TCJA went into effect which requires the capitalization of research and development costs in the year incurred and requires taxpayers to amortize such costs over five years and 15 years for domestic and foreign expense, respectively. The Company evaluated the impact of the TCJA and prepared the provision by following the treatment of research and development expenditures for tax purposes under Section 174.

MONOPAR THERAPEUTICS INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

December 31, 2023

Note 8 – Loss per Share

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

(in thousands, except for net loss per share)	Years Ended December 31, 2023	2022
Numerator:		
Net loss	$ (8,402)	$ (10,516)
Denominator:		
Weighted-average common shares outstanding, basic and diluted	13,824	12,718
Net loss per common share, basic and diluted	$ (0.61)	$ (0.83)
Anti-dilutive potential common stock equivalents excluded from the calculation of net loss per share		
Stock options to purchase common stock	2,109	1,642
Unvested restricted stock units	418	272

Note 9– 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 we achieve 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 December 31, 2023, the Company 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.

Onxeo S.A.

In June 2016, the Company executed an agreement with Onxeo S.A., a French public company, which gave Monopar the exclusive option to license (on a world-wide exclusive basis) Validive (clonidine hydrocholoride mucobuccal tablet; clonidine HCI MBT) a mucoadhesive tablet of clonidine based on the Lauriad mucoadhesive technology. In September 2017, Monopar exercised the option to license Validive from Onxeo for $1 million. On March 27, 2023, Monopar discontinued its Validive Phase 2b/3 VOICE trial based upon the Data Safety Monitoring Board's determination that the trial did not meet the pre-defined threshold for efficacy of a 15% absolute difference in severe oral mucositis prevention between Validive and placebo. The Company has not incurred any license or royalty obligations and the license has been terminated effective January 2024.

Operating Leases

The Company is currently leasing office space for its executive headquarters at 1000 Skokie Blvd., in the Village of Wilmette, Illinois for $4,238 per month. In February 2022, the Company entered into a 24-month lease for 1,202 square feet of the office space for $2,379 per month. In May 2022, the Company entered into a 22-month lease for 939 square feet of additional office space for $1,859 per month.

As of December 31, 2023, in accordance with ASC 842, *Leases*, the two leases were recorded as an operating lease right-of-use ("ROU") asset and a lease liability included in accounts payable, accrued expenses and other current liabilities, and non-current operating lease liability on the Company's consolidated balance sheets. The initial ROU asset and associated liability is equal to the present value of the minimum lease payments. Since the rate implicit in the lease is rarely readily determinable, the Company applied an incremental borrowing rate taking into consideration the Company's credit quality and borrowing rate for similar assets. The lease terms used to calculate the ROU asset and related lease liability does not include an option to extend but does include an option to terminate the lease. Lease costs for operating leases are recognized on a straight-line basis over the expected lease term and recorded as general and administrative expenses on the Company's consolidated statements of operations and comprehensive loss. Amortization of the ROU asset commenced on April 1, 2022, and June 1, 2022, for the two operating leases, respectively. No ROU asset or lease liability was recorded in 2021 as the lease obligation was less than one year.

The components of lease expense were as follows:

	Years Ended December 31,	
	2023	**2022**
Total lease costs	$ 50,856	$ 34,424

Maturities of the lease liability as of December 31, 2023 are as follows:

Fiscal Year	**Operating Leases**
December 31, 2024	$ 8,476
Total lease payments	8,476
Less: imputed interest	(68)
Total lease liability as of December 31, 2023	$ **8,408**

The remaining lease liability will be paid in 2024.

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

	December 31,	
	2023	2022
Lease term:		
Operating leases (in years)	0.2	1.2
Discount rate:		
Operating lease	6.50%	6.50%

Supplemental balance sheet information:

	As of December 31,	
	2023	2022
ROU asset - non-current	$ 12,646	61,228
Total ROU asset	$ **12,646**	**61,228**
Operating lease liability - current	$ 8,408	48,582
Operating lease liability - non-current	—	8,408
Total operating lease liabilities	$ **8,408**	**56,990**

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 10 - Subsequent Events

From January 1 to March 8, 2024, under the Company's at-the-market agreement with JonesTrading, the Company sold 2,545,305 shares of its common stock at an average gross price per share of $1.29 for net proceeds of $3,194,310, after fees and commissions of $81,932.

EXHIBIT 4.1

DESCRIPTION OF REGISTERED SECURITIES

We have the authority to issue 40,000,000 shares of Common Stock, $0.001 par value.

Common Stock

Voting Rights

The holders of shares of our common stock are entitled to one vote per share for the election of directors and on all other matters submitted to a vote of stockholders. Shares of our common stock do not have cumulative voting rights. The election of our Board of Directors ("Board") is decided by a plurality of the votes cast at a meeting of our stockholders by the holders of stock entitled to vote in the election.

Dividends

Holders of our common stock are entitled to receive such dividends as may be declared by our Board out of funds legally available therefor.

Liquidation

Upon our dissolution and liquidation, holders of our common stock are entitled to a ratable share of our net assets remaining after payments to our creditors.

Rights and Preferences

Our stockholders have no preemptive rights to acquire additional shares of our common stock or other securities. The shares of our common stock are not subject to redemption.

Preferred Stock

We have no preferred stock authorized or outstanding.

Anti-Takeover Provisions

Delaware Law

We are subject to Section 203 of the Delaware General Corporation Law. Subject to certain exceptions, Section 203 prevents a publicly held Delaware corporation from engaging in a "business combination" with any "interested stockholder" for three years following the date that the person became an interested stockholder, unless the interested stockholder attained such status with the approval of our Board or unless the business combination is approved in a prescribed manner. A "business combination" includes, among other things, a merger or consolidation involving us and the "interested stockholder" and the sale of more than 10% of our assets. In general, an "interested stockholder" is any entity or person beneficially owning 15% or more of our outstanding voting stock and any entity or person affiliated with or controlling or controlled by such entity or person.

Authorized but Unissued Shares

The authorized but unissued shares of our common stock are available for future issuance without stockholder approval, subject to any limitations imposed by the listing standards of any exchange on which our shares are listed. These additional shares may be used for a variety of corporate finance transactions, acquisitions and employee benefit plans. The existence of authorized but unissued and unreserved common stock could make more difficult or discourage an attempt to obtain control of us by means of a proxy contest, tender offer, merger or otherwise.

Election of Director by Plurality of Shares; Vacancies

Our Amended and Restated By-laws provide that directors will be elected by a plurality of votes cast by the shares present in person or by proxy at a meeting of the stockholders and entitled to vote thereon, a quorum being present at such meeting. There is no cumulative voting, meaning that Directors may be elected with a vote of holders of less than a majority of the outstanding common stock.

Our Amended and Restated By-laws also provide that vacancies occurring on our Board may be filled by the affirmative votes of a majority of the remaining members of our Board or by the sole remaining director, and not by our stockholders. Such provisions in our corporate organizational documents and under Delaware law may prevent or frustrate attempts by our stockholders to change our management or hinder efforts to acquire a controlling interest in us. The inability to make changes to our Board could prevent or discourage an attempt to take control of the Company by means of a proxy contest, tender offer, merger or otherwise.

Special Meeting of Stockholders; Advance Notice Requirements for Stockholder Proposals and Director Nominations; Stockholder Action

Our Amended and Restated By-laws provide that, except as otherwise required by law, special meetings of the stockholders can only be called by our Board.

Stockholders at a special meeting may only consider matters set forth in the notice of the meeting. These provisions could have the effect of delaying until the next stockholder meeting stockholder actions that may be favored by the holders of a majority of our outstanding voting securities.

Super Majority Voting

The General Corporation Law of the State of Delaware provides generally that the affirmative vote of a majority of the shares entitled to vote on any matter is required to amend a corporation's certificate of incorporation or by-laws, unless a corporation's certificate of incorporation or by-laws, as the case may be, requires a greater percentage. Our Amended and Restated By-laws may be amended or repealed by a majority vote of our Board or the affirmative vote of the holders of at least a majority of the votes that all our stockholders would be entitled to cast in any election of Directors.

Registration Rights

We are subject to an agreement with TacticGem, LLC (“TacticGem”), our largest stockholder, which obligates us to file a Form S-3 or other appropriate form of registration statement covering the resale of any of our Common Stock by TacticGem, or its members Gem Pharmaceuticals, LLC, or Tactic Pharma, LLC, upon direction by TacticGem at any time after we have been subject to the reporting requirements of the 1934 Act for at least twelve months (the “Initial Holding Period”).. We are required to use our best efforts to have such registration statement declared effective as soon as practical after it is filed. In the event that such registration statement for resale is not approved by the SEC, and TacticGem submits a written request, we are required to prepare and file a registration statement on Form S-1 registering such Common Stock for resale and to use our best efforts to have such registration statement declared effective as soon as practical thereafter. After registration, pursuant to these rights, these shares will become freely tradable without restriction under the Securities Act other than pursuant to restrictions on affiliates under Rule 144.

Listing

Our common stock is listed on the Nasdaq Capital Market under the symbol “MNPR.”

Transfer Agent and Registrar

The transfer agent and registrar for our common stock is VStock Transfer, LLC (“VStock”). VStock’s address is 18 Lafayette Place, Woodmere, NY 11598.

Exhibit 10.1

CONSULTING AGREEMENT

This Consulting Agreement (herein referred to as "**Agreement**") is made and entered into on December 13, 2022, effective as of January 1, 2023 (the "**Effective Date**"), by and between Monopar Therapeutics Inc. (herein referred to as "**Monopar**"), a Delaware corporation, located at 1000 Skokie Blvd., Suite 350, Wilmette, IL 60091, and pRx Consulting, LLC (herein referred to as pRx), a Delaware corporation located at # (each herein referred to as "**Party**" and collectively as "**Parties**").

RECITALS

WHEREAS, pRx specializes in the field of clinical development, including but not limited to clinical trial design, statistical modeling, clinical operations, regulatory strategy, investor due diligence, and the duties of a Chief Medical Officer.

WHEREAS, Monopar desires to contract with pRx to provide certain consultation services as requested by Monopar, and pRx wishes to provide such services to Monopar, upon the terms and conditions set forth below.

NOW, THEREFORE, in consideration of the premises and mutual covenants contained herein, the Parties agree as follows:

1. Consulting Arrangement. pRx agrees to perform consulting services as described herein upon the terms and conditions herein set forth.

2. Term of Agreement. Subject to the provision for early termination set forth below and in **Section 5** of this Agreement, this Agreement shall commence as of the Effective Date and shall continue for a period of twelve (12) months from the Effective Date (the "**Term**"). Either Party may terminate this Agreement without cause with 10-days' prior written notice.

3. Duties of pRx.

   3.1 Specific Duties. pRx shall provide consulting services to Monopar, such duties to include the general duties of a Chief Medical Officer, clinical trial design, statistical modeling, clinical operations oversight, regulatory strategy, and investor due diligence, and Dr. Rioux shall remain director of Monopar's French subsidiary with such other specific requirements as Monopar may specify from time to time during the Term (herein referred to as the "**Services**").

   3.2 pRx's Obligations. The president of pRx, Dr. Patrice Rioux, shall spend on the average over the course of the Term one (1.0) work day per week working on Monopar matters, be diligent in the performance of Services, and be professional in its commitment to meeting its obligations hereunder. pRx represents and warrants that pRx is not party to any other existing agreement, which any of them would prevent pRx from entering into this Agreement or which would adversely affect this Agreement. pRx shall not perform Services for any other individuals or entities in direct competition with Monopar, except as provided for by mutual written agreement of the Parties. pRx shall not perform services for any party which would require or facilitate the unauthorized disclosure of any confidential or proprietary information of Monopar.

3.3 Reporting. pRx will report to and liaise with Chandler Robinson, MD, and/or any other assigned Monopar employee or consultant as may be designated in writing by Monopar.

3.4 Compensation. Monopar shall pay pRx as follows:

a. Two thousand dollars ($2,000) per month payable within thirty (30) days of the end of each month.

b. Upon Board approval, Dr. P. Rioux, president of pRx Consulting, LLC shall be granted stock options to purchase up to 10,000 shares of Monopar's common stock. The exercise price shall be based upon the closing price of our Common Stock on Nasdaq the later of: (1) the day of Board approval; or (2) the effective date of this Agreement. Such stock option shall vest pro-rata monthly over 12 months from the effective date of this Agreement, which is January 1, 2023. Such vesting shall terminate upon the termination of this Agreement. The number of shares, the exercise price thereof and the rights granted under this Agreement are subject to adjustment and modification as provided in the Monopar Therapeutics Inc. 2016 Stock Incentive Plan.

c. pRx shall not be reimbursed, and is responsible for the facilities and equipment necessary to perform Services required under this Agreement.

4. Reimbursement of Other Expenses. So long as Monopar's prior approval has been obtained, Monopar shall promptly reimburse pRx for all direct expenses incurred in providing the Services to Monopar pursuant to this Agreement, including travel, meals and lodging. The invoice submitted by pRx pursuant to this **Section 4** shall also include a detail of all reimbursable expenses incurred during the period covered by such invoice.

5. Termination of Agreement - Failure to perform. In the event that pRx ceases to perform the Services or breaches its obligations as required hereunder for any reason, Monopar shall have the right to immediately terminate this Agreement upon notice to pRx and to enforce such other rights and remedies as it may have as a result of said breach.

6. Certain Liabilities. It is understood and agreed that pRx shall be acting as an independent contractor and not as an agent or employee of, or partner, joint venturer or in any other relationship with Monopar. pRx will be solely responsible for all insurance, employment taxes, FICA taxes and all obligations to governments or other organizations for it and its employees arising out of this consulting assignment. pRx acknowledges that no income, social security or other taxes shall be withheld or accrued by Monopar for pRx's or its employees' benefit. pRx assumes all risks and hazards encountered in the performance of duties by it or its employees under this Agreement. Unless Monopar has provided prior written approval, pRx shall not use any sub-contractors to perform pRx's obligations hereunder. pRx shall be solely responsible for any and all injuries, including death, to all persons and any and all loss or damage to property, which may result from performance under this Agreement.

7. Indemnities. pRx hereby agrees to indemnify Monopar and hold Monopar harmless from and against all claims (whether asserted by a person, firm, entity or governmental unit or otherwise), liabilities, losses, damages, expenses, charges and fees which Monopar may sustain or incur arising out of or attributable to any breach, gross negligence or willful misconduct by pRx or its employees or contractors, as applicable, in the performance under this Agreement. Monopar hereby agrees to indemnify pRx and hold pRx harmless from and against all liabilities, losses, damages, expenses, charges and fees which pRx may sustain or incur by reason of any claim which may be asserted against pRx by any person, firm, corporation or governmental unit and which may arise out of or be attributable to any gross negligence or willful misconduct by Monopar or its employees or contractors, as applicable, in the performance of this Agreement.

8. Warranties. The Services shall be performed in a professional manner, consistent with industry standards. In performing the Services, neither pRx nor any of its employees shall make any unauthorized use of any confidential or proprietary information of any other party or infringe the intellectual property rights of any other party.

9. Arbitration. Any controversy or claim between Monopar and pRx arising out of or relating to this Agreement, or the breach thereof, shall be submitted to arbitration in accordance with the rules of the American Arbitration Association. The site of the arbitration shall be Chicago, IL, and except as provided herein the arbitration shall be conducted in accordance with the Rules of the American Arbitration Association prevailing at the time the demand for arbitration is made hereunder. At least one member of the arbitration panel shall be an expert knowledgeable in the area of biopharmaceutical clinical development. Judgment upon any award rendered by the arbitrator(s) may be entered in any court of competent jurisdiction and shall be binding and final. The cost of arbitration shall be borne by the losing Party, as determined by the arbitrator(s).

10. Confidential Information. pRx has executed a confidential disclosure agreement with Monopar on September 29, 2021. pRx hereby represents and warrants that the obligations thereunder shall be binding upon it and its employees, and that it shall obtain written commitments from such employees thereto.

11. Inventions. pRx agrees that all ideas, developments, suggestions and inventions which an employee or other parties contracted conceive or reduce to practice arising out of or during the course of performance under this Agreement shall be the exclusive property of Monopar and shall be promptly communicated and assigned to Monopar. pRx shall require any employees of or other parties contracted by pRx to disclose the same to pRx and to be bound by the provisions of this paragraph. During the period of this Agreement and thereafter at any reasonable time when called upon to do so by Monopar, pRx shall require any employees of or other parties contracted by pRx to execute patent applications, assignments to Monopar (or any designee of Monopar) and other papers and to perform acts which Monopar believes necessary to secure to Monopar full protection and ownership of the rights in and to the services performed by pRx and/or for the preparation, filing and prosecution of applications for patents or inventions made by any employees of or other parties contracted by pRx hereunder. The decision to file patent applications on inventions made by any employees of or other parties contracted by pRx shall be made by Monopar and shall be for such countries as Monopar shall elect. Monopar agrees to bear all the expense in connection with the preparation, filing and prosecution of applications for patents and for all matters provided in this paragraph requiring the time and/or assistance of pRx as to such inventions.

12. Miscellaneous.

12.1 Notice. Any notices to be given hereunder by either Party to the other may be effectuated, in writing, by personal delivery or by mail, registered or certified, postage prepaid, with return receipt requested, or by electronic mail. Mailed notices shall be addressed to the Parties at the following addresses:

If to Monopar:
Monopar Therapeutics Inc.
1000 Skokie Blvd., Suite 350
Wilmette, IL 60091
Attention: Chandler Robinson, MD MBA MSc
Email: #

If to pRx:
pRx Consulting, LLC
#
Attention: Patrice Rioux, MD, PhD
Email: #

or at such other addresses as either Monopar or pRx may designate by written notice to each other. Notices delivered personally shall be deemed duly given on the date of actual receipt; mailed notices shall be deemed duly given as of the fourth day after the date so mailed. If sent by electronic mail, such notice will be deemed given upon confirmation of receipt by recipient.

12.2 Waiver of Breach. The waiver by either Party to a breach of any provision in this Agreement cannot operate or be construed as a waiver of any subsequent breach by either Party.

12.3 Severability. If any provision of this Agreement is determined by a court of competent jurisdiction to be invalid or unenforceable, that provision shall be deemed modified to the extent necessary to make it valid or enforceable, or if it cannot be so modified, then severed, and the remainder of the Agreement shall continue in full force and effect as if the Agreement had been signed with the invalid portion so modified or severed.

12.4 Choice of Law. This Agreement has been made and entered into in the State of Illinois, and the laws of such state, excluding its choice of law rules, shall govern the validity and interpretation of this Agreement and the performance due hereunder. The losing party in any dispute hereunder shall pay the attorneys' fees and disbursements of the prevailing party.

12.5 Integration. The drafting, execution and delivery of this Agreement by the Parties have been induced by no representations, statements, warranties or agreements other than those expressed herein. This Agreement embodies the entire understanding of the Parties, and there are no further or other agreements or understandings, written or oral, in effect between the Parties relating to the subject matter hereof unless expressly referred to herein.

12.6 Modification. This Agreement may not be modified unless such is in writing and signed by both Parties to this Agreement.

12.7 Assignment. pRx shall not be permitted to assign this Agreement to any other person or entity without the prior written consent of Monopar. pRx hereby agrees that Monopar shall be permitted to assign this Agreement to any affiliate of Monopar. This Agreement shall be binding upon and shall inure to the benefit of the successors and permitted assigns of the parties.

12.8 Survival. The provisions of **Sections** 7, **8, 9, 10,** and **11** shall survive expiration or termination of this Agreement for any reason. Expiration or termination of this Agreement shall not affect Monopar's obligations to pay any amounts that may then be due to pRx.

IN WI1NESS WHEREOF, the Parties hereto have executed this Agreement as of the day and year first above written.

ACCEPTED AND AGREED TO:

PRx Consulting, LLC

/s/ Patrice Rioux
By: Patrice P. Rioux
Its: President

Monopar Therapeutics Inc.

/s/ Chandler Robinson
By: Chandler Robinson
Its: Chief Executive Officer

EXHIBIT 21.1

Subsidiaries of Monopar Therapeutics Inc. as of December 31, 2023

Name	Direct Parent	Ownership	Jurisdiction of Incorporation
Monopar Therapeutics Australia Ltd Pty	Monopar Therapeutics Inc.	100%	Australia
Monopar Therapeutics, SARL	Monopar Therapeutics Inc.	100%	France

EXHIBIT 23.1

Consent of Independent Registered Public Accounting Firm

We hereby consent to the incorporation by reference in the Registration Statements on Form S-3 (333-268935) and on Form S-8 (333-266828, 333-235790 and 333-250046) of our report dated March 27, 2024, relating to the consolidated financial statements of Monopar Therapeutics Inc. as of December 31, 2023, which appears in this Annual Report on Form 10-K.

/s/ BPM LLP
BPM LLP

Walnut Creek, California

March 27, 2024

EXHIBIT 31.1

CERTIFICATION

I, Chandler D. Robinson, certify that:

1. I have reviewed this Annual Report on Form 10-K 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: March 28, 2024

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

EXHIBIT 31.2

CERTIFICATION

I, Kim R. Tsuchimoto, certify that:

1. I have reviewed this Annual Report on Form 10-K 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: March 28, 2024

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

EXHIBIT 32.1

CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350,

AS ADOPTED PURSUANT TO

SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report on Form 10-K of Monopar Therapeutics Inc. (the Company) for the year ended December 31, 2023, as filed with the Securities and Exchange Commission on the date hereof (the Report), we, Chandler D. Robinson, and Kim R. Tsuchimoto, hereby certify, pursuant to 18 U.S.C. §1350, as adopted pursuant to §906 of the Sarbanes-Oxley Act of 2002, that:

(1) the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

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

March 28, 2024

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

March 28, 2024

This certification accompanies the Form 10-K 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-K), irrespective of any general incorporation language contained in such filing.

Compensation Recovery

Compensation Recoupment Policy (Required by Nasdaq Listing Rule 5608)

Subject to the limited exceptions set forth herein, with respect to the compensation of executive officers and former executive officers subject to this policy as described under "Applicability" below, Monopar Therapeutics Inc. (the "**Company**") will recover reasonably promptly the amount of erroneously awarded incentive-based compensation in the event that the Company is required to prepare an accounting restatement due to the material noncompliance of the Company with any financial reporting requirement under the securities laws, including any required accounting restatement to correct an error in previously issued financial statements that is material to the previously issued financial statements (also known as a big "R" restatement), or that would result in a material misstatement if the error were corrected in the current period or left uncorrected in the current period (also known as a little "r" restatement).

For purposes of this policy, "**incentive-based compensation**" is any compensation that is granted, earned, or vested based wholly or in part upon the attainment of a financial reporting measure. A "**financial reporting measure**" is a measure that is determined and presented in accordance with the accounting principles used in preparing the Company's financial statements, and any measures that are derived wholly or in part from such measures. Stock price and total shareholder return are also financial reporting measures. A financial reporting measure need not be presented within the financial statements or included in a filing with the Securities and Exchange Commission.

Applicability

This policy applies to incentive-based compensation received (as defined below) by a person: (i) after beginning service as an executive officer; (ii) who served as an executive officer at any time during the performance period for that incentive-based compensation; (iii) while the Company's common shares remain listed on Nasdaq (or another national securities exchange or a national securities association); and (iv) during the three completed fiscal years immediately preceding the date that the Company is required to prepare an accounting restatement as described under "Compensation Recovery" above (plus any transition period to the extent required by Nasdaq rules in the event of a change in fiscal year).

For purposes of clause (iv) above, the date the Company is required to prepare such an accounting restatement is the earlier of: (1) the date the board of directors (the "**Board**"), a committee of the Board, or the officer or officers of the Company authorized to take such action if Board action is not required, concludes, or reasonably should have concluded, that the Company is required to prepare such an accounting restatement; and (2) the date a court, regulator, or other legally authorized body directs the Company to prepare such an accounting restatement.

For purposes of this policy, "**executive officer**" means the Company's president, principal financial officer, principal accounting officer (or if there is no such accounting officer, the

controller), any vice-president in charge of a principal business unit, division, or function (such as sales, administration, or finance), any other officer who performs a policy-making function, or any other person who performs similar policy-making functions for the Company. Executive officers of the Company's subsidiaries are deemed executive officers of the Company if they perform such policy making functions for the Company. Policy-making function is not intended to include policy-making functions that are not significant. Identification of an executive officer for purposes of this section would include at a minimum executive officers identified pursuant to Item 401(b) of Regulation S-K.

For purposes of this policy, incentive-based compensation is deemed "**received**" in the fiscal period during which the financial reporting measure specified in the incentive-based compensation award is attained, even if the payment or grant of the incentive-based compensation occurs after the end of that period.

This policy only applies to incentive-based compensation received (as defined above) on or after October 2, 2023.

Determination of Amount Subject to Recovery

The amount of incentive-based compensation subject to recovery under this policy ("**erroneously awarded compensation**") is the amount of incentive-based compensation received that exceeds the amount of incentive-based compensation that otherwise would have been received had it been determined based on the restated amounts, and must be computed without regard to any taxes paid.

For incentive-based compensation based on stock price or total shareholder return, where the amount of erroneously awarded compensation is not subject to mathematical recalculation directly from the information in an accounting restatement: (i) the amount must be based on a reasonable estimate of the effect of the accounting restatement on the stock price or total shareholder return upon which the incentive-based compensation was received; and (ii) the Company must maintain documentation of the determination of that reasonable estimate and provide such documentation to Nasdaq as provided by the rules thereof.

Limited Exceptions

The Company must recover erroneously awarded compensation in compliance with this policy except to the extent that one of the exceptions described in this section is applicable, and the Company's Compensation Committee, or in the absence of such a committee or in the event it is not comprised solely of independent directors, a majority of the independent directors serving on the Board, has made a determination that recovery would be impracticable.

The exceptions referred to in the previous paragraph are as follows:

Direct Third-Party Expense Exceeds Recoverable Amount. The direct expense paid to a third party to assist in enforcing this policy would exceed the amount to be recovered. Before concluding that it would be impracticable to recover any amount of erroneously awarded compensation based on expense of enforcement, the Company must make a reasonable attempt to

recover such erroneously awarded compensation, document such reasonable attempt(s) to recover, and provide that documentation to Nasdaq as provided by the rules thereof.

Tax-Qualified Retirement Plans. Recovery would likely cause an otherwise tax-qualified retirement plan, under which benefits are broadly available to employees of the Company, to fail to meet the requirements of 26 U.S.C. 401(a)(13) or 26 U.S.C. 411(a) and regulations thereunder.

No Indemnification or Insurance

The Company will not indemnify or insure any executive officer or former executive officer against the loss of erroneously awarded compensation

Disclosure

The Company will comply with all disclosure requirements with respect to this policy in accordance with the requirements of the applicable securities laws and Nasdaq rules.

No Duplication of Recovery

To the extent that any compensation recoverable under this policy is also recoverable other than pursuant to this policy, including pursuant applicable law such as Section 304 of the Sarbanes- Oxley Act or pursuant to any other policy or agreement of the Company, then this policy will be administered in order to avoid duplicative recovery to the extent permitted by applicable law and Nasdaq rules. If any amounts that would also be recoverable hereunder have already been reimbursed by a person to the Company pursuant to applicable law or another policy or agreement, such amounts may be credited against amounts recoverable from such person hereunder.

Administration

This policy will be administered by the Company's Compensation Committee, or in the absence of such a committee or in the event it is not comprised solely of independent directors, a majority of the independent directors serving on the Board (the "**Administrator**").

This policy is intended to comply with Nasdaq Listing Rule 5608 and the applicable provisions Rule 10D-1 under the Securities Exchange Act of 1934, and shall be administered and interpreted in a manner consistent with such rules and the applicable guidance of Nasdaq and the Securities and Exchange Commission with respect thereto.

Subject to the foregoing, the Administrator is authorized to interpret this policy and to make all determinations necessary, appropriate or advisable for the administration of this policy. Any interpretations or determinations made by the Administrator shall be final and binding on the Company and all affected individuals