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

FORM 10/A

GENERAL FORM FOR REGISTRATION OF SECURITIES
Pursuant to Section 12(b) or (g) of the Securities Exchange Act of 1934

MONOPAR THERAPEUTICS INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of incorporation)

32-0463781
(IRS Employer Identification No.)

5 Revere Drive, Suite 200
Northbrook, Illinois
(Address of principal executive offices)

60062
(Zip Code)

Registrant's telephone number, including area code: **(847) 373-0025**

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

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

Common Stock, \$0.001 par value
(Title of Class)

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer	<input type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input type="checkbox"/> (Do not check if a smaller reporting company)	Smaller reporting company	<input checked="" type="checkbox"/>
		Emerging growth company	<input checked="" type="checkbox"/>

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

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EXPLANATORY NOTE

Monopar Therapeutics Inc. is filing this General Form for Registration of Securities on Form 10, which we refer to as the Registration Statement, to register our common stock, par value \$0.001 per share, pursuant to Section 12(g) of the Securities Exchange Act of 1934, as amended, or the “Exchange Act” or the “34 Act.” Unless otherwise mentioned or unless the context requires otherwise, when used in this Registration Statement, the terms "Monopar," "Company," "we," "us," and "our" refer to Monopar Therapeutics Inc.

FORWARD-LOOKING STATEMENTS AND INDUSTRY DATA

Forward-Looking Statements

This Registration Statement contains “forward-looking statements.” All statements other than statements of historical facts included in this Registration Statement 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. Forward-looking statements contained in this Registration Statement include without limitation statements about the market for cancer products in general and statements about our:

- projections and related assumptions;
- business and corporate strategy;
- plans, objectives, expectations, and intentions;
- clinical and preclinical pipeline and the anticipated development of our technologies, products, and operations;
- anticipated revenue and growth in revenue from various product offerings;
- future operating results;
- intellectual property portfolio;
- projected liquidity and capital expenditures;
- development and expansion of strategic relationships, collaborations, and alliances; and
- market opportunity, including without limitation the potential market acceptance of our technologies and products and the size of the market for cancer products.

Although we believe that the expectations reflected in such forward-looking statements are appropriate, we can give no assurance that such expectations will be realized. Cautionary statements are disclosed in this Registration Statement, including without limitation statements in the section entitled “**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 Registration Statement or elsewhere, including without limitation any forward-looking statements, except as required by law.

WHERE YOU CAN FIND MORE INFORMATION ABOUT US

When this Registration Statement becomes effective, we will begin to file reports, proxy statements, information statements and other information with the United States Securities and Exchange Commission, or SEC. You may read and copy this information, for a copying fee, at the SEC's Public Reference Room at 100 F Street, N.E., Washington, D.C. 20549. Please call the SEC at 1-800-SEC-0330 for more information on its Public Reference Room. Our SEC filings will also be available to the public from commercial document retrieval services, and at the website maintained by the SEC at <http://www.sec.gov>.

Our Internet website address is <http://www.monopartherapeutics.com>. Information contained on the website does not constitute part of this Registration Statement. We have included our website address in this Registration Statement solely as an inactive textual reference. When this Registration Statement is effective, we will make available, through a link to the SEC's website, electronic copies of the materials we file with the SEC, including annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, the Section 16 reports filed by our executive officers, directors and 10% stockholders and amendments to those reports.

Item 1. Business.

Background and General Development of our Business

The Company was initially formed as a Delaware limited liability company in December 2014, with the name Monopar Therapeutics, LLC, at which time Tactic Pharma, LLC (“Tactic Pharma”) contributed technology and related assets to the Company. In May 2015 we entered into a Clinical Trial and Option Agreement with Cancer Research UK with respect to our initial drug product candidate, MNPR-101 (huATN-658), pursuant to which Cancer Research is conducting preclinical work and plans to conduct a Phase Ia/Ib clinical trial in cancer patients. See “**Material Agreements.**” In December 2015 the Company was converted into a Delaware corporation and all outstanding membership Units were exchanged for shares of stock on a ten for one basis (the “Reorganization”). In June 2016 we entered into an option agreement with Onxeo S.A. pursuant to which we received the right to license the Phase III-ready drug product candidate Validive®. In March 2017, shares of Series Z Preferred Stock converted to Common Stock on a 1 for 1 basis and shares of Series A Preferred Stock converted to Common Stock on a 1.2 for 1 basis (the “Conversion”). Concurrent with the Conversion, the Company effected a 70 for 1 common stock split. All of our preferred stock was eliminated pursuant to the Conversion so that only our common stock is authorized and issued.

On June 27, 2017, we signed a term sheet with Gem Pharmaceuticals, LLC (“Gem”) pursuant to which Gem was to transfer assets related to certain of its drug product candidate programs to Monopar in exchange for 32% of our outstanding common stock on a fully-diluted basis. The Gem transaction was structured through a limited liability company, TacticGem LLC (“TacticGem”) which Gem formed with Tactic Pharma, LLC (“Tactic Pharma”), our largest shareholder at that time. Gem contributed certain of Gem’s drug product candidates’ intellectual property and agreements associated primarily with Gem’s GPX-150 drug product candidate program, along with \$5,000,000 in cash (the “Gem Contributed Assets”) to TacticGem for a 42.633% interest, and Tactic Pharma contributed 4,111,272.88 shares of common stock of Monopar to TacticGem for a 57.367% interest. Then, TacticGem contributed the Gem Contributed Assets to Monopar in exchange for 3,055,394.12 newly issued shares of common stock of Monopar resulting in 31.4% ownership of Monopar on a fully-diluted basis (the two contributions collectively, the “Gem Transaction”). The Gem Transaction closed on August 25, 2017. Following the Gem Transaction, TacticGem owns 7,166,667 (77.1%) shares of our stock as of December 1, 2017. Pursuant to the TacticGem limited liability company agreement, all votes of Monopar’s common stock by TacticGem (aside from the election of Monopar’s Board of Directors) are to be passed through to Tactic Pharma and Gem based on their percentage interests. Tactic Pharma has voting and investment power over 4,111,272.88 shares of Monopar’s common stock and Gem has voting and investment power over 3,055,394.12 shares of Monopar’s common stock). Pursuant to the Gem Transaction, we are required to use our best efforts to file a Form 10 within 90 days of the effective date of the transaction to register our common stock under the Securities Exchange Act of 1934.

In September 2017, we exercised our exclusive option with Onxeo S.A. to license the Phase III-ready drug Validive (clonidine mucobuccal tablet; clonidine MBT), a mucoadhesive local cytokine-suppressing tablet for the prevention and treatment of severe oral mucositis (“SOM”), resulting from chemoradiotherapy in head and neck cancer patients. See “**Our Drug Product Candidates – Validive®.**”

Overview

Our mission is to develop innovative drug combinations to improve clinical outcomes for cancer patients. We are building a drug development pipeline through the licensing or acquisition of oncology therapeutics at the late preclinical through advanced clinical development stage that have demonstrated good antitumor efficacy and safety when used in combination, de-risking clinical development.

Plan of Operations and Strategy

The oncology therapeutic field is extremely competitive and the failure rate of potential therapies in the clinic is high. Clinical failure can be due to lack of efficacy, unacceptable safety profile, and/or side effects. In spite of thorough preclinical evaluation, testing in a human clinical setting is nearly always required to fully appreciate the potential therapeutic value of any given therapy. For an emerging company, obtaining the funds to cover these “up-front” expenses of early clinical studies can be challenging as it is hard to gauge what the future evidence of clinical efficacy and safety will be. We believe that acquiring drug candidates that have shown evidence of efficacy and/or improved safety helps reduce the risk of potential clinical failure.

We currently have three drug product candidates under development and we continue to seek opportunities to acquire or in-license additional drug product candidates. All of our current drug product candidates are either in preclinical or clinical trial testing stages. As a result, we have not out-licensed or sold any of our drug product candidates and have not received any revenue from operations since we began operations in December 2014. Our ability to eventually generate revenue will depend on, among other things, successful completion of human clinical trials of one or more of our drug product candidates; obtaining necessary regulatory approvals from the U.S. Food and Drug Administration (“FDA”) and/or international regulatory agencies; establishing manufacturing, sales, and marketing capabilities internally or with third parties or licensing or selling drug product candidates to third parties.

Until we are able to generate revenues from operations, our strategy has been to fund operations by raising capital from investors and to control development costs by collaborating with third parties to share costs and risk and focusing resources on drug product candidates that we believe have the greatest potential to reach marketability. Therefore, we have chosen to partner with Cancer Research UK to balance the risk profile of our MNPR-101 program. Cancer Research UK has agreed to cover all the costs of manufacturing and carrying out the Phase Ia and Ib clinical studies. It is our expectation that the clinical data from these early human studies in cancer patients will allow us to make an informed decision of the therapeutic potential of MNPR-101. This arrangement allows us to shift much of the human proof-of-concept financial risk to Cancer Research UK, while still allowing us the option of moving the program forward internally if the clinical results are positive. See “**Risk Factors – Risks Related to Our Reliance on Third Parties.**”

In June of 2016, we executed an option agreement to obtain the right to license Validive, a Phase III-ready molecule for the potential treatment of SOM in patients undergoing chemoradiotherapy for head and neck cancer. The licensing or purchasing of a Phase III clinical trial ready program allows us to take advantage of existing preclinical and Phase I/II clinical trial data. This reduces the time and cost of advancing the program to this late stage, reducing the ordinary bench discovery to commercialization timeline by investing at the Phase III clinical trial stage rather than at the discovery or preclinical or early-clinical stage of development. In September 2017, we exercised the option in order to advance the clinical development of Validive.

In August 2017, we expanded our drug development pipeline through the acquisition of the Phase II drug development program, GPX-150 (5-imino-13-deoxydoxorubicin), a proprietary analog of doxorubicin. Doxorubicin has been a mainstay of cancer chemotherapy for several decades and is used in the treatment of a number of solid and blood cancers. However, its use is often limited by its toxicity including irreversible damage to the heart (cardiotoxicity). GPX-150 has been engineered specifically to retain the anticancer activity of doxorubicin while minimizing toxic effects on the heart. We plan to develop a clinical development plan when funding is available to advance the clinical development of GPX-150.

In March and August 2017, we commenced private offerings in which we received total net proceeds in the amount of approximately \$4.7 million. Additionally, the Gem Transaction included a contribution to us of \$5 million, resulting in us having approximately \$10.6 million of cash, cash equivalents and restricted cash as of September 30, 2017. We believe that this provides us with sufficient cash to fund planned operations for at least the next 12 months. We plan to seek additional equity financing to further develop our drug product candidates, enable us to potentially acquire or in-license additional drug product candidates, and for operating expenses and other general corporate and working capital purposes.

In September 2017, we paid \$1 million to exercise an option we held to acquire the rights to Validive, a Phase III-ready drug product candidate. See “**Material Agreements.**” We plan, over the next 12 months, to focus our efforts primarily on advancing the development of Validive, including the initiation of a Phase III clinical trial. Our partnership with Cancer Research UK provides for the continuing development of our drug product candidate MNPR-101 without any significant additional funding required from us until completion of a Phase Ia/Ib clinical trial in cancer patients, at which time we will have an option to acquire the data from the clinical trial. With respect to GPX-150, after we raise additional capital, within the next 24 months we anticipate initiating a Phase II clinical trial that will evaluate GPX-150 in cancer indications where previous studies have shown that doxorubicin showed efficacy but its use is currently restricted due to cardiotoxicity.

Within the next 24 months, we plan to raise additional capital to complete the clinical development of Validive, advance the clinical development of GPX-150, acquire or in-license additional drug product candidates in varying stages of development, and promote public and biotech investor awareness of us and pursue a NASDAQ uplisting. Uplisting to NASDAQ will require us to meet NASDAQ's initial listing requirements and may require a public offering of our common stock or another public stock transaction. See **“Risk Factors – Our ability to uplist to NASDAQ in the future will require significant additional capital and likely require a public stock transaction; failure to qualify to trade on NASDAQ will make it more difficult to raise capital.”** There is no assurance we will be able to achieve any or all of these. See **“Risk Factors - Risks Associated with Our Capital Stock.”**

Our Drug Product Candidates

MONOPAR PRODUCT PIPELINE

Candidate	Status	Potential Indications	Partnerships
Validive®	Phase III-ready	Severe Oral Mucositis	
GPX-150	Phase II	Advanced solid and blood cancers	
MNPR-101 (huATN-658)	Pre-IND	Advanced solid Cancers	Cancer Research UK
Anti-uPAR MAbs	Preclinical	Advanced solid Cancers	

Validive® (clonidine mucobuccal tablet; clonidine MBT)

Validive (clonidine MBT) is a mucobuccal tablet (MBT) of clonidine based on the Lauriad mucoadhesive technology. The Lauriad technology significantly increases the mucous and salivary concentrations of the active ingredient it contains, with decreased systemic absorption.

Mechanism of action

Validive is designed to deliver high concentrations of the active pharmaceutical ingredient clonidine, a modulator of alpha-2 adrenergic receptors, locally in the oral cavity, the site of irradiation in the treatment of head and neck cancer. Clonidine reduces the production of cytokines, the molecules that are responsible for the ulcerations and pain in SOM, by white blood cells called monocytes and macrophages in the oral mucosa. The Lauriad MBT delivery technology provides high salivary concentrations of clonidine and minimizes systemic absorption allowing for maximal local dosing of drug to the at risk oral mucosa. Onxeo's preclinical studies and Phase II clinical trial have provided evidence confirming Validive's mechanism of action and demonstrated its therapeutic potential for reducing the development of SOM, improving oral mucositis-related symptoms, decreasing radiotherapy-related adverse events, while exhibiting a favorable safety profile and high compliance rate with patients.

Severe Oral Mucositis (SOM)

SOM is induced by radiation treatment and is a frequent major adverse effect observed in patients with head and neck cancer (“HNC”). In the near term, SOM induces intense oral pain and limits a patient’s ability to eat and drink, which often leads to severe weight loss and a requirement for enteral or parenteral nutritional support. A large proportion of patients that develop SOM require hospitalization, and symptoms can force patients to stop cancer treatment for an undefined period of time or terminate early, thus reducing cancer treatment efficacy. Thus, SOM impacts both quality of life and clinical outcomes in HNC patients. Long term, HNC patients that are unable to consume food or liquid due to SOM while receiving treatment have persistent problems such as difficulty in swallowing, often leading to problems with aspiration pneumonia, pain and fibrosis (Machtay et al., 2012).

Currently, patients that develop radiation induced SOM have no effective preventive or therapeutic options. There is a significant unmet medical need for this condition. Radiation is a critical part (and will continue to be for the foreseeable future) of the standard of care for HNC regardless of anatomical location of the tumor. The incidence of HNC in the United States is estimated to be 62,000 cases in 2016 is expected to increase to more than 93,000 new cases in 2030. A similar increase is also predicted in the EU5. The incidence of HNC in Japan is estimated to be 18,000 new cases per year and the incidence in Asia (China + South-East region) is estimated at 180,000 in 2016, about 25% of the global incidence. The global incidence of HNC was approximately 690,000 new cases in 2012 (Globocan 2012) and recent studies showed that up to 85% of those patients receiving standard of care high-dose head and neck radiation suffered from SOM (Peterson et al, 2011). By 2030, a significant increase in the incidence of HNC is expected with approximately 1.03M new cases per year. Oropharyngeal cancer (“OPC”) is projected world-wide to be the major form of HNC by 2030, with greater than 50% of OPC being HPV+.

These projections include all HNC patients regardless of the anatomic location of their disease. However, the most rapidly growing sub-population of HNC in the United States and Europe are patients with OPC. The oropharynx is the part of the throat at the back of the mouth, which includes the soft palate, the base (rear one third) of the tongue, and the tonsils. Over the past decade, OPC due to smoking and alcohol consumption has decreased significantly while OPC due to infection with the human papilloma virus (HPV) has increased dramatically. The increase in incidence of OPC has outpaced the incidence of other HNC in the United States and Europe by 4 to 5-fold over the past decade (Chaturvedi et al., 2011; Castellsagué et al, 2017) and this trend is projected to continue for the next 15 to 20 years. OPC patients are now primarily non-smokers in early to mid-life. Recent data (Vatka et al, 2014) has demonstrated that non-smoker patients with OPC have a 2.7-fold higher risk of developing SOM during radiation treatment. We believe, based on these observations and Validive’s mechanism of action, that OPC patients are especially highly likely to benefit from Validive treatment and this group could be the primary driver for market growth for Validive, if approved.

Clinical Data

In November 2012, Onxeo submitted an Investigational New Drug application ("IND") for Validive with the FDA for the prevention and treatment of oral mucositis induced by radiotherapy and/or chemotherapy in cancer patients. The IND was transferred to us in December 2017. We believe that Onxeo's Phase II data supports the development of Validive for severe oral mucositis ("SOM") in OPC patients, with a superior response anticipated in HPV+ patients. Patients with HPV+ OPC have a 6.9-fold higher risk of developing severe oral mucositis (Vatca et al., 2014) making them more amenable to Validive treatment. HPV+ OPC is characterized by the increased presence of immune cells in the tumor due to the presence of the HPV infection (Lyford-Pike et al., 2013; Vatca et al., 2014) that may release oral mucosa damaging cytokines in response to radiation and may therefore be more responsive to Validive, which suppresses the production of these cytokines.

In October 2015, the results from an international Phase II clinical trial of Validive were announced by Onxeo, demonstrating encouraging evidence of clinical activity and safety compared to placebo. The trial enrolled 183 patients and was conducted in more than thirty centers in Europe and the United States. This global, multi-center, double-blind, randomized, placebo-controlled, three-arm study (NCT01385748) compared the efficacy and safety of Validive (50 microgram (μg) and 100 μg) to placebo in patients with HNC receiving chemoradiation therapy. Validive and placebo were applied to the gum of the mouth once daily beginning 1 to 3 days prior to chemoradiotherapy and continuing until the end of chemoradiation treatment.

The safety profile of Validive was similar to placebo. Patients treated with Validive experienced less nausea and dysphagia compared to placebo.

Compliance and acceptability of the treatment found that the mean overall patient compliance to be approximately 90% across all treatment groups. Overall compliance according to patient diaries was similar in all treatment groups and consistent with the compliance according to the investigator's evaluation.

The analysis of OPC patients in this study showed:

- The incidence of severe oral mucositis (primary endpoint) was reduced by 26.3% (40% relative to placebo) in OPC patients treated with Validive (100 μg) ($p=0.09$ † which is a meaningful trend but not statistically significant). 65.2% of OPC patients on placebo experienced severe oral mucositis compared to only 38.9% of OPC patients on Validive 100 μg .
- Secondary endpoints of severe drinking, eating, and speaking limitations due to mouth and throat soreness ("MTS"), score were reduced in the Validive (100 μg) treated cohort ($p<0.05$).
- Decreases in other indicators of clinical benefit including decreased duration of severe oral mucositis (by 15 days versus placebo), weight loss, decreased opiate use and increased cumulative dose of radiation received strongly favored the Validive (100 μg) treated cohort.
- A dose response was observed with the Validive (100 μg) dose demonstrating a trend toward superiority over the Validive (50 μg) dose as well as placebo.

†P-value or probability value, is a statistical measurement of how likely a drug doesn't work based on the clinical data against a control such as a placebo (with no active pharmaceutical ingredient). In general, the FDA requires a p-value of less than 5% or $p < 0.05$, which is considered statistically significant, for marketing approval. A p-value of $p<0.05$ for a clinical trial comparing a drug and placebo means that there is less than a 5% chance the drug is actually inactive.

Our review of Onxeo's Phase II data indicated that the effect of Validive was much greater in OPC compared to non-OPC patients and we believe provides a rationale for developing Validive for the treatment of radiation induced SOM in OPC patients as a first indication. The most rapidly growing sub-population of HNC in the United States and Europe are patients with human papilloma virus positive (HPV+) disease, which are primarily HNC patients with oropharyngeal cancer ("OPC"). The oropharynx is the part of the throat at the back of the mouth, which includes the soft palate, the base (rear one third) of the tongue, and the tonsils. HPV+ OPC is a molecularly defined population of HNC characterized by the expression of a protein biomarker, p16 INK4a, and the presence of HPV DNA or RNA in the tumor. Evaluation of HPV status is part of the routine clinical assessment of patients with OPC prior to initiating treatment. The incidence of HPV+ OPC has outpaced the incidence of HPV- HNC in the United States and Europe by 4 to 5-fold over the past decade (Chaturvedi et al., 2011; Castellsagué et al, 2017). This trend is projected to continue for the next 15 to 20 years and mirrors the increase in HPV infections in the general population. Recent data (Vatca et al, 2014) has demonstrated that HPV+ OPC patients have a 6.9-fold increase in the risk of developing SOM during radiation treatment and that onset of SOM occurs sooner than HPV- HNC patients. These observations indicate that HPV+ OPC patients are highly likely to benefit from Validive treatment and could drive market growth for Validive, if approved. HPV+ OPC is characterized by the increased presence of immune cells in the tumor due to the presence of the HPV infection (Lyford-Pike et al., 2013; Vatca et al., 2014) that may release oral mucosa damaging cytokines in response to radiation and are therefore more responsive to Validive, which suppresses the production of these cytokines.

Validive® Development Strategy

Based on the existing Phase II data in patients with OPC treated with Validive, we are planning an adaptive trial that will evaluate Validive compared to placebo in OPC patients. A planned interim analysis will allow for a sample size re-estimation based on the effect of Validive on the incidence of SOM in patients with HPV+ vs HPV- OPC. This two-stage design will allow us to prospectively confirm the observations made from the Phase II trial data, that Validive will be most effective in preventing and treating radiation-induced SOM in patients with OPC, to evaluate if it performs better in the HPV+ OPC cohort, and then build a sufficient database to support registration. We are currently working with the United States and E.U. regulatory agencies to design a development plan to move Validive toward registration in both a time- and cost- efficient manner.

GPX-150 (5-imino-13-deoxydoxorubicin)

GPX-150 is a proprietary analog of doxorubicin.

Doxorubicin is used to treat a variety of adult and pediatric solid and blood (hematologic) cancers including breast, gastric, ovarian and bladder cancer, soft tissue sarcomas and leukemias and lymphomas. Doxorubicin is often used in combination with other cancer drugs and is frequently used to treat metastatic disease in patients with advanced solid cancers. Doxorubicin is currently indicated by the FDA for use in 14 different cancer types. However, reaching optimal efficacy of doxorubicin has been limited historically by the risk of patients developing irreversible

cardiotoxicity. GPX-150 has been engineered specifically to retain the anticancer activity of doxorubicin while minimizing toxic effects on the heart. Given extensive clinical data supporting the benefit of higher doses of doxorubicin for longer periods of time, along with the potential to combine a non-cardiotoxic version of doxorubicin with other anticancer agents, we believe that there is a large market opportunity in a broad spectrum of cancer types for GPX-150.

Decreased cardiotoxicity observed with GPX-150 in preclinical studies has been shown to be mediated through several mechanisms including: reduced reduction-oxidation cycling, which is the recurring exchange of electrons between two chemicals whereby one chemical loses an electron and is oxidized and the other chemical gains the electron and is reduced; primary metabolite formation; and reduced interaction with topoisomerase II β in the heart. The antitumor effects of GPX-150 are mediated through a mechanism similar to doxorubicin and other anthracycline drugs through stabilization of the topoisomerase II complex after a DNA strand break by intercalation with the DNA, thereby preventing replication in a tumor cell, leading to apoptosis (cell death).

Clinical Data

In February 2007, Gem submitted an IND for GPX-150 for the treatment of cancer. The IND remains open and was transferred to us in September 2017. Several clinical studies of GPX-150 have been completed. A Phase I dose escalation study conducted at the University of Iowa enrolled 24 patients at 5 different dose levels of GPX-150 ranging from 14-265 mg/M². No evidence of cardiotoxicity was observed in any of these patients, including 4 patients that had received prior anthracycline (doxorubicin or related molecules) treatment. In the four highest dose levels (>84 mg/M²), 9/17 patients showed a stabilization of disease including 3 out of 4 patients with leiomyosarcoma, which is a type of cancer that originates in connective tissue and smooth muscle most commonly in the uterus, stomach and small intestine.

Based on the demonstration of stable disease in patients with leiomyosarcoma in the Phase I trial, a multi-center open label single arm Phase II trial was run in doxorubicin-naïve patients with non-resectable or metastatic soft tissue sarcoma (“STS”). Doxorubicin has historically been the standard of care for the treatment of leiomyosarcoma and other STS. This Phase II clinical trial enrolled 22 patients and was completed in early 2017. GPX-150 was administered intravenously at 265 mg/M² every 3 weeks for up to 16 doses and there was no evidence of irreversible cardiotoxicity.

GPX-150 Development Strategy

We will need to raise additional funds to support the next stage of clinical development of GPX-150 which is expected to include a Phase II clinical trial that will evaluate GPX-150 in cancer indications where doxorubicin exhibits efficacy but its use is restricted due to cardiotoxicity. The objective of this clinical trial would be to demonstrate the ability to improve efficacy where GPX-150 dosing does not have to be restricted due to cardiotoxicity. For example, concurrent doxorubicin (60 mg/M², 8 cycles) and paclitaxel yielded a 94% overall response rate in patients with metastatic breast cancer but led to 18% of patients developing congestive heart failure (Gianni et al, 1995). Reduction of doxorubicin to 4-6 cycles of treatment decreased occurrence of congestive heart failure, but also reduced response rate to 30-45%. Consequently, one arm of our future Phase II clinical trial would evaluate concurrent GPX-150 plus paclitaxel to see if a higher

response rate than 30-45% could be observed in the absence of cardiotoxicity. Similar arms will be designed for the combination of GPX-150+trastuzumab in metastatic HER2+ breast cancer patients, and GPX-150 plus Yondelis in soft tissue sarcoma. The results of this multi-arm screening “bucket” trial would be used to inform an initial registration strategy for GPX-150, as well as to support collaborative clinical development efforts with co-operative groups and oncology foundations that could expand the breadth of GPX-150 clinical studies.

MNPR-101 (huATN-658)

No IND is required for MNPR-101 at this time because it is not yet in human clinical trials.

uPA/uPAR Antibodies

A significant body of in vitro and in vivo data has established the urokinase plasminogen activator ("uPA") system as being central to the processes of angiogenesis and metastasis, and therefore as a potentially promising target for cancer drug development. The uPA system is involved in the tissue remodeling and tumor signaling that leads to the progression of cancer. Recent evidence suggests that, in addition to uPA, its cell surface receptor, uPAR, may also be a suitable target for cancer therapeutics and diagnostics because it:

- is selectively expressed on metastatic tumor, tumor-associated immune and angiogenic endothelial cells, but not on most normal cells (several Phase I imaging studies in human advanced cancer patients show that uPAR can only be detected in the tumor and not in normal tissues);
- is central to several extracellular and intracellular oncogenic pathways required for metastasis (inhibiting the uPA system in turn inhibits many other downstream targets that are currently being targeted by other companies);
- is expressed on immune cells that allow the tumor to evade recognition by the immune system and;
- has the potential to interfere at several different signaling pathways that converge at uPAR.

Thus, uPAR-targeted therapies may have broad-spectrum activity against many different cancer types.

We have developed a set of monoclonal antibodies that target uPA and uPAR. Our lead antibody, huATN-658 which we now refer to as MNPR-101, demonstrated significant anti-tumor activity in numerous preclinical models of tumor growth and is being advanced for clinical evaluation. Based on the selective expression of uPAR in tumor, MNPR-101 is expected to be well-tolerated and amenable to a variety of combination treatment approaches.

Market Opportunity

The development of solid tumors is one of the leading causes of death in the United States and the treatment of these tumors is a multi-billion dollar market. We believe that currently available therapeutics intended to address this large and growing market generally provide only marginal clinical benefit. In contrast to most current cancer therapeutics, which work by poisoning rapidly dividing cells, our drug product candidate MNPR-101 is designed to selectively disrupt multiple cellular processes important to tumor growth, metastasis and survival. We believe MNPR-101 may improve treatment outcomes for cancer patients.

Efficacy and Safety

Most current cancer drugs, unfortunately, do not distinguish between rapidly growing healthy cells and cancer cells. This leads to serious side effects and a very narrow therapeutic index. Often, treatment is discontinued because of adverse effects or cumulative toxicities, rendering chronic treatment impossible. Since tumors are generally not completely eradicated by chemotherapy, cessation of treatment often leads to a regrowth of the malignancy. Furthermore, many tumors mutate rapidly and develop resistance to chemotoxic drugs, thereby rendering further existing treatments ineffective. There is an urgent need for new drugs to improve cancer treatment.

Advances in the understanding of how tumor cells differ from normal tissue have made possible the development of a new class of targeted cancer therapies that interrupt processes important to tumor survival and progression. These include anti-angiogenic drugs, anti-metastatic drugs, and cell-signaling inhibitors.

MNPR-101 is designed to interrupt several pathways required for tumor growth and progression. The compound's mechanism of action is designed to block several particular cellular activities that are only turned "on" in a tumor rather than to destroy the tumor cell directly. For this reason, we believe that MNPR-101 may have fewer side effects than current cytotoxic agents which kill cells indiscriminately. In addition, by inhibiting multiple pathways required for tumor growth and progression, we believe MNPR-101 may lead to more effective tumor control than therapies that target only a single such pathway. We believe that most tumors, regardless of the tissue from which they originate, rely on the pathways that we are targeting; therefore, therapies directed at such pathways have the potential to be used against many different types of cancers.

Drug Resistance

MNPR-101 may also avoid some of the drug resistance problems caused by genetic instability that plague many conventional chemotherapies. Cancerous cells mutate and reproduce rapidly, meaning that there is great genetic heterogeneity among cells in a tumor. A given chemotherapy may be effective against the vast majority of these cells, but if even a small number have mutations that confer resistance, these cells will likely survive the treatment. The tumor will grow back composed almost entirely of these mutated cells, making the cancer resistant to further treatments with that particular chemotherapy. By targeting multiple tumor progression pathways, using drugs in combination regimens, and targeting more genetically stable endothelial and immune cells in addition to tumor cells, we believe that MNPR-101 has the potential to avoid these drug resistance problems.

Combination Use

Published preclinical data has shown the ability of MNPR-101 to enhance the anti-tumor activity of chemotherapies such as paclitaxel and gemcitabine (Bauer et al., 2005; Kenny et al., 2011). The expression and targeting of uPAR in general also suggests that MNPR-101 may combine with other targeted agents that affect signaling leading to tumor growth including the ability of tumors to evade immune response. In particular, uPAR is selectively expressed on cells of the myeloid lineage such as myeloid derived suppressor cells, neutrophils and macrophages, all of which drive tumor progression.

Reports of successful cancer therapy increasingly involve the use of drug combinations that target multiple metabolic pathways simultaneously. To that end, oncologists are increasingly exploring the combined use of approved drugs when treating their patients. MNPR-101 is not expected to replace existing therapies, but rather to complement them. MNPR-101 is intended to be combined with existing therapies used to reduce tumor mass in order to make the overall treatment more effective in the acute setting. MNPR-101 could make chemotherapy more effective by making tumors more susceptible to chemotherapy by interrupting the tumors' protective mechanisms. MNPR-101 could also potentially be used as a standard follow-up therapy after chemotherapy to prevent tumor regrowth and metastasis or in combination with immunotherapy including immune checkpoint inhibitors. Cancer is generally not fatal unless tumors metastasize beyond their primary site and interfere with normal function in critical organs of the body. Current thinking suggests that by containing or preventing tumor growth, it may be possible to transform cancer into a manageable, non-fatal condition treated with chronic drug therapy. Given these potential uses, new treatments that target multiple pathways and are designed to be used in drug combinations, like MNPR-101, have the potential to significantly improve treatment outcomes, rather than merely competing with each other in the market.

Material Agreements

Since our inception, we have entered into three material agreements, one with Cancer Research UK, one with XOMA Ltd., and one with Onxeo S.A. None of the agreements requires any issuance of equity or any annual maintenance fee. See the summary of each material agreement below.

On May 15, 2015, we entered into a Clinical Trial and Option Agreement ("CTOA") with Cancer Research UK. Being a new entity at the time of the agreement negotiations, one of the requirements under the CTOA, which has already been fulfilled, was for us to deposit \$800,000 into an escrow to cover indemnities in the event of third party claims resulting from actions or inactions of ours, patent infringement claims, or potential costs on termination of the CTOA by Cancer Research UK for cause. Under the CTOA, Cancer Research UK will pay costs to manufacture the antibody, complete any remaining preclinical work, and conduct a Phase Ia/Ib clinical trial in cancer patients. On completion of the clinical trial, we will have an exclusive option to acquire the data from the trial. Under the terms of the CTOA, the first payment due from us, should we elect to license the data from the trial, is toward the end of the Phase Ib clinical trial in cancer patients. We will decide whether or not to license the data based on the results of the Phase Ib trial. Should we elect to license the data after completion of the Phase Ib clinical trial, we would pay an upfront option fee, plus additional payments required in the future upon meeting certain developmental milestones, sales milestones, and royalties on a product-by-product and country-by-country basis in the single digits payable based on the net sales of each product. The option fee is expressed in British pounds and therefore the value in U.S. dollars may vary slightly depending on the exchange rate at the time of payment; however, payment of the option fee is not expected to have a material effect on our financial position. Upon taking the license, we will be required to pay all future MNPR-101 development costs. We would need to raise additional capital to cover further MNPR-101 development costs once we exercise our license to the data with Cancer Research UK. Should we decline to take the license to the data, we will pay nothing to Cancer Research UK moving forward, and Cancer Research UK will then have the opportunity to be assigned our intellectual property to continue the development and commercialization of MNPR-101 in exchange for a net revenue share and minimum royalty. Since entering into the

CTOA with Cancer Research UK, it has significantly improved the manufacturing efficiency of MNPR-101 with a new cell line and plans to test the new cell line against the original cell line in a comparability study. Upon a positive result in the comparability study, Cancer Research UK plans to start scaling up manufacturing production in order to supply clinical material for a Phase I clinical trial. It is anticipated that it will be at least 12 months before they are ready to commence a Phase I clinical trial, assuming positive results from the comparability study.

To humanize our ATN-658 antibody, we have taken a non-exclusive license to XOMA Ltd.'s humanization technology and know-how. Under the terms of the license, we are to pay only upon developmental and sales milestone achievements which could reach up to \$14.925 million if we achieve all milestones. There can be no assurance that we will reach any milestones. XOMA Ltd. will receive no royalty. The first milestone payment is payable upon first dosing of a human patient in a Phase II clinical trial.

In June 2016, we executed an agreement with Onxeo S.A., a French public company, which gave us the option to license Validive (clonidine mucobuccal tablet), a mucoadhesive tablet of clonidine based on the Lauriad mucoadhesive technology to potentially treat severe oral mucositis in patients undergoing treatment for head and neck cancers. The pre-negotiated license terms included as part of the option agreement included clinical, regulatory, developmental and sales milestones that could reach up to \$108 million if we achieve all milestones, and escalating royalties on net sales from 5 - 10%. On September 8, 2017, pursuant to the Onxeo license option agreement, we exercised the option to license Validive for \$1 million. The exercise of the option assigns all of Onxeo's rights to the Validive intellectual property to us, which allows us to commence the planning of our Phase III clinical trial in severe oral mucositis. Under the agreement, we are required to pay royalties to Onxeo on a product-by-product and country-by-country basis until the later of (1) the date when a given product is no longer within the scope of a patent claim in the country of sale or manufacture, (2) the expiry of any extended exclusivity period in the relevant country (such as orphan drug exclusivity, pediatric exclusivity, new chemical entity exclusivity, or other exclusivity granted beyond the expiry of the relevant patent), or (3) a specific time period after the first commercial sale of the product in such country. In most countries, including the U.S., the patent term is generally 20 years from the earliest claimed filing date of a non-provisional patent application in the applicable country, not taking into consideration any potential patent term adjustment that may be filed in the future or any regulatory extensions that may be obtained. The royalty termination provision pursuant to (3) described above is shorter than 20 years and is the least likely cause of termination of royalty payments.

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

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 radiation, which is 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.**"

Intellectual Property Portfolio

An important part of our strategy is obtaining patent protection to help preserve the proprietary nature of our drug 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 United States and in foreign countries. Our general practice is to seek patent protection in major markets worldwide. 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 allowed patent applications and corresponding (granted and pending) patents and patent applications in twenty-two 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.

We license all intellectual property related to Validive from Onxeo S.A., a French public company. See “**Material Agreements**”. Validive is covered by 32 issued patents and allowed patent applications and corresponding patents and applications in 32 jurisdictions, including the United States, E.U., Japan, and other Asian countries, and has orphan drug designation in the E.U as well as Fast Track designation from the United States Food and Drug Administration (“FDA”). These patents are methods of use patents that cover the use of Validive to prevent and/or treat inflammation and inflammatory pain of the mucosa including cancer therapy-induced mucositis, and have been assigned to us pursuant to our license agreement with Onxeo. These patents expire in 2029.

GPX-150 is covered by both composition of matter as well as 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 most likely non-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 GPX-150 with paclitaxel for the treatment of cancer, plus covering the method of use of these two drugs for this purpose. Our GPX-150 patent portfolio, which is still in the process of completing transfer of ownership subsequent to the Gem Transaction, contains seven issued and allowed U.S. patents and allowed patent applications and one U.S. pending patent application. We have certain corresponding patents and applications in twenty-nine foreign jurisdictions, including the United States, E.U., Japan, and other Asian countries. The composition of matter patents will expire in 2018, the process patents for the synthesis of GPX-150 intermediates will expires in 2024 and the patents covering the combination use of GPX-150 and its analogs with taxanes will expire in 2026. We may pursue patent term extensions where appropriate. We do not believe that expiration of the GPX-150 composition of matter patents will significantly affect our ability to develop or maintain our proprietary position around GPX-150, given that we have obtained patent protection around the intermediates and process used to manufacture GPX-150, will have Hatch-Waxman exclusivity (applicable to new chemical entities) for 5 years that will prevent generic competition, and have obtained U.S. orphan drug status in soft tissue sarcoma with additional orphan cancer indications to follow. We also have a pending International Nonproprietary Name (INN) request with the World Health Organization for a non-proprietary (generic) name for GPX-150.

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 United States, 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.

See “**Risk Factors – Risks Related to Our Intellectual Property.**”

Manufacturing

We do not currently own or operate manufacturing facilities for the production or testing of MNPR-101, Validive, GPX-150 or any other product candidates, 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, or APIs and finished drug products for our preclinical and clinical studies. We have not yet executed manufacturing agreements for our API and supplies of MNPR-101, GPX-150 or Validive. See **“Risk Factors – Risks Related to Our Reliance on Third Parties.”**

Research and Development Costs

Research and development (“R&D”) costs are expensed as incurred. Major components of research and development expenses include materials and supplies and fees paid to consultants and to the entities that conduct certain development activities on our behalf. R&D expense, including upfront fees and milestones paid to collaborators, are expensed as goods are received or services rendered. Costs to acquire technologies to be used in research and development that have not reached technological feasibility and have no alternative future use are also expensed as incurred, except in the case of a business combination when such costs are capitalized as part of the purchase price allocation. During the last two fiscal years we spent approximately \$382,000 on research and development costs (plus approximately \$1.5 million spent by Gem in development of GPX-150). Research and development costs for the nine months ended September 30, 2017 were \$1.6 million. See **“Risk Factors – Risks Related to Clinical Development and Regulatory Approval.”**

Government Regulation and Product Approval

Government authorities in the United States, at the federal, state and local level, and other countries 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 drug product candidates that we develop must be approved by the FDA before they may be legally marketed in the United States. See **“Risk Factors – Risks Related to Clinical Development and Regulatory Approval.”**

United States Pharmaceutical Product Development Process

In the United States, 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 United States 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 United States generally involves the following:

- Completion of preclinical laboratory tests, animal studies and formulation studies according to Good Laboratory Practices (“GLP”), or 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 and efficacy of the proposed pharmaceutical product for its intended use;
- Submission to the FDA of a New Drug Application (“NDA”), 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;
- Potential FDA audit of the preclinical and clinical study sites that generated the data in support of the NDA; and
- FDA review and approval of the NDA.

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 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 the 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 II, and before an NDA 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 II meeting to discuss their Phase II clinical results and present their plans for the pivotal Phase III clinical (registration) trial 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 design of the Phase III 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 I. The pharmaceutical product is initially introduced into healthy human subjects and tested for safety, dosage tolerance, absorption, metabolism, distribution and excretion.

- Phase II. 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 III. 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 III studies are required by the FDA for an NDA approval, depending on the disease severity and other available treatment options.
- Post-approval studies, or phase IV 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 I, Phase II and Phase III 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.

United States 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 requesting approval to market the product. The submission of an NDA 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 or supplement to an NDA 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 submitted before it accepts them for filing and may request additional information rather than accepting an NDA for filing. Once the submission is accepted for filing, the FDA begins an in-depth review of the NDA. 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 and respond to the applicant, and six months for a priority NDA. The FDA does not always meet its PDUFA goal dates for standard and priority NDAs. The review process and the PDUFA goal date may be extended by three months if the FDA requests or if the NDA 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 submission is accepted for filing, the FDA reviews the NDA 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 must submit a proposed REMS; the FDA will not approve the NDA without a REMS, if required.

Before approving an NDA, 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, 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 review and approval process is lengthy and difficult and the FDA may refuse to approve an NDA 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 is submitted, the FDA may ultimately decide that the NDA 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. The complete response letter usually describes all of the specific deficiencies in the NDA 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, 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 IV 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.

Expedited Development and Review Programs

The FDA has a Fast Track program that is intended to expedite or facilitate the process for reviewing new pharmaceutical products that meet certain criteria. Specifically, new pharmaceutical products are eligible for Fast Track designation if they are intended to treat a serious or life-threatening condition and demonstrate the potential to address unmet medical needs for the condition. The Fast Track designation must be requested by the sponsor. Fast Track designation applies to the combination of the product and the specific indication for which it is being studied. Unique to a Fast Track product, the FDA may consider for review sections of the NDA on a rolling basis before the complete application is submitted, if the sponsor provides a schedule for the submission of the sections of the NDA, if the FDA agrees to accept sections of the NDA and determines that the schedule is acceptable and if the sponsor pays any required user fees upon submission of the first section of the NDA.

Any product submitted to the FDA for marketing approval, including a Fast Track program, may also be eligible for other types of FDA programs intended to expedite development and review, such as priority review and accelerated approval. Any product is eligible for priority review if it has the potential to provide safe and effective therapy where no satisfactory alternative therapy exists or a significant improvement in the treatment, diagnosis or prevention of a disease compared to marketed products. The FDA will attempt to direct additional resources to the evaluation of an

application for a new pharmaceutical product designated for priority review in an effort to facilitate the review. Additionally, a product may be eligible for accelerated approval. Pharmaceutical products studied for their safety and effectiveness in treating serious or life-threatening illnesses and that provide meaningful therapeutic benefit over existing treatments may receive accelerated approval, which means that the products may be approved on the basis of adequate and well-controlled clinical studies establishing that the product has an effect on a surrogate endpoint that is reasonably likely to predict a clinical benefit, or on the basis of an effect on a clinical endpoint other than survival or irreversible morbidity. As a condition of approval, the FDA may require that a sponsor of a pharmaceutical product receiving accelerated approval perform adequate and well-controlled post-marketing clinical studies. In addition, the FDA currently requires as a condition for accelerated approval pre-approval of promotional materials, which could adversely impact the timing of the commercial launch of the product. Fast Track designation, priority review and accelerated approval do not change the standards for approval but may expedite the development or approval process.

European Union Drug Review and Approval

In the European Economic Area (“EEA”) (which is comprised of the 28 Member States of the European Union plus Norway, Iceland and Liechtenstein), medicinal products can only be commercialized after obtaining a Marketing Authorization (“MA”). There are two types of MA:

The Community MA, which is issued by the European Commission through the Centralized Procedure, based on the opinion of the CHMP, or Committee for Medicinal Products for Human Use, of the European Medicines Agency (“EMA”), is valid throughout the entire territory of the EEA. The Centralized Procedure is mandatory for certain types of products, such as biotechnology medicinal products, orphan medicinal products, and medicinal products containing a new active substance indicated for the treatment of AIDS, cancer, neurodegenerative disorders, diabetes and auto-immune and viral diseases. The Centralized Procedure is optional for products containing a new active substance not yet authorized in the EEA, or for products that constitute a significant therapeutic, scientific or technical innovation or which are in the interest of public health in the EU.

National MAs, which are issued by the competent authorities of the Member States of the EEA and only cover their respective territory, are available for products not falling within the mandatory scope of the Centralized Procedure. Where a product has already been authorized for marketing in a Member State of the EEA, this National MA can be recognized in other Member States through the Mutual Recognition Procedure. If the product has not received a National MA in any Member State at the time of application, it can be approved simultaneously in various Member States through the Decentralized Procedure. Under the above described procedures, before granting the MA, the EMA or the competent authorities of the Member States of the EEA make an assessment of the risk-benefit balance of the product on the basis of scientific criteria concerning its quality, safety and efficacy.

The following chart provides the FDA Approval status and clinical status of each of our drug product candidates:

Candidate	FDA Approval Status	Clinical Status
Validive®	Not Approved	Phase II completed; designing Phase III
GPX-150	Not Approved	Small Phase II completed; designing additional Phase II study
MNPR-101	Not Approved	Pre-IND
Anti-uPAR MAb	Not Approved	Preclinical

Post-Approval Requirements

Any pharmaceutical products for which a sponsor receives FDA approvals are subject to continuing regulation by the FDA, including, among other things, record-keeping requirements, reporting of adverse experiences with the product, providing the FDA with updated safety and efficacy information, product sampling and distribution requirements, complying with certain electronic records and signature requirements and complying with FDA and FTC promotion and advertising requirements, which include, among others, standards for direct-to-consumer advertising, prohibitions on promoting pharmaceutical products for uses or in patient populations that are not described in the pharmaceutical product's approved labeling (known as "off-label use"), industry-sponsored scientific and educational activities and promotional activities involving the internet. Failure to comply with FDA requirements can have negative consequences, including adverse publicity, enforcement letters from the FDA, actions by the United States Department of Justice and/or United States Department of Health and Human Services Office of Inspector General, mandated corrective advertising or communications with doctors, and civil or criminal penalties. Although physicians may prescribe legally available pharmaceutical products for off-label uses, manufacturers may not directly or indirectly market or promote such off-label uses.

Manufacturers of FDA approved products are required to comply with applicable FDA manufacturing requirements contained in the FDA's cGMP regulations. cGMP regulations require, among other things, quality control and quality assurance, as well as the corresponding maintenance of records and documentation. Pharmaceutical product manufacturers and other entities involved in the manufacture and distribution of approved pharmaceutical products are required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMP and other laws. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain cGMP compliance. Discovery of problems with a product after approval may result in restrictions on a product, manufacturer or holder of an approved NDA, including withdrawal of the product from the market. In addition, changes to the manufacturing process generally require prior FDA approval before being implemented and other types of changes to the approved product, such as adding new indications and additional labeling claims, are also subject to further FDA review and approval. The FDA also may require post-marketing testing, known as Phase IV testing, risk minimization action plans and surveillance to monitor the effects of an approved product or place conditions on an approval that could restrict the distribution or use of the product.

United States Foreign Corrupt Practices Act

The United States Foreign Corrupt Practices Act (“FCPA”), prohibits certain individuals and entities from promising, paying, offering to pay, or authorizing the payment of anything of value to any foreign government official, directly or indirectly, to obtain or retain business or an improper advantage. The United States Department of Justice and the SEC have increased their enforcement efforts with respect to the FCPA. Violations of the FCPA may result in large civil and criminal penalties and could result in an adverse effect on a company’s reputation, operations, and financial condition. A company may also face collateral consequences such as debarment and the loss of export privileges.

Federal and State Fraud and Abuse Laws

In addition to FDA restrictions on marketing of pharmaceutical products, several other types of state and federal laws have been applied to restrict certain business practices in the biopharmaceutical industry in recent years. These laws include anti-kickback statutes and false claims statutes. The federal Anti-Kickback Statute prohibits, among other things, knowingly and willfully offering, paying, soliciting, or receiving remuneration to induce or in return for purchasing, leasing, ordering, or arranging for the purchase, lease, or order of any healthcare item or service reimbursable under Medicare, Medicaid, or other federally financed healthcare programs. The term “remuneration” has been broadly interpreted to include anything of value, including for example, gifts, discounts, the furnishing of supplies or equipment, credit arrangements, payments of cash, waivers of payment, ownership interests and providing anything at less than its fair market value. The Anti-Kickback Statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on one hand and prescribers, purchasers, and formulary managers on the other. Although there are a number of statutory exemptions and regulatory safe harbors protecting certain common activities from prosecution, the exemptions and safe harbors are drawn narrowly, and a company’s practices may not in all cases meet all of the criteria for statutory exemptions or safe harbor protection. Practices that involve remuneration that may be alleged to be intended to induce prescribing, purchases, or recommendations may be subject to scrutiny if they do not qualify for an exemption or safe harbor. Several courts have interpreted the statute’s intent requirement to mean that if any one purpose of an arrangement involving remuneration is to induce referrals of federal healthcare covered business, the statute has been violated. The reach of the Anti-Kickback Statute was also broadened by the PPACA, which, among other things, amends the intent requirement of the federal Anti-Kickback Statute. Pursuant to the statutory amendment, a person or entity no longer needs to have actual knowledge of this statute or specific intent to violate it in order to have committed a violation. In addition, the PPACA provides that the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the civil False Claims Act (discussed below) or the civil monetary penalties statute, which imposes penalties against any person who is determined to have presented or caused to be presented a claim to a federal health program that the person knows or should know is for an item or service that was not provided as claimed or is false or fraudulent.

The federal False Claims Act prohibits any person from knowingly presenting, or causing to be presented, a false claim for payment to the federal government. Recently, several pharmaceutical and other healthcare companies have been prosecuted under these laws for allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product. Other companies have been prosecuted for causing false claims to be submitted because of the companies' marketing of the product for unapproved, and thus non-reimbursable, uses. Many states also have statutes or regulations similar to the federal Anti-Kickback Statute and False Claims Act, which state laws apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payer. Also, the federal Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), created new federal criminal statutes that prohibit knowingly and willfully executing a scheme to defraud any healthcare benefit program, including private third-party payers and knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services. Because of the breadth of these laws and the narrowness of the federal Anti-Kickback Statute's safe harbors, it is possible that some of a company's business activities could be subject to challenge under one or more of such laws. Such a challenge could have a material adverse effect on a company's business, financial condition and results of operations. See "**Risk Factors - Risks Related to Commercialization of Our Product Candidates.**" HIPAA, as amended by the Health Information Technology and Clinical Health Act ("HITECH"), and its implementing regulations, imposes certain requirements relating to the privacy, security and transmission of individually identifiable health information. Among other things, HITECH makes HIPAA's privacy and security standards directly applicable to "business associates"—independent contractors or agents of covered entities that receive or obtain protected health information in connection with providing a service on behalf of a covered entity. HITECH also increased the civil and criminal penalties that may be imposed against covered entities, business associates and possibly other persons, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorney's fees and costs associated with pursuing federal civil actions. In addition, state laws govern the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts. See "**Risk Factors - Risks Related to Commercialization of Our Product Candidates.**"

In the United States and foreign jurisdictions, there have been a number of legislative and regulatory changes to the healthcare system, in particular, there have been and continue to be a number of initiatives at the United States federal and state levels that seek to reduce healthcare costs. The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 ("MMA"), imposed new requirements for the distribution and pricing of prescription drugs for Medicare beneficiaries. Under Part D, Medicare beneficiaries may enroll in prescription drug plans offered by private entities, which will provide coverage of outpatient prescription drugs. Part D plans include both stand-alone prescription drug benefit plans and prescription drug coverage as a supplement to Medicare Advantage plans. Unlike Medicare Part A and B, Part D coverage is not standardized. Part D prescription drug plan sponsors are not required to pay for all covered Part D

drugs, and each drug plan can develop its own drug formulary that identifies which drugs it will cover and at what tier or level. However, Part D prescription drug formularies must include drugs within each therapeutic category and class of covered Part D drugs, though not necessarily all the drugs in each category or class. Any formulary used by a Part D prescription drug plan must be developed and reviewed by a pharmacy and therapeutic committee. Moreover, while the MMA applies only to drug benefits for Medicare beneficiaries, private payers often follow Medicare coverage policy and payment limitations in setting their own payment rates. Any reduction in payment that results from Medicare Part D may result in a similar reduction in payments from non-governmental payers.

The American Recovery and Reinvestment Act of 2009 provides funding for the federal government to compare the effectiveness of different treatments for the same illness. A plan for the research will be developed by the Department of Health and Human Services, the Agency for Healthcare Research and Quality and the National Institutes for Health, and periodic reports on the status of the research and related expenditures will be made to Congress. Although the results of the comparative effectiveness studies are not intended to mandate coverage policies for public or private payers, it is not clear what effect, if any, the research will have on the sales of any product, if any such product or the condition that it is intended to treat is the subject of a study.

In March 2010 the PPACA was enacted, which includes measures to significantly change the way healthcare is financed by both governmental and private insurers. Among the provisions of the PPACA of importance to the pharmaceutical and biotechnology industry are the following:

- an annual, nondeductible fee on any entity that manufactures or imports certain branded prescription drugs and biologic agents, apportioned among these entities according to their market share in certain government healthcare programs, that began in 2011;
- an increase in the rebates a manufacturer must pay under the Medicaid Drug Rebate Program to 23.1% and 13% of the average manufacturer price for branded and generic drugs, respectively;
- a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% point-of-sale discounts to negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D;
- extension of manufacturers' Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations;
- expansion of eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to additional individuals and by adding new mandatory eligibility categories for certain individuals with income at or below 133% of the Federal Poverty Level beginning in 2014, thereby potentially increasing manufacturers' Medicaid rebate liability;
- expansion of the entities eligible for discounts under the Public Health Service pharmaceutical pricing program

- new requirements under the federal Open Payments program, created under Section 6002 of the PPACA and its implementing regulations, that manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children’s Health Insurance Program (with certain exceptions) report annually to the United States Department of Health and Human Services (“HHS”), information related to “payments or other transfers of value” made or distributed to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, and that applicable manufacturers and applicable group purchasing organizations report annually to HHS ownership and investment interests held by physicians (as defined above) and their immediate family members, with data collection required beginning August 1, 2013 and reporting to the Centers for Medicare & Medicaid Services (“CMS”), required by March 31, 2014 and by the 90th day of each subsequent calendar year;
- a requirement to annually report drug samples that manufacturers and distributors provide to physicians, effective April 1, 2012;
- expansion of health care fraud and abuse laws, including the False Claims Act and the Anti-Kickback Statute, new government investigative powers, and enhanced penalties for noncompliance;
- a licensure framework for follow-on biologic products;
- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research;
- creation of the Independent Payment Advisory Board which, beginning in 2014, will have authority to recommend certain changes to the Medicare program that could result in reduced payments for prescription drugs and those recommendations could have the effect of law even if Congress does not act on the recommendations; and
- establishment of a Center for Medicare Innovation at CMS to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drug spending that began on January 1, 2011.

In addition, other legislative changes have been proposed and adopted since the PPACA was enacted. In August 2011, the President signed into law the Budget Control Act of 2011, which, among other things, created the Joint Select Committee on Deficit Reduction, or joint committee, to recommend proposals in spending reductions to Congress. The joint committee did not achieve its targeted deficit reduction of at least \$1.2 trillion and for the years 2013 through 2021, triggering automatic reductions to several government programs. These reductions include aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, starting in 2013. In January 2013, the President signed into law the American Taxpayer Relief Act of 2012, which, among other things, reduced Medicare payments to several providers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. These new laws may result in additional reductions in Medicare and other healthcare funding.

There have been a number of proposals in the U.S. Congress to repeal or replace parts of the PPACA. Some of the proposals include the repeal of the tax on prescription medications, repeal of the medical device excise tax for sales, and repeal of the elimination of a deduction for expenses allocable to Medicare Part D subsidy. It is uncertain whether any repeal or replace legislation will be passed and signed into law or what effect any such legislation may have on our commercialization strategy. See “**Risk Factors - Future Legislation or Executive Action May Increase the Difficulty and Cost for us to Commercialize our Products and Affect the Prices Obtained for Such Products.**”

Patent Term Restoration and Marketing Exclusivity

Depending upon the timing, duration and specifics of the FDA approval of the use of our pharmaceutical product candidates, some of our products to be licensed under United States patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, commonly referred to as the Hatch-Waxman Amendments. The Hatch-Waxman Amendments permits a patent restoration term of up to five years as compensation for patent term lost during product development and the FDA regulatory review process. However, patent term restoration cannot extend the remaining term of a patent beyond a total of 14 years from the product’s approval date. The patent term restoration period is generally one-half the time between the effective date of an IND and the submission date of an NDA plus the time between the submission date of an NDA and the approval of that application. Only one patent applicable to an approved pharmaceutical product is eligible for the extension and the application for the extension must be submitted prior to the expiration of the patent. The United States Patent and Trademark Office (“USPTO”), in consultation with the FDA, reviews and approves the application for any patent term extension or restoration.

Market exclusivity provisions under the United States Food, Drug, and Cosmetic Act can also delay the submission or the approval of certain applications of other companies seeking to reference another company’s NDA.

Pharmaceutical Coverage, Pricing and Reimbursement

Significant uncertainty exists as to the coverage and reimbursement status of any pharmaceutical product candidates for which we obtain regulatory approval. In the United States and markets in other countries, sales of any products for which we receive regulatory approval for commercial sale will depend in part upon the availability of reimbursement from third-party payers. Third-party payers include government payers such as Medicare and Medicaid, managed care providers, private health insurers and other organizations. The process for determining whether a payer will provide coverage for a pharmaceutical product may be separate from the process for setting the price or reimbursement rate that the payer will pay for the pharmaceutical product. Third-party payers may limit coverage to specific pharmaceutical products on an approved list, or formulary, which might not include all of the FDA-approved pharmaceutical products for a particular indication. Third-party payers are increasingly challenging the price and examining the medical necessity and cost-effectiveness of medical products and services, in addition to their safety and efficacy. We may need to conduct expensive pharmaco-economic studies in order to demonstrate

the medical necessity and cost-effectiveness of its products, in addition to the costs required to obtain the FDA approvals. A payer's decision to provide coverage for a pharmaceutical product does not imply that an adequate reimbursement rate will be approved.

In 2003, the federal government enacted legislation providing a partial prescription drug benefit for Medicare recipients, which became effective at the beginning of 2006. However, to obtain payments under this program, a company would be required to sell products to Medicare recipients through prescription drug plans operating pursuant to this legislation. As part of their participation in the Medicare prescription drug program, these plans negotiate discounted prices for prescription drugs. Federal, state and local governments in the United States continue to consider legislation to limit the growth of health care costs, including the cost of prescription drugs. Future legislation and regulations could limit payments for pharmaceuticals such as the drug product candidates that we are developing.

Different pricing and reimbursement schemes exist in other countries. In the European Community, governments influence the price of pharmaceutical products through their pricing and reimbursement rules and control of national health care systems that fund a large part of the cost of those products to consumers. Some jurisdictions operate positive and negative list systems under which products may only be marketed once a reimbursement price has been agreed upon. To obtain reimbursement or pricing approval, some of these countries may require the completion of clinical studies that compare the cost-effectiveness of a particular pharmaceutical product candidate to currently available therapies. Other member states allow companies to fix their own prices for medicines, but monitor and control company profits. The downward pressure on health care costs in general, particularly prescription drugs, has become very intense. As a result, increasingly high barriers are being erected to the entry of new products. In addition, in some countries, cross-border imports from low-priced markets exert a commercial pressure on pricing within a country.

International Regulation

In addition to regulations in the United States, there are a variety of foreign regulations governing clinical studies and commercial sales and distribution of our future product candidates. Whether or not FDA 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 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 must be submitted under a centralized procedure to the European Medicines Agency ("EMA"). The centralized procedure provides for the grant 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 United States 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 and the United States, 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 and commercialization of Validive, GPX-150, MNPR-101, or any future product candidates internationally.

Employees

Our operations are currently overseen by five individuals, including three with a PhD, two with an MD, one with an MBA, one with an MSc in health economics and policy, and one with an inactive CPA. They have worked at industry leading companies such as BioMarin Pharmaceutical Inc., Raptor Pharmaceuticals, Abbott Laboratories, and Onyx Pharmaceuticals. As of December 1, 2017, we have five employees; four of them are full-time employees. For information regarding our executive officers, see the section entitled “**EXECUTIVE OFFICERS AND BOARD MEMBERS.**”

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 Form 10, 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 Form 10 are not exhaustive; other significant risks may exist that are not identified in this Form 10, 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 a limited operating history of almost three years. Therefore, there is limited historical financial 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 stages of operations. Most companies in our industry and at our stage of development never become profitable and go out of business without ever successfully developing any product that generates revenue from commercial sales.

From inception in December 2014 through September 30, 2017, we have incurred losses of approximately \$17.7 million. 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 drug product candidates.

The amount of future losses and when, if ever, we will become profitable are uncertain. We do not have any products that have generated any 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, sales, and marketing arrangements with third parties; obtaining adequate reimbursement by third party payers; and raising sufficient funds to finance our activities. We might not succeed at any of these undertakings. 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.

After the filing of this Form 10, we will be a reporting company and will be subject to reporting and other requirements, which will lead to increased operating costs in order to meet these requirements.

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

Developing a new drug and conducting clinical trials 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 so. 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. See discussion of our material development agreements in “**Material Agreements**”. 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 produce our drug product candidates;
- higher than expected costs for preclinical testing;
- an increase in the number, size, duration, or complexity of our clinical trials;
- slower than expected progress in developing Validive, GPX-150, MNPR-101, or other drug product candidates;
- higher than expected costs associated with attempting to obtain regulatory approvals, including without limitation additional costs caused by delays;
- higher than expected personnel or other costs, such as adding personnel 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.

If 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 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.

In addition, any additional financing might not be available and even if available, may not be available on terms favorable to us or our then-existing investors. We may seek to raise funds through public or private equity offerings, 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 may experience significant 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 may have to reduce expenses, including without limitation by curtailing operations, abandoning opportunities, selling off assets, reducing costs, or ceasing operations entirely.

Risks Related to Clinical Development and Regulatory Approval

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

In order for us to commercialize any treatment for a cancer indication or for any other clinical indication, we must obtain regulatory approvals of such treatment for that indication. Satisfying regulatory requirements is an expensive process that typically 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 are safe and effective, that our clinical trials will demonstrate the necessary safety and effectiveness of our drug 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 otherwise expose us to significant commercial and legal risks.
- It may take longer than expected to determine whether or not a treatment is effective.
- Patients involved in our clinical trials may die, whether as a result of treatment with our products, the withholding of such treatment, or other reasons (whether within or outside of our control).
- We may fail to enroll a sufficient number of patients in our clinical trials.
- Patients enrolled in our clinical trials may not have the characteristics necessary to obtain regulatory approval for a particular indication.
- We may be unable to produce sufficient quantities of product to complete the clinical trials.
- Even if we are successful in our clinical trials, any 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 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 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 drug and thus may be poorly equipped to gauge, and may prove unable to manage risks relating to obtaining such approval.

Outside the United States, our ability to market a product is contingent upon receiving clearances from appropriate non-United States regulatory authorities. Non-United States regulatory approval typically includes all of the risks associated with FDA clearance discussed above as well as the additional uncertainties and potential prejudices faced by United States companies conducting business abroad.

If we or our licensees, development collaborators, or suppliers are unable to manufacture our products in sufficient quantities 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 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 currently contract with outside sources to manufacture MNPR-101. In order to be able to manufacture sufficient quantities of MNPR-101 to be able to proceed with human clinical trials, Cancer Research UK has developed a new cell line and is in the process of testing the new line against the original cell line. There can be no assurance that such testing will be successful or that sufficient quantities of MNPR-101 will be able to be manufactured. We in the future 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 Validive, GPX-150, MNPR-101, 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 the FDA's current Good Manufacturing Practices requirements, commonly known as "cGMP", and applicable non-United States regulatory requirements. The cGMP requirements govern quality control and

documentation policies and procedures. Complying with cGMP and non-United States 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 approval. Failure to pass a pre-approval inspection may significantly delay or prevent FDA 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.

It is uncertain whether 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. 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 are contracting for general liability insurance in connection with our ongoing business, 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. Furthermore, there can be no assurance that suitable insurance will continue to be available on terms acceptable to us or at all, or that, if obtained, the insurance coverage will be appropriate and sufficient to cover any potential claims or liabilities.

Risks Related to Our Reliance on Third Parties

Corporate, non-profit, and academic collaborators may take 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 drug product candidates is heavily dependent on us entering into collaborations with corporations, non-profits, academic institutions, licensors, licensees, and other parties. There can be no assurance that we will be successful in establishing such collaborations. Some of our existing collaborations are, and future collaborations may be, terminable at the sole discretion of the collaborator, such as the Cancer Research UK Clinical Trial and Option Agreement. Replacement collaborations might not be available on attractive terms, or at all. The activities of any collaborator will not be within our 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 or 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.

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 in 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. We have exercised our option to license Validive; as such, Onxeo has the ability to terminate the license if we breach our obligations under the option and license agreement. A termination of the option and license agreement might force us to cease developing and/or selling Validive.

Data provided by collaborators and other parties upon which we rely has not been independently verified and could turn out to be false, 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 rely on a single supplier for a particular manufacturing material, 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 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 such alternative source of supply or in negotiating acceptable terms with such prospective supplier.

Risks Related to Commercialization of Our Product Candidates

Our product development efforts are at an early stage. We have not yet undertaken any marketing efforts, and there can be no assurances that we will be successful in either developing or marketing any product.

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. Commercializing 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 products, if successfully developed, 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, patients, or both), adequately reimbursed by third party payers, or that competitive products will not perform better and/or be marketed more successfully.

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 may 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 product. To market any products directly, we would have to establish a marketing, sales, and distribution force that had 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 and patients.

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

- prevalence and severity of adverse side effects;
- potential advantages over alternative treatments;
- cost effectiveness;
- convenience and ease of administration;
- sufficient third-party coverage or reimbursement;
- strength of marketing and distribution support; and
- our ability to provide acceptable 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 and patients, we may generate little or no product revenue and may not become profitable.

Our products may not be accepted for reimbursement or properly 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 are not subject to adequate reimbursement, physicians may not prescribe for our products in sufficient amounts to make our products profitable.

Comparative effectiveness research demonstrating benefits in a competitor's product could adversely affect the sales of our drug 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.

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 product development. 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 and/or reimburse our products at a lower rate.

In addition, emphasis on managed care 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.

Healthcare reform and other changes in the healthcare industry could hinder or prevent the commercial success of our product candidates.

Third-party payers are increasingly attempting to contain healthcare costs by limiting both coverage and the level of reimbursement for new medical treatment products. Any development along these lines could materially and adversely affect our prospects. We are unable to predict what 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.

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, which may increase our operating costs.

If we obtain FDA approval for any of our product candidates and begin commercializing those products in the United States, 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 laws or any other governmental regulations that apply to us, we may be subject to criminal and significant civil monetary penalties, which could adversely affect our ability to operate our business and our results of operations.

If our operations are found to be in violation of any of the federal and state laws described above 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 will likely 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 will likely be lower than the prices we might otherwise obtain.

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. We filed and have been granted in the U.S. and various countries around the world patents for antibodies that target uPAR. Our GPX-150 patent portfolio is in the process of completing transfer of ownership subsequent to the Gem Transaction. 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 license all intellectual property related to Validive from Onxeo S.A., a French public company. See “**Material Agreements**”. 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 “**Intellectual Property Portfolio**”. 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 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 addition, the 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 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. See “**Intellectual Property Portfolio**”.

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 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. If any of these events for which we cannot provide assurances occurs, or we otherwise lose protection for our trade secrets or proprietary know-how, the value of this information may be greatly reduced.

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 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 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 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. In addition, 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.

Risks Related to Our Business Operations and Industry

We have a limited operating history as we are a new entity.

As of December 1, 2017, we have engaged exclusively in acquiring pharmaceutical drug product candidates, licensing rights to drug product candidates and entering into the CTOA with Cancer Research UK, and have not completed any clinical trials, received any governmental approvals, brought any product to market, manufactured or produced products in commercial quantities or sold any pharmaceutical products. 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. We have limited history of conducting acquisitions, and negotiating and acquiring licenses. 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 business development.

If we lose key management, leadership, or scientific personnel, cannot recruit qualified employees, directors, officers, or other significant personnel, or experiences increases in compensation costs, then our business may 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, Chandler D. Robinson, our President and CEO, and Andrew P. Mazar, our Executive Vice President of Research and Development, and Chief Scientific Officer, could materially disrupt our business and materially delay or prevent the successful commercialization of our product candidates. We have an employment agreement with Dr. Robinson which has no term but is for at-will employment, and we have an employment agreement with Dr. Mazar which has no term but is for at-will employment.

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 ability to identify, hire, and retain highly skilled personnel may cause our compensation costs to increase materially.

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. Therefore, we may not be subject to the same new or revised accounting standards as other public companies that are not “emerging growth companies.”

For as long as we continue to be an emerging growth company, we also 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.

After we become a reporting company under the 34 Act, we will remain an emerging growth company until the earliest of (i) the end of the fiscal year in which the market value of our common stock that is held by non-affiliates exceeds \$700 million as of the end of the second fiscal quarter, (ii) the end of the fiscal year in which we have total annual gross revenues of \$1 billion or more during such fiscal year, (iii) the date on which we issue more than \$1 billion in non-convertible debt in a three-year period or (iv) the end of the fiscal year following the fifth anniversary of the date of the first sale of our Common Stock pursuant to an effective registration statement filed under the Act.

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

The biopharmaceutical industry is subject to rapid technological change. We have many potential competitors, including major drug and chemical companies, specialized biopharmaceutical firms,

and 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 obsolete or non-competitive. 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 regulatory approval process for product candidates.

If product liability lawsuits are brought against us, we may incur substantial costs to defend them and address any damages awarded, and demand for our products could be reduced as a result of such lawsuits.

The testing and marketing of medical products is subject to an inherent risk of product liability claims. Since we currently are not sponsoring a clinical trial, we do not have product liability insurance coverage, but plan to obtain appropriate coverage when we enroll patients in a Validive or other clinical trial. Regardless of their merit or eventual outcome, product liability claims may result in:

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

We use hazardous materials, including radioactive materials, in our business, and any claims relating to improper handling, storage, or disposal of these materials could materially harm our business.

Our business involves the use of a broad range of hazardous chemicals and materials, including radioactive materials. Environmental laws impose stringent civil and criminal penalties for improper handling, disposal, and storage of these materials. In addition, in the event of an improper or unauthorized release of, or exposure of individuals to, hazardous materials, we could be subject to civil damages due to personal injury or property damage caused by the release or exposure. A failure to comply with environmental laws could result in fines and the revocation of environmental permits, which could prevent us from conducting our business.

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 and integrity in handling our affairs, our Second Amended and Restated Certificate of Incorporation (the “Certificate of Incorporation”), provides that our directors will be indemnified to the fullest extent permitted under Delaware law. As a result, our stockholders may have fewer rights against our directors than they would have absent such provisions in our Certificate of Incorporation, 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 if our Board Member (a) has acted in good faith, in a manner the Board Member reasonably believes to be in or not opposed to our best interests, and (b) with respect to any criminal action or proceeding, if the Board Member had no reasonable cause to believe the conduct was unlawful.

Pursuant to the Certificate of Incorporation, each director and (to the extent approved by our Board) each of our officers who is made a party to a legal proceeding because he or she is or was a Board Member or officer, is indemnified by us from and against any and all liability, except that we may not indemnify a Board Member 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 Board Member 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 Board Member or officer unless such indemnification has been approved by a disinterested majority of Board Members or by a majority in interest of disinterested stockholders. We are required to pay or reimburse attorney's fees and expenses of a Board Member seeking indemnification as they are incurred, provided the director 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 action may increase the difficulty and cost for us to commercialize our products and affect the prices obtained for such products.

President Trump ran for office on a platform that supported the repeal of the Patient Protection and Affordable Care Act (the "PPACA"); therefore modification and partial or complete repeal of the Affordable Care Act is possible. Healthcare reform measures that may be adopted in the future may result in more rigorous coverage criteria and lower reimbursement, and in additional downward pressure on the price that may be charged for any of our product candidates, if approved. This could materially and adversely affect our business by reducing our ability to generate revenues, raise capital, obtain additional licensees and market our products.

Additionally, Executive Orders and policy statements issued by President Trump have increased the uncertainty regarding the timing for the FDA's interpretation and implementation of requirements under the Federal Food, Drug and Cosmetic Act ("FDCA"). Some of these executive actions may also negatively affect the FDA's exercise of regulatory oversight and ability to timely review industry submissions and applications in connection with the drug development and approval process. Notably, on April 12, 2017, the Director for the Office of Management and Budget ("OMB") implemented a long-term plan to reduce the size of the federal workforce. An under-staffed FDA could result in increasing delays in the FDA's responsiveness or in its ability to review applications, issue regulations or guidance, or implement or enforce regulatory requirements in a timely fashion or at all. A January 30, 2017 Executive Order also included a budget neutrality provision that requires the total incremental cost of all new regulations in the 2017 fiscal year, including repealed regulations, to be no greater than zero, except in limited circumstances. It is difficult to predict how these requirements will be interpreted and implemented, and the extent to which they will impact the FDA's ability to continue engaging in its regulatory authorities under the FDCA. If executive actions impose restrictions on FDA's ability to engage in oversight and implementation activities in the normal course, our business may be negatively impacted.

There is no assurance that federal or state health care 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 will affect the pharmaceutical industry in general and our business in particular. There can be no assurance that our product candidates, if approved, will be considered cost-effective by third-party payers, that an adequate level of reimbursement will be available or that the third-party payers' reimbursement policies will not adversely affect our ability to sell our products profitably. If reimbursement of our products are unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our business could be adversely affected.

Our business may be negatively impacted by tax reform measures. If tax reform measures are passed, there can be no assurance that we will continue to receive favorable tax treatment related to our patents. For example, current tax reform proposals being considered could result in the following if passed (among others): self-created patents would no longer qualify as a capital asset, patents transferred prior to commercialization would not qualify for long-term capital gain treatment, and the drug manufacturer credit of 50% of qualified clinical testing expenses would be repealed. It is difficult to predict what tax reform measures, if any, could be implemented and the extent to which they will impact our accounting practices and our business.

Our anticipated operating expenses over the next year are based upon our management's estimates of possible future events. Actual amounts 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 and will cause the actual results to vary substantially from the anticipated 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 "**RISK FACTORS**" in this Form 10. In view of the foregoing, investors should not rely on these estimates in making a decision to invest in us.

Risks Associated with Our Capital Stock

We may never provide liquidity to our investors.

No public market exists with respect to any of our securities. There is no assurance that any public offering, merger, combination, sale, or other liquidity event relating to us will ever take place, or that any public offering, merger, combination, sale, or other event that might take place would provide liquidity for our investors or that we will be able to provide liquidity to our investors in any fashion. In the event that we are unable to affect a public offering, merger, combination, sale, or other liquidity event, our investors would likely be unable to sell their interests in us.

Existing and new investors will experience dilution as a result of our option plan and potential future stock sales.

Our Board Members, 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 1,600,000 shares of our Common Stock may be issued as stock options or restricted stock under the Amended and Restated Monopar Therapeutics Inc. 2016 Stock Incentive Plan, and stock options for the purchase of up to 658,592 shares of our common stock have already been granted. See “**Stock Option Plan.**” The issuance of such equity and/or the exercise of such options will dilute both our existing and our new investors. As of December 1, 2017, no stock options have been exercised.

Our existing and our new investors will likely 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, intellectual property licensing, acquisition, or commercialization arrangements.

Holders of the shares of our Common Stock will have no control of our operations or in connection with major transactions.

Our business and affairs will be 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 owns 7,166,667 shares of common stock (77.1%). The limited liability company agreement of TacticGem, LLC provides that the manager will vote its shares of Monopar to elect to the Board of Directors those persons nominated by TacticPharma LLC plus one person nominated by Gem Pharmaceuticals, LLC. Additionally, other than in the elections of directors the limited liability company agreement requires TacticGem to pass through votes to its members in proportion to their membership percentages in TacticGem. As a result, Tactic Pharma, our initial investor, holds an approximately 46% beneficial interest in us and together with Gem’s beneficial ownership of approximately 33%, the two entities control a majority of our stock and will be able to elect all Board Members and control our affairs. Some of our Board Members and

executive officers own and control Tactic Pharma. Although no single person has a controlling interest in Tactic Pharma, acting together they are able to control Tactic Pharma and a large voting block of Monopar and elect over a majority of our Board of Directors. See “**Security Ownership of Certain Beneficial Owners and Management.**”

We may not be able to raise funds as an Over the Counter Bulletin Board (“OTCBB”) traded company. If we are unable to raise funds, we may have to cease or reduce operations.

If we succeed in trading on the OTCBB, we may not be successful in raising additional capital due to the limitations many traditional healthcare investors have in investing in OTCBB companies. Also, companies trading on the OTCBB typically experience low trading volume compared to NASDAQ and NYSE listed companies, which may result in higher trading price volatility. Low trading volume and high price volatility could make raising funds challenging. If we are unable to raise funds, we may have to cease or reduce operations.

Our ability to uplist to NASDAQ in the future will require raising significant additional capital and likely require a public stock transaction; failure to qualify to trade on NASDAQ will make it more difficult to raise capital.

We will need to raise significant funds in the next 24 months to execute our clinical development plans and we believe that if our stock is trading on NASDAQ’s Capital Market it will provide better access to capital. NASDAQ has listing requirements for inclusion of securities for trading on the NASDAQ Capital Market, including stockholders equity of \$4 million (market value standard) or \$5 million (equity standard), market value of publicly held shares of \$15 million, an operating history of 2 years under the equity standard or a market value of listed securities of \$50 million under the market value standard, 1 million publicly held shares, 300 shareholders, three market makers and a \$4 bid price or a closing price of \$3 (equity standard) or \$2 (market value standard). If we are unable to eventually uplist to NASDAQ due to lack of external market support, lack of trading volume, low stock price or failing other initial listing requirements, it could make it harder for us to raise capital in the long-term. If we are unable to raise capital when needed in the future, we may have to cease or reduce operations.

Item 2. Financial Information.

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 Registration Statement. Some of the information contained in this discussion and analysis or set forth elsewhere in this Registration Statement, including information with respect to our plans and strategy for our business and related financing, includes forward-looking statements that involve risks and uncertainties. You should read the "Risk Factors" section of this Registration Statement 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

Our mission is to develop innovative drug combinations to improve clinical outcomes for cancer patients. We are building a drug development pipeline through the licensing or acquisition of oncology therapeutics at the late preclinical through advanced clinical development stage.

In August 2017, we acquired GPX-150 (13-imino-13-deoxydoxorubicin), a proprietary analog of doxorubicin from TacticGem. GPX-150 has been engineered specifically to retain the anticancer activity of doxorubicin while minimizing toxic effects on the heart.

Validive is being developed for the treatment of radiation-induced severe oral mucositis ("SOM"). SOM is a frequent major adverse side effect for patients with head and neck cancer who are treated by radiation treatment. SOM causes intense oral pain and limits a patient's ability to eat and drink, which causes additional complications. Many affected patients require hospitalization and the symptoms can force patients to stop cancer treatments early, which reduces the success of treatments. Validive is designed to deliver the active ingredient, clonidine, at the site of radiation treatment. Clonidine reduces the production of cytokines, the molecules that cause sores and pain in SOM patients. Preclinical studies and a Phase II clinical trial have demonstrated that Validive has the potential for reducing the frequency of developing SOM in addition to improving its symptoms, as compared to a placebo. We have an exclusive option to license Validive and on September 8, 2017 we exercised the option in order to advance the development of Validive with the near-term goal of commencing a Phase III clinical trial. If successful, this Phase III program may allow us to apply for marketing approval. See "**Material Agreements**" and "**Strategy**."

MNPR-101 is a drug product candidate designed to reduce tumor growth by targeting a specific receptor, the urokinase plasminogen activator receptor ("uPAR"), which is present in a range of tumor types, including pancreatic and ovarian tumors. uPAR is part of the normal cell repair process in non-cancerous cells; however, in cancerous cells the tumor hijacks uPAR to help the tumor grow and spread. Pre-clinical models have shown that MNPR-101 is effective at reducing tumor growth, both used alone and in combination with existing therapies. Pursuant to a collaboration agreement, Cancer Research UK is conducting MNPR-101's early development through a planned Phase Ib clinical trial in cancer patients.

Over the next three years, we plan to execute a Phase III clinical trial for Validive, work with Cancer Research UK in the clinical development of MNPR-101, potentially commence clinical development of GPX-150, raise additional capital to fund our drug development programs, acquire or in-license additional drug product candidates and promote public and biotech investor awareness of us.

Developing a new drug and conducting clinical trials for one or more disease indications involves substantial costs and resources. Our operating and financial strategy for the development, clinical testing, manufacture and commercialization of drug product candidates is heavily dependent on our entering into collaborations with corporations, non-profits, scientific institutions, licensors, licensees and other parties, which enables us to utilize their financial and other resources to assist in the drug development. Additionally, we will need to raise significant funds in the next 12–24 months to execute our clinical development of Validive and potential commercialization plans. We believe that we will have better access to capital if we are a public reporting company and a trading market develops for our stock. This would increase corporate visibility, provide potential liquidity for our stockholders, and create a market value for our drug product candidates. Therefore, we plan to become a public reporting company under the Securities Exchange Act of 1934 (the “34 Act”) through the filing of this Form 10 registration statement with the SEC. Subsequent to this Form 10 registration, we will work with investment bankers or stock traders to become market makers, which will allow us to trade our Common Stock on the OTCBB, with the intention of uplisting to NASDAQ as soon as we are able to meet the capitalization and other requirements for such a listing. Uplisting to NASDAQ will require us to meet NASDAQ’s strict listing requirements and will also likely require a public offering of our stock or another public stock transaction. See “**Risk Factors – Our ability to uplist to NASDAQ in the future will require significant additional capital and likely require a public stock transaction; failure to qualify to trade on NASDAQ will make it more difficult to raise capital.**” There can be no assurance that we will be successful in including our stock for trading on either OTCBB or NASDAQ or that a market will develop for our stock. See “**Risk Factors – Risks Related to Our Financial Condition and Capital Requirements**”, and “**Risks Related to Our Business Operations and Industry.**”

Conversion of Preferred Stock to Common Stock

In March 2017, holders of a majority in interest of our Series A Preferred Stock and holders of a majority in interest of our Series Z Preferred Stock voted to adopt the Second Amended and Restated Certificate of Incorporation of the Company (the “Certificate of Incorporation”). When the Certificate of Incorporation took effect, each share of Series A Preferred Stock was automatically converted into 84 shares of Common Stock of the Company (a 1.2 for 1 conversion to Common Stock concurrent with a 70 for 1 stock split) and each share of Series Z Preferred Stock was automatically converted into 70 shares of Common Stock of the Company (a 1 for 1 conversion to Common Stock concurrent with a 70 for 1 stock split) and Series A Preferred Stock and Series Z Preferred Stock were eliminated (the “Conversion”). 100,000 shares of Series Z Preferred Stock was converted into 7,000,000 shares of common stock and 15,893.801 shares of Series A Preferred Stock was converted into 1,335,079.284 shares of common stock. All references

in this “Management’s Discussion and Analysis of Financial Conditions and Results of Operations” to common stock authorized, issued and outstanding and common stock options take into account the stock split that occurred as part of the Conversion.

Critical Accounting Policies and Use of Estimates

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

Use of Estimates

The preparation of financial statements in conformity with U.S. GAAP requires our 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 revenues and expenses in the financial statements and accompanying notes. Actual results could differ from those estimates.

Going Concern Assessment

We adopted Accounting Standards Updates (“ASU”) 2014-15, *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. The ASU 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 December 2017, we analyzed our minimum cash requirements through December 2018 and have determined that, based upon our current available cash, we have no substantial doubt about our ability to continue as a going concern. See “**Risk Factors**” – our anticipated operating expenses over the next year are based upon our management’s estimates of possible future events. Actual amounts could differ materially from those estimated by our management.

Revenue

We are an emerging growth company, have no approved drugs and have not generated any revenues. See “**Overview – Revenues**”. To date, we have engaged in acquiring pharmaceutical drug product candidates, licensing rights to 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 drug product candidates. We do not anticipate revenues from operations until we complete testing and development of one of our drug product candidates and obtain marketing approval or we sell or out-license one of our drug product candidates to a third party. See “**Liquidity and Capital Resources**”.

Research and Development Expenses

Research and development (“R&D”) costs are expensed as incurred. Major components of research and development expenses include materials and supplies and fees paid to consultants and to the entities that conduct certain development activities on our behalf. R&D expense, including upfront license fees and milestones paid to collaborators, are expensed as goods are received or services rendered.

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 and clinical trial sites. We determine the estimates through 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 research and development expenses. Clinical trial site costs related to patient enrollment are accrued as patients are entered into the trial. During the previous two fiscal years, we had no clinical trials in progress.

The successful development of our product pipeline remains highly uncertain. We cannot reasonably estimate the nature, timing or costs of the efforts that will be necessary to complete the remainder of the development of any of our drug product candidates or the period, if any, in which material net cash inflows from our drug product candidates may commence. This is due to the numerous risks and uncertainties associated with developing drug product candidates, including:

- receiving less funding than we require;
- slower than expected progress in developing Validive, GPX-150, MNPR-101 or other drug product candidates;
- higher than expected costs to produce our current and future drug product candidates;
- higher than expected costs for preclinical testing of our future and current acquired and/or in-licensed programs;
- future clinical trial costs, including an increase in the number, size, duration, or complexity of future clinical trials;
- future clinical trial results;
- higher than expected costs associated with attempting to obtain regulatory approvals, including without limitation additional costs caused by delays;
- higher than expected personnel or other costs, such as adding personnel or pursuing the acquisition or licensing of additional assets;
- higher than expected costs to protect our intellectual property portfolio or otherwise pursue our intellectual property strategy;
- the potential benefits of our product candidates over other therapies; and
- our ability to market, commercialize and achieve market acceptance for any of our product candidates that we are developing or may develop in the future.

There are other risks described in “**Risk Factors**”. A change in the outcome of any of these variables with respect to the development of a drug product candidate could mean a significant change in the costs and timing associated with the development of that drug product candidate. We expect that research and development expenses will increase in future periods as a result of increased payroll, increased consulting, future preclinical and clinical trial costs, including clinical drug product manufacturing and related costs.

In-process Research and Development

In-process research and development expense represents the costs to acquire technologies to be used in research and development that have not reached technological feasibility and have no alternative future uses and are expensed as incurred.

General and Administrative Expenses

General and administrative expenses consist primarily of compensation and expenses related to the employment of our executive personnel, stock-based compensation expense related to stock options issued to our executive team, legal and audit expenses, general and administrative consulting, board fees and expenses, patent legal and application fees, and facilities and related expenses. Future general and administrative expenses may also include: compensation and expenses related to the employment of finance, human resources and business development personnel, depreciation and amortization of general and administrative fixed assets, investor relations and annual meeting expense, and stock-based compensation expense related to general and administrative personnel. We expect that our general and administrative expenses will increase in future periods as a result of increased payroll, expanded infrastructure, increased consulting, legal, accounting and investor relations expenses associated with being a public company and costs incurred to seek and establish collaborations with respect to any of our drug product candidates.

Collaborative Arrangements

The Company and our collaborative partners are active participants in a collaborative arrangement and all parties are exposed to significant risks and rewards depending on the commercial success of the activities. Contractual payments to the other parties in the collaboration agreement and costs incurred by us when we are deemed to be the principal participant for a given transaction are recognized on a gross basis in research and development expenses. Royalties and license payments are recorded as earned.

On July 9, 2015, we entered into a CTOA with Cancer Research UK and Cancer Research Technology Limited, a wholly-owned subsidiary of Cancer Research UK, in which Cancer Research UK will manufacture MNPR-101, perform preclinical studies and conduct a Phase Ia/Ib clinical trial. At our discretion, we will pay an option fee for the right to the Phase Ia/Ib clinical data, after which time, we may choose to enter into a pre-negotiated license with Cancer Research Technology Limited, which includes developmental and clinical milestones, sales milestones, and royalties on a product-by-product and country-by-country basis in the single digits payable based on the net sales of each product. If we enter into a pre-negotiated license, we will carry 100% of the future development costs. The option fee is expressed in British pounds and therefore the value in U.S. dollars may vary slightly depending on the exchange rate at the time of payment; however, payment of the option fee is not expected to have a material effect on our financial position. Should we decline to license the clinical data, we will pay nothing to Cancer Research UK or Cancer Research Technology Limited, and Cancer Research Technology Limited will be assigned our intellectual property to continue the development and commercialization of MNPR-101 in exchange for a revenue share and minimum royalty.

In addition, we have a non-exclusive license with XOMA Ltd. for its humanization technology and know-how utilized in the development of MNPR-101. Under the terms of the license, we are required to pay developmental and sales milestones which could reach up to \$14.925 million if we achieve all milestones, and zero royalties. There can be no assurance that we will reach any milestones.

From inception in December 2014 through December 1, 2017, no milestones were met and no royalties were earned, therefore, we did not pay or accrue/expense any milestone or royalty payments under the CTOA and XOMA Ltd. license agreement.

License Option Agreement

In June 2016, we executed an agreement with Onxeo S.A., a French public company, which gave us the option to license Validive (clonidine mucobuccal tablet), a mucoadhesive tablet of clonidine based on the Lauriad mucoadhesive technology to potentially treat severe oral mucositis in patients undergoing treatment for head and neck cancers. The pre-negotiated license terms included as part of the option agreement included clinical, regulatory, developmental and sales milestones that could reach up to \$108 million if we achieve all milestones, and escalating royalties on net sales from 5 - 10%. On September 8, 2017, we exercised the option to license Validive in order to commence the clinical development of the drug product candidate.

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

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

From the execution of the agreement through December 1, 2017, no milestones were met and no royalties were earned, therefore, we did not pay or accrue/expense any milestone or royalty payments under the Onxeo option agreement.

Income Taxes

From December 2014 to December 16, 2015, we were a limited liability company (an "LLC") taxed as a partnership under the Internal Revenue Code, during which period the members separately accounted for their pro-rata share of income, deductions, losses, and credits of the Company. On December 16, 2015, we converted from an LLC to a C Corporation. Beginning on December 16, 2015, we use 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 our financial statements, but have not been reflected in our taxable income. Estimates and judgments occur 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 carry forwards. 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.

We regularly assess the likelihood that our deferred income tax assets will be realized from recoverable income taxes or recovered from future taxable income. To the extent that we believe any amounts are more likely not to be realized, we record a valuation allowance to reduce the deferred income tax assets. In the event we determine 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 we subsequently realize deferred income tax assets that were previously determined to be unrealizable, the respective valuation allowance would be reversed, resulting in an adjustment to earnings in the period such determination is made.

Internal Revenue Code Section 382 provides that, after an ownership change, the amount of a loss corporation's taxable income or net operating loss ("NOL") for any post-change year that may be offset by pre-change losses shall not exceed the section 382 limitation for that year. Because we will continue to raise equity in the coming years, section 382 may limit our usage of NOLs in the future.

Based on the available evidence, we believe that the Company was not likely to be able to utilize our minimal deferred tax assets in the future and, as a result, we recorded a full valuation allowance as of September 30, 2017 and for the year ended December 31, 2016 and the short period from December 16, 2015 to December 31, 2015. We intend to maintain the valuation allowance until sufficient evidence exists to support its reversal. We regularly review our tax positions and 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. Our policy is to recognize interest and penalties related to income tax matters as an income tax expense. For the nine months ended September 30, 2017, the year ended December 31, 2016 and the short tax year from December 16, 2015 to December 31, 2015, the Company did not have any interest or penalties associated with unrecognized tax benefits.

We are subject to U.S. federal, Illinois and California income taxes. Tax regulations within each jurisdiction are subject to the interpretation of the related tax laws and regulations and require significant judgment to apply. We converted from an LLC taxed as a partnership to a corporation on December 16, 2015 and are subject to U.S. federal, state and local tax examinations by tax authorities for the year ended December 31, 2016 and for the short tax period from December 16, 2015 to December 31, 2015. We do not anticipate significant changes to our current uncertain tax positions through December 31, 2017. We plan on filing our tax returns for the year ending December 31, 2017 prior to the respective filing deadlines in all applicable jurisdictions.

Stock-Based Compensation

We account for stock-based compensation arrangements with employees, nonemployee directors and consultants using a fair value method, which requires the recognition of compensation expense for costs related to all stock-based payments, including stock options. 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.

Stock-based compensation costs for options granted to our employees and nonemployee directors are based on the fair value of the underlying option calculated using the Black-Scholes option-pricing model on the date of grant for stock options 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 stock price volatility, forfeiture rates and expected term. The expected volatility rates are estimated based on the actual volatility of comparable public companies over the expected term. We selected these companies based on comparable characteristics, including enterprise value, risk profiles, stage of development and with historical share price information sufficient to meet the expected life of the stock-based awards. The expected term for options granted during the nine months ended September 30,

2017 and the year ended December 31, 2016 is estimated using the simplified method. There were no options granted during the year ended December 31, 2015. Forfeitures are estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. We have not paid dividends and do not anticipate paying a cash dividend in the foreseeable future 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. The measurement of consultant share-based compensation is subject to periodic adjustments as the underlying equity instruments vest and is recognized as an expense over the period over which services are rendered.

Stock Option Plan

In April 2016 our Board and the preferred stockholders representing a majority in interest of our outstanding stock approved the Amended and Restated Monopar Therapeutics Inc. 2016 Stock Incentive Plan (the "Plan"), allowing us to grant up to an aggregate 700,000 shares (as adjusted subsequent to the Conversion) of stock awards, stock options, stock appreciation rights and other stock-based awards to our employees, directors and consultants. Through December 1, 2017, our Board granted to Board Members, our Chief Financial Officer, our Acting Chief Medical Officer, and our Senior Vice President of Clinical Development stock options to purchase up to an aggregate 555,520 shares of our common stock at an exercise price of \$0.001 par value and stock options to purchase up to an aggregate 103,072 shares of our common stock at an exercise price of \$6.00 based upon the third party valuations of our common stock and based on the price per share at which common stock was sold in our most recent private offering.

Under the Plan, the per share exercise price for the shares to be issued upon exercise of an option is determined by our Plan administrator, except that the per share exercise price cannot be less than 100% of the fair market value per share on the grant date. In connection with our stock options issued in April 2016, December 2016, and February 2017, fair market value was established by our Plan Administrator using recently obtained third party valuation reports. In connection with our stock options issued in September 2017 and November 2017, fair market value was established by our Plan Administrator based on the price per share at which common stock was sold in our most recent private offering. Options generally expire after ten years.

The fair market value of the 273,000 options granted in April 2016, the 7,000 options granted in December 2016 and the 275,520 options granted in February 2017 was nominal at the time of grant because of both the low number of options granted prior to Conversion in March 2017 and the low exercise price (equal to par value \$0.001). In September 2017, we granted three Board members options to purchase up to 21,024 shares of our common stock each. These options have a six month vesting cliff and vest between 24 and 48 months, depending on the Board member's prior months of service. The fair market value of the aggregate 63,072 options totalled \$3,612 during the nine months ended September 30, 2017.

We recognize as an expense the fair value of options granted to persons who are neither employees nor directors. The fair value of expensed options was based on the Black-Scholes option-pricing model assuming the following factors: 6.0 to 4.3 year expected term, 57% volatility, 1.9% to 1.7% risk free interest rate and zero dividends. Stock-based compensation expense for non-employees for the nine months ended September 30, 2017 was \$238,404 of which \$189,271 was recorded as research and development expenses and \$49,133 as general and administrative expenses.

Stock option activity under the Plan through September 30, 2017 is as follows:

	Options Outstanding		
	Options Available	Number of Options	Weighted-Average Exercise Price
Balances, December 31, 2015	-	-	-
Option pool	700,000*	-	-
Granted ⁽¹⁾	(280,000)	280,000	\$ 0.001
Forfeited	-	-	-
Exercised	-	-	-
Balances, December 31, 2016	420,000	280,000	\$ 0.001
Granted ⁽²⁾	(338,592)	338,592	\$ 1.12
Balances, September 30, 2017	81,408	618,592	\$ 0.61

- 273,000 options vested 50% upon grant date, 25% upon the 6-month anniversary of grant date and 25% upon the 1-year anniversary of grant date; 7,000 options vested pro rata over 6 months.
- 296,544 options vest 6/48^{ths} at the six-month anniversary of grant date and 1/48th per month thereafter, 21,024 options vest 6/24^{ths} on the six-month anniversary of grant date and 1/24th per month thereafter, and 21,024 options vest 6/42^{nds} on the six-month anniversary of grant date and 1/42nd per month thereafter.

* The option pool was increased to 1,600,000 effective October 26, 2017.

A summary of options outstanding as of September 30, 2017 is shown below:

Exercise Prices	Number of Shares Subject to Options Outstanding	Weighted Average Remaining Contractual Term	Number of Shares Subject to Options Fully Vested and Exercisable	Weighted Average Remaining Contractual Term
\$ 0.001	555,520	9.0	320,180	8.6
\$ 6.00	63,072	10.0	-	N/A

A summary of options outstanding as of December 31, 2016 is shown below:

Exercise Prices	Number of Shares Subject to Options Outstanding	Weighted Average Remaining Contractual Term	Number of Shares Subject to Options Fully Vested and Exercisable	Weighted Average Remaining Contractual Term
\$ 0.001	280,000	9.3	204,750	9.3

There were no options granted during the fiscal year ended December 31, 2015. No income tax benefits have been recognized in the statements of operations for stock-based compensation arrangements.

