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

FORM 10-K

(Mark One)

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

For the Fiscal Year Ended December 31, 2018

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

For the transition period from _____ to _____

Commission File Number: 000-55866

MONOPAR THERAPEUTICS INC.

(Exact name of registrant as specified in its charter)

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

(847) 388-0349

(Registrant's telephone number, including area code)

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

Title of each class	**Name of each exchange on which registered**
N/A	**N/A**

Securities registered pursuant to section 12(g) of the Act:
Common stock, $0.001 par value

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

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

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes ☒ No ☐

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§ 229.405 of this chapter) is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. Yes ☒ No ☐

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

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

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

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

Indicate by check mark whether the registrant has filed all documents and reports required to be filed by Section 12, 13 or 15(d) of the Securities Exchange Act of 1934 (the "Exchange Act") subsequent to the distribution of securities under a plan confirmed by a court. Yes ☐ No ☐

Not Applicable.

The number of shares outstanding with respect to each of the classes of our common stock, as of February 26, 2019, is set forth below:

Class	Number of shares outstanding
Class A common stock, par value $0.001 per share	9,291,420.614

Documents incorporated by reference:

MONOPAR THERAPEUTICS INC.
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Forward-Looking Statements

This Annual Report on Form 10-K contains "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933, as amended (the "Act") and Section 21E of the 34 Act. All statements other than statements of historical facts included in this Annual Report on Form 10-K are forward-looking statements. The words "hopes," "believes," "anticipates," "plans," "seeks," "estimates," "projects," "expects," "intends," "may," "could," "should," "would," "will," "continue," and similar expressions are intended to identify forward-looking statements. Forward-looking statements contained in this Annual Report on Form 10-K 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 Annual Report on Form 10-K, 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 Annual Report on Form 10-K or elsewhere, including without limitation any forward-looking statements, except as required by law.

PART I

Item 1. Business

You should read the following discussion in conjunction with our financial statements as of December 31, 2018 and the notes to such financial statements included elsewhere in this Annual Report on Form 10-K.

Overview

We are a clinical stage biopharmaceutical company focused on developing proprietary therapeutics designed to improve clinical outcomes for cancer patients. We are building a drug development pipeline through licensing and acquisition of oncology therapeutics in late preclinical and clinical development stages. We leverage our scientific and clinical expertise to help de-risk and accelerate the clinical development of our drug product candidates.

We intend to begin a Phase 3 clinical development program for our lead product candidate, Validive (clonidine mucobuccal tablet; clonidine MBT), in mid-2019. Validive is designed to be used prophylactically to reduce the incidence, delay the time to onset, and decrease the duration of severe oral mucositis ("SOM") in patients undergoing chemoradiotherapy ("CRT") for oropharyngeal cancer ("OPC"). SOM is a painful and debilitating inflammation and ulceration of the mucous membranes lining the oral cavity and oropharynx. Patients receiving CRT to treat their OPC often develop SOM, which remains one of the most common and troubling side effects of treatment in this indication. The potential clinical benefits to patients of reducing or delaying the incidence of SOM, or reducing the duration of SOM, include: reduced treatment discontinuations leading to potentially improved overall survival outcomes; reduced mouth and throat pain avoiding the need to receive parenteral nutrition; and decreased long-term and often permanent debilitation arising from swallowing difficulties, neck and throat spasms, and lung complications due to food aspiration. Our mucobuccal tablet ("MBT") formulation is a novel delivery system for clonidine that allows for prolonged and enhanced local delivery of drug in the regions of mucosal radiation damage in patients with OPC. Validive has been granted fast track designation in the U.S., orphan drug designation in the EU, and has global intellectual property patent protection through mid-2029 not accounting for possible extensions.