We recognize as an expense the fair value of options granted to persons who are neither our employees nor directors. The fair value of expensed options is based on the Black-Scholes option-pricing.

Results of Operations

Comparison of the Nine Months Ended September 30, 2017 and September 30, 2016

The following table summarizes the results of our operations for the nine months ended September 30 2017 and September 30, 2016:

(in thousands)	Nine Months Ended September 30,		Increase (Decrease)
	2017	2016	
Revenue	\$ -	\$ -	\$ -
Research and development expenses	1,626	183	1,443
In-process research and development expenses	13,501	-	13,501
General and administrative expenses	739	688	51
Total operating expenses	15,866	871	14,995
Operating loss	(15,866)	(871)	(14,995)
Interest income	25	6	19
Net loss	\$ (15,841)	\$ (865)	\$ (14,976)

Research and Development ("R&D") Expenses

Research and development expenses for the nine months ended September 30, 2017 were approximately \$1.62 million, compared to approximately \$0.18 million for the nine months ended September 30, 2016, an increase of approximately \$1.44 million. This increase was primarily attributable to:

[table on next page]

	Nine months ended September 30, 2017 versus nine months ended September 30, 2016
Research and Development Exp. (in thousands)	
License fee for Validive in 2017	\$ 1,000
Increased consulting in clinical development for Validive in 2017	247
Stock-based compensation (non-cash) for consultants in 2017	189
Other, net	7
	<hr/>
Net increase in R&D expenses	<u>\$ 1,443</u>

In-process Research and Development ("IPR&D") Expenses

IPR&D of \$13.5 million represents the value of GPX-150, including transaction costs, acquired in the Gem Transaction in August 2017. The value was expensed because GPX-150 has not reached technological feasibility and has no alternative future use.

General and Administrative ("G&A") Expenses

General and administrative expenses for the nine months ended September 30, 2017 were approximately \$0.74 million, compared to approximately \$0.69 million for the nine months ended September 30, 2016, an increase of approximately \$0.05 million. This increase was primarily attributed to:

	Nine months ended September 30, 2017 versus nine months ended September 30, 2016
General and Administration Exp. (in thousands)	
Intellectual property legal costs in 2017	\$ 121
CEO benefits in 2017	58
Stock-based compensation (non-cash) consultant in 2017	49
New Board member in 2017	42
Website revisions in 2017	16
Other, net	9
Consulting for potential transaction not repeated in 2017	(39)
Legal expenses for a potential transaction not repeated in 2017	(205)
	<hr/>
Net increase in G&A expenses	<u>\$ 51</u>

Interest income for the nine months ended September 30, 2017 increased by approximately \$0.02 million versus the nine months ended September 30, 2016 due to higher bank balances resulting from funds raised in 2017. Interest income was related to interest earned on our cash equivalent investments in two business savings accounts and on our escrow account.

Comparison of the Years Ended December 31, 2016 and December 31, 2015

The following table summarizes the results of our operations for each of the years ended December 31, 2016 and 2015:

(in thousands)	Year Ended December 31,		Increase (Decrease)
	2016	2015	
Revenue	\$ -	\$ -	\$ -
Research and development expenses	280	101	179
General and administrative expenses	913	587	326
Total operating expenses	1,193	688	505
Operating loss	(1,193)	(688)	(505)
Interest income	7	1	6
Net loss	\$ (1,186)	\$ (687)	\$ (499)

Revenue

We are an emerging growth company, have no approved drugs and have not generated any revenues. See “**Overview – Revenues**”.

Research and Development (“R&D”) Expenses

Research and development expenses for the year ended December 31, 2016 were approximately \$0.28 million, compared to approximately \$0.10 million for the year ended December 31, 2015, an increase of approximately \$0.18 million. This increase was primarily attributable to:

Research and Development Exp. (in thousands)	Year ended December 31, 2016 versus year ended December 31, 2015
Increase in consulting R&D due to increased time of acting chief scientific officer	\$ 112
Increase in allocated executive expenses not allocated in 2015	64
Other, net	3
Net increase in R&D expenses	\$ 179

General and Administrative Expenses

General and administrative expenses for the year ended December 31, 2016 were approximately \$0.91 million, compared to approximately \$0.59 million for the year ended December 31, 2015, an increase of approximately \$0.32 million. This increase was primarily attributable to:

	Year ended December 31, 2016 versus year ended December 31, 2015
General and Administration (“G&A”) Exp. (in thousands)	
Compensation, taxes and benefits related to chief executive officer compensation recorded as consulting G&A in 2015	\$ 390
Increase in legal due to legal projects performed in Q2 2016	152
Increase in board fees due to the appointment of Dr. Starr to the board whose fees were previously recorded as consulting G&A in 2015	96
Increase in accounting fees due to the engagement for the year-end audit and interim review	48
Increase due to software subscription that commenced in 2016	13
Increase in rent due to lease for headquarters executed in May 2016	10
Increase in tax fees due to the filing of our initial corporation tax returns	5
Decrease in investor relations expense due to advisory costs incurred in 2015 not repeated in 2016	(17)
Increase in allocation of executive expenses to R&D related to Dr. Robinson’s time spent on clinical development	(64)
Decrease in patent expenses related to historical MNPR-101 patent expenses incurred in 2015	(128)
Decrease in consulting G&A to due the classification of Dr. Robinson as an employee in 2016 and as Dr. Starr as a Board member in 2016, such expenses are recorded as compensation and board fees, respectively	(188)
Other, net	9
Net increase in G&A expenses	<u>\$ 326</u>

Interest Income

Interest income for the years ended December 31, 2016 and 2015 was nominal. Interest income was related to interest earned on our cash equivalent investments in a business savings account and on our escrow account.

Liquidity and Capital Resources

Sources of Liquidity

We have incurred losses and cumulative negative cash flows from operations since our inception in December 2014 and, as of September 30, 2017 we had an accumulated deficit of approximately \$17.7 million. We anticipate that we will continue to incur losses for the foreseeable future. We expect that our research and development and general and administrative expenses will increase, and, as a result, we anticipate that we will need to raise additional capital to fund our operations, which we may seek to obtain through a combination of equity offerings, debt financings, strategic collaborations and grant funding. From our inception, through December 1, 2017, we have financed our operations primarily through private placements of our preferred stock and common stock, the \$5 million received in the Gem Transaction, and our Cancer Research UK collaboration. As of December 1, 2017, we have received net proceeds of approximately \$4.70 million from the sale of our preferred stock which have been converted into common stock and we sold 789,674.33 shares of our common stock for net proceeds of approximately \$4.72 million. We anticipate that the funds raised to-date will fund our planned operations through 2018.

We invest our cash equivalents in two money market accounts.

Contribution to Capital

In August 2017, our largest stockholder, TacticPharma, LLC, surrendered 2,888,727.12 shares of common stock back to us as a contribution to the capital of the Company. This resulted in reducing TacticPharma's ownership in us from 79.5% to 69.9%.

The Gem Transaction

On August 25, 2017, TacticPharma and Gem Pharmaceuticals formed a limited liability company, TacticGem, LLC, with TacticPharma contributing 4,111,272.88 shares of our common stock and Gem contributing assets and \$5 million in cash. TacticGem then contributed the Gem assets and cash to us in exchange for 3,055,394.12 shares of our common stock. This has resulted in TacticGem owning 77.1% of our outstanding common stock as of December 1, 2017. The contribution by TacticGem, made in conjunction with contributions from outside investors in a private offering, was intended to qualify for tax-free treatment and to satisfy a condition to the Gem Transaction that we have a certain level of cash on hand prior to the contribution.

The Gem Transaction was recorded on our financial statements for the nine months ended September 30, 2017 as follows:

Cash to be recorded on our Balance Sheet	\$ 5,000,000
Assembled Workforce to be recorded as In-process Research and Development Expense on our Statement of Operations	9,886
GPX-150 recorded as In-process Research and Development Expense on our Statement of Operations	13,491,736
Total Gem Transaction	<u>\$ 18,501,622</u>

Cash Flows

The following table provides information regarding our cash flows for the nine months ended September 30, 2017 and 2016 and the years ended December 31, 2016 and 2015.

(in thousands)	Nine months ended September 30, 2017	Nine months ended September 30, 2016	Increase (decrease) nine months ended September 30, 2017 over September 30, 2016
Cash used in operating activities	\$ (1,811)	\$ (727)	\$ (1,084)
Cash provided by financing activities	9,526	1,262	8,264
Net change in cash, cash equivalents and restricted cash	<u>\$ 7,715</u>	<u>\$ 535</u>	<u>\$ 7,180</u>

(in thousands)	Year Ended December 31, 2016	Year Ended December 31, 2015	Increase (Decrease) Year Ended December 31, 2016 over December 31, 2015
Cash used in operating activities	\$ (1,195)	\$ (636)	\$ (559)
Cash provided by financing activities	1,263	3,441	(2,178)
Net change in cash, cash equivalents and restricted cash	<u>\$ 68</u>	<u>\$ 2,805</u>	<u>\$ (2,737)</u>

We had no operations from December 5, 2014 (inception) through December 31, 2014.

During the nine months ended September 30, 2017 and 2016, we had net cash inflows of \$7.72 million and \$0.54 million, respectively.

During the years ended December 31, 2016 and 2015, we had net cash inflows of \$0.07 million and \$2.81 million, respectively.

Cash Flow Used in Operating Activities

The increase to cash used in operating activities during the nine months ended September 30, 2017 compared to the nine months ended September 30, 2016 of approximately \$1.08 million was primarily due to the \$1.0 million license fee for Validive paid in 2017 plus the increase in clinical development consulting for planning our Phase III clinical trial for Validive. Cash used in operating activities of approximately \$1.81 million for the nine months ended September 30, 2017 was primarily a result of our approximately \$15.84 million net loss offset by non-cash in-process research and development of \$13.50 million, non-cash stock-based compensation of \$0.24 million and changes in operating assets and liabilities of approximately \$0.29 million. Cash used in operating activities of approximately \$0.73 million for the nine months ended September 30, 2016 was primarily a result of our approximately \$0.87 million net loss offset by changes in our operating assets and liabilities of approximately \$0.14 million.

The increase to cash used in operating activities during the year ended December 31, 2016 compared to the year ended December 31, 2015 of approximately \$0.56 million was primarily because our operations began in June 2015, and 2016 reflects a full year of activity including the employment of Dr. Robinson, our chief executive officer and the engagement of consultants (acting chief scientific officer and acting chief financial officer) and our Executive Chairman of the Board for the full 12 months in 2016 versus approximately 7 months in 2015. Cash used in operating activities of approximately \$1.19 million for the year ended December 31, 2016 was primarily a result of our approximately \$1.19 million net loss offset by nominal changes in operating assets and liabilities. Cash used in operating activities of approximately \$0.64 million for the year ended December 31, 2015 was primarily a result of our approximately \$0.69 million net loss offset by changes in our operating assets and liabilities of approximately \$0.05 million.

Cash Flow Used in Investing Activities

There was no cash provided by or used in investing activities for the nine months ended September 30, 2017 and 2016 and the years ended December 31, 2016 and 2015.

Cash Flow Provided by Financing Activities

The increase of cash provided by financing activities during the nine months ended September 30, 2017 compared to the nine months ended September 30, 2016 of approximately \$8.26 million was due to the sale of common stock during the nine months ended September 30, 2017 at \$6.00 per share for aggregate net proceeds of \$4.69 million plus \$4.83 million of net proceeds from the Gem Transaction less \$1.26 million raised during the nine months ended September 30, 2016 from the sale of convertible preferred stock.

The decrease of cash provided by financing activities during the year ended December 31, 2016 compared to the year ended December 31, 2015 of approximately \$2.18 million was primarily due to our series A preferred financing, which commenced in May 2015 and ended in October 2015, with a smaller financing effort in March/April 2016 on the same terms as the 2015 financing.

During the years ended December 31, 2016 and 2015, we sold 357,000.0 shares and 978,079.3 shares of our Common Stock (previously Series A Preferred Stock), respectively, at \$3.57 per share for net proceeds of \$1.26 million and \$3.44 million, respectively. The sale of our stock at \$3.57 per share takes into the account a 1:10 split effected upon our conversion from an LLC to a Corporation in December 2015 and the Conversion which took effect in March 2017.

Future Funding Requirements

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 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 a third 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 and clinical trials of, and seek regulatory approval for, our current and future drug product candidates. If we are able to uplist to NASDAQ or another national stock exchange, we expect to incur additional costs associated with operating as a public company. In addition, subject to obtaining regulatory approval of any of our current and future drug product candidates, we anticipate that we will need substantial additional funding in connection with our continuing operations.

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

- continue the preclinical and clinical development of MNPR-101;
- advance the clinical development and execute the regulatory strategy of Validive;
- continue the clinical development of GPX-150;
- acquire and/or license additional pipeline drug product candidates and pursue the future preclinical and/or clinical development of such molecules;
- seek regulatory approvals for any of our current and future drug product candidates that successfully complete registration trials;
- establish a sales, marketing and distribution infrastructure and increase or develop our manufacturing capabilities to commercialize any products for which we may obtain regulatory approval; and
- add operational, financial and management information systems and personnel, including personnel to support our drug product candidate development and planned commercialization efforts.

We anticipate that the funds raised to-date will fund our planned operations at least through the next 12 months. 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 additional collaborations with third parties to participate in the development and commercialization of our drug product candidates, we are unable to estimate the amounts of 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 preclinical and clinical development of MNPR-101;
- the progress of regulatory interactions and clinical development of Validive;
- the progress of clinical development of GPX-150;
- the number and characteristics of other drug product candidates that we may pursue;
- the scope, progress, timing, cost and results of research, preclinical development and clinical trials;
- the costs, timing and outcome of seeking and obtaining FDA and non-U.S. regulatory approvals;
- the costs associated with manufacturing and establishing 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 additional management, scientific and medical personnel;
- the effect of competing products that may limit market penetration of our drug product candidates;
- our need to implement additional internal systems and infrastructure; and
- the economic and other terms, timing and success of our existing collaboration and licensing arrangements and any collaboration, licensing or other arrangements into which we may enter in the future, including the timing of receipt of any milestone or royalty payments under these arrangements.

See “**Risk Factors**”. In the first quarter of 2018, expenditures are expected to increase in employee compensation as a result of hiring various employees and consultants to support the planning of our Phase III clinical trial of Validive, in preparation for public market listing via this Form 10 process, and in adjusting employee compensation to align with comparable public companies. 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; however, our spending could be significantly accelerated in 2018 if additional compounds are acquired and enter clinical development. In this event, we may be required to expand our management team, and pay much higher insurance rates, contract manufacturing costs, contract research organization fees or other clinical development costs that are not currently anticipated. We, under this scenario, would plan to pursue raising additional capital in the next 12 months. The anticipated operating cost increases from 2018 through 2019 are expected to be primarily driven by the funding of our planned Validive Phase III clinical program. Office space rent in 2018 and 2019 will also likely increase as a result of requiring additional space as we hire additional employees. The \$1 million fee to Onxeo in 2017 is a one-time payment required for us to exercise our license option for the exclusive world-wide license to Validive.

Until we can generate a sufficient amount of product revenue to finance our cash requirements, we expect to finance our future cash needs primarily through a combination of equity offerings, debt financings, strategic collaborations and grant funding. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interest of our stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect our stockholders’ rights. See “**Risk Factors – Existing and new investors will experience dilution as a result of our option plan and potential future stock sales.**”. 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 third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or grant licenses on terms that may not be favorable to us. 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 develop and market product candidates that we would otherwise prefer to develop and market ourselves.

Contractual Obligations and Commitments

Development and Collaboration Agreements

Cancer Research UK

In July 2015, we entered into a Clinical Trial and Option Agreement (“CTOA”) with Cancer Research UK and Cancer Research Technology Limited, a wholly-owned subsidiary of Cancer Research UK. As part of the CTOA, we were obligated to deposit \$0.8 million in escrow to cover certain potential future claims, intellectual property infringement costs or termination costs incurred by Cancer Research UK.

Under the CTOA, Cancer Research UK plans to manufacture MNPR-101, perform preclinical studies and conduct a Phase Ia/Ib clinical trial in cancer patients. At our discretion, we will pay an option fee for the right to the Phase Ia/Ib clinical data, after which time, we may choose to enter into a pre-negotiated license with Cancer Research Technology Limited which includes developmental and clinical milestones, sales milestones, and royalties on a product-by-product and country-by-country basis in the single digits payable based on the net sales of each product. The option fee is expressed in British pounds and therefore the value in U.S. dollars may vary slightly depending on the exchange rate at the time of payment; however, payment of the option fee is not expected to have a material effect on our financial position. If we enter into the pre-negotiated license agreement, we will carry 100% of the future development costs. Should we decline to enter into the pre-negotiated license, we will pay nothing to Cancer Research UK or Cancer Research Technology Limited, and Cancer Research Technology Limited will be assigned our intellectual property to continue the development and commercialization of MNPR-101 in exchange for a revenue share and minimum royalty. As of December 1, 2017, the Phase Ia/Ib clinical trial has not commenced and we have not entered into the pre-negotiated license agreement with Cancer Research Technology Limited and have not been required to pay Cancer Research UK or Cancer Research Technology Limited any funds under the CTOA.

XOMA Ltd.

The intellectual property rights contributed by Tactic Pharma, LLC to us included the non-exclusive license agreement with XOMA Ltd. for the humanization technology used in the development of MNPR-101. Pursuant to such license agreement, 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 and zero royalties. There can be no assurance that we will achieve any milestones. As of December 1, 2017, we had not reached any milestones and had not been required to pay XOMA Ltd. any funds under this license agreement.

Onxeo SA

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 mucobuccal tablet; clonidine MBT a mucoadhesive tablet of clonidine based on the Lauriad mucoadhesive technology) to potentially treat severe oral mucositis in patients undergoing chemoradiation treatment for head and neck cancers. The agreement includes clinical, regulatory, developmental and sales milestones that could reach up to \$108 million if we achieve all milestones, and escalating royalties on net sales from 5 - 10%. In September 2017, we exercised the option to license Validive from Onxeo for \$1 million, but as of December 1, 2017, we have not been required to pay Onxeo any other funds under the agreement.

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

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

Given the strength of the Phase II data, we paid the \$1 million fee to Onxeo and exercised the license option in order to advance the clinical development of Validive. We fully anticipate the need to raise significant funds to support the completion of clinical development of Validive.

Service Providers

In the normal course of business, we contract with service providers to assist in the performance of research and development, 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 additional collaborative research, contract research, manufacturing and supplier agreements in the future, which may require upfront payments and/or long-term commitments of cash.

Office Lease

In May 2016, we executed a six-month office lease in Northbrook, Illinois for \$1,340 per month, which was extended to December 31, 2017. Effective January 1, 2018, we leased office space in the Village of Wilmette for \$2,379 per month for 24 months. This office space represents our current headquarters. On November 1, 2017 we executed a month-to-month office lease in Seattle, Washington for \$1,249 per month for the first three months, but which tiers up to \$2,495 on the last month.

Legal Contingencies

We are currently not, and to date have never been, a party to any 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 and Amended and Restated Bylaws we have indemnification obligations to our officers and Board Members 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 “**Indemnification of Directors and Officers.**”

Off-Balance Sheet Arrangements

To date, we have not had any off-balance sheet arrangements, as defined under SEC rules.

Recent Accounting Pronouncements

In August 2014, FASB issued ASU 2014-15, *Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern*, which provides guidance on determining when and how reporting companies must disclose going-concern uncertainties in their financial statements. The ASU 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.” This ASU is effective for annual periods ending after December 15, 2016 and interim periods within annual periods beginning after December 15, 2016. Early adoption is permitted. We have adopted this new accounting standard on our financial statements and footnote disclosures.

In November 2015, the FASB issued ASU 2015-17, *Balance Sheet Classification of Deferred Taxes*. This is part of FASB's simplification initiative. The amendments in this ASU require that deferred tax liabilities and assets be classified as noncurrent in a classified statement of financial position. This ASU is effective for us in the first quarter of 2017. Early adoption is permitted. We have adopted this ASU and determined that it does not have a material effect on our financial condition and results of operations for the nine months ended September 30, 2017.

In January 2016, the FASB issued ASU 2016-01, *Recognition and Measurement of Financial Assets and Financial Liabilities*. The purpose is to enhance the reporting model for financial instruments to provide users of financial statements with more decision-useful information. This ASU is effective for us in the first quarter of 2018. Early adoption is not permitted except for limited provisions. We do not expect the adoption of this amendment to have a material effect on our financial condition and results of operations.

In February 2016, the FASB issued ASU 2016-02, *Leases*, which for operating leases, requires a lessee to recognize a right-of-use asset and a lease liability, initially measured at the present value of the lease payments, in its balance sheet. The standard also requires a lessee to recognize a single lease cost, calculated so that the cost of the lease is allocated over the lease term, on a generally straight-line basis. ASU 2016-02 will be effective for us in the first quarter of 2019, and early adoption is permitted. We are currently assessing the impact that adopting this new accounting standard will have on our financial statements and footnote disclosures.

In March 2016, the FASB issued ASU 2016-09, *Improvements to Employee Share-Based Payment Accounting*, which simplifies several aspects of the accounting for employee share-based payment transactions for both public and nonpublic companies, including the accounting for income taxes, forfeitures, and statutory tax withholding requirements, as well as classification in the statement of cash flows. The ASU will be effective for us in the first quarter of 2017, and early adoption is permitted. We have adopted this ASU and determined that it does not have a material effect on our financial condition and results of operations for the nine months ended September 30, 2017.

In November 2016, the FASB issued ASU 2016-18, *Statement of Cash Flows (Topic 230): Restricted Cash*. The amendments apply to all entities that have restricted cash or restricted cash equivalents and are required to present a statement of cash flows. The amendments address diversity in practice that exists in the classification and presentation of changes in restricted cash on the statement of cash flows. The amendments require that a statement of cash flows explain the change during the period in the total of cash, cash equivalents, and amounts generally described as restricted cash or restricted cash equivalents. As a result, amounts generally described as restricted cash and restricted cash equivalents should be included with cash and cash equivalents when reconciling the beginning-of-period and end-of-period total amounts shown on the statement of cash flows. The amendments do not provide a definition of restricted cash or restricted cash equivalents. The amendments are effective for public business entities for fiscal years beginning after December 15, 2017, and interim periods within those fiscal years. For all other entities, the amendments are effective for fiscal years beginning after December 15, 2018, and interim periods within fiscal years beginning after December 15, 2019. Early adoption is permitted. We have early adopted the amendments and have applied them using a retrospective transition method to each period presented. Therefore, we have included restricted cash in cash equivalents and restricted cash on our statements of cash flows for the nine months ended September 30, 2017 and 2016.

In January 2017, the FASB issued ASU No. 2017-01, *Business Combinations (Topic 805): Clarifying the Definition of a Business* (“ASU No. 2017-01”). The amendments in ASU No. 2017-01 clarify the definition of a business with the objective of adding guidance to assist entities with evaluating whether transactions should be accounted for as acquisitions (or disposals) of assets or businesses. The definition of a business affects many areas of accounting including acquisitions, disposals, goodwill and consolidation. For public companies, the amendments are effective for annual periods beginning after December 15, 2017, including interim periods within those periods. For all other companies and organizations, the amendments are effective for annual periods beginning after December 15, 2018, and interim periods within annual periods beginning after December 15, 2019. The Company is currently assessing the impact that adopting this new accounting standard will have on its financial statements and footnote disclosures.

In May 2017, the FASB issued ASU No. 2017-09, *Compensation-Stock Compensation (Topic 718): Scope of Modification Accounting*. The amendment amends the scope of modification accounting for share-based payment arrangements, provides guidance on the types of changes to the terms or conditions of share-based payment awards to which an entity would be required to apply modification accounting under ASC 718. This ASU is effective for all entities for annual periods, and interim periods within those annual periods, beginning after December 15, 2017. Early adoption is permitted, including adoption in any interim period for: (a) public business entities for reporting periods for which financial statements have not yet been issued, and (b) all other entities for reporting periods for which financial statements have not yet been made available for issuance. The Company is currently assessing the impact that adopting this new accounting standard will have on its financial statements and footnote disclosures.

In July 2017, the FASB issued ASU No. 2017-11, *Earnings Per Share (Topic 260) Distinguishing Liabilities from Equity (Topic 480) Derivatives and Hedging (Topic 815) (Part I) Accounting for Certain Financial Instruments with Down Round Features, (Part II) Replacement of the Indefinite Deferral for Mandatorily Redeemable Financial Instruments of Certain Nonpublic Entities and Certain Mandatorily Redeemable Noncontrolling Interests with a Scope Exception*. This ASU simplifies the accounting for certain financial instruments with down round features, a provision in an equity-linked financial instrument (or embedded feature) that provides a downward adjustment of the current exercise price based on the price of future equity offerings. Down round features are common in warrants, preferred shares, and convertible debt instruments issued by private companies and development-stage public companies. This new ASU requires companies to disregard the down round feature when assessing whether the instrument is indexed to its own stock, for purposes of determining liability or equity classification. The provisions of this new ASU related to down rounds are effective for public business entities for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2018. For all other entities, the amendments are effective for fiscal years beginning after December 15, 2019, and interim periods within fiscal years beginning after December 15, 2020. Early adoption is permitted for all entities. The Company is currently assessing the impact that adopting this new accounting standard will have on its financial statements and footnote disclosures.

QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT OUR MARKET RISK

Our cash and cash equivalents as of September 30, 2017, December 31, 2016 and December 31, 2015 consisted of a checking and a business savings fund with a second business savings fund added in 2017. Our primary exposure to market risk is interest income sensitivity, which is affected by changes in the general level of U.S. interest rates. However, because of the short-term nature of our business savings fund and nominal amount of interest earned, a sudden change in market interest rates would not be expected to have a material impact on the fair market value of our cash equivalents. Accordingly, we would not expect our operating results or cash flows to be affected to any significant degree by the effect of a sudden change in market interest rates on our cash equivalents. We do not have any foreign currency or other derivative financial instruments.

Our collaboration and option agreement with Cancer Research UK may subject us to foreign currency rate fluctuation exposure, if any payments are due under the agreement. As of December 1, 2017, no such payments have been due. Transactions denominated in currencies other than U.S. dollars are recorded based on exchange rates at the time such transactions arise. As of September 30, 2017, December 31, 2016, and December 31, 2015, substantially all of our total liabilities were denominated in U.S. dollars. Inflation generally affects us by increasing our cost of labor and facilities expenses. We do not believe that inflation has had a material effect on our results of operations during the nine months ended September 30, 2017, or the years ended December 31, 2016 and December 31, 2015.

Item 3. Properties.

We lease space in the Village of Wilmette, Illinois for our corporate offices, under a lease which runs through the end of 2019. We lease approximately 160 square feet in our Seattle, Washington office. We believe that we will require additional office space within the next 12 months as we begin to hire additional personnel.

Item 4. Security Ownership of Certain Beneficial Owners and Management.

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 December 1, 2017 (subsequent to the Conversion) by:

- each of our directors;
- each of our named executive officers;
- all of our current 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 December 1, 2017, pursuant to the exercise of options or warrants, 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.

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	Shares of Common Stock Beneficially Owned (A)	Percent of Class Held (A)
*Unless otherwise noted, addresses are: 5 Revere Dr., Suite 200, Northbrook, IL 60062		
TacticGem, LLC	7,166,667(B)	77.1%
Tactic Pharma LLC	4,277,939.88(B)	46.0%
Gem Pharmaceutical LLC 941 Lake Forest Cir. Birmingham, AL 35244	3,055,394.12(B)	32.9%
Chandler D. Robinson, Chief Executive Officer and Director	117,252.8	1.2%
Christopher M. Starr, Executive Chairman	152,650	1.6%
Andrew P. Mazar, Executive Vice President of Research and Development, Chief Scientific Officer and Director	117,252.8	1.2%
Michael J. Brown, Director	210,000	2.3%
Raymond "Bill" Anderson, Director	1,000	*
Arthur Klausner, Director	5,000	*
Kim R. Tsuchimoto, Chief Financial Officer	26,390	*
Patrice P. Rioux, Acting Chief Medical Officer	7,000	*
Named executive officers and directors as a group ^(C)	7,803,212.6	81.0%

[Legend on next page]

- (A) Beneficial ownership is based upon 9,291,420.614 shares of our Common Stock outstanding; and includes common stock options that vest within 60 days after December 1, 2017 as follows – Chandler D. Robinson, Christopher M. Starr and Andrew P. Mazar options to purchase up to 103,250 shares of common stock, Kim R. Tsuchimoto options to purchase up to 26,390 shares of common stock and Patrice P. Rioux options to purchase up to 7,000 shares. These vested option shares are deemed to be outstanding and beneficially owned by the person holding the applicable options for the purpose of computing the percentage ownership of that person, but they are not treated as outstanding for the purpose of computing the percentage ownership of any other person.
- (B) Tactic Pharma LLC (“Tactic Pharma”) shares voting and investment power over 4,111,272.88 shares of our common stock owned by TacticGem, and Gem Pharmaceutical LLC (“Gem”) shares voting and investment power over 3,055,394.12 shares of our common stock owned by TacticGem, because pursuant to the TacticGem limited liability company agreement all votes of our common stock (other than votes for the election of directors) are passed through to Tactic Pharma and Gem in proportion to their percentage interests in TacticGem, and after an initial holding period, which ends after we have been subject to the reporting requirements of the Exchange Act and have 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. Mr. Brown, Dr. Mazar and Dr. Robinson are managers of Tactic Pharma; because of this, they control voting and dispositive power over 4,111,272.88 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.
- (C) Shares held by TacticGem are only included in the total beneficial ownership of our named executive officers and directors because the limited liability agreement of TacticGem provides that the Manager of TacticGem will vote our common stock held by TacticGem to elect Tactic Pharma’s nominees plus one person designated by Gem to our Board, and acting together the directors are able to control Tactic Pharma, LLC, and how it selects its nominees for our Board of Directors.

* Less than 1%

Item 5. Directors and Executive Officers.

The Members of our Board of Directors, each of whom serves until the next annual meeting of stockholders, and the executive officers of the Company, each of whom serves at the discretion of the Board of Directors are as follows:

Name	Age	Positions	Director Since
Christopher M. Starr, Ph.D.	65	Executive Chairman, Director, Member of the Audit Committee, the Compensation Committee, and the Corporate Governance & Nominating Committee	December 2014
Chandler D. Robinson, MD MBA MSc	33	Chief Executive Officer, Director	December 2014
Andrew P. Mazar, Ph.D.	55	Executive Vice President of Research and Development, Chief Scientific Officer, Director	December 2014
Kim R. Tsuchimoto	54	Chief Financial Officer	-
Patrice Rioux, MD Ph.D.	66	Acting Chief Medical Officer	-
Michael J. Brown, MSc	60	Director, Member of the Audit Committee, the Compensation Committee, and the Corporate Governance & Nominating Committee	December 2014
Raymond “Bill” Anderson	75	Director, Chair of the Audit Committee, Member of the Compensation Committee and the Corporate Governance & Nominating Committee	April 2017
Arthur Klausner, MBA	57	Director, Member of the Audit Committee, the Compensation Committee, and the Corporate Governance & Nominating Committee	August 2017
Kirsten Anderson	50	Senior Vice President, Clinical Development	-

Backgrounds of our executive officers and board members are discussed below.

Executive Officers and Board Members

Christopher M. Starr, PhD - Executive Chairman

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’s

primary responsibility as our Executive Chairman is to work with our Chief Executive Officer and the rest of our Board to set our strategic direction and provide guidance to, and oversight of our Chief Executive Officer. Our Chairman also sets the agenda for Board meetings and presides over them. Dr. Starr was the co-Founder and served as the initial chief executive officer (“CEO”) at Raptor Pharmaceuticals (“Raptor”), a public company (NASDAQ: RPTP), since 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 is the development and commercialization of treatments for rare diseases. Dr. Starr’s primary responsibilities as CEO included the day to day leadership and performance of Raptor which had one approved drug marketed in the U.S. and Europe. Dr. Starr co-founded BioMarin in 1997, a public company (NASDAQ: BMRN) where he last served as Senior Vice President and Chief Scientific Officer overseeing the approval of three drugs until starting Raptor in 2006. As Senior Vice President at BioMarin, Dr. Starr was responsible for managing a Scientific Operations team of 181 research, process development, manufacturing and quality personnel through the successful development of commercial manufacturing processes for its biologic enzyme replacement therapy and small molecule products, and supervised the cGMP design, construction and licensing of BioMarin’s proprietary biological manufacturing facility. From 1991 to 1997, Dr. Starr supervised research and commercial programs at BioMarin’s predecessor company, Glyko, Inc., where he served as Vice President of Research and Development. Prior to his tenure at Glyko, Inc., Dr. Starr was a National Research Council Associate at the National Institutes of Health. 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.

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

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. Dr. Robinson’s primary responsibilities as CEO are for our day to day leadership and performance. Since 2010, Dr. Robinson has been, and continues to be, a manager of Tactic Pharma LLC (“Tactic”), which he co-founded and led as CEO until it became a holding company in April 2014. Tactic acquired and developed preclinical and clinical stage compounds. In 2010, Tactic Pharma acquired a drug on which Dr. Robinson conducted research at Northwestern University. Tactic licensed the drug to a company in Europe and manufactured it for sale on a Named Patient basis throughout Europe. In April 2014, Tactic Pharma sold its remaining rights to the compound to three large European investment firms and this compound is currently in a Phase III clinical trial for Wilson disease. Among his previous experiences, Dr. Robinson in 2008 worked at Onyx Pharmaceuticals 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 13th year, and from 2006 to 2007 as part of a quantitative internal hedge-fund style team at Bear Stearns investment bank. He was previously on the board of Wilson Therapeutics, 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.

Andrew P. Mazar, PhD – Executive Vice President of Research and Development, and Chief Scientific Officer

Dr. Mazar is a co-founder and has been our Chief Scientific Officer and a Board Member of ours and our predecessor Monopar Therapeutics, LLC, since inception in December 2014. Dr. Mazar became our Executive Vice President of Research and Development effective as of November 1, 2017. Dr. Mazar's primary responsibilities for us are the day to day leadership and performance of our research and development activities. Dr. Mazar has spent 28 years working on drug discovery and development at the interface of academia and industry and has founded or co-founded 8 start-up companies to commercialize new drug discoveries, including Tactic Pharma LLC ("Tactic"), which acquired and developed preclinical and clinical stage compounds. He is also internationally recognized for his basic research work on the role of the urokinase plasminogen activator (uPA) system in tumor progression as well as mechanisms of cancer invasion and metastasis. Prior to joining Tactic Pharma, LLC in 2010 and the Chemistry of Life Processes Institute at Northwestern University in 2009, Dr. Mazar was the Chief Scientific Officer at Attenuon, LLC in San Diego from 2000 to 2009 and led discovery and development efforts resulting in three drugs entering oncology clinical trials. Dr. Mazar has now overseen 18 IND-enabling efforts, many of these focused on drugs discovered in academia.

Dr. Mazar is the previous Chair of the NCI Nanotechnology Alliance Animal Model working group (2011-2015) and has been a member of the NHLBI Scientific Review Board (SRB) for the SMARTT program since 2011. Dr. Mazar served as Associate Editor for Recent Patent Reviews on Anti - Cancer Drug Discovery (2010-2013) and is currently a member of the editorial board of Clinical Cancer Research. He most recently served as a charter member of the NIH Developmental Therapeutics Study Section (2012-2016), and has also served on study sections for the NCI, NIDDK, NHLBI, NIH Special Emphasis Panels, VA Oncology Merit Review, AHA and the Phillip Morris External Research Program. He is also the co-author of 110 peer reviewed publications and 18 reviews and book chapters, most recently contributing chapters on Cancer Invasion and Metastasis to the Oxford Textbook of Clinical Oncology and The Oxford Textbook of Cancer Biology. Dr. Mazar has founded or advised several start-up companies over the past 5 years including Tactic Pharma LLC, Valence Therapeutics, Wilson Therapeutics, Panther Biotechnology, Lung Therapeutics Inc., Actuate Therapeutics, AvidTox and Tempus.

Kim R. Tsuchimoto –Chief Financial Officer

Ms. Tsuchimoto was our Acting Chief Financial Officer since June 2015, and became employed as our Chief Financial Officer effective November 1, 2017. Ms. Tsuchimoto spent over nine years at Raptor, 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 served 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 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.

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

Dr. Rioux has been our Acting Chief Medical Officer since December 2016. Dr. Rioux's primary responsibilities include clinical development and regulatory (FDA & EMA) planning, coordination of clinical operations and statistical strategy, support of investor relationship. Dr. Rioux has been deeply involved in development of drugs for rare diseases for the last 20 years. His background includes development of drugs and biologic products for various indications across neurodegenerative diseases, immunology, pain management, oncology and metabolic diseases. 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. From 2009 to October 2014, Dr. Rioux was the Chief Medical Officer at Raptor where he was responsible for securing regulatory approval of PROCYSBI, a delayed-release cysteamine for the treatment of a lysosomal storage disease, nephropathic cystinosis, in both the United States and Europe. From 2005 to 2008 he served as the Chief Medical Officer at Edison Pharmaceuticals, and as from 2000 to 2003, he served as Vice President Clinical at Repligen, where he gained significant orphan disease experience in mitochondrial diseases as well as in autism, and auto-immune diseases. After several years as a clinical researcher at INSERM (France), he started his career in the pharmaceutical industry at Biogen in October 1995, working on multiple sclerosis, before joining Variagenics, Inc. in 1998, one of the first pharmacogenomic companies. Dr. Rioux received his Medical Education at Faculté de Médecine Pitié-Salpêtrière, his Ph.D. in Mathematical Statistics at Faculté des Sciences, and his Degree of Pharmacology (pharmacokinetics and clinical pharmacology) at Faculté de Médecine Pitié-Salpêtrière.

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. Mr. Brown is also the Administrator of the Monopar 2016 Stock Incentive Plan. Mr. Brown is the Co-Founder, and since 1994 has served as Chairman, and since 1996 as CEO, of Euronet Worldwide Inc. ("Euronet"), a public company (NASDAQ: EEFT) which offers payment and transaction processing and distribution solutions to financial institutions, retailers, service providers and individual consumer. Mr. Brown has been President of Euronet since December 2014 and also served as President of Euronet from December 2006 to June 2007. Mr. Brown has been a member of the Euronet board of directors since December 1996 and also served on the boards of Euronet's predecessor companies.. He has a Master of Science in molecular and cellular biology.

Raymond W. Anderson, MBA MS – Board Member

Mr. Anderson has been a Board Member of Monopar since April 2017. He has been chair of the audit committee since October 2017. Mr. Anderson has more than 35 years of biopharmaceutical/medical technology sector experience, primarily focused in financial management. Mr. Anderson worked at Dow Pharmaceutical Sciences, Inc. from July 2003 until 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 medical technology company. Prior to that, Mr. Anderson served as

Chief Operating Officer and Chief Financial Officer at BioMarin Pharmaceutical Inc. from June 1998 to January 2002. Prior to June 1998, Mr. Anderson held similar executive-level positions with other biopharmaceutical companies, including Syntex Laboratories, Chiron Corporation, Glycomed Incorporated and Fusion Medical Technologies. Mr. Anderson served as a board member and chair of the audit committee at Raptor Pharmaceutical Inc. from its founding in 2006 to its acquisition in 2016. Mr. Anderson also served as an officer in the United States Army Corps of Engineers, as a strategic planner and operational profit and loss manager at General Electric and as a finance manager at Memorex. 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 United States Military Academy.

Arthur Klausner – Board Member

Mr. Klausner has been a consultant to the biopharmaceutical industry since 2009. He served as Chief Executive Officer of Gem Pharmaceuticals, LLC (“Gem”) from September 2012 until Gem’s drug development assets were acquired by us in 2017. Gem’s lead, Phase II drug product candidate was GPX-150 (5-imino-13-deoxydoxorubicin), a proprietary analog of doxorubicin engineered specifically to retain the anticancer activity of doxorubicin while minimizing toxic effects on the heart. In addition to his role at Gem, Mr. Klausner served as CEO of Jade Therapeutics Inc. (“Jade”) from September 2012 until December 2015. Jade’s focus was on the development of proprietary, cross-linked hyaluronic acid formulations for ophthalmic applications until its March 2016 acquisition by EyeGate Pharmaceuticals, Inc. (NASDAQ: EYEG). Previously, Mr. Klausner spent a total of 18 years at the life science venture capital firms Domain Associates and Pappas Ventures, where he was involved in the investment in and subsequent nurturing of a variety of biotechnology, specialty pharmaceutical, and medical device companies. During that time, he was a member of the board of directors at Santarus (acquired by Salix Pharmaceuticals), X-Cepto Therapeutics (acquired by Exelixis), Orexigen Therapeutics, Inc. (NASDAQ: OREX), and Syndax Pharmaceuticals (NASDAQ: SNDX), and a board observer at Peninsula Pharmaceuticals (acquired by Johnson & Johnson) and Cerexa (acquired by Forest Laboratories). Mr. Klausner currently serves on the board of directors of Cennerv Pharma (S) Pte. Ltd. (Singapore), and on advisory boards for Neurotez, Inc., and the New York University Innovation Venture Fund. He received his M.B.A. from the Stanford University Graduate School of Business and his undergraduate degree in Biology from Princeton University.

Kirsten Anderson - Senior Vice President, Clinical Development

Ms. Anderson has more than 25 years of experience in the biotech and pharmaceutical industry, with expertise in oncology drug development, most recently as an independent clinical development consultant for us from February 2017 through October 2017. She became our Senior Vice President of Clinical Development effective November 1, 2017. From 2008 to 2016, she was at OncoGenex Pharmaceuticals, where she served as Vice President of Clinical Operations (March 2015 to November 2016). Since 2008, she has also held the following positions with OncoGenex: Director, Clinical Research (2008 to December 2010) and Senior Director, Clinical Research (January 2012 to February 2015). Prior to joining OncoGenex, Ms Anderson held clinical trial management positions at Sonus Pharmaceuticals, Xcyte Therapies, and Immunex, including the oversight of global clinical operations, drug safety and data management. She has a laboratory research background and began her career at the University of Pennsylvania. Ms. Anderson earned a degree in Biology from the University of Vermont and is completing her Masters in Biotech Enterprise (expected 2018) from Johns Hopkins University.

Agreement Regarding Election of Directors

The limited liability company agreement of TacticGem provides that the Manager of TacticGem is required to vote TacticGem's shares of our common stock to elect Tactic Pharma's nominees to our Board plus one person designated by Gem. The Gem board nomination right terminates at such time as we achieve a listing on a national stock exchange (e.g. NASDAQ, the NYSE or similar national stock exchange). Gem's initial designee for election to our Board was Arthur Klausner.

Board Composition and Election of Directors

Independence of the Board of Directors

We believe it is important to have independent directors on our Board who can make decisions without being influenced by personal interests. Additionally, because one of our goals is to qualify for listing with NASDAQ we are following the NASDAQ Stock Market ("NASDAQ") listing standards, which requires that a majority of the members of our Board of Directors must qualify as "independent," as affirmatively determined by our Board. Our Board consults with our counsel to ensure that our Board's determinations are consistent with relevant securities and other laws and regulations regarding the definition of "independent," including those set forth in pertinent listing standards of NASDAQ, as in effect from time to time.

Consistent with these considerations, after review of all relevant identified transactions or relationships between each director, or any of his 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. Dr. Robinson, our President and Chief Executive Officer, is not an independent director by virtue of his employment relationship with us, and similarly Dr. Mazar by virtue of his employment relationship with us is not an independent director.

There are no family relationships among any of our directors or executive officers.

Board Leadership Structure

We have structured our Board in a way that we believe effectively serves our objectives of corporate governance and management oversight. We separate the roles of Chief Executive Officer and Chairman of the Board in recognition of the differences between the two roles. We believe that the Chief Executive Officer should be responsible for Monopar's day to day leadership and performance, while our Executive Chairman of the Board should work with our Chief Executive Officer and the rest of our Board to set our strategic direction and provide guidance to, and oversight of our Chief Executive Officer. Our Executive Chairman also sets the agenda for Board meetings and presides over them.

Audit Committee

Our Board has formed an audit committee. Mr. Anderson has been appointed as chair of the audit committee. Mr. Anderson is a financial expert as defined by NASDAQ and is an independent board member as contemplated by Rule 10A-3 under the Exchange Act. In addition, Dr. Starr, Mr. Klausner and Mr. Brown have been appointed as independent members of the audit committee.

It is anticipated that the functions of our Audit Committee will include, among other things:

- appointing, approving the compensation of and assessing the independence of our independent public accounting firm;
- overseeing the work of our independent public accounting firm, including through the receipt and consideration of reports from such firm;
- reviewing and discussing with management and the independent public accounting firm our annual and quarterly financial statements and related disclosures;
- monitoring our internal control over financial reporting, disclosure controls and procedures and code of business conduct and ethics;
- overseeing our risk assessment and risk management policies;
- establishing policies and procedures for the receipt and retention of accounting related complaints and concerns;
- meeting independently with our independent public accounting firm and management;
- reviewing and approving or ratifying any related person transactions; and
- preparing the audit committee report required by SEC rules.

Corporate Governance and Nominating Committee

The Board has formed a Corporate Governance and Nominating Committee and has appointed Dr. Starr, Mr. Brown, Mr. Anderson and Mr. Klausner as members of the committee.

It is anticipated that the functions of our corporate governance and nominating committee will include, among other things:

- identifying individuals qualified to become board members;
- recommending to our board the persons to be nominated for election as directors and to each of the board's committees;
- reviewing and making recommendations to the board with respect to management succession planning;
- developing and recommending to the board corporate governance guidelines; and
- overseeing an annual evaluation of the board.

Compensation Committee

Our Board has also formed a Compensation Committee consisting of Mr. Brown Dr. Starr, Mr. Anderson and Mr. Klausner as independent members. It is anticipated that the compensation committee will engage independent third party compensation experts as needed.

The functions of our Compensation Committee is anticipated to include, among other things:

- annually reviewing and approving corporate goals and objectives relevant to our chief executive officer's compensation;
- determining our chief executive officer's compensation;
- reviewing and approving, or making recommendations to our board with respect to, the compensation of our other executive officers;
- overseeing an evaluation of our senior executives;
- overseeing and administering our equity incentive plans;
- reviewing and making recommendations to our board with respect to director compensation; and
- preparing the annual compensation committee report to the extent required by SEC rules.

Item 6. Executive Compensation.

Summary Compensation Table

The following table sets forth for the fiscal years ended December 31, 2017 and 2016, the compensation of the Company's Chief Executive Officer and the Company's two highest compensated executive officers whose compensation exceeded \$100,000 during our last fiscal year.

<i>Name and Positions</i>	<i>Fiscal Year</i>	<i>Salary (\$)</i>	<i>Bonus (\$)</i>	<i>Option Awards (\$)</i>	<i>All Other Compensation (\$)</i>	<i>Total (\$)</i>
Chandler D. Robinson, M.D., Chief Executive Officer and Director	2017	318,750	-	23(1)	70,000(2)	388,773
	2016	300,000	-	41(1)	75,000(2)	375,041
Andrew P. Mazar, Ph.D., Chief Scientific Officer and Director	2017	87,500	-	220,466(1)	238,750(3)	546,716
	2016	-	-	41(1)	197,500(3)	197,541
Kirsten Anderson, Senior Vice President, Clinical Development(4)	2017	43,333	25,000	5,502	78,550	152,385
	2016	-	-	-	-	-

(1) In 2016, each of Dr. Robinson and Dr. Mazar was granted options to purchase up to 84,000 shares of our common stock 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 stock options was \$41 and the value of Dr. Mazar's stock options was \$41 for the year ended December 31, 2016. The options 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).

In 2017, each of Dr. Robinson and Dr. Mazar was granted options to purchase up to 84,000 shares of our common stock 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 stock options outstanding as of December 31, 2017 was \$23 and the value of Dr. Mazar's stock options outstanding as of December 31, 2017 was \$220,466 for the year ended December 31, 2017. The options granted in 2017 vested 6/48ths on the six month anniversary of grant date (August 20, 2017) and 1/48th per month thereafter.

(2) Consisting of an employer funded 401(k) in the amount of \$54,000 and \$53,000 for 2017 and 2016, respectively, plus \$16,000 and \$22,000 in lieu of benefits for 2017 and 2016, respectively.

(3) Until November 1, 2017, Dr. Mazar was a consultant acting as chief scientific officer for \$225,000 and \$197,500 in consulting fees in 2017 and 2016, respectively, with no additional compensation for board member services. As of November 1, 2017, Dr. Mazar became employed as our Executive Vice President of Research and Development, and Chief Scientific Officer at an annual base salary of \$350,000 and in lieu of benefits of \$55,000. A pro rata amount of in lieu of benefits of \$13,750 is included in All Other Compensation.

(4) Until November 1, 2017, Ms. Anderson was a consultant during 2017 providing clinical development strategy for \$78,550 in consulting fees. As of November 1, 2017, Ms. Anderson became employed as our Senior Vice President, Clinical Development at an annual base salary of \$260,000 and a sign-on bonus of \$25,000. On November 1, 2017, Ms. Anderson was granted options to purchase up to 40,000 shares of our common stock 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 Ms. Anderson's stock options outstanding as of December 31, 2017 was \$5,523. The options vest 6/48ths on the six month anniversary of grant date (May 1, 2018) and 1/48th per month thereafter.

Employment Agreements

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 employment agreement, Dr. Robinson currently receives a \$375,000 per year 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 will be eligible for an annual performance bonus, of up to 50% of his base salary, based on achieving goals as determined by our Board and our Compensation Committee. Until we obtain retirement and healthcare benefits for our eligible employees and Dr. Robinson elects to opt in to such benefits, Dr. Robinson is entitled to an additional salary of at least \$4,583.33 per month (or such greater amount as determined by our Board) in lieu of such benefits.

On November 1, 2017, we entered into an employment agreement with Dr. Mazar for his role as our Executive Vice President of Research and Development and Chief Scientific Officer. Dr. Mazar's employment agreement is for an indefinite term (for at-will employment). Under his employment agreement, Dr. Mazar receives a \$350,000 per year base salary, which may be adjusted from time to time in accordance with normal business practice and in our sole discretion. In addition, Dr. Mazar will be eligible for an annual performance bonus, of up to 40% of his base salary, based on achieving goals as determined by our Board and our Compensation Committee. Until we obtain retirement and healthcare benefits for our eligible employees and Dr. Mazar elects to opt in to such benefits, Dr. Mazar is entitled to an additional salary of at least \$4,583.33 per month (or such greater amount as determined by our Board) in lieu of such benefits.

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). Under her employment agreement, Ms. Tsuchimoto receives a \$68,750 per year base salary to reflect 25% time, which may be adjusted from time to time in accordance with normal business practice and in our sole discretion. In addition, Ms. Tsuchimoto will be eligible for an annual performance bonus determined by our Board and our Compensation Committee.

On November 1, 2017, we entered into an employment agreement with Ms. Anderson for her role as our Senior Vice President of Clinical Development. Ms. Anderson's employment agreement is for an indefinite term (for at-will employment). Under her employment agreement, Ms. Anderson

receives a \$260,000 per year base salary, which may be adjusted from time to time in accordance with normal business practice and in our sole discretion. Ms. Anderson's employment agreement includes a \$25,000 sign-on bonus. In addition, Ms. Anderson will be eligible for an annual performance bonus determined by our Board and our Compensation Committee.

Outstanding Equity Awards at Fiscal Year End

The following table sets forth outstanding stock option awards held by named executive officers as of December 31, 2017. There were no outstanding stock awards as of December 31, 2017.

<i>Name</i>	<i>Number of securities underlying unexercised options (#) exercisable</i>	<i>Number of securities underlying unexercised options (#) unexercisable</i>	<i>Option exercise price (\$)</i>	<i>Option expiration date</i>
Chandler D. Robinson, M.D.	17,500(1)	66,500(1)	\$0.001	February 19, 2027
	84,000(2)	-	\$0.001	April 3, 2026
Andrew P. Mazar, Ph.D	17,500(1)	66,500(1)	\$0.001	February 19, 2027
	84,000(2)	-	\$0.001	April 3, 2026
Kirsten Anderson	- (3)	40,000(3)	\$6.00	October 31, 2027

(1) Both Dr. Robinson and Dr. Mazar 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.

(2) Both Dr. Robinson and Dr. Mazar 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).

(3) Ms. Anderson was granted a stock option award on November 1, 2017 which vests 6/48ths on the six month anniversary of grant date (May 1, 2018) and 1/48th per month thereafter.

Potential Payments upon Termination or Change in Control

Each of Dr. Mazar's and Dr. Robinson's employment agreements provides that upon execution and effectiveness of a release of claims, Dr. Mazar and Dr. Robinson will be entitled to severance payments if we terminate their employment without cause, as defined in the employment agreement, or if Dr. Mazar or Dr. Robinson terminates his employment with us for good reason, as defined in the employment agreement. If employment terminates under these circumstances, in each case absent a change in control, as defined in the employment agreements, we will be obligated for a period of twelve months, (1) to pay base salary, (2) to provide that any equity

awards will continue vesting, (3) to pay the monthly premiums for COBRA coverage equal to the amount paid for similarly situated employees and (4) to the extent allowed by applicable law and the applicable plan documents, continue to provide all of our employee benefit plans and arrangements that the employee was receiving at the time of termination. In addition, equity awards held by the terminated employee, that vest solely on the passage of time, will be accelerated by 12 months. If employment terminates under these circumstances, within 12 months following a change in control, in addition to the severance described above, we will be obligated to accelerate in full the vesting of all of the employee's outstanding equity awards. [In the case of a change in control, instead of the 12 months of base salary described above, we will be obligated to provide an amount equal to one-and-a-half times the sum of the base salary and target bonus for the fiscal year in which termination occurred. If either of Dr. Mazar's or Dr. Robinson's employment is terminated because of death or permanent disability, we will be obligated to provide the severance described above, but for a period of three months instead of twelve months.](#)

Ms. Anderson's employment agreement provides that upon execution and effectiveness of a release of claims, Ms. Anderson will be entitled to severance payments if we terminate her employment without cause, as defined in the employment agreement, or if Ms. Anderson terminates her employment with us for good reason, as defined in the employment agreement. If employment terminates under these circumstances, absent a change in control, as defined in the employment agreement, we will be obligated for a period of three months to pay base salary, and for a period of six months (1) to provide that any vested and unexercised equity awards continue to be exercisable and (2) to pay the monthly premiums for COBRA coverage. If employment terminates within six months following a change in control, we will be obligated to pay six months base salary and monthly premiums for COBRA coverage for six months and accelerate in full the vesting of all of the employee's outstanding equity awards which would be exercisable for two years from termination. [If Ms. Anderson's employment is terminated because of death or permanent disability, we will be obligated to provide base salary for two months and monthly premiums for COBRA coverage for two months.](#)

Stock Option Plan

In April 2016, our Board and stockholders holding more than a majority of our outstanding convertible preferred stock approved the Monopar Therapeutics Inc. 2016 Stock Incentive Plan (as subsequently amended, the "Plan"), allowing us to grant up to an aggregate 700,000 shares of stock awards, stock options, stock appreciation rights and other stock-based awards to employees, directors and consultants. Concurrently, our Board granted to board members and our acting chief financial officer stock options to purchase up to an aggregate 273,000 shares of our common stock at an exercise price of \$0.001 per share (the par value) based upon a third party valuation of the our common stock. Such stock options vest 50% on grant date, 25% on the six month anniversary of the grant date and 25% on the one year anniversary of the grant date. In December 2016, our Board granted to our acting chief medical officer options to purchase up to 7,000 shares of our common stock. Such options vest pro rata monthly over six months from the grant date. In February 2017, our Board granted to board members and our acting chief financial officer stock options to purchase up to an aggregate 275,520 shares of our common stock at an exercise price of \$0.001 per share (the par value) based upon a third party valuation of the our common stock. Such options vest 6/48ths upon the six month anniversary of the grant date and 1/48th per month thereafter. In September 2017 and November 2017, stock options to purchase up to an aggregate 103,072 shares of our common stock were granted at an exercise price of \$6.00, based on the price per share at which common stock was sold in our most recent private offering. 61,024 of such options vest 6/48ths upon the six month anniversary of the grant date and 1/48th per month thereafter, 21,024 of such options vest 6/42nd upon the six month anniversary of the grant date and 1/42nd per month thereafter and 21,024 of such options vest 6/24ths upon the six month anniversary of the grant date and 1/24th per month thereafter. All outstanding stock options have a ten year term. 658,592 stock options were outstanding as of December 1, 2017.

Under the Plan, the per share exercise price for the shares to be issued upon exercise of an option is to be determined by the Plan administrator, except that the per share exercise price may be no less than 100% of the fair market value per share on the grant date. Fair market value is established by our Board, using third party valuation reports. Stock options generally expire after ten years.

The Plan provides that the Plan administrator will be our Board, a committee designated by our Board, or an individual designee. Our independent Directors reaffirmed the appointment of Mr. Brown as the Board-representative Administrator of our 2016 Stock Incentive Plan. The Administrator has exclusive authority, consistent with laws and the terms of the Plan, to designate recipients of options to be granted thereunder and to determine the number and type of options and the number of shares subject thereto. In March 2017, at the time of the Conversion, which resulted in a 70 for 1 split of our common stock, the Administrator effected the 70 for 1 stock split for the Plan which increased the stock option pool from 10,000 to 700,000 and changed the stock options granted in 2016 and in February 2017 by a 70 for 1 factor. No other features were changed on the outstanding stock options granted.

The Plan was subsequently amended and restated in October 2017, which was approved by stockholders holding more than a majority of our outstanding common stock, as the Amended and Restated Monopar Therapeutics Inc. 2016 Stock Incentive Plan, in order to increase the maximum aggregate grants under the Plan from 700,000 to 1,600,000 shares of stock awards, stock options, stock appreciation rights and other stock-based awards.

Director Compensation for Fiscal Year Ended December 31, 2017

The following table sets forth the compensation of our Board of Directors who were not also named executive officers during the year ended December 31, 2017.

<i>Name</i>	<i>Fees earned or paid in cash (\$)</i>	<i>Option Awards (\$)</i>	<i>All Other Compensation (\$)</i>	<i>Total (\$)</i>
Christopher M. Starr, Ph.D.	100,897	23(1)	-	100,920
Michael J. Brown	20,000	9,652(2)	-	29,652
Raymond "Bill" Anderson	37,500	5,672(3)	-	43,172
Arthur Klausner	14,022	5,615(4)	-	19,637

(1) Based upon the Black-Scholes valuation model for stock option compensation expense, the value of Dr. Starr's stock options outstanding as of December 31, 2017 was \$23 for the year ended December 31, 2017. Dr. Starr was granted a stock option award 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. In 2016, Dr. Starr was granted a stock option award 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).

(2) Based upon the Black-Scholes valuation model for stock option compensation expense, the value of Mr. Brown's stock options outstanding as of December 31, 2017 was \$9,652 for the year ended December 31, 2017. Mr. Brown was granted a stock option award on September 18, 2017 which vests 6/24ths on the six month anniversary of grant date (March 18, 2018) and 1/24th per month thereafter.

(3) Based upon the Black-Scholes valuation model for stock option compensation expense, the value of Mr. Anderson's stock options outstanding as of December 31, 2017 was \$5,672 for the year ended December 31, 2017. Mr. Anderson was granted a stock option award on September 18, 2017 which vests 6/42nds on the six month anniversary of grant date (March 18, 2018) and 1/42nd per month thereafter.

(4) Based upon the Black-Scholes valuation model for stock option compensation expense, the value of Mr. Klausner's stock options outstanding as of December 31, 2017 was \$5,615 for the year ended December 31, 2017. Mr. Klausner was granted a stock option award on September 1, 2017 which vests 6/48ths on the six month anniversary of grant date (March 1, 2018) and 1/48th per month thereafter.

Options Exercised and Stock Vested

None of our executive officers exercised any options during the years ended December 31 2017 and 2016.

Item 7. Certain Relationships and Related Transactions, and Director Independence.

Since January 2015, we (including as Monopar Therapeutics, LLC) have engaged in the following transactions with our directors, executive officers, holders of more than 5% of our voting securities, and affiliates or immediately family members of our directors, executive officers and holders of more than 5% of our voting securities, and our co-founders. We believe that all of these transactions were on terms as favorable as could have been obtained from unrelated third parties.

Contributions by Tactic Pharma, LLC

We were initially formed as a Delaware limited liability company in December 2014, with the name Monopar Therapeutics, LLC, at which time Tactic Pharma contributed technology and related assets to us, in exchange for 1,000,000 shares of Series Z Preferred Units, which were

exchanged for 100,000 shares of Series Z Preferred Stock at the time of our conversion to a corporation. The issued Series Z Preferred Stock was recorded at par value \$0.001 per share on our balance sheet reflecting the historical capitalized cost basis, due to the fact that MNPR-101's development costs were previously expensed (not capitalized) by Tactic Pharma. In March 2017, the 100,000 shares of Series Z Preferred Stock were converted into 7,000,000 shares of our common stock, \$.0001 par value in connection with the Conversion. See "**Conversion of Preferred Stock to Common Stock**".

In August 2017, Tactic Pharma surrendered 2,888,727.12 shares of our common stock back to us in order to satisfy one of the pre-closing conditions in the Gem Transaction. This reduced its ownership percentage of our common stock from 79.5% to 69.9%.

Gem Transaction

On June 27, 2017, we signed a term sheet with Gem Pharmaceuticals, LLC ("Gem") pursuant to which Gem was to transfer assets related to certain of its drug product candidate programs to us in exchange for 32% of our outstanding common stock on a fully-diluted basis. The Gem transaction was structured through a limited liability company, TacticGem, which Gem formed with Tactic Pharma, LLC ("Tactic Pharma"), our largest shareholder at that time. Gem contributed certain of Gem's drug product candidates' intellectual property and agreements associated primarily with Gem's GPX-150 drug product candidate program, along with \$5,000,000 in cash (the "Gem Contributed Assets") to TacticGem for a 42.633% interest, and Tactic Pharma contributed 4,111,272.88 shares of our common stock to TacticGem for a 57.367% interest. Then, TacticGem contributed the Gem Contributed Assets to us in exchange for 3,055,394.12 newly issued shares of our common stock (31.4% on a fully-diluted basis) (the two contributions collectively, the "Gem Transaction"). The contribution by TacticGem, made in conjunction with contributions from outside investors in a private offering, was intended to qualify for tax-free treatment and to satisfy a condition to the Gem Transaction that we have a certain level of cash on hand prior to the contribution. The Gem Transaction closed on August 25, 2017. Following the Gem Transaction, TacticGem owns 7,166,667 shares of our stock. Pursuant to the TacticGem limited liability company agreement, all votes of our common stock by TacticGem (aside from the election of our Board of Directors) is required to be passed through to Tactic Pharma and Gem based on their percentage interest (currently pursuant to this voting agreement, Tactic has voting and investment power over 4,111,272.88 shares of our common stock and Gem has voting and investment power over 3,055,394.12 shares of our common stock). Neither Gem nor TacticGem was a related person prior to the Gem Transaction. The TacticGem limited liability company agreement provides that its manager will vote all shares of our common stock held by it to elect Tactic Pharma's nominees to our Board of Directors plus one person nominated by Gem, initially Arthur Klausner.

Pursuant to the Conversion and the Gem Transaction and sales of our common stock in September 2017, Tactic Pharma now holds voting and investment power over 4,277,939.88 shares of our Common Stock, which is 46.0% of our outstanding common stock. In the ordinary course of business, we have reimbursed and continue to reimburse Tactic Pharma for expenses Tactic Pharma has paid on our behalf, which historically included legal patent fees and storage rental fees. Certain of our Board Members and executive officers own and control Tactic Pharma. Although no single person has a controlling interest in Tactic Pharma, acting together they are able to control Tactic Pharma and a large voting block of our common stock.

We reimbursed Tactic Pharma a de minimus amount in monthly storage fees during the nine months ended September 30, 2017 and the year ended December 31, 2016. In April 2017, Tactic Pharma purchased 166,667 shares of our common stock at \$6.00 per share.

During the nine months ended September 30, 2017 and the year ended December 31, 2016, we paid or accrued legal fees to Baker & Hostetler, LLP, a large national law firm in which Barry Robinson, our Chief Executive Officer's family member is a law partner, of approximately \$201,508 and \$54,000, respectively. The family member billed a de minimis amount of time on our legal engagement with Baker & Hostetler, LLP.

Stock Purchases by Directors and Executive Officers

The following table sets forth the number of shares of our common stock owned by our co-founders; each co-founder purchased such shares at \$3.57 per share (taking into account the Conversion) in 2016.

Name	Related Person Status	# Shares of Common Stock	Transaction Value (and Related Person's Interest) (\$)
Christopher M. Starr, Ph.D.	Executive Chairman	29,400	105,000
Chandler D. Robinson, M.D.	Director, Chief Executive Officer	14,002.3	50,010
Andrew P. Mazar, Ph.D.	Director, Chief Scientific Officer	14,002.3	50,010

Also in 2016, Michael Brown (Director), purchased 210,000 shares of our common stock (taking into account the Conversion), at \$3.57 per share, for a total transaction value of \$750,000.

In 2017, Board members purchased shares of our common stock at \$6.00 per share, as follows: Dr. Starr purchased 20,000 shares for a transaction value of \$120,000.00; Mr. Anderson purchased 1,000 shares for a transaction value of \$6,000.00; and Mr. Klausner purchased 5,000 shares for a transaction value of \$30,000.00.

Promoters and Certain Control Persons

We have not had any promoters since our formation in December 2014.

Parent Companies

Prior to the Gem Transaction, Tactic Pharma was our parent company, having a controlling interest in us. After the Gem Transaction, TacticGem became our parent company, currently having a 77.1% controlling interest in us. See “**Contribution by Tactic Pharma, LLC**” and “**Gem Transaction**”.

Director Independence

We have decided to follow the NASDAQ Stock Market, or NASDAQ, listing standards, which require that a majority of the members of our Board of Directors, or our Board, must qualify as “independent,” as affirmatively determined by our Board. Our Board consults with our counsel to ensure that our Board’s determinations are consistent with relevant securities and other laws and regulations regarding the definition of “independent,” including those set forth in pertinent listing standards of NASDAQ, as in effect from time to time.

Consistent with these considerations, after review of all relevant identified transactions or relationships between each director, or any of his family members, and us, our senior management and our independent registered public accounting firm, our Board has affirmatively determined that the following four 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. Dr. Robinson, our President and Chief Executive Officer is not an independent director by virtue of his employment relationship with us, and similarly, Dr. Mazar by virtue of his employment relationship with us is not an independent director.

There are no family relationships among any of our directors or executive officers.

Relationships Considered in Determining Director Independence

In addition to the stock transactions described above, in considering director independence, we considered the following transactions:

During the six months ended June 30, 2017 and the year ended December 31, 2016, we were advised by four members of our Board of Directors, who were Managers of the LLC prior to our conversion to a C Corporation. The four former Managers are also our current common stockholders (owning approximately an aggregate 3% of our common stock outstanding as of June 30, 2017). Three of the former Managers are also Managers of Tactic Pharma, LLC, which was, prior to the Gem Transaction, our largest and controlling stockholder (owning 82.6% of us at June 30, 2017). The Managers of Tactic Pharma, LLC were paid the following during the six months ended June 30, 2017 and the year ended December 31, 2016: Chandler D. Robinson, our Co-Founder, Chief Executive Officer, common stockholder, Manager of Tactic Pharma, LLC and former Manager of Monopar Therapeutics, LLC, \$161,000 and \$322,000, respectively; and Andrew P. Mazar, our Co-Founder, Chief Scientific Officer, common stockholder, Manager of Tactic Pharma, LLC and former Manager of Monopar Therapeutics, LLC, \$150,000 and \$197,500, respectively. We also paid Christopher M. Starr, our Co-Founder, Executive Chairman of the Board of Directors, common stockholder and former Manager of Monopar Therapeutics, LLC, \$50,449 and \$96,339 during the six months ended June 30, 2017 and the year ended December 31, 2016, respectively.

In the normal course of business, our Chief Executive Officer, Board Members and consultants incur expenses on behalf of us and are reimbursed within 30 days of submission of relevant expense reports.

Item 8. Legal Proceedings.

We are not party to any material legal proceedings.

Item 9. Market Price of and Dividends on the Registrant's Common Equity and Related Stockholder Matters.***Market Information***

There is no established public trading market in our common stock. Our securities are not listed for trading on any national securities exchange nor are bid or asked quotations reported in any over-the-counter quotation service.

Rule 144 Eligibility

As of December 1, 2017, 1,335,079.3 shares of our common stock are eligible for sale under Rule 144.

We expect approximately 1,335,079.3 shares of our common stock will be eligible for sale under Rule 144 following the effective date of this Form 10. We cannot estimate the number of shares of our common stock that our existing stockholders will elect to sell under Rule 144.

Holdings

As of December 1, 2017, there were 9,291,420.614 shares of our common stock outstanding held by 43 holders. In addition there were nine holders of stock options to purchase up to 658,592 shares of our common stock.

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.

Securities Authorized for Issuance Under Equity Compensation Plans

As of December 31, 2015, we did not have any stock options outstanding. The following table provides information as of December 31, 2016, with respect to shares of our common stock that may be issued under existing equity compensation plans. There are no equity compensation plans that have not been approved by our security holders.

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)	280,000	\$.001	420,000

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

Registration Rights

We are subject to an agreement with TacticGem (pursuant to the Gem Transaction), which obligates us to file Form S-3 or other appropriate form of registration statement covering the resale of any of our Common Stock by TacticGem, Gem, or Tactic, 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.

Item 10. Recent Sales of Unregistered Securities.

Set forth below is information regarding shares of common stock issued and options granted by us since our formation in December 2014, that were not registered under the Securities Act. Also included is the consideration, if any, received by us, for such shares and options and information relating to the Securities Act, or rule of the SEC, under which exemption from registration was claimed. No underwriters were involved in the foregoing issuances of securities. Below this description of recent sales of unregistered securities is a description of the exemptions from registration which were applicable to each sale or grant.

(a) In December 2014, 1,000,000 Common Class Z Units of Monopar Therapeutics, LLC, our predecessor entity, were sold to Tactic Pharma, LLC in exchange for the contribution of all intellectual property rights related to MNPR-101, valued at \$30 per Unit. These Units were converted into 100,000 shares of Series Z Preferred Stock when we converted to a corporation on December 16, 2015, and were further converted into 7,000,000 shares of our Common Stock pursuant to the “Conversion” in March 2017. This was a private placement of Securities to a single owner upon the formation of the Company, and the Units were sold pursuant to the exemption from registration under the Act, set forth in Section 4(a)(2) of the Act.

(b) In May and June 2015, 116,438 Preferred Class A Units of Monopar Therapeutics, LLC, our predecessor entity, were sold to accredited investors at a price of \$30 per Unit. These Units were converted into 11,643.8 shares of Series A Preferred Stock when we converted to a corporation on December 16, 2015 and were further converted into 978,079.3 shares of our Common Stock pursuant to the “Conversion” in March 2017.

(c) During March and April 2016, 4,250 shares of Series A Preferred Stock were sold to accredited investors, at a price of \$300 per share (after a 10:1 split of the previous shares). These shares were converted into 357,000 shares of our Common Stock pursuant to the “Conversion” in March 2017.

(d) On April 4, 2016, we granted stock options for 1,200 shares of our Common Stock to each of Dr. Christopher M. Starr, Dr. Chandler D. Robinson, and Dr. Andrew P. Mazar in exchange for services. Pursuant to the “Conversion” in March 2017, these options were each adjusted to be for 84,000 shares. On the same date, we granted a stock option for 300 shares of our Common Stock to Kim R. Tsuchimoto in exchange for services, which was adjusted to be for 21,000 shares pursuant to the Conversion. The exercise price of each of these stock options was \$0.001 per share and the stock options expire on April 3, 2026.

(e) On December 15, 2016, we granted an option for 100 shares of our Common Stock to Dr. Patrice P. Rioux in exchange for services. Pursuant to the “Conversion” in March 2017, the option was adjusted to be for 7,000 shares. The exercise price of the option was \$0.001 per share and the option expires on December 14, 2026.

(f) On February 20, 2017, we granted stock options for 1,200 shares of our Common Stock to each of Dr. Christopher M. Starr, Dr. Chandler D. Robinson, and Dr. Andrew P. Mazar in exchange for services. Pursuant to the “Conversion” in March 2017, these stock options were each adjusted to be for 84,000 shares. On the same date, we granted a stock option for 336 shares of our Common Stock to Kim R. Tsuchimoto in exchange for services, which was adjusted to be for 23,520 shares pursuant to the Conversion. The exercise price of each of these options was \$0.001 per share and the options expire on February 19, 2027.

(g) During March 2017 through June 2017, 340,840.33 shares of Common Stock were sold to accredited investors at a price of \$6.00 per share.

(h) During August 2017 through September 2017, 448, 834 shares of Common Stock were sold to accredited investors at a price of \$6.00 per share.

(i) On September 1, 2017, we granted options for 21,024 shares of Common Stock to Arthur Klausner, and on September 18, 2017, we granted options for 21,024 shares of Common Stock to each of Michael J. Brown and Raymond W. Anderson, in exchange for services. The exercise price of the options was \$6.00 per share and the options expire on August 31, 2027 and September 17, 2027, respectively.

(j) On August 25, 2017, 3,055,394.12 shares of our Common Stock were issued to TacticGem in exchange for the Gem Contributed Assets (including assets and \$5 million in cash) as part of the Gem Transaction.

(k) On November 1, 2017, we granted options for 40,000 shares of Common Stock to Kirsten Anderson in exchange for services. The exercise price of the options was \$6.00 per share and the options expire on October 31, 2027.

(l) On January 1, 2018, we granted options for 32,004 shares of Common Stock to Patrice Rioux in exchange for services. The exercise price of the option was \$6.00 per share and the options expire on December 31, 2027.

The offers, sales and issuances of the securities described in paragraphs (d), (e), (f), (i), and (k) were deemed to be exempt from registration under the Securities Act in reliance on both Section 4(a)(2) of the Act and Rule 701 in that the transactions were under compensatory benefit plans and contracts relating to compensation as provided under Rule 701. The recipients of such securities were our employees, officers, bona fide consultants and advisors and received the securities under our Plan. Appropriate legends were affixed to the securities issued in these transactions. Each of the recipients of securities in these transactions had adequate access, through employment, business or other relationships, to information about us and had knowledge and experience to make the decision to accept the stock options.

The offers, sales and issuances of the securities described in paragraph (b), (c), (g), (h), and (j) were deemed to be exempt from registration under the Securities Act in reliance on Rule 506(b) of Regulation D in that the issuance of securities to the accredited investors did not involve a public offering. The recipients of securities in each of these transactions acquired the securities for investment only and not with a view to or for sale in connection with any distribution thereof. Each of the recipients of securities in these transactions was an accredited investor under Rule 501 of Regulation D. Form D was filed related to the offer described in paragraph (b) on June 18, 2015; Form D was filed related to the offer described in paragraph (c) on June 18, 2015; Form D was filed related to the offer described in paragraph (g) on March 28, 2017; and Form D was filed related to the offer described in paragraph (h) on August 23, 2017.

Item 11. Description of Registrant's Securities to be Registered.

We are registering on this Registration Statement only our common stock. We have the authority to issue 40,000,000 shares of Common Stock, \$0.001 par value. As of December 1, 2017 there were 9,291,420.614 shares of our Common Stock issued and outstanding.

We have reserved 1,600,000 shares of our Common Stock for issuance under our 2016 Stock Incentive Plan, as subsequently amended (the "Plan"), and as of December 1, 2017, we have granted stock options to purchase up to 658,592 shares of our Common Stock under the Plan. See "**Stock Option Plan**".

Dividend Rights

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

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 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.

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 of directors 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 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.

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

Our Second Amended and Restated Certificate of Incorporation and 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 of Directors. In addition, our Amended and Restated By-laws establish an advance notice procedure for proposals to be brought before a special meeting of our stockholders. 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 are 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, require a greater percentage. Our Amended and Restated By-laws may be amended or repealed by a majority vote of our board of directors 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.

Item 12. Indemnification of Directors and Officers.

Delaware Law

Section 102 of the General Corporation Law of the State of Delaware permits a corporation to eliminate the personal liability of directors of a corporation to the corporation or its stockholders for monetary damages for a breach of fiduciary duty as a director, except where the director breached his duty of loyalty, failed to act in good faith, engaged in intentional misconduct or knowingly violated a law, authorized the payment of a dividend or approved a stock repurchase in violation of Delaware corporate law or obtained an improper personal benefit.

Section 145 of the General Corporation Law of the State of Delaware provides that a corporation has the power to indemnify a director, officer, employee, or agent of the corporation, or a person serving at the request of the corporation for another corporation, partnership, joint venture, trust or other enterprise in related capacities against expenses, including attorneys' fees, judgments, fines and amounts paid in settlement actually and reasonably incurred by the person in connection with an action, suit or proceeding to which he was or is a party or is threatened to be made a party to any threatened, pending or completed action, suit or proceeding by reason of such position, if such person acted in good faith and in a manner he reasonably believed to be in or not opposed to the best interests of the corporation, and, in any criminal action or proceeding, had no reasonable cause to believe his conduct was unlawful, except that, in the case of actions brought by or in the right of the corporation, no indemnification shall be made with respect to any claim, issue or matter

as to which such person shall have been adjudged to be liable to the corporation unless and only to the extent that the Court of Chancery or other adjudicating court determines that, despite the adjudication of liability but in view of all of the circumstances of the case, such person is fairly and reasonably entitled to indemnity for such expenses which the Court of Chancery or such other court shall deem proper.

Second Amended and Restated Certificate of Incorporation

Our Certificate of Incorporation provides that we are required to provide indemnification and advancement of expenses to our directors, officers or other agents to the fullest extent permitted by Delaware's General Corporation Law. Our Certificate of Incorporation limits the personal liability of directors for breach of fiduciary duty to the maximum extent permitted by the Delaware General Corporation Law and provides that no director will have personal liability to us or to our stockholders for monetary damages for breach of fiduciary duty or other duty as a director. However, these provisions do not eliminate or limit the liability of any of our directors for:

- for any breach of the director's duty of loyalty to us or our stockholders;
- or acts or omissions not in good faith or that involve intentional misconduct or a knowing violation of law, fraud, or gross negligence;
- for voting for or assenting to unlawful payments of dividends, stock repurchases or other distributions; or
- for any transaction from which the director derived an improper personal benefit.

In addition, our Certificate of Incorporation provides that, to the fullest extent permitted by Delaware's General Corporation Law, we will indemnify each person who was or is a party or threatened to be made a party to any threatened, pending or completed action, suit or proceeding, other than an action by or in the right of the Company, by reason of the fact that he or she is or was, or has agreed to become, a director or officer, or is or was serving, or has agreed to serve, at our request as a director, officer, partner, employee or trustee of, or in a similar capacity with, another corporation, partnership, joint venture, trust or other enterprise (all such persons being referred to as an "Indemnitee"), or by reason of any action alleged to have been taken or omitted in such capacity, against all expenses, including attorneys' fees, judgments, fines and amounts paid in settlement actually and reasonably incurred in connection with such action, suit or proceeding and any appeal therefrom, if such Indemnitee acted in good faith and in a manner he or she reasonably believed to be in, or not opposed to, our best interests, and, with respect to any criminal action or proceeding, he or she had no reasonable cause to believe his or her conduct was unlawful.

Indemnification Agreements

We have previously entered into consulting agreements with certain of our officers and directors, Andrew P. Mazar and Kim Tsuchimoto, pursuant to which we have agreed to indemnify each of such officers and directors from and against all liabilities, losses, damages, expenses, charges and fees which he or she may sustain or incur by reason of any claim which may be asserted against such officer or director arising out of or attributable to us or our employees or contractors.

Insurance

We maintain a general liability insurance policy that covers certain liabilities of directors and officers of our corporation arising out of claims based on acts or omissions in their capacities as directors or officers.

Item 13. Financial Statements and Supplementary Data.

Our audited financial statements for the years ended December 31, 2016 and 2015, and unaudited condensed financial statements for the nine months ended September 30, 2017 and 2016 may be found beginning on page F-1 of this Registration Statement.

Item 14. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure.

None.

Item 15. Financial Statements and Exhibits

(a) Financial Statements

	Page Number
Unaudited condensed financial statements for the nine months ended September 30, 2017 and 2016	F-1
Audited financial statements for the years ended December 31, 2016 and 2015	F-45

(b) Exhibit Index

Exhibit	Document
3.1	Second Amended and Restated Certificate of Incorporation
3.2	Amended and Restated Bylaws
10.1*	Clinical Trial and Option Agreement with Cancer Research UK
10.2*	License Agreement with XOMA Ltd.
10.3*	Option and License Agreement with Onxeo S.A.
10.4*	Contribution Agreement (351) – Containing Registration Rights Agreement with TacticGem
10.5	Amended and Restated 2016 Stock Incentive Plan
10.6	Employment Agreement of Chandler D. Robinson – terminated October 31, 2017
10.7	Employment Agreement of Chandler D. Robinson – effective November 1, 2017
10.8	Consulting Agreement of Kim Tsuchimoto – terminated October 31, 2017
10.9	Employment Agreement of Kim Tsuchimoto – effective November 1, 2017
10.1	Consulting Agreement of Andrew P. Mazar – terminated October 31, 2017
10.11	Employment Agreement of Andrew P. Mazar – effective November 1, 2017
10.12	Consulting Agreement of pRx Consulting (Patrice Rioux)
10.13	Employment Agreement of Kirsten Anderson
10.14	Consulting Agreement of pRx Consulting (Patrice Rioux) - effective January 1, 2018
11	Statement Regarding Computation of Per Share Earnings
23.1	Consent Of Independent Registered Public Accounting Firm

Confidential Information has been omitted and filed separately with the Securities and Exchange Commission on exhibits marked with (*). Confidential treatment has been requested with respect to the omitted information.

Monopar Therapeutics Inc.
Condensed Financial Statements
September 30, 2017 and 2016
(Unaudited)

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Condensed Statements of Operations	F-3
Condensed Statements of Stockholders' Equity	F-4
Condensed Statements of Cash Flows	F-5
Notes to Condensed Financial Statements	F-6 to F-21

Monopar Therapeutics Inc.

Condensed Consolidated Balance Sheets

ASSETS	September 30, 2017	December 31, 2016
	(unaudited)	
Cash and cash equivalents	\$ 9,787,945	\$ 2,072,611
Prepaid expenses and other current assets	9,785	22,562
Total current assets	9,797,730	2,095,173
Restricted cash	800,000	800,393
Total assets	<u>\$ 10,597,730</u>	<u>\$ 2,895,566</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and accrued expenses	\$ 337,936	\$ 64,510
Total current liabilities	337,936	64,510
Long-term liabilities		
Total liabilities	<u>-</u>	<u>-</u>
Commitments		
Stockholders' equity:		
Preferred stock, \$0.001 par value; 200,000 shares authorized;		
115,894 shares issued and outstanding, aggregate liquidation preference of \$34,768,140 at December 31, 2016;		
zero shares authorized, issued and outstanding at September 30, 2017	-	116
Common stock, \$0.001 par value; 40,000,000 shares authorized;		
zero shares issued and outstanding at December 31, 2016;		
9,291,421 shares issued and outstanding at September 30, 2017	9,291	-
Additional paid-in capital	27,964,700	4,703,848
Accumulated deficit	<u>(17,714,197)</u>	<u>(1,872,908)</u>
Total stockholders' equity	<u>10,259,794</u>	<u>2,831,056</u>
Total liabilities and stockholders' equity	<u>\$ 10,597,730</u>	<u>\$ 2,895,566</u>

(*) Derived from the Company's audited financial statements.

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

Monopar Therapeutics Inc.
Condensed Consolidated Statements of Operations
Unaudited

	<u>Nine Months Ended September 30,</u> 2017	<u>2016</u>
Revenues:	\$ -	\$ -
Operating expenses:		
Research and development	1,626,004	183,027
In-process research and development	13,501,622	-
General and administrative	<u>738,701</u>	<u>688,180</u>
Total operating expenses	<u>15,866,327</u>	<u>871,207</u>
Operating loss	(15,866,327)	(871,207)
Other income:		
Interest and other income	<u>25,038</u>	<u>6,083</u>
Net loss	<u>\$ (15,841,289)</u>	<u>\$ (865,124)</u>
Net loss per share:		
Basic and diluted	<u>\$ (1.84)</u>	<u>N/A</u>
Basic and diluted	<u>8,610,376</u>	<u>N/A</u>

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

Monopar Therapeutics Inc.

Condensed Consolidated Statements of Stockholders' Equity

Unaudited

	Series A and Z Preferred Stock		Common Stock		Additional	Accumulated	Total
	Shares	Amount	Shares	Amount	Paid-in Capital	Deficit	Stockholders' Equity
Balance, January 1, 2015	-	\$ -	-	\$ -	\$ -	\$ -	\$ -
Issuance of series A convertible preferred stock	11,644	12	-	-	3,441,452	-	3,441,464
at \$300 per share for cash, net of							
\$51,676 issuance costs							
Issuance of series Z convertible preferred stock	100,000	100	-	-	(100)	-	-
in exchange for intellectual property rights							
Net loss	-	-	-	-	-	(687,311)	(687,311)
Balance, December 31, 2015	111,644	112	-	-	3,441,352	(687,311)	2,754,153
Issuance of series A convertible preferred stock	4,250	4	-	-	1,262,496	-	1,262,500
at \$300 per share for cash, net of							
\$12,500 issuance costs							
Net loss	-	-	-	-	-	(1,185,597)	(1,185,597)
Balance, December 31, 2016	115,894	116	-	-	4,703,848	(1,872,908)	2,831,056
Conversion of series A and Z convertible preferred stock to common stock concurrent with a							
70 for 1 common stock split	(115,894)	(116)	8,335,080	8,335	(8,219)	-	-
Issuance of common stock							
at \$6 per share for cash, net of							
\$42,400 issuance costs	-	-	789,674	790	4,694,856	-	4,695,646
Tactic Pharma, LLC shares forfeited			(2,888,727)	(2,889)	2,889		-
Shares issued in Gem transaction, net of issuance costs							
of \$169,258			3,055,394	3,055	18,329,310		18,332,365
Non-cash stock-based compensation	-	-	-	-	242,016	-	242,016
Net loss	-	-	-	-	-	(15,841,289)	(15,841,289)
Balance September 30, 2017	-	\$ -	9,291,421	\$ 9,291	\$27,964,700	\$17,714,197	\$10,259,794

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

Monopar Therapeutics Inc.

Condensed Consolidated Statements of Cash Flows

Unaudited

	Nine Months Ended September 30	
	2017	2016
Cash flows from operating activities:		
Net loss	\$(15,841,289)	\$ (865,124)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	242,016	-
In-process research and development	13,501,622	-
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	12,777	6,026
Accounts receivable	-	(33,011)
Accounts payable and accrued expenses	273,427	164,810
Net cash used in operating activities	<u>(1,811,447)</u>	<u>(727,299)</u>
Cash flows from financing activities:		
Proceeds from sale of series A convertible preferred stock	-	1,275,000
Cash received from Gem, net of transaction costs	4,830,742	-
Proceeds from the sale of common stock	4,738,046	-
Issuance costs related to the sale of stock	<u>(42,400)</u>	<u>(12,500)</u>
Net cash provided by financing activities	<u>9,526,388</u>	<u>1,262,500</u>
Net increase in cash, cash equivalents and restricted cash	7,714,941	535,201
Cash, cash equivalents and restricted cash, beginning of period	<u>2,873,004</u>	<u>2,805,136</u>
Cash, cash equivalents and restricted cash, end of period	<u>\$ 10,587,945</u>	<u>\$ 3,340,337</u>

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

Monopar Therapeutics Inc.

Notes to Condensed Consolidated Financial Statements

September 30, 2017

1. Nature of Business and Liquidity

Nature of Business

Monopar Therapeutics Inc. (the "Company") is an emerging biopharmaceutical company focused on developing innovative drug candidates to improve clinical outcomes in cancer patients. Monopar currently has three compounds in development: Validive® (clonidine mucobuccal tablet; clonidine MBT), a Phase III-ready, first-in-class mucoadhesive local anti-inflammatory tablet for the prevention and treatment of radiation induced severe oral mucositis (SOM) in head and neck cancer patients; MNPR-201 (GPX-150 5-imino-13-deoxydoxorubicin), a proprietary analog of doxorubicin engineered specifically to retain the anticancer activity of doxorubicin while minimizing toxic effects on the heart; and MNPR-101 (formerly huATN-658), a near-to-the-clinic humanized monoclonal antibody, which targets the urokinase plasminogen activator receptor (uPAR), for the treatment of advanced solid cancers. MNPR-101 (huATN-658) is being developed in collaboration with Cancer Research UK.

The Company was originally formed in the State of Delaware on December 5, 2014 as a limited liability company ("LLC") and on December 16, 2015 converted to a C Corporation in a tax-free exchange. In March 2017, the Company's Series A Preferred Stock and Series Z Preferred Stock converted to common stock at a conversion rate of 1.2 for 1 and 1 for 1, respectively, along with a concurrent common stock split of 70 for 1 and the elimination all shares of Series A Preferred Stock and Series Z Preferred Stock. All references to common stock authorized, issued and outstanding and common stock options take into account the 70 for 1 stock split.

Liquidity

The Company has incurred an accumulated loss of approximately \$17.7 million as of September 30, 2017. To date, the Company has primarily funded its operations with the net proceeds from private placements of convertible preferred stock and common stock and from the cash provided in the Gem transaction discussed in detail in Note 6 below. Management believes that currently available resources will provide sufficient funds to enable the Company to meet its minimum obligations through 2018. The Company's ability to fund its future operations, including the clinical development of Validive, is dependent primarily upon its ability to execute on its business strategy and obtain additional funding or execute collaboration research transactions. There can be no certainty that future financing or collaborative research transactions will occur.

2. Significant Accounting Policies

Basis of Presentation

These condensed consolidated financial statements include the books of Monopar Therapeutics Inc., its French branch and its wholly-owned French subsidiary, Monopar Therapeutics, SARL and have been prepared in accordance with accounting principles generally accepted in the United States ("U.S. GAAP") and include all disclosures required by GAAP for interim financial reporting. The principal accounting policies applied in the preparation of these condensed consolidated financial statements are set out below and have been consistently applied to all periods presented. The Company has been primarily involved in performing research activities, developing product technologies, and raising capital to support and expand these activities.

Monopar Therapeutics Inc.

Notes to Condensed Consolidated Financial Statements

September 30, 2017

2. Significant Accounting Policies, continued

Comprehensive Loss

Comprehensive loss represents net loss plus any gains or losses not reported in the condensed consolidated statements of operations, such as foreign currency translations gains and losses that are typically reflected on a company's statements of stockholders' equity. There were no differences between net loss for the nine months ended September 30, 2017 and 2016, and comprehensive loss for those periods.

Use of Estimates

The preparation of condensed consolidated financial statements in conformity with U.S. 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 revenues and expenses in the condensed consolidated financial statements and accompanying notes. Actual results could differ from those estimates.

Unaudited Interim Financial Data

The accompanying condensed consolidated balance sheet as of September 30, 2017, condensed consolidated statements of operations for the nine months ended September 30, 2017 and 2016 and condensed consolidated statements of cash flows for the nine months ended September 30, 2017 and 2016 are unaudited. The unaudited interim condensed consolidated financial statements have been prepared on a basis consistent with the audited financial statements and, in the opinion of management, reflect all adjustments (consisting of normal recurring adjustments) considered necessary to state fairly our financial position as of September 30, 2017 and the results of operations for the nine months ended September 30, 2017 and 2016 and cash flows for the nine months ended September 30, 2017 and 2016. The financial data and other information disclosed in these notes to the condensed consolidated financial statements related to the nine months ended September 30, 2017 and 2016 are unaudited. The results for the nine months ended September 30, 2017 are not necessarily indicative of the results to be expected for the year ending December 31, 2017 or for any other interim period. These unaudited consolidated financial statements are condensed and should be read in conjunction with the audited financial statements and notes thereto for the year ended December 31, 2016.

Going Concern Assessment

The Company adopted Accounting Standards Updates ("ASU") 2014-15, *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. The ASU 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 December 2017, the Company analyzed its minimum cash requirements through December 2018 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 Condensed Consolidated Financial Statements

September 30, 2017

2. Significant Accounting Policies, continued

Cash Equivalents

The Company considers all highly liquid investments purchased with an original maturity of 90 days or less to be cash equivalents. Cash equivalents as of September 30, 2017 and December 31, 2016 consist entirely of money market accounts.

Restricted Cash

On July 9, 2015, the Company entered into a Clinical Trial and Option Agreement (“CTOA”) with Cancer Research UK. Pursuant to the CTOA, the Company deposited \$0.8 million into an escrow account to cover certain future indemnities, claims or potential termination costs incurred by Cancer Research UK. Restricted cash was \$0.8 million as of September 30, 2017 and December 31, 2016.

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 include insurance premiums and software costs that are expensed monthly over the life of the contract and prepaid legal patent fees that will be expensed as incurred.

Concentration of Credit Risk

Financial instruments that potentially subject the Company to concentration of credit risk consist of cash and cash equivalents and restricted cash. The Company maintains cash and cash equivalents at one financial institution and restricted cash at another financial institution. As of September 30, 2017, and December 31, 2016, cash and cash equivalents and restricted cash balances at these two financial institutions were in excess of the \$250,000 Federal Deposit Insurance Corporation (“FDIC”) insurable limit.

Fair Value of Financial Instruments

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

The Company adopted Accounting Standard Codification (“ASC”) 820, *Fair Value Measurements and Disclosures*, as amended, addressing 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.

Monopar Therapeutics Inc.

Notes to Condensed Consolidated Financial Statements

September 30, 2017

2. Significant Accounting Policies, continued

Fair Value of Financial Instruments, continued

In determining fair values of all reported assets and liabilities that represent financial instruments, the Company uses the carrying market values of such amounts. 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 in 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 nine months ended September 30, 2017 and the year ended December 31, 2016. The following table presents the assets and liabilities recorded that are reported at fair value on our balance sheets on a recurring basis.

Assets and Liabilities Measured at Fair Value on a Recurring Basis

September 30, 2017	Level 1	Level 2	Total
Assets			
Cash equivalents ⁽¹⁾	\$ 9,476,102	\$ -	\$ 9,476,102
Restricted cash ⁽²⁾	-	800,000	800,000
Total	\$ 9,476,102	\$ 800,000	\$ 10,276,102

Cash equivalents represent the fair value of the Company's investments in two money market accounts at September 30, 2017.

Restricted cash represents the fair value of the Company's investments in an \$800,000 certificate of deposit at September 30,

(1) 2017.

(2)

December 31, 2016	Level 1	Level 2	Total
Assets			
Cash equivalents ⁽¹⁾	\$ 2,009,018	\$ -	\$ 2,009,018
Restricted cash ⁽²⁾	393	800,000	800,393
Total	\$ 2,009,411	\$ 800,000	\$ 2,809,411

(1) Cash equivalents represent the fair value of the Company's investments in a money market account at December 31, 2016.

(2) Restricted cash represents the fair value of the Company's investments in an \$800,000 certificate of deposit and \$383 in a money market account at December 31, 2016.

Monopar Therapeutics Inc.

Notes to Condensed Consolidated Financial Statements

September 30, 2017

2. Significant Accounting Policies, continued

Net Loss per Share

Net loss per share for the nine months ended September 30, 2017 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 nine months ended September 30, 2017 is calculated by dividing net loss by the weighted-average shares of common stock outstanding and potential shares of common stock during the period. As of September 30, 2017, potentially dilutive securities included 618,592 options to purchase common stock.

During the nine months ended September 30, 2016 there were no shares of common stock outstanding.

Research and Development Expenses

Research and development (“R&D”) costs are expensed as incurred. Major components of research and development expenses include materials and supplies and fees paid to consultants and to the entities that conduct certain development activities on the Company’s behalf. R&D expense, including upfront license fees and milestones paid to collaborators, are expensed as goods are received or services rendered.

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 and clinical trial sites. The Company determines the estimates through 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 research and development expenses. Clinical trial site costs related to patient enrollment are accrued as patients are entered into the trial. During the nine months ended September 30, 2017 and 2016, the Company had no clinical trials in progress.

In-process Research and Development

In-process research and development expense represents the costs to acquire technologies to be used in research and development that have not reached technological feasibility and have no alternative future uses and are expensed as incurred.

Collaborative Arrangements

The Company and its collaborative partner are active participants in a collaborative arrangement and all parties are exposed to significant risks and rewards depending on the technical and commercial success of the activities. Contractual payments to the other party in the collaboration agreement 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 research and development expenses. Royalties and license payments are recorded as earned.

During the nine months ended September 30, 2017 and 2016, no milestones were met and no royalties were earned, therefore, the Company did not pay or accrue/expense any milestone or royalty payments.

Monopar Therapeutics Inc.

Notes to Condensed Consolidated Financial Statements

September 30, 2017

2. Significant Accounting Policies, continued

Licensing Agreements

The Company has various agreements to license technology utilized in the development of its programs. The licenses contain success milestone obligations and royalties on future sales. During the nine months ended September 30, 2017 and 2016, no milestones were met and no royalties were earned, therefore, the Company did not pay or accrue/expense any milestone or royalty payments under and 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 the accompanying condensed consolidated statements of operations.

Income Taxes

From December 2014 to December 16, 2015, the Company was a limited liability company (an "LLC") taxed as a partnership under the Internal Revenue Code, during which period the members separately accounted for their pro-rata share of income, deductions, losses, and credits of the Company. On December 16, 2015, the Company converted from an LLC to a C Corporation. Beginning on December 16, 2015, 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 occur 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 carry forwards. 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.

Monopar Therapeutics Inc.

Notes to Condensed Consolidated Financial Statements

September 30, 2017

2. Significant Accounting Policies, continued

Income Taxes, continued

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 more likely 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 realizes deferred income tax assets that were previously determined to be unrealizable, the respective valuation allowance would be reversed, resulting in an adjustment to earnings in the period such determination is made.

Internal Revenue Code Section 382 provides that, after an ownership change, the amount of a loss corporation's taxable income or net operating loss ("NOL") for any post-change year that may be offset by pre-change losses shall not exceed the section 382 limitation for that year. Because the Company will continue to raise equity in the coming years, section 382 may limit the Company's usage of NOLs in the future.

Based on the available evidence, the Company believed it was not likely to utilize its minimal deferred tax assets in the future and as a result, the Company recorded a full valuation allowance as of September 30, 2017 and December 31, 2016. The Company intends to maintain the valuation allowance until sufficient evidence exists to support its reversal. The Company regularly reviews its tax positions and 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 nine months ended September 30, 2017 and the year ended December 31, 2016, 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 income taxes. Tax regulations within each jurisdiction are subject to the interpretation of the related tax laws and regulations and require significant judgment to apply. The Company was incorporated on December 16, 2015 and is subject to U.S. federal, state and local tax examinations by tax authorities for the year ended December 31, 2016 and the short tax period December 16, 2015 to December 31, 2015. The Company does not anticipate significant changes to its current uncertain tax positions through September 30, 2017. The Company plans on filing its tax returns for the year ending December 31, 2017 prior to the filing deadlines in all jurisdictions.

Stock-Based Compensation

The Company accounts for stock-based compensation arrangements with employees, nonemployee directors and consultants using a fair value method, which requires the recognition of compensation expense for costs related to all stock-based payments, including stock options. 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.

Stock-based compensation costs for options granted to employees and nonemployee directors are based on the fair value of the underlying option calculated using the Black-Scholes option-pricing model on the date of grant for stock options and recognized as expense on a straight-line basis over the requisite service

Monopar Therapeutics Inc.

Notes to Condensed Consolidated Financial Statements

September 30, 2017

2. Significant Accounting Policies, continued

Stock-Based Compensation, continued

period, which is the vesting period. Determining the appropriate fair value model and related assumptions requires judgment, including estimating stock price volatility, forfeiture rates and expected term. The expected volatility rates are estimated based on the actual volatility of comparable public companies over the expected term. The Company selected these companies based on comparable characteristics, including enterprise value, risk profiles, stage of development and with historical share price information sufficient to meet the expected life of the stock-based awards. The expected term for options granted to date is estimated using the simplified method. Forfeitures are estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. The Company has not paid dividends and does not anticipate paying a cash dividend in the foreseeable future 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. The measurement of consultant share-based compensation is subject to periodic adjustments as the underlying equity instruments vest and is recognized as an expense over the period over which services are rendered.

Recent Accounting Pronouncements

In August 2014, FASB issued ASU 2014-15, *Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern*, which provides guidance on determining when and how reporting companies must disclose going-concern uncertainties in their financial statements. The ASU 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." This ASU became effective for annual periods ending after December 15, 2016 and interim periods within annual periods beginning after December 15, 2016. The Company has adopted this new accounting standard on its financial statements and footnote disclosures.

In November 2015, the FASB issued ASU 2015-17, *Balance Sheet Classification of Deferred Taxes*. This is part of FASB's simplification initiative. The amendments in this ASU require that deferred tax liabilities and assets be classified as noncurrent in a classified statement of financial position. This ASU became effective for the Company in the first quarter of 2017. The Company has adopted this ASU and determined that it does not have a material effect on its financial condition and results of operations for the nine months ended September 30, 2017.

In January 2016, the FASB issued ASU 2016-01, *Recognition and Measurement of Financial Assets and Financial Liabilities*. The purpose is to enhance the reporting model for financial instruments to provide users of financial statements with more decision-useful information. This ASU is effective for the Company in the first quarter of 2018. Early adoption is not permitted except for limited provisions. The Company does not expect the adoption of this amendment to have a material effect on its financial condition and results of operations.

Monopar Therapeutics Inc.

Notes to Condensed Consolidated Financial Statements

September 30, 2017

2. Significant Accounting Policies, continued

Recent Accounting Pronouncements, continued

In February 2016, the FASB issued ASU 2016-02, *Leases*, which for operating leases, requires a lessee to recognize a right-of-use asset and a lease liability, initially measured at the present value of the lease payments, in its balance sheet. The standard also requires a lessee to recognize a single lease cost, calculated so that the cost of the lease is allocated over the lease term, generally on a straight-line basis. ASU 2016-02 will be effective for the Company in the first quarter of 2019, and early adoption is permitted. The Company is currently assessing the impact that adopting this new accounting standard will have on its condensed consolidated financial statements and footnote disclosures.

In March 2016, the FASB issued ASU 2016-09, *Improvements to Employee Share-Based Payment Accounting*, which simplifies several aspects of the accounting for employee share-based payment transactions for both public and nonpublic companies, including the accounting for income taxes, forfeitures, and statutory tax withholding requirements, as well as classification in the statement of cash flows. The ASU became effective for the Company in the first quarter of 2017. The Company has adopted this ASU and determined that it does not have a material effect on its financial condition and results of operations for the nine months ended September 30, 2017.

In November 2016, the FASB issued ASU 2016-18, *Statement of Cash Flows (Topic 230): Restricted Cash*. The amendments apply to all entities that have restricted cash or restricted cash equivalents and are required to present a statement of cash flows. The amendments address diversity in practice that exists in the classification and presentation of changes in restricted cash on the statement of cash flows. The amendments require that a statement of cash flows explain the change during the period in the total of cash, cash equivalents, and amounts generally described as restricted cash or restricted cash equivalents. As a result, amounts generally described as restricted cash and restricted cash equivalents should be included with cash and cash equivalents when reconciling the beginning-of-period and end-of-period total amounts shown on the statement of cash flows. The amendments do not provide a definition of restricted cash or restricted cash equivalents. The amendments are effective for public business entities for fiscal years beginning after December 15, 2017, and interim periods within those fiscal years. For all other entities, the amendments are effective for fiscal years beginning after December 15, 2018, and interim periods within fiscal years beginning after December 15, 2019. Early adoption is permitted. The Company has early adopted the amendments and has applied them using a retrospective transition method to each period presented. Therefore, the Company has included restricted cash in cash equivalents and restricted cash on its statements of cash flows for the nine months ended September 30, 2017 and 2016.

In January 2017, the FASB issued ASU No. 2017-01, *Business Combinations (Topic 805): Clarifying the Definition of a Business* ("ASU No. 2017-01"). The amendments in ASU No. 2017-01 clarify the definition of a business with the objective of adding guidance to assist entities with evaluating whether transactions should be accounted for as acquisitions (or disposals) of assets or businesses. The definition of a business affects many areas of accounting including acquisitions, disposals, goodwill and consolidation. For public companies, the amendments are effective for annual periods beginning after December 15, 2017, including interim periods within those periods. For all other companies and organizations, the amendments are effective for annual periods beginning after December 15, 2018, and interim periods within annual periods beginning after December 15, 2019. The Company is currently assessing the impact that adopting this new accounting standard will have on its condensed consolidated financial statements and footnote disclosures.

Monopar Therapeutics Inc.

Notes to Condensed Consolidated Financial Statements

September 30, 2017

2. Significant Accounting Policies, continued

Recent Accounting Pronouncements, continued

In May 2017, the FASB issued ASU No. 2017-09, *Compensation-Stock Compensation (Topic 718): Scope of Modification Accounting*. The amendment amends the scope of modification accounting for share-based payment arrangements, provides guidance on the types of changes to the terms or conditions of share-based payment awards to which an entity would be required to apply modification accounting under ASC 718. This ASU is effective for all entities for annual periods, and interim periods within those annual periods, beginning after December 15, 2017. Early adoption is permitted, including adoption in any interim period for: (a) public business entities for reporting periods for which financial statements have not yet been issued, and (b) all other entities for reporting periods for which financial statements have not yet been made available for issuance. The Company is currently assessing the impact that adopting this new accounting standard will have on its condensed consolidated financial statements and footnote disclosures.

In July 2017, the FASB issued ASU No. 2017-11, *Earnings Per Share (Topic 260) Distinguishing Liabilities from Equity (Topic 480) Derivatives and Hedging (Topic 815) (Part I) Accounting for Certain Financial Instruments with Down Round Features, (Part II) Replacement of the Indefinite Deferral for Mandatorily Redeemable Financial Instruments of Certain Nonpublic Entities and Certain Mandatorily Redeemable Noncontrolling Interests with a Scope Exception*. This ASU simplifies the accounting for certain financial instruments with down round features, a provision in an equity-linked financial instrument (or embedded feature) that provides a downward adjustment of the current exercise price based on the price of future equity offerings. Down round features are common in warrants, convertible preferred shares, and convertible debt instruments issued by private companies and development-stage public companies. This new ASU requires companies to disregard the down round feature when assessing whether the instrument is indexed to its own stock, for purposes of determining liability or equity classification. The provisions of this new ASU related to down rounds are effective for public business entities for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2018. For all other entities, the amendments are effective for fiscal years beginning after December 15, 2019, and interim periods within fiscal years beginning after December 15, 2020. Early adoption is permitted for all entities. The Company is currently assessing the impact that adopting this new accounting standard will have on its condensed consolidated financial statements and footnote disclosures.

3. Capital Stock

On December 16, 2015, the Company converted from an LLC to a C Corporation at which time the Company effected a 1 for 10 reverse stock split. All references to preferred stock authorized, issued and outstanding and common stock authorized take into account the 1 for 10 reverse stock split. In March 2017, the Company's Series A Preferred Stock and Series Z Preferred Stock converted to common stock at a conversion rate of 1.2 for 1 and 1 for 1, respectively, along with a simultaneous common stock split of 70 for 1 and the elimination all shares of Series A Preferred Stock and Series Z Preferred Stock (collectively, the "Conversion"). 100,000 shares of Series Z Preferred Stock were converted into 7,000,000 shares of common stock and 15,893.801 shares of Series A Preferred Stock was converted into 1,335,079.284 shares of common stock. All references to common stock authorized, issued and outstanding and common stock options take into account the 70 for 1 stock split.

Monopar Therapeutics Inc.

Notes to Condensed Consolidated Financial Statements

September 30, 2017

3. Capital Stock, continued

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. 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 directors and 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.

Contribution to Capital

In August 2017, the Company's largest stockholder, Tactic Pharma, LLC ("Tactic Pharma"), surrendered 2,888,727.12 shares of common stock back to the Company as a contribution to the capital of the Company. This resulted in reducing Tactic Pharma's ownership in Monopar from 79.5% to 69.9%.

Sales of Common Stock

Pursuant to an active private placement memorandum, during the period from July 1, 2017 through September 30, 2017, Monopar sold 448,834 shares of common stock at \$6 per share for proceeds of approximately \$2.7 million. This financing closed on September 30, 2017.

Issuance of Common Stock in the Gem Transaction

Pursuant to the Gem Transaction, discussed in detail in Note 6 below, the Company issued 3,055,394.12 shares of its common stock in exchange for cash and intellectual property related to GPX-150.

As of September 30, 2017, the Company had 9,291,421 shares of common stock issued and outstanding. The Company no longer has any shares of Preferred Stock authorized or outstanding.

In April 2016, the Company adopted the 2016 Stock Incentive Plan and the Company's Board of Directors reserved 700,000 shares of common stock for issuances under the plan (as adjusted subsequent to the Conversion). In October 2017, the Company's Board of Directors increased the stock option pool to 1,600,000 shares of common stock.

4. Stock Option Plan

In April 2016, the Company's Board of Directors and the convertible preferred stockholders representing a majority of the Company's outstanding stock approved, the Monopar Therapeutics Inc. 2016 Stock Incentive Plan (the "Plan") allowing the Company to grant up to an aggregate 700,000 shares of stock awards, stock options, stock appreciation rights and other stock-based awards to employees, directors and consultants. Concurrently, the Board of Directors granted to certain board members and the Company's acting chief financial officer stock options to purchase up to an aggregate 273,000 shares of the Company's common stock at an exercise price of \$0.001 par value based upon a third-party valuation of the Company's common stock.

Monopar Therapeutics Inc.

Notes to Condensed Consolidated Financial Statements

September 30, 2017

4. Stock Option Plan, continued

In December 2016, the Board of Directors granted stock options to purchase up to 7,000 shares of the Company's common stock at an exercise price of \$0.001 par value to the Company's acting chief medical officer.

In February 2017, the Board of Directors granted to certain board members and the Company's acting chief financial officer stock options to purchase up to an aggregate 275,520 shares of the Company's common stock at an exercise price of \$0.001 par value based upon a third-party valuation of the Company's common stock. In September 2017, the Board of Directors represented by the designated Plan Administrator, granted options to purchase up to 21,024 shares of common stock to each of the three new Board members at an exercise price of \$6 per share based on the price per share at which common stock was sold in the Company's most recent private offering.

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 established by the Company's Board of Directors, using third party valuation reports and recent financings. Options generally expire after ten years.

Stock option activity under the Plan is as follows:

	Options Available ⁽³⁾	Options Outstanding	
		Number of Options	Weighted-Average Exercise Price
Balances, December 31, 2015	-	-	-
Option pool	700,000	-	-
Granted ⁽¹⁾	(280,000)	280,000	\$ 0.001
Forfeited	-	-	-
Exercised	-	-	-
Balances, December 31, 2016	420,000	280,000	\$ 0.001
Granted ⁽²⁾	(338,592)	338,592	\$ 1.12
Forfeited	-	-	-
Exercised	-	-	-
Balances, September 30, 2017	81,408	618,592	\$ 0.61

(1) 273,000 options vested 50% upon grant date, 25% upon the 6-month anniversary of grant date and 25% upon the 1-year anniversary of grant date; 7,000 options vested pro rata over 6 months.

(2) 296,544 options vest 6/48^{ths} at the six-month anniversary of grant date and 1/48th per month thereafter; 21,024 options vest 6/24^{ths} on the six-month anniversary of grant date and 1/24th per month thereafter; and 21,024 options vest 6/42^{nds} on the six-month anniversary of grant date and 1/42nd per month thereafter.

(3) In October 2017, the Company's Board of Directors increased the option pool to 1,600,000 shares.

Monopar Therapeutics Inc.

Notes to Condensed Consolidated Financial Statements

September 30, 2017

4. Stock Option Plan, continued

A summary of options outstanding as of September 30, 2017 is shown below:

Exercise Prices	Number of Shares Outstanding	Weighted Average Remaining Contractual Term	Number of Shares Fully Vested and Exercisable	Weighted Average Remaining Contractual Term
\$ 0.001	555,520	9.0 years	320,180	8.6 years
\$ 6.00	63,072	10.0 years	-	N/A
	<u>618,592</u>		<u>320,180</u>	

During the nine months ended September 30, 2017, the Company recognized \$3,612 of employee stock-based compensation expense as general and administrative expenses. The compensation expense is allocated on a departmental basis, based on the classification of the option holder. No income tax benefits have been recognized in the statements of operations for stock-based compensation arrangements.

The Company recognizes as an expense the fair value of options granted to persons who are neither employees nor directors. The fair value of expensed options was based on the Black-Scholes option-pricing model assuming the following factors: 6.0 to 4.3 year expected term, 57% volatility, 1.9% to 1.7% risk free interest rate and zero dividends. Stock-based compensation expense for non-employees for the nine months ended September 30, 2017 was \$238,404 for both periods of which \$189,271 was recorded as research and development expenses and \$49,133 as general and administrative expenses. At September 30, 2017 unamortized unvested balance of stock base compensation was \$198,949, to be amortized over 3.1 years.

5. Development and Collaboration Agreements

Cancer Research UK

In July 2015, the Company entered into a CTOA with Cancer Research UK and Cancer Research Technology Limited, a wholly-owned subsidiary of Cancer Research UK. As part of the CTOA, the Company was obligated to submit \$0.8 million in escrow to cover certain potential future claims, intellectual property infringement costs or termination costs incurred by Cancer Research UK.

Under the CTOA, Cancer Research UK will manufacture MNPR-101, perform preclinical studies and conduct a Phase Ia/Ib clinical trial. At the Company's discretion, the Company has the option to pay an option fee for the right to the Phase Ia/Ib clinical data, after which time, the Company may choose to enter into a pre-negotiated license with Cancer Research Technology Limited which includes developmental and clinical milestones, sales milestones, and royalties on a product-by-product and country-by-country basis in the single digits payable based on the net sales of each product. The option fee is expressed in British pounds and therefore the value in U.S. dollars may vary slightly depending on the exchange rate at the time of payment; however, payment of the option fee is not expected to have a material effect on the Company's financial position. If the Company enters into the pre-negotiated license agreement, the Company will carry 100% of the development costs. Should the Company decline to enter into the pre-negotiated license, the Company will pay nothing to Cancer Research UK or Cancer Research Technology Limited, and Cancer Research Technology Limited will be assigned the Company's intellectual property to continue the development and commercialization of huATN-658 in exchange for a revenue share and minimum royalty. As of September 30, 2017, the Phase Ia/Ib clinical trial has not commenced and the Company has not entered into the pre-negotiated license agreement with Cancer Research Technology Limited and has not been required to pay Cancer Research UK or Cancer Research Technology Limited any funds under the CTOA.

Monopar Therapeutics Inc.

Notes to Condensed Consolidated Financial Statements

September 30, 2017

5. Development and Collaboration Agreements, continued

XOMA Ltd.

The intellectual property rights contributed by Tactic Pharma to the Company included the non-exclusive license agreement with XOMA Ltd. for the humanization technology used in the development of MNPR-101. Pursuant to such license agreement, the Company is obligated to pay XOMA Ltd. clinical, regulatory and sales milestones for MNPR-101 that could reach up to \$14.925 million if the Company achieves all milestones and zero royalties. There can be no assurance that the Company will reach any milestones. As of September 30, 2017, the Company has not reached any milestones and has not been required to pay XOMA Ltd. any funds under this license agreement.

Onxeo SA

The pre-negotiated Onxeo license agreement included as part of the option agreement includes clinical, regulatory, developmental and sales milestones that could reach up to \$108 million if the Company achieves all milestones, and escalating royalties on net sales from 5 - 10%. On September 8, 2017, the Company exercised the option, and therefore was required to pay Onxeo the \$1 million fee under the option and license agreement.

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

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

The Company plans to internally develop Validive with the near-term goal of commencing a Phase III clinical trial, which, if successful, may allow the Company to apply for marketing approval within the next few years. The Company will need to raise significant funds to support the further development of Validive.

6. The Gem Transaction

On August 25, 2017, the Company executed definitive agreements with Gem Pharmaceuticals, LLC (“Gem”), pursuant to which Gem formed a limited liability company, TacticGem LLC (“TacticGem”) with Tactic Pharma, the Company’s largest shareholder at that time. Gem contributed certain of Gem’s drug candidates’ intellectual property and agreements associated primarily with Gem’s GPX-150 drug candidate program, along with \$5,000,000 in cash (the “Gem Contributed Assets”) to TacticGem for a 42.633% interest, and Tactic Pharma contributed 4,111,272.88 shares of common stock of Monopar to TacticGem for a 57.367% interest. Then, TacticGem contributed the Gem Contributed Assets to the Company in exchange for 3,055,394.12 newly issued shares of common stock of the Company (32.5% on a fully-diluted basis) (the two contributions collectively, the “Gem Transaction”). The Gem Transaction closed on August 25, 2017. Following the Gem Transaction, TacticGem owns 7,166,667 (77.1%) shares of Monopar’s common stock as of September 30, 2017.

The Gem drug candidate GPX-150 has been renamed MNPR-201.

Monopar Therapeutics Inc.

Notes to Condensed Consolidated Financial Statements

September 30, 2017

6. The Gem Transaction, continued

The transaction was recorded as of August 25, 2017 as follows:

Cash recorded on the Company's Balance Sheet	\$ 5,000,000
Assembled Workforce recorded as In-process Research and Development Expense on the Company's Statement of Operations	9,886
GPX-150 recorded as In-process Research and Development Expense on the Company's Statement of Operations	13,491,736
Total Gem Transaction	<u>\$ 18,501,622</u>

Within 90 days of the effective date of the transaction, Monopar is required to use its best efforts to file a Form 10 to register Monopar's common stock under the Securities Exchange Act of 1934. Additionally, Arthur Klausner, current CEO of Gem, has been added to the Monopar Board of Directors (the "Board") and will remain on the Board at least until Monopar achieves a listing on a major stock exchange (such as Nasdaq or NYSE). Richard Olson and Gerald Walsh, CSO and President of Gem, respectively, have been retained with one-year consulting agreements to aid in an efficient transfer of Gem's GPX-150 and associated programs.

It is anticipated that this transaction will increase the Company's annual cash burn by at least \$750,000, and will be significantly higher if the Company chooses to conduct clinical trials with the Gem drug candidate programs.

7. Related Party Transactions

During the nine months ended September 30, 2017 and the year ended December 31, 2016, the Company was advised by four members of its Board of Directors, who were Managers of the LLC prior to the Company's conversion to a C Corporation. The four former Managers are also current common stockholders (owning approximately an aggregate 3% of the common stock outstanding as of September 30, 2017). Three of the former Managers are also Managing Members of Tactic Pharma the Company's largest and controlling stockholder (owning 46% of the Company at September 30, 2017 and in partnership with Gem through TacticGem owning 77%). Monopar paid Managing Members of Tactic Pharma the following during the nine months ended September 30, 2017 and the year ended December 31, 2016: Chandler D. Robinson, the Company's Co-Founder, Chief Executive Officer, common stockholder, Managing Member of Tactic Pharma and former Manager of the predecessor LLC \$241,500 and \$322,000, respectively; and Andrew P. Mazar, the Company's Co-Founder, Chief Scientific Officer, common

Monopar Therapeutics Inc.

Notes to Condensed Consolidated Financial Statements

September 30, 2017

7. Related Party Transactions, continued

stockholder, Managing Member of Tactic Pharma and former Manager of the predecessor LLC, \$225,000 and \$197,500, respectively. The Company also paid Christopher M. Starr, the Company's Co-Founder, Executive Chairman of the Board of Directors, common stockholder and former Manager of the predecessor LLC \$75,673 and \$96,339 during the nine months ended September 30, 2017 and the year ended December 31, 2016, respectively.

In the normal course of business, the Company's Chief Executive Officer, Board Members and consultants incur expenses on behalf of the Company and are reimbursed within 30 days of submission of relevant expense reports.

The Company reimbursed Tactic Pharma, a de minimis amount in monthly storage fees during the nine months ended September 30, 2017 and the year ended December 31, 2016. In March 2017, Tactic Pharma wired \$1 million to the Company in advance of the sale of the Company's common stock at \$6 per share under a private placement memorandum. In April, the Company issued to Tactic Pharma 166,667 shares in exchange for the \$1 million at \$6 per share once the Company began selling stock to unaffiliated parties under the private placement memorandum. In August 2017, Tactic Pharma surrendered 2,888,727.12 shares of common stock back to the Company as a contribution to the capital of the Company. This resulted in reducing Tactic Pharma's ownership in Monopar from 79.5% to 69.9%. Following the surrender of the common stock, Tactic Pharma contributed 4,111,272.88 shares of its holdings in Monopar's common stock to TacticGem pursuant to the Gem Transaction discussed in detail in Note 6 above. As of September 30, 2017, Tactic Pharma owned 46% of Monopar's common stock, and TacticGem owned 77% of Monopar's common stock.

During the nine months ended September 30, 2017 and the year ended December 31, 2016, the Company paid or accrued legal fees to a large national law firm, in which a family member of the Company's Chief Executive Officer is a law partner, of approximately \$201,508 and \$54,000, respectively. The family member personally billed a de minimis amount of time on the Company's legal engagement with the law firm in these periods.

8. Subsequent Events

The Company has evaluated all events occurring from September 30, 2017 through December 19, 2017, the date which these financial statements were available to be issued, and did not identify any additional material disclosable subsequent events.

Monopar Therapeutics Inc.
Financial Statements
December 31, 2016 and 2015

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Monopar Therapeutics Inc.
Independent Auditors' Report

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

We have audited the accompanying balance sheets of Monopar Therapeutics Inc. (the "Company") as of December 31, 2016 and 2015, and the related statements of operations, changes in stockholders' equity, and cash flows for the years then ended. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States) and auditing standards generally accepted in the United States of America. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free from material misstatement. The company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. Our audit included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the company's internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our audit opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of Monopar Therapeutics Inc. as of December 31, 2016 and 2015, and the results of its operations and its cash flows for the years ended December 31, 2016 and 2015, in conformity with accounting principles generally accepted in the United States of America.

/s/ BPM LLP

San Francisco, California
February 14, 2017

Monopar Therapeutics Inc.

Balance Sheets

December 31, 2016 and 2015

ASSETS	December 31,	
	2016	2015
Current assets:		
Cash and cash equivalents	\$ 2,072,611	\$ 2,005,136
Prepaid expenses and other	22,562	22,860
Total current assets	2,095,173	2,027,996
Restricted cash	800,393	800,000
Total assets	<u>\$ 2,895,566</u>	<u>\$ 2,827,996</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and accrued expenses	\$ 64,510	\$ 73,843
Total current liabilities	64,510	73,843
Commitments and contingencies (Note 8)		
Stockholders' equity:		
Preferred stock, \$0.001 par value; 200,000 shares authorized; 111,644 shares issued and outstanding; aggregate liquidation preference of \$33,493,140 at December 31, 2015; 115,894 shares issued and outstanding; aggregate liquidation preference of \$34,768,140 at December 31, 2016	116	112
Common stock, \$0.001 par value; 300,000 shares authorized; zero shares issued and outstanding	-	-
Additional paid-in capital	4,703,848	3,441,352
Accumulated deficit	(1,872,908)	(687,311)
Total stockholders' equity	<u>2,831,056</u>	<u>2,754,153</u>
Total liabilities and stockholders' equity	<u>\$ 2,895,566</u>	<u>\$ 2,827,996</u>

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

Monopar Therapeutics Inc.

Statements of Operations

For the years ended December 31, 2016 and 2015

	Year Ended December 31,	
	2016	2015
Revenues:	\$ -	\$ -
Operating expenses:		
Research and development	280,355	101,487
General and administrative	912,474	587,075
Total operating expenses	1,192,829	688,562
Operating loss	(1,192,829)	(688,562)
Other income:		
Interest and other income	7,232	1,251
Net loss	\$ (1,185,597)	\$ (687,311)

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

Monopar Therapeutics Inc.

Statement of Changes in Stockholders' Equity

For the years ended December 31, 2016 and 2015

	Series A and Z Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount	Shares	Amount			
Balance, January 1, 2015	-	\$ -	-	\$ -	\$ -	\$ -	\$ -
Issuance of series A convertible preferred stock							
at \$300 per share for cash, net of \$51,676 issuance costs	11,644	12	-	-	3,441,452	-	3,441,464
Issuance of series Z convertible preferred stock							
in exchange for intellectual property rights	100,000	100	-	-	(100)	-	-
Net loss	-	-	-	-	-	(687,311)	(687,311)
Balance, December 31, 2015	111,644	112	-	-	3,441,352	(687,311)	2,754,153
Issuance of series A convertible preferred stock							
at \$300 per share for cash, net of \$12,500 issuance costs	4,250	4	-	-	1,262,496	-	1,262,500
Net loss	-	-	-	-	-	(1,185,597)	(1,185,597)
Balance, December 31, 2016	<u>115,894</u>	<u>\$ 116</u>	<u>-</u>	<u>\$ -</u>	<u>\$4,703,848</u>	<u>\$1,872,908</u>	<u>\$2,831,056</u>

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

Monopar Therapeutics Inc.

Statements of Cash Flows

For the years ended December 31, 2016 and 2015

	<u>Year Ended December 31,</u>	
	<u>2016</u>	<u>2015</u>
Cash flows from operating activities:		
Net loss	\$ (1,185,597)	\$ (687,311)
Adjustments to reconcile net loss to net cash used in		
operating activities:		
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	298	(22,860)
Accounts payable and accrued expenses	(9,333)	73,843
Net cash used in operating activities	<u>(1,194,632)</u>	<u>(636,328)</u>
Cash flows from financing activities:		
Proceeds from issuance of series A convertible preferred stock	1,275,000	3,493,140
Issuance costs	<u>(12,500)</u>	<u>(51,676)</u>
Net cash provided by financing activities	<u>1,262,500</u>	<u>3,441,464</u>
Net increase in cash, cash equivalents and restricted cash	67,868	2,805,136
Cash, cash equivalents and restricted cash, beginning of period	<u>2,805,136</u>	<u>-</u>
Cash, cash equivalents and restricted cash, end of period	<u>\$ 2,873,004</u>	<u>\$ 2,805,136</u>

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

Monopar Therapeutics Inc.

Notes to Financial Statements

December 31, 2016 and 2015

1. Nature of Business and Liquidity

Nature of Business

Monopar Therapeutics Inc. (the “Company”) is an emerging biopharmaceutical company focused on developing orphan oncology drugs. Monopar currently has two compounds in development: Validive® (clonidine mucobuccal tablet; clonidine MBT), a mucoadhesive local anti-inflammatory tablet for the prevention and treatment of severe oral mucositis in head and neck cancer patients; and huATN-658, a humanized monoclonal antibody, which targets the urokinase plasminogen activator receptor (“uPAR”), for the treatment of advanced solid cancers. Pursuant to a collaboration agreement, Cancer Research UK is conducting huATN-658’s early development, including a planned Phase I clinical trial. The Company was originally formed in the State of Delaware on December 5, 2014 as a Limited Liability Company (“LLC”) and on December 16, 2015 converted to a C Corporation as a tax-free exchange.

Liquidity

The Company has incurred an accumulated loss of approximately \$1.9 million as of December 31, 2016.

To date, the Company has primarily funded its operations with the net proceeds from private placements of convertible preferred stock. Management believes that currently available resources will provide sufficient funds to enable the Company to meet its minimum obligations into Q1 2018. The Company’s ability to fund its future operations, including the clinical development of Validive, is dependent primarily upon its ability to execute on its business strategy and obtain additional funding or execute collaboration research transactions. There can be no certainty that future financing or collaborative research transactions will occur.

2. Significant Accounting Policies

Basis of Presentation

These financial statements have been prepared in accordance with accounting principles generally accepted in the United States (“U.S. GAAP”). The principal accounting policies applied in the preparation of these financial statements are set out below and have been consistently applied to all periods presented. Certain reclassifications have been made to conform to the current year presentation. The Company has been primarily involved in performing research activities, developing product technologies, and raising capital to support and expand these activities.

Going Concern Assessment

The Company adopted Accounting Standards Updates (“ASU”) 2014-15, *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. The ASU requires management to perform interim

Continued

Monopar Therapeutics Inc.

Notes to Financial Statements

December 31, 2016 and 2015

2. Significant Accounting Policies, continued

Going Concern Assessment, continued

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 January 2017, the Company analyzed its minimum cash requirements through February 2018 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.

Use of Estimates

The preparation of financial statements in conformity with U.S. 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 revenues and expenses in the financial statements and accompanying notes. Actual results could differ from those estimates.

Cash Equivalents

The Company considers all highly liquid investments purchased with an original maturity of 90 days or less to be cash equivalents. Cash equivalents as of December 31, 2016 and 2015 consist entirely of business savings funds.

Restricted Cash

On July 9, 2015, the Company entered into a Clinical Trial and Option Agreement ("CTOA") with Cancer Research UK. Pursuant to the CTOA, the Company deposited \$0.8 million into an escrow account to cover certain future indemnities, claims or potential termination costs incurred by Cancer Research UK. Restricted cash was \$0.8 million as of December 31, 2016 and 2015.

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 include insurance premiums and software costs that are expensed monthly over the life of the contract and prepaid legal patent fees that will be expensed as incurred.

Concentration of Credit Risk

Financial instruments that potentially subject the Company to concentration of credit risk consist of cash and cash equivalents and restricted cash. The Company maintains cash and cash equivalents at one financial institution and restricted cash at another financial institution. As of December 31, 2016 and 2015, cash and cash equivalents and restricted cash balances at these two financial institutions were in excess of the \$250,000 Federal Deposit Insurance Corporation ("FDIC") insurable limit.

Continued

Monopar Therapeutics Inc.

Notes to Financial Statements

December 31, 2016 and 2015

2. Significant Accounting Policies, continued

Fair Value of Financial Instruments

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

The Company adopted Accounting Standard Codification (“ASC”) 820, *Fair Value Measurements and Disclosures*, as amended, addressing 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.

In determining fair values of all reported assets and liabilities that represent financial instruments, the Company uses the carrying market values of such amounts. 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 in 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, 2016 and 2015. The following table presents the assets and liabilities recorded that are reported at fair value on our balance sheets on a recurring basis.

Assets and Liabilities Measured at Fair Value on a Recurring Basis

	December 31, 2016	Level 1	Level 2	Total
Assets				
Cash equivalents ⁽¹⁾		\$ 2,009,018	\$ -	\$ 2,009,018
Restricted cash ⁽²⁾		393	800,000	800,393
Total		<u>\$ 2,009,411</u>	<u>\$ 800,000</u>	<u>\$ 2,809,411</u>

(1)Cash equivalents represent the fair value of the Company’s investments in a business savings account at December 31, 2016.

(2)Restricted cash represents the fair value of the Company’s investments in an \$800,000 certificate of deposit and \$393 in a money market account.

Continued

Monopar Therapeutics Inc.

Notes to Financial Statements

December 31, 2016 and 2015

2. Significant Accounting Policies, continued

Fair Value of Financial Instruments

December 31, 2015	<u>Level 1</u>	<u>Level 2</u>	<u>Total</u>
Assets			
Cash equivalents ⁽¹⁾	\$ 1,901,266	\$ -	\$ 1,901,266
Restricted cash ⁽²⁾	<u>-</u>	<u>800,000</u>	<u>800,000</u>
Total	<u>\$ 1,901,266</u>	<u>\$ 800,000</u>	<u>\$ 2,701,266</u>

(1) Cash equivalents represent the fair value of the Company's investments in a business savings account at December 31, 2016 and 2015.

(2) Restricted cash represents the fair value of the Company's investments in an \$800,000 certificate of deposit.

Research and Development Expenses

Research and development ("R&D") costs are expensed as incurred. Major components of research and development expenses include materials and supplies and fees paid to consultants and to the entities that conduct certain development activities on the Company's behalf. R&D expense, including upfront fees and milestones paid to collaborators, are expensed as goods are received or services rendered. Costs to acquire technologies to be used in research and development that have not reached technological feasibility and have no alternative future use are also expensed as incurred.

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 and clinical trial sites. The Company determines the estimates through 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 research and development expenses. Clinical trial site costs related to patient enrollment are accrued as patients are entered into the trial. During the years ended December 31, 2016 and 2015, the Company had no clinical trials in progress.

Collaborative Arrangements

The Company and its collaborative partner are active participants in a collaborative arrangement and all parties are exposed to significant risks and rewards depending on the commercial success of the activities. Contractual payments to the other party in the collaboration agreement 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 research and development expenses. Royalties and license payments are recorded as earned.

On July 9, 2015, the Company entered into a CTOA with Cancer Research UK and Cancer Research Technology Limited, a wholly-owned subsidiary of Cancer Research UK, in which Cancer Research UK will manufacture huATN-658, perform preclinical studies and conduct a Phase Ia/Ib clinical trial. At the Company's discretion, the Company will pay an option fee for the right to the Phase Ia/Ib clinical data, after which time, the Company may choose to enter into a pre-negotiated license with Cancer Research

Continued

Monopar Therapeutics Inc.

Notes to Financial Statements

December 31, 2016 and 2015

2. Significant Accounting Policies, continued

Collaborative Arrangements, continued

Technology Limited, which includes developmental and clinical milestones, sales milestones and royalties, after which time, the Company will carry 100% of the development costs. Should the Company decline to license the clinical data, the Company will pay nothing to Cancer Research UK or Cancer Research Technology Limited, and Cancer Research Technology Limited will be assigned the Company's intellectual property to continue the development and commercialization of huATN-658 in exchange for a revenue share and minimum royalty.

In addition, the Company has a non-exclusive license with XOMA Ltd. for its humanization technology and know-how utilized in the development of huATN-658. Under the terms of the license, the Company is required to pay developmental and sales milestones and zero royalties.

During the years ended December 31, 2016 and 2015, no milestones were met and no royalties were earned, therefore, the Company did not pay or accrue/expense any milestone or royalty payments under the CTOA and XOMA Ltd. license agreement.

License Option Agreement

In June 2016, the Company executed an agreement with Onxeo S.A., a French public company, which gives Monopar the option to license Validive (clonidine mucobuccal tablet), a mucoadhesive tablet of clonidine based on the Lauriad mucoadhesive technology to potentially treat severe oral mucositis in patients undergoing treatment for head and neck cancers. The pre-negotiated license agreement included as part of the option agreement includes clinical and regulatory developmental milestones, along with sales milestones and royalties.

During the years ended December 31, 2016 and 2015, no milestones were met and no royalties were earned, therefore, the Company did not pay or accrue/expense any milestone or royalty payments under the Onxeo option agreement.

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 the accompanying statements of operations.

Income Taxes

In December 2014, the Company originally elected LLC status under the Internal Revenue Code, in which the members separately account for their pro-rata share of income, deductions, losses, and credits. On December 16, 2015, the Company converted from an LLC to a C Corporation. Beginning on December 16, 2015, 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

Continued

Monopar Therapeutics Inc.

Notes to Financial Statements

December 31, 2016 and 2015

2. Significant Accounting Policies, continued

Income Taxes, continued

events that have been recognized in its financial statements, but have not been reflected in its taxable income. Estimates and judgments occur 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 carry forwards. 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 more likely 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 realizes deferred income tax assets that were previously determined to be unrealizable, the respective valuation allowance would be reversed, resulting in an adjustment to earnings in the period such determination is made.

Based on the available evidence, the Company believed it was not likely able to utilize its minimal deferred tax assets in the future and as a result, the Company recorded a full valuation allowance as of December 31, 2016 and 2015. The Company intends to maintain the valuation allowance until sufficient evidence exists to support its reversal. The Company regularly reviews its tax positions and 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 year ended December 31, 2016 and the short tax year from December 16, 2015 to December 31, 2015, the Company did not have any interest or penalties associated with unrecognized tax benefits.

As of December 31, 2016, the Company had research and development ("R&D") credit carryforwards of approximately \$4,357 and \$171 available to reduce future taxable income, if any, for both Federal and state income tax purposes, respectively. The Federal R&D credit carryforwards expire beginning 2035, California R&D credit carryforward indefinitely and Illinois R&D credit carryforwards expire beginning 2020. As of December 31, 2016, the Company had \$260,000 of net operating loss carryforwards, which begin to expire beginning 2035. As of December 31, 2015, the Company had de minimus R&D credits and net operating loss carryforwards.

The Company is subject to U.S. federal, Illinois and California income taxes. Tax regulations within each jurisdiction are subject to the interpretation of the related tax laws and regulations and require significant judgment to apply. The Company was incorporated on December 16, 2015 and is subject to U.S. federal, state and local tax examinations by tax authorities for the year ended December 31, 2016 and for the short tax period from December 16, 2015 to December 31, 2015. The Company does not anticipate significant changes to its current uncertain tax positions through December 31, 2016.

Continued

Monopar Therapeutics Inc.

Notes to Financial Statements

December 31, 2016 and 2015

2. Significant Accounting Policies, continued

Stock-Based Compensation

The Company accounts for stock-based compensation arrangements with employees, nonemployee directors and consultants using a fair value method, which requires the recognition of compensation expense for costs related to all stock-based payments, including stock options. 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.

Stock-based compensation costs for options granted to employees and nonemployee directors are based on the fair value of the underlying option calculated using the Black-Scholes option-pricing model on the date of grant for stock options 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 stock price volatility, forfeiture rates and expected term. The expected volatility rates are estimated based on the actual volatility of comparable public companies over the expected term. The Company selected these companies based on comparable characteristics, including enterprise value, risk profiles, stage of development and with historical share price information sufficient to meet the expected life of the stock-based awards. The expected term for options granted during the year ended December 31, 2016 is estimated using the simplified method. Forfeitures are estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. The Company has not paid dividends and does not anticipate paying a cash dividend in the foreseeable future 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. The measurement of consultant share-based compensation is subject to periodic adjustments as the underlying equity instruments vest and is recognized as an expense over the period over which services are rendered.

Recent Accounting Pronouncements

In August 2014, FASB issued ASU 2014-15, *Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern*, which provides guidance on determining when and how reporting companies must disclose going-concern uncertainties in their financial statements. The ASU 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." This ASU is effective for annual periods ending after December 15, 2016 and interim periods within annual periods beginning after December 15, 2016, and early adoption permitted. The Company has adopted this new accounting standard on its financial statements and footnote disclosures.

In November 2015, the FASB issued ASU 2015-17, *Balance Sheet Classification of Deferred Taxes*. This is part of FASB's simplification initiative. The amendments in this ASU require that deferred tax liabilities and assets be classified as noncurrent in a classified statement of financial position. This ASU is effective for the Company in the first quarter of 2017. Early adoption is permitted. The Company does not expect the adoption of this amendment to have a material effect on its financial condition and results of operations.

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Monopar Therapeutics Inc.

Notes to Financial Statements

December 31, 2016 and 2015

2. Significant Accounting Policies, continued

Recent Accounting Pronouncements, continued

In January 2016, the FASB issued ASU 2016-01, *Recognition and Measurement of Financial Assets and Financial Liabilities*. The purpose is to enhance the reporting model for financial instruments to provide users of financial statements with more decision-useful information. This ASU is effective for the Company in the first quarter of 2018. Early adoption is not permitted except for limited provisions. The Company does not expect the adoption of this amendment to have a material effect on its financial condition and results of operations.

In February 2016, the FASB issued ASU 2016-02, *Leases*, which for operating leases, requires a lessee to recognize a right-of-use asset and a lease liability, initially measured at the present value of the lease payments, in its balance sheet. The standard also requires a lessee to recognize a single lease cost, calculated so that the cost of the lease is allocated over the lease term, on a generally straight-line basis. ASU 2016-02 will be effective for the Company in the first quarter of 2019, and early adoption is permitted. The Company is currently assessing the impact that adopting this new accounting standard will have on its financial statements and footnote disclosures.

In March 2016, the FASB issued ASU 2016-09, *Improvements to Employee Share-Based Payment Accounting*, which simplifies several aspects of the accounting for employee share-based payment transactions for both public and nonpublic companies, including the accounting for income taxes, forfeitures, and statutory tax withholding requirements, as well as classification in the statement of cash flows. The ASU will be effective for the Company in the first quarter of 2017, and early adoption is permitted. The Company is currently assessing the impact that adopting this new accounting standard will have on its financial statements and footnote disclosures.

In November 2016, the FASB issued ASU 2016-18, *Statement of Cash Flows (Topic 230): Restricted Cash*. The amendments apply to all entities that have restricted cash or restricted cash equivalents and are required to present a statement of cash flows. The amendments address diversity in practice that exists in the classification and presentation of changes in restricted cash on the statement of cash flows. The amendments require that a statement of cash flows explain the change during the period in the total of cash, cash equivalents, and amounts generally described as restricted cash or restricted cash equivalents. As a result, amounts generally described as restricted cash and restricted cash equivalents should be included with cash and cash equivalents when reconciling the beginning-of-period and end-of-period total amounts shown on the statement of cash flows. The amendments do not provide a definition of restricted cash or restricted cash equivalents. The amendments are effective for public business entities for fiscal years beginning after December 15, 2017, and interim periods within those fiscal years. For all other entities, the amendments are effective for fiscal years beginning after December 15, 2018, and interim periods within fiscal years beginning after December 15, 2019. Early adoption is permitted. The Company has early adopted the amendments and has applied them using a retrospective transition method to each period presented. Therefore, the Company has included restricted cash in cash equivalents and restricted cash on its statements of cash flows for the years ended December 31, 2016 and 2015.

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Monopar Therapeutics Inc.

Notes to Financial Statements

December 31, 2016 and 2015

3. Capital Stock

Convertible Preferred Stock

On December 16, 2015, the Company converted from an LLC to a C Corporation at which time the Company effected a 1 for 10 reverse stock split. All references to convertible preferred stock authorized, issued and outstanding and common stock authorized take into account the 1 for 10 reverse stock split.

The Company is authorized to issue 200,000 shares of convertible preferred stock with a par value of \$0.001 per share. As of December 31, 2016, the Company has the following convertible preferred stock authorized, issued and outstanding:

Series	Number of Shares Authorized	Number of Shares Issued and Outstanding	Liquidation Preference Per Share	Aggregate Liquidation Preference
A	50,000	15,894	\$ 300	\$ 4,768,140
Z	150,000	100,000	\$ 300	30,000,000
	<u>200,000</u>	<u>115,894</u>		<u>\$ 34,768,140</u>

As of December 31, 2015, the Company has the following convertible preferred stock authorized, issued and outstanding:

Series	Number of Shares Authorized	Number of Shares Issued and Outstanding	Liquidation Preference Per Share	Aggregate Liquidation Preference
A	50,000	11,644	\$ 300	\$ 3,493,140
Z	150,000	100,000	\$ 300	30,000,000
	<u>200,000</u>	<u>111,644</u>		<u>\$ 33,493,140</u>

The Company's initial investor, Tactic Pharma, LLC, contributed to the Company technology and intangible assets related to the development of huATN-658 in exchange for 100,000 shares of Series Z convertible preferred stock, representing approximately 86.3% ownership of the Company as of December 31, 2016. At the time of the contribution, the Company valued the Series Z convertible preferred stock at \$300 per share. The issued Series Z convertible preferred stock is recorded at par value \$0.001 per share on the balance sheet reflecting the historical capitalized cost basis, due to the fact that huATN-658's development costs were previously expensed (not capitalized) by Tactic Pharma, LLC.

From May 2015 to April 2016, the Company sold Series A convertible preferred stock at \$300 per share to various accredited private investors, issuing a total of 15,894 shares of Series A convertible preferred stock for aggregate proceeds to the Company of approximately \$4.8 million.

Continued

Monopar Therapeutics Inc.

Notes to Financial Statements

December 31, 2016 and 2015

3. Capital Stock, continued

Convertible Preferred Stock, continued

The rights, preferences, privileges, and restrictions for the convertible preferred stock are as follows:

- Holders of Series A convertible preferred stock (in preference to Series Z convertible preferred stock and common stock) and Series Z convertible preferred stock (in preference to common stock) are entitled to receive cumulative dividends at the dividend rate of up to \$300 on each outstanding share.
- Once such preferential dividends have been paid to the holders of convertible preferred stock, any additional dividends declared by the Board of Directors will be distributed ratably between the holders of common stock and convertible preferred stock, with convertible preferred stock participating on a one-for-one basis as common stock. As of December 31, 2016, no dividends on convertible preferred stock or common stock have been declared by the Board of Directors.
- In the event of any liquidation, dissolution, or winding up of the Company, the holders of Series A convertible preferred stock (in preference to Series Z convertible preferred stock and common stock) and Series Z convertible preferred stock (in preference to common stock) are entitled to receive an amount equal to \$300 per share less any cumulative dividends already received, plus any declared but unpaid dividends. Any remaining amounts shall be distributed to the holders of common stock in proportion to the shares of common stock held.
- Holders of Series A convertible preferred stock and Series Z convertible preferred stock are entitled to one vote for each share of convertible preferred stock on all matters submitted to a vote of the stockholders of the Company.
- If any further new or additional shares of any class of stock, other than the 10,000 common shares set aside in the additional common stock pool, are issued to investors by the Company at a per share price which is less than \$300 per share, the Company is required to issue new or additional shares to holders of Series A convertible preferred stock at the time of such issuance.
- If the Company's Board of Directors newly authorizes the sale of additional shares of stock, the Amended and Restated Certificate of Incorporation requires the shares to be first offered to all of the then existing stockholders, who, for a period of 30 days, will have the right to purchase their proportionate part of the offered shares on the terms and conditions specified in the offer. If the existing stockholders do not elect to purchase all of the offered shares, the Board of Directors may proceed with the issuance of the remaining shares to such other persons as the Board of Directors may choose, on the terms and conditions specified in the offer. Any issuance of equity based compensation, including profit shares, options, or other equity-based incentive does not trigger the preemptive rights. The Company can issue up to 10,000 shares of common stock, including to existing stockholders, without triggering pre-emptive rights or anti-dilution rights. In April 2016, the Company adopted a stock option plan and the Company's Board of Directors reserved 10,000 shares of common stock for issuances under the plan.
- All shares of convertible preferred stock are convertible at the liquidation price, on a one to one basis into common stock at the option of the holder, at any time after the date of issuance, subject to adjustment for stock splits, stock dividends, and dilution. Shares of convertible preferred stock will automatically convert into common stock at a one-for one conversion ratio upon the affirmative vote of the majority of the then outstanding shares of convertible preferred stock, voting as a single class

Continued

Monopar Therapeutics Inc.

Notes to Financial Statements

December 31, 2016 and 2015

3. Capital Stock, continued

Convertible Preferred Stock, continued

or upon the completion of an initial public offering at a minimum per share price of \$300 subject to adjustment for stock splits, stock dividends, and dilution.

- Under the Company's Bylaws, if a third party offers to purchase 100% of the outstanding shares of stock, at a total purchase price of not less than \$36 million, and stockholders holding 55% or more of the outstanding shares of the Company accept the offer, all of the stockholders must transfer their shares to the offeror on the same terms and conditions as the accepting stockholders.

Common Stock

Subject to any senior rights of the Series A convertible preferred stock and the Series Z convertible preferred stock which may from time to time be outstanding, 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. 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 and to the holders of the Series A convertible preferred stock and the Series Z convertible preferred stock of the full preferential amounts to which they may be entitled. The holders of shares of 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, and vote without distinction as to class with the holders of the Series A convertible preferred stock and the holders of the Series Z convertible preferred stock.

The Company's amended and restated certificate of incorporation authorize the Company to issue 300,000 shares of common stock with a par value of \$0.001 per share. As of December 31, 2016, the Company had zero shares of common stock issued and outstanding.

In addition, the Company's amended and restated certificate of incorporation authorizes the Company's Board of Directors to issue a common stock pool of up to 10,000 shares. In April 2016, the Company adopted the 2016 Stock Incentive Plan and the Company's Board of Directors reserved 10,000 shares of common stock for issuances under the plan.

4. Stock Option Plan

In April 2016, the Company's Board of Directors and the convertible preferred stockholders representing a majority of the Company's outstanding stock approved, the Monopar Therapeutics Inc. 2016 Stock Incentive Plan (the "Plan") allowing the Company to grant up to an aggregate 10,000 shares of stock awards, stock options, stock appreciation rights and other stock-based awards to employees, directors and consultants. Concurrently, the Board of Directors granted to certain board members and the Company's acting chief financial officer stock options to purchase up to an aggregate 3,900 shares of the Company's common stock at an exercise price of \$0.001 par value based upon a third party valuation of the Company's common stock.

In December 2016, the Board of Directors granted stock options to purchase up to 100 shares of the Company's common stock at an exercise price of \$0.001 par value to the Company's acting chief medical officer. 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 established by the Company's Board of Directors, using third party valuation reports. Options generally expire after ten years.

Continued

Monopar Therapeutics Inc.

Notes to Financial Statements

December 31, 2016 and 2015

4. Stock Option Plan, continued

The fair market value of the 4,000 options granted during 2016 was de minimis.

Stock option activity under the Plan is as follows:

	<u>Options Available</u>	<u>Number of Options</u>	<u>Options Outstanding</u> Weighted-Average Exercise Price
Balances, December 31, 2015	-	-	-
Option pool	10,000	-	-
Granted	(4,000)	4,000	\$ 0.001
Forfeited	-	-	-
Exercised	-	-	-
Balances, December 31, 2016	<u>6,000</u>	<u>4,000</u>	\$ 0.001

A summary of options outstanding as of December 31, 2016 is shown below:

<u>Exercise Prices</u>	<u>Number of Shares Outstanding</u>	<u>Weighted Average Remaining Contractual Term</u>	<u>Number of Shares Fully Vested and Exercisable</u>	<u>Weighted Average Remaining Contractual Term</u>
\$ 0.001	4,000	9.28	2,925	9.26

No income tax benefits have been recognized in the statements of operations for stock-based compensation arrangements and no stock-based compensation costs have been capitalized as part of inventory or property and equipment as of December 31, 2016 and 2015.

The Company recognizes as an expense the fair value of options granted to persons who are neither employees nor directors.

Continued

Monopar Therapeutics Inc.

Notes to Financial Statements

December 31, 2016 and 2015

5. Related Party Transactions

During the year ended December 31, 2015, the Company was advised by four members of its Board of Directors, who were Managing Members of the LLC prior to the Company's conversion to a C Corporation. The four former Managing Members are also current Series A convertible preferred stockholders (owning approximately an aggregate 27% of the Series A convertible preferred stock outstanding as of December 31, 2015). Three of the former Managing Members are also Managing Members of Tactic Pharma, LLC, the Company's largest and controlling stockholder (owning 89.6% of the Company at December 31, 2015). The Company paid the following Managing Member fees during the year ended December 31, 2015 to such individuals described above: Chandler D. Robinson, the Company's Co-Founder, Chief Executive Officer, Series A convertible preferred stockholder, Managing Member of Tactic Pharma, LLC and former Managing Member of the Company \$218,750; Christopher M. Starr, the Company's Co-Founder, Executive Chairman of the Board of Directors, Series A convertible preferred stockholder and former Managing Member of the Company \$35,000; Andrew P. Mazar, the Company's Co-Founder, Chief Scientific Officer, Series A convertible preferred stockholder, Managing Member of Tactic Pharma, LLC and former Managing Member of the Company \$87,500; and Michael Brown, Managing Member of Tactic Pharma, LLC and former Managing Member of the Company, owning approximately 21% of the Series A convertible preferred stock as of December 31, 2015 was paid no fees.

At December 31, 2016, Tactic Pharma, LLC owned 86.3% of the Company and Managing Members of Tactic Pharma, LLC were paid the following during the year ended December 31, 2016: Chandler D. Robinson, the Company's Co-Founder, Chief Executive Officer, Series A convertible preferred stockholder, Managing Member of Tactic Pharma, LLC and former Managing Member of the Company \$322,000; and Andrew P. Mazar, the Company's Co-Founder, Chief Scientific Officer, Series A convertible preferred stockholder, Managing Member of Tactic Pharma, LLC and former Managing Member of the Company \$197,500. We also paid Christopher M. Starr, the Company's Co-Founder, Executive Chairman of the Board of Directors, Series A convertible preferred stockholder and former Managing Member of the Company \$96,339 during the year ended December 31, 2016.

The Company reimbursed Tactic Pharma, LLC, \$2,000 in storage fees during the year ended December 31, 2016 and \$103,400 in legal fees and \$1,300 in storage fees during the year ended December 31, 2015.

During the years ended December 31, 2016 and 2015, the Company paid legal fees to a large national law firm, in which the Company's Chief Executive Officer's family member is a law partner, of approximately \$54,000 and \$38,000, respectively. The family member billed a de minimis amount of time on the Company's legal engagement with the law firm.

6. Income Taxes

ASC 740 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 more likely than not to be realized. Accordingly, the valuation allowance has not been released related to these assets. The valuation allowance increased by \$460,003 during the year ended December 31, 2016 and increased by \$75,251 during the short tax year from December 16, 2015 to December 31, 2015.

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Monopar Therapeutics Inc.

Notes to Financial Statements

December 31, 2016 and 2015

6. Income Taxes, continued

The provision for income taxes for December 31, 2016 and 2015 consists of the following:

	As of December 31,	
	2016	2015
Current:		
Federal	\$ -	\$ -
State	800	-
Total current	800	-
Deferred:		
Federal	463,520	56,323
State	71,734	18,928
Total deferred	535,254	75,251
Full valuation allowance	(535,254)	(75,251)
Total provision⁽¹⁾	\$ 800	\$ -

- (1) Total provision consists of California minimum tax which the Company has recorded in general and administrative expenses on its statements of operations.

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

	%
Federal income tax	34.00%
State income taxes, less federal benefit	4.45%
Tax credits	-0.35%
Permanent differences	-0.01%
Tax basis intangibles	-26.62%
Change in valuation allowance	-11.47%
Effective tax rate	0.00%

Deferred tax assets and liabilities consist of the following:

	As of December 31,	
	2016	2015
Deferred tax assets:		
Net operating loss carryforwards	\$ 111,245	\$ 12,346
Tax credit carryforwards	4,470	284
Intangible asset basis differences	419,539	62,621
	535,254	75,251
Valuation allowance	(535,254)	(75,251)
Net deferred tax assets	\$ -	\$ -
Net deferred tax liabilities	\$ -	\$ -

Continued

Monopar Therapeutics Inc.

Notes to Financial Statements

December 31, 2016 and 2015

6. Income Taxes, continued

As of December 31, 2016, the Company had federal net operating loss carryforwards of approximately \$260,000, which will begin to expire in 2035 for federal tax purposes. At December 31, 2016, the Company had state net operating loss carryforwards of approximately \$260,000, which will begin to expire in 2027. The net operating loss related deferred tax assets do not include excess tax benefits from employee stock option exercises.

As of December 31, 2016, the Company had R&D credit carryforwards of approximately \$4,357 and \$171 available to reduce future taxable income, if any, for both Federal and state income tax purposes, respectively. The Federal R&D credit carryforwards expire beginning 2035, California R&D credits carryforward indefinitely and Illinois R&D credit carryforwards expire beginning 2020.

The Tax Reform Act of 1986 limits the use of net operating carryforwards 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 could be limited. The Company has not performed such a study.

On January 1, 2015, the Company adopted the provisions of FASB 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 expected to be taken on a tax return. The cumulative effect of adopting ASC 740-10 resulted in no adjustment to retained earnings as of December 31, 2016. It is Company's policy to include penalties and interest expense related to income taxes as a component of other expense and interest expense, respectively, as necessary.

No liability is recorded on the financial statements related to uncertain tax positions. There are no unrecognized tax benefits as of December 31, 2016. The Company does not expect that uncertain tax benefits will materially change in the next 12 months.

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.

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Monopar Therapeutics Inc.

Notes to Financial Statements

December 31, 2016 and 2015

7. Development and Collaboration Agreements

Cancer Research UK

In July 2015, the Company entered into a CTOA with Cancer Research UK and Cancer Research Technology Limited, a wholly-owned subsidiary of Cancer Research UK. As part of the CTOA, the Company was obligated to submit \$0.8 million in escrow to cover certain potential future claims, intellectual property infringement costs or termination costs incurred by Cancer Research UK.

Under the CTOA, Cancer Research UK will manufacture huATN-658, perform preclinical studies and conduct a Phase Ia/Ib clinical trial. At the Company's discretion, the Company will pay an option fee for the right to the Phase Ia/Ib clinical data, after which time, the Company may choose to enter into a pre-negotiated license with Cancer Research Technology Limited which includes developmental and clinical milestones, sales milestones and royalties. If the Company enters into the pre-negotiated license agreement, the Company will carry 100% of the development costs. Should the Company decline to enter into the pre-negotiated license, the Company will pay nothing to Cancer Research UK or Cancer Research Technology Limited, and Cancer Research Technology Limited will be assigned the Company's intellectual property to continue the development and commercialization of huATN-658 in exchange for a revenue share and minimum royalty. As of December 31, 2016, the Phase Ia/Ib clinical trial has not commenced and the Company has not entered into the pre-negotiated license agreement with Cancer Research Technology Limited and has not been required to pay Cancer Research UK or Cancer Research Technology Limited any funds under the CTOA.

XOMA Ltd.

The intellectual property rights contributed by Tactic Pharma, LLC to the Company included the non-exclusive license agreement with XOMA Ltd. for the humanization technology used in the development of huATN-658. Pursuant to such license agreement, the Company is obligated to pay XOMA Ltd. clinical, regulatory and sales milestones for huATN-658 and zero royalties. As of December 31, 2016, the Company has not reached any milestones and has not been required to pay XOMA Ltd. any funds under this license agreement.

Onxeo SA

In June 2016, the Company executed an agreement with Onxeo S.A., a French public company, which gives Monopar the option to license Validive® (clonidine mucobuccal tablet), a mucoadhesive tablet of clonidine based on the Lauriad mucoadhesive technology to potentially treat severe oral mucositis in patients undergoing treatment for head and neck cancers. The pre-negotiated license agreement included as part of the option agreement includes clinical and regulatory developmental milestones, along with sales milestones and royalties. As of December 31, 2016, the Company has not exercised the option nor entered into the pre-negotiated license agreement with Onxeo, and has not been required to pay Onxeo any funds under the license option agreement.

Continued

Monopar Therapeutics Inc.

Notes to Financial Statements

December 31, 2016 and 2015

7. Development and Collaboration Agreements, continued

Onxeo SA, continued

The Company plans to internally develop Validive with the near-term goal of commencing a Phase III clinical trial, which, if successful, may allow the Company to apply for marketing approval within the next few years. The Company will need to raise significant funds to support the further development of Validive.

8. Commitments and Contingencies

Development and Collaboration Agreements

In July 2015, the Company entered into a CTOA with Cancer Research UK and Cancer Research Technology Limited, a wholly-owned subsidiary of Cancer Research UK. As part of the CTOA, the Company was obligated to submit \$0.8 million in escrow to cover certain potential future claims, intellectual property infringement costs or termination costs incurred by Cancer Research UK. Under the CTOA, Cancer Research UK will manufacture huATN-658, perform preclinical studies and conduct a Phase Ia/Ib clinical trial. At the Company's discretion, the Company will pay an option fee for the right to the Phase Ia/Ib clinical data, after which time, the Company may choose to enter into a pre-negotiated license with Cancer Research Technology Limited which includes developmental and clinical milestones, sales milestones and royalties. If the Company enters into the pre-negotiated license agreement, the Company will carry 100% of the development costs. Should the Company decline to enter into the pre-negotiated license, the Company will pay nothing to Cancer Research UK or Cancer Research Technology Limited, who be assigned the Company's intellectual property to continue the development and commercialization of huATN-658 in exchange for a revenue share and minimum royalty. As of December 31, 2016, the Phase Ia/Ib clinical trial has not commenced and the Company has not entered into the pre-negotiated license agreement with Cancer Research Technology Limited and has not been required to pay Cancer Research UK or Cancer Research Technology Limited any funds under the CTOA.

The intellectual property rights contributed by Tactic Pharma, LLC to the Company included the non-exclusive license agreement with XOMA Ltd. for the humanization technology used in the development of huATN-658. Pursuant to such license agreement, the Company is obligated to pay XOMA Ltd. clinical, regulatory and sales milestones for huATN-658 and zero royalties. As of December 31, 2016, the Company has not reached any milestones and has not been required to pay XOMA Ltd. any funds under this license agreement.

Legal Contingencies

The Company is subject to claims and assessments from time to time in the ordinary course of business. The Company's management does not believe that any such matters, individually or in the aggregate, will have a material adverse effect on the Company's business, financial condition, results of operations or cash flows.

Continued

Monopar Therapeutics Inc.

Notes to Financial Statements

December 31, 2016 and 2015

8. Commitments and Contingencies, continued

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 or been required to defend any action related to its indemnification obligations. However, the Company may record charges in the future as a result of these indemnification obligations.

In accordance with its amended and restated certificate of incorporation and bylaws, the Company has indemnification obligations to its officers and directors for certain events or occurrences, subject to certain limits, while they are serving at the Company's request in such capacity. There have been no claims to date.

9. Subsequent Events

The Company has evaluated all events occurring from December 31, 2016 through February 14, 2017, the date which these financial statements were available to be issued, and did not identify any additional material disclosable subsequent events.

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Monopar Therapeutics Inc.

Date: January 8, 2018

By: /s/ Chandler D. Robinson

Chandler D. Robinson
Chief Executive Officer

CONSULTING AGREEMENT

This Consulting Agreement (herein referred to as “**Agreement**”) is made and entered into on December 8, 2017, effective as of January 1, 2018 (the “**Effective Date**”), by and between Monopar Therapeutics, Inc. (herein referred to as “**Monopar**”), a Delaware corporation, located at 5 Revere Dr., Suite 200, Northbrook, IL 60062, 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 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, 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. P. Rioux, shall spend on the average over the course of the Term one-and-a-half (1.5) work days 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
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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 Andrew P. Mazar, Ph.D., Chandler Robinson, M.D., 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. Four thousand dollars (\$4,000) per month payable within thirty (30) days of the end of each month.

b. Dr. P. Rioux, president of pRx Consulting, LLC shall be granted stock options to purchase up to 32,004 shares of Monopar's common stock at an exercise price of \$6.00. Such stock option shall vest as follows: on January 1, 2018, options to purchase up to 12,000 shares; and options to purchase up to 1,667 shares on the 1st of each subsequent month thereafter. 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.

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 the attached confidential disclosure agreement referenced herein as **Appendix A** prior to commencement of the Services. 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.

5 Revere Dr., Suite 200
Northbrook, IL, 60062
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 WITNESS 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

Monopar Therapeutics Inc.

/s/ Chandler Robinson

BY: PATRICE RIOUX, MD, PHD
ITS: PRESIDENT

BY: CHANDLER ROBINSON
ITS: CHIEF EXECUTIVE OFFICER

APPENDIX A

See executed CDA attached