In September 2017, we exercised an option to license Validive from Onxeo S.A., the company that developed Validive through its Phase 2 clinical trial. In the completed Phase 2 clinical trial, Validive demonstrated clinically meaningful efficacy signals within the 64-patient OPC population randomized to placebo, Validive 50 μg dose and Validive 100 μg dose. The absolute incidence of SOM in OPC patients who received a dose of Validive 100 μg once per day was reduced by 26.3% (incidence rate of 65.2% in placebo, 45.0% in Validive 50 μg group, and 38.9% in Validive 100 μg group). The median time to onset of SOM was 37 days in the placebo cohort; 45 days in the Validive 50 μg cohort and no median time of onset was reached in the Validive 100 μg group since fewer than half of this cohort of patients developed SOM. There was also a 37.8% reduction in the median duration of the SOM for the Validive 100 μg group versus placebo (41.0 days placebo group, 34.0 days Validive 50 μg group, and 25.5 days Validive 100 μg group) in patients that developed SOM. Median duration of SOM across all patients, inclusive of both those that did and did not develop SOM, was 17 days in the placebo group and 0 days in each of the Validive 50 and 100 μg groups. A positive dose response was seen in each of these three clinical endpoints. Additionally, patients in the Validive cohorts in the Phase 2 clinical trial demonstrated a safety profile similar to that of placebo. While not designed by us, Onxeo's preclinical studies and Phase 2 clinical trial have informed the design and conduct of what we believe will be an effective Phase 3 clinical program.

SOM typically arises in the macrophages-rich immune tissue located at the back of the tongue and throat, which comprise the oropharynx, resulting in acute severe tissue damage and pain that prevents patients from swallowing, eating and drinking. Validive stimulates the alpha-2 adrenergic receptor (alpha-2AR) on macrophages (white blood cells that comprise the immune tissues of the oropharynx) suppressing pro-inflammatory cytokine expression. Validive exerts its effects locally in the mouth over a prolonged period of time through its unique MBT formulation. Patients who develop SOM are also at increased risk of developing late onset toxicities, including trismus (jaw, neck, and throat spasms), dysphagia, and lung complications, which are often irreversible and lead to increased hospitalization and the need for further interventions sometimes years after completion of chemoradiotherapy. We believe that a reduction in the incidence and duration of SOM by Validive will have the potential for both near- and long-term clinical impact in the OPC patient population by minimizing mouth and throat pain, improving the ability to tolerate food and liquid by mouth (and avoid parenteral feeding tube placement) during chemoradiation, reducing treatment discontinuation and/or delay thereby leading to improved survival outcomes, and reducing long-term morbidities.

The OPC target population for Validive is the most rapidly growing segment of head and neck cancer ("HNC") patients, with an estimated 40,000 cases of OPC in the U.S alone in 2019. The increasing prevalence of oral human papilloma virus ("HPV") infections in the U.S. and around the world is the major driver for the increasing incidence of OPC. Despite the availability of a pediatric/adolescent HPV vaccine, due to low adoption of the vaccine to date, the rate of OPC incidence in adults is not anticipated to be impacted for many decades. As a result, the incidence of HPV-driven OPC is projected to increase for many years to come and will continue to support a clinical need for Validive for the prevention of chemoradiotherapy-induced SOM in patients with OPC.

A pre-Phase 3 meeting with the FDA was held in early May 2018. Based on the meeting discussion, a Phase 3 clinical protocol and accompanying statistical analysis plan ("SAP") was submitted to the FDA for review and comments. We also received protocol assistance and advice on our Phase 3 protocol and SAP from the European Medicines Agency Committee on Human Medicinal Products (EMA/CHMP/SAWP) in June 2018. Based on comments and guidance provided by FDA and EMA, we intend to initiate a Phase 3 clinical development program in mid-2019 to support registration. This program will consist of an adaptive design trial with an interim analysis planned for approximately twelve months after the first patient is dosed, and a confirmatory second trial planned to commence shortly after completion of this interim analysis.

Our second product candidate, MNPR-201, is a novel analog of doxorubicin that has been designed to eliminate the cardiotoxic side effects typically generated by doxorubicin and other anthracycline cancer drugs. MNPR-201 is not metabolized to the derivatives that are believed to be responsible for doxorubicin's cardiotoxic effects but retains anti-cancer activity. A Phase 2 clinical trial for MNPR-201 has been completed in patients with unresectable or metastatic sarcoma, showing 6-month progression free survival ("PFS") of 38%, compared to doxorubicin historical values of 23-33%. No irreversible cardiotoxicity was observed. Based on this preliminary clinical evidence of anti-cancer activity at a well-tolerated dose and schedule, we plan to continue the development of MNPR-201 in one of the cancer settings for which doxorubicin is currently used as the standard of care but cumulative exposure is limited due to concerns over cardiotoxicity. The aim is to provide MNPR-201 for more cycles of administration than can be used for doxorubicin, improving efficacy.

In addition, we plan to advance the development of MNPR-101, a novel first-in-class humanized monoclonal antibody to the urokinase plasminogen activator receptor ("uPAR") for the treatment of advanced cancers. The IND-enabling work is nearly completed and we anticipate requesting a pre-IND meeting with the FDA once we have engaged a clinical manufacturer for the production of MNPR-101 clinical material.

Our management team has extensive experience in developing therapeutics through regulatory approval and commercialization. In aggregate, companies they co-founded have achieved four drug approvals in the U.S. and the EU, successfully sold an asset developed by management which is currently in Phase 3 clinical trials, and completed the sale of a company for over $800 million in cash. Understanding the preclinical, clinical, regulatory and commercial development processes and hurdles are key factors in successful drug development and the expertise demonstrated by our management team across all of these areas increases the probability of success in advancing the product candidates in our product pipeline.

Our Product Pipeline

Our Product Candidates

Validive (clonidine mucobuccal tablet; clonidine MBT)

Validive is a MBT of clonidine. The MBT formulation was developed to enhance the oral mucosal drug delivery and significantly increase the salivary concentrations of the active ingredient while minimizing systemic absorption. The Validive tablet is tasteless and administered once daily by affixing it to the inner side of the patient's upper lip where it dissolves slowly over the period of several hours, resulting in the extended release of clonidine into the oral cavity and oropharynx, the site of SOM following chemoradiation treatment for OPC. Validive therapy is designed to begin on the first day of chemoradiation treatment and continue daily through the last day of treatment.

SOM is a painful and debilitating inflammation and ulceration of the mucous membranes lining the oral cavity and oropharynx. Patients receiving CRT to treat their OPC often develop SOM, which remains one of the most common and troubling side effects of treatment in this indication. We believe Validive has the potential to address several critical elements that affect SOM patients, including:

Reduction in the incidence of SOM. SOM can increase the risk of acute and chronic comorbidities, including dysphagia, trismus and lung complications, which are often irreversible and lead to increased hospitalization and the need for additional interventions. In a Phase 2 clinical trial, the OPC patient cohort treated with Validive 100 µg demonstrated a reduction in the absolute incidence of SOM compared to placebo of 26.3% (incidence rate of 65.2% in placebo, 45.0% in Validive 50 µg group, 38.9% in Validive 100 µg group). A reduced incidence of SOM in OPC patients may lower the risk of acute and chronic morbidities and improve quality of life.

Delay in the time to onset of SOM. SOM can cause cancer treatment delay and/or discontinuation, which may impact overall survival outcomes. In a Phase 2 clinical trial, the OPC patients had a time to onset of SOM of 37 days in the placebo cohort; 45-day time to onset of SOM in the Validive 50 µg cohort; and median was not reached as fewer than half of the patients developed SOM in the Validive 100 µg group. Prolonging time to onset of SOM may lead to fewer missed chemoradiotherapy treatments, resulting in improved overall survival outcomes.

Decrease in the duration of SOM. Longer duration of SOM leads to a higher risk of the need for parenteral nutrition and lower quality of life. SOM patients experience inability to drink and/or eat, and difficulty swallowing often resulting in malnourishment and feeding tube intervention. The Phase 2 clinical trial data demonstrated a 15.5-day reduction (by 37.8%) in the duration of SOM for patients treated with Validive 100 µg (41 day median duration with placebo, 34 days with the Validive 50 µg group, and 25.5 days for the Validive 100 µg group) in patients that developed SOM. Median duration across all patients, inclusive of both those that did and did not develop SOM, was 17 days in the placebo group and 0 days in each of the Validive 50 and 100 µg groups. Reduced duration of SOM may result in lower risk of malnourishment and feeding tube intervention, and fewer treatment terminations/delays.

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

MNPR-201 (5-imino-13-deoxydoxorubicin) is a proprietary doxorubicin analog that is selective for topoisomerase II-alpha. Doxorubicin is used to treat adult and pediatric solid and blood (hematologic) cancers, including breast, gastric, ovarian and bladder cancers, soft tissue sarcomas, leukemias and lymphomas. The optimal clinical efficacy of doxorubicin has historically been limited by the risk of patients developing irreversible, potentially life-threatening cardiotoxicity despite clinical studies demonstrating the anti-cancer benefit of higher doses of doxorubicin administered for longer periods of time. For example, several clinical studies completed in the 1990s demonstrated that concurrent doxorubicin (60 mg/m2, 8 cycles) and paclitaxel gave a 94% overall response rate in patients with metastatic breast cancer but led to 18% of these patients developing congestive heart failure. Reduction of doxorubicin to 4-6 cycles of treatment decreased occurrence of congestive heart failure, but also reduced response rates to 45-55%.

MNPR-201 has been engineered specifically to retain the anticancer activity of doxorubicin while minimizing the toxic effects on the heart. We believe the results of these studies, along with the potential to combine a less or non-cardiotoxic analog of doxorubicin with other anticancer agents, offer the opportunity to develop a large market opportunity for MNPR-201 in a broad spectrum of cancer types.

The antitumor effects of MNPR-201 are mediated through the stabilization of the topoisomerase II complex after a DNA strand break and DNA intercalation leading to apoptosis (cell death) through a mechanism similar to doxorubicin and other anthracycline drugs. Inhibiting the topoisomerase II-alpha isoform is desired for the anti-cancer effect, while inhibiting the topoisomerase II-beta isoform has been demonstrated to mediate, at least in part, the cardiotoxicity associated with all anthracycline drugs currently used in the clinic. MNPR-201 is substantially more selective than doxorubicin for inhibiting topoisomerase II-alpha versus topoisomerase II-beta. This selectivity may at least partly explain the minimal cardiotoxicity that has been observed for MNPR-201 in preclinical and clinical studies to date.

MNPR-101 (formerly huATN-658)

MNPR-101 is a novel, preclinical stage drug candidate. It is a first-in-class humanized monoclonal antibody to the urokinase plasminogen activator receptor (“uPAR”), a well-credentialed cancer therapeutic target. uPAR is a protein receptor that sits on the cell surface of, and is overexpressed in, many deadly cancers, but has little to no expression in healthy tissue; several Phase 1 imaging studies in human advanced cancer patients show that uPAR can only be detected in the tumor and not in normal tissues.

In normal cells, uPAR is transiently expressed as part of a highly regulated process required for the breakdown of extracellular matrix during normal tissue remodeling. In cancer, however, uPAR is constitutively over-expressed by the tumor cell and the uPAR extracellular matrix degrading function is hijacked by the tumor to support tissue invasion, metastasis, and angiogenesis. It is important to tumor cell survival, and the uPAR expression increases in high grade and metastatic disease.

MNPR-101 has demonstrated significant anti-tumor activity in numerous preclinical models of tumor growth, both as a monotherapy and in combination with other therapeutics and is being advanced toward an IND. Based on the selective expression of uPAR in numerous tumor types, we anticipate MNPR-101 will be well-tolerated and amenable to a variety of combination treatment approaches in the clinic.

Our Strategy

Leveraging the experience and the demonstrated competencies of our management team, our strategic goal is to acquire, develop and commercialize promising oncology product candidates that address the unmet medical needs of cancer patients. The key elements of our strategy to achieve this goal are to:

- **Leverage data generated from the Phase 2 Validive clinical trial to position us well for a successful Phase 3 clinical trial program for Validive for SOM in OPC.** In a Phase 2 clinical trial the absolute incidence of SOM in OPC patients was reduced by 26.3%, the time to onset was delayed, and the duration in patients that developed SOM was decreased by 15.5 days in the Validive 100 µg cohort versus placebo. In addition to the data from the Phase 2 clinical trial, we believe the guidance from our key opinion leaders (“KOLs”) as well as from the FDA and EMA, and our own internal clinical trial design expertise, position us well for a successful Phase 3 clinical trial program.

- **Obtain FDA approval of Validive and maximize the commercial potential of Validive in the U.S. and the EU, seeking partnerships outside these markets.** Following a potentially successful Phase 3 clinical program of Validive and potential FDA approval, we intend to commercialize Validive in the U.S. and the EU which may include establishing our own specialty sales force and seeking partnerships outside of these territories for regulatory approval and drug sales and distribution.

- **Advance the clinical development of MNPR-201, by pursuing existing clinical settings where doxorubicin has demonstrated efficacy.** We plan to expand on the data generated in a Phase 2 clinical trial of MNPR-201 in patients with unresectable or metastatic sarcoma. In this study, the 6-month progression free survival (“PFS”) was 38%, compared to doxorubicin historical values of 23-33%. We anticipate being able to treat patients with MNPR-201 at higher doses for longer periods of time given the reduced cardiotoxicity observed thus far in human clinical studies, which may lead to improved clinical outcomes.

- **Continue the development of MNPR-101 and expand our drug development pipeline through in-license and acquisition of oncology product candidates.** We plan to continue the development of MNPR-101 and the expansion of our drug development pipeline through acquiring or in-licensing additional oncology product candidates, particularly those that leverage existing scientific and clinical data that helps de-risk the next steps in clinical development.

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

Risks Associated with our Business

Investing in our common stock involves a high degree of risk. You should carefully consider the risks described in Item 1-A "Risk Factors" before making a decision to invest in our common stock. If any of these risks actually occurs, our business, financial condition, results of operations and prospects would likely be materially adversely affected. In that event, the trading price of our common stock could decline, and you could lose part or all of your investment. Below is a summary of some of the principal risks we face:

- We have a limited operating history, no revenues from operations, expect to incur significant operating losses and are dependent upon raising capital to continue our drug development programs. We have a high risk of never being profitable.
- We do not have and may never have any approved products on the market. Our business is highly dependent upon receiving approvals from various U.S. and international governmental agencies and will be severely harmed if we are not granted approval to manufacture and sell our product candidates.
- Our clinical trials may not yield sufficiently conclusive results for regulatory agencies to approve the use of our products.
- If we experience delays or difficulties in the enrollment of subjects in clinical trials, our receipt of necessary regulatory approvals could be delayed or prevented, which could materially affect our financial condition.
- We rely on third parties to conduct our non-clinical studies and our clinical trials. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may be unable to obtain regulatory approval for or commercialize our current product candidates or any future products and our financial condition will be adversely affected.
- Funds raised in the near term may not be sufficient to complete our Phase 3 clinical development of Validive, which would require that we raise additional funds. If we raise additional funds in the future to complete our Phase 3 clinical program for Validive, it may not be at favorable terms. If we are unable to raise enough funds in the future, we may have to discontinue or delay our operations.
- We face significant competition from other biotechnology and pharmaceutical companies, and our operating results will suffer if we fail to compete effectively. Competition and technological change may make our product candidates obsolete or non-competitive.
- The termination of third-party licenses could adversely affect our rights to important compounds or technologies.
- 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 development efforts to develop competing drugs.
- If we lose key management leadership, and/or scientific personnel, and if we cannot recruit qualified employees or other significant personnel, we may experience program delays and increased compensation costs, and our business may be materially disrupted.

Implications of Being an Emerging Growth Company

We qualify as an "emerging growth company" as defined in the Jumpstart our Business Startups Act of 2012 ("JOBS Act"). An emerging growth company may take advantage of specified reduced reporting and other burdens that are otherwise applicable generally to public companies. These provisions include:

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

We may take advantage of these provisions until we are no longer an emerging growth company. We will remain an emerging growth company until the earliest of (1) the last day of the year (a) following the fifth anniversary of the completion of an initial public offering, (b) in which we have total annual gross revenue of at least $1.07 billion or (c) in which we are deemed to be a large accelerated filer, which means the market value of our common stock that is held by non-affiliates exceeds $700 million as of the prior June 30th, and (2) the date on which we have issued more than $1.0 billion in non-convertible debt during the prior three-year period.

We have taken advantage of the reduced reporting requirements in this Annual Report on Form 10-K. Accordingly, the information contained herein is different from the information you receive from other public companies that are not emerging growth companies.

The JOBS Act permits an emerging growth company such as us to take advantage of an extended transition period to comply with new or revised accounting standards applicable to public companies until those standards would otherwise apply to private companies. We have irrevocably elected to opt out of this provision and, as a result, we will comply with new or revised accounting standards when they are required to be adopted by public companies that are not emerging growth companies. In addition, we are also a "smaller reporting company" as defined in Rule 12b-2 of the Exchange Act and have elected to take advantage of certain of the scaled disclosure

requirements available to smaller reporting companies such as extensive narrative disclosure required of other reporting companies, particularly in the description of executive compensation.

Corporate Information

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

Trademark notice

We have registered trademarks with the U.S. Patent and Trademark Office ("USPTO"), for the following trademarks: "Validive", "Baxefyn", "Vidarys", "Cotilix", "Arvita" and "Clonidol". All other trademarks, service marks and trade names in this Annual Report on Form 10-K are the property of their respective owners. We have omitted the ® and ™ designations, as applicable, for the trademarks used herein.

Validive (clonidine mucobuccal tablet; clonidine MBT)

Validive U.S. Market Opportunity

The incidence of HNC (all anatomical types, including larynx, oral cavity, oropharynx, etc.) in the U.S. was estimated to be approximately 65,000 cases in 2017 (American Society of Clinical Oncology, cancer.net). The most rapidly growing type of HNC is OPC. The oropharynx is comprised largely of immune tissue and includes the soft palate, the base (rear one third) of the tongue, and the tonsils. In the U.S., the incidence of OPC is estimated to be around 40,000 cases in 2019. The majority of these OPC patients (approximately 70%) are HPV+. The incidence of OPC is also increasing in the rest of the world (>30% of HNC), with >50% of all OPC being HPV+. While certain types of HNC have been in decline in the U.S., such as laryngeal cancer as a result of a reduction in the smoking population, the total incidence of HNC has been growing steadily primarily due to OPC. The increase in OPC is directly associated with increased infection with the human papilloma virus. The incidence of HPV+ OPC has outpaced the incidence of HPV– HNC by 4-5-fold over the past decade. This trend of HPV+ OPC driving an increase in overall HNC is expected to continue for some time as the relatively recent introduction of a vaccine designed to prevent the transfer and colonization with HPV is only effective if administered prior to infection, and it is recommended only for those under the age of 26. Even for those under the age of 26 who are eligible for the vaccine, oral HPV infections are predicted to increase due to the lack of adequate use of HPV vaccinations. Only around 50% of eligible females and 33% of eligible males are presently being vaccinated.

Most OPC is caused by the HPV16 strain, with virus detectable in the tumor. More than 3% of adult men and 1% of adult woman have HPV16 detectable in their saliva at any one time. The virus is transmitted through sexual contact and studies estimate 3-5% of adolescents and 5-10% of all adults in the U.S. have an active oral HPV infection. The latency period for that proportion that does go on to develop HPV+ OPC is 15-20+ years. This HPV+ OPC population is expected to be a long-term driver of the incidence of OPC and the resultant SOM associated with what is frequently curative therapy for this serious malignancy.

In previous studies describing SOM in OPC patients receiving the CRT regimen we are proposing for our Validive Phase 3 clinical program, patients had a SOM incidence rate of 55%-90% across studies. In the Validive Phase 2 trial, the incidence of SOM in OPC patients receiving placebo was 65.2% (see "*Validive Phase 2 Clinical Trial Data"* section below). Currently there is no way to predict which patients will develop SOM, so any preventive treatment for SOM will likely be used in most OPC patients receiving CRT. With approximately 40,000 annual cases of OPC in the U.S., and a consistently growing incidence rate of OPC as a result of the human papillomavirus, there is the potential for a substantial and growing market for Validive.

Validive Mechanism of Action

Validive is designed to deliver high local concentrations of clonidine, an agonist of alpha-2AR, to the oral cavity and oropharynx, the site of irradiation in the treatment of OPC. In the oropharynx, alpha-2AR is expressed on macrophages, immune cells that produce inflammatory cytokines, the molecules that are responsible for the development of SOM, in response to chemoradiation. A recent clinical study demonstrated that radiation treatment substantially increased salivary cytokine levels and that these were positively associated with the formation of SOM in patients with head and neck cancer. Patients with human papilloma virus positive ("HPV+") OPC demonstrate an increased accumulation of macrophages in the tumor microenvironment compared to patients with OPC without human papilloma virus ("HPV–"), thus further priming HPV+ OPC patients for the development of SOM. The alpha-2AR regulates the expression of cytokines by macrophages, and clonidine reduces this cytokine production. Macrophages are the primary immune cells in the oropharynx that express alpha-2AR, making clonidine's mechanism of cytokine suppression macrophage selective and distinct from the mechanism of other anti-inflammatory drugs. Further, Validive delivers clonidine to the mucosal surface, the site of radiation treatment in OPC. This results in high salivary concentrations of clonidine, minimizing systemic absorption, and allowing for maximal exposure of drug to the at-risk oral mucosa and the OPC microenvironment. Preclinical studies and a Phase 2 clinical trial of Validive have provided data that support Validive's mechanism of action and therapeutic potential for reducing the development of SOM in patients with OPC, improving oral mucositis-related symptoms, and decreasing chemoradiotherapy-related adverse events, while exhibiting a favorable safety profile and high compliance rate in patients.

Validive Development Strategy

A pre-Phase 3 meeting with the FDA was held in early May 2018. Based on the meeting discussion, a Phase 3 clinical protocol and

accompanying statistical analysis plan ("SAP") were submitted to the FDA for review and comments. Based on guidance received from the FDA after review of these documents, we plan to initiate a Phase 3 clinical development program in mid-2019 to support registration. This program will consist of an adaptive design trial with an interim analysis planned for approximately twelve months after the first patient is dosed, and a confirmatory second trial planned to commence shortly after completion of this interim analysis. Each trial will be randomized, double-blinded, placebo-controlled, with a two-sided alpha of 0.05 ($p < 0.05$). The dose for both trials will be Validive 100 µg, once daily. The primary endpoint will be the proportion of subjects that develop SOM (World Health Organization grade ≥ 3).

Validive Phase 2 Clinical Trial Data

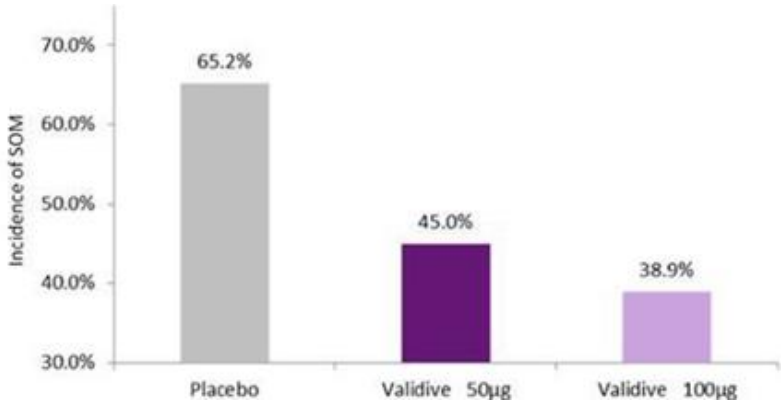
In October 2015, the results from an international Phase 2 clinical trial of Validive were announced, demonstrating encouraging signs of clinical activity and safety compared to placebo. The trial enrolled 183 patients and was conducted in more than thirty centers in Europe and the United States. HNC patients who had undergone surgical resection of their head and neck cancer with curative intent and who were planned to receive at least 50 Gray (Gy) of radiation in combination with chemotherapy, regardless of anatomical location of disease, were included in this study. This global, multi-center, double-blind, randomized, placebo-controlled, three-arm study (NCT01385748) compared the efficacy and safety of Validive 50 µg and 100 µg to placebo in patients with HNC receiving chemoradiotherapy. Of the 183 HNC patients, 64 had OPC (placebo = 24, Validive 50 µg = 21, Validive 100 µg = 19). 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.

We believe the Phase 2 clinical trial data support the development of Validive for reducing the incidence, delaying the time to onset, and reducing the duration of SOM in OPC patients. We believe there is the potential for an enhanced benefit in HPV+ patients. These patients have an increased prevalence of macrophages in the oropharynx, and a 6.9-fold higher risk of developing SOM. The onset of SOM also occurs sooner in HPV+ patients than in HPV– OPC patients, likely due to the increased accumulation of immune cells such as macrophages in the tumor due to the presence of the HPV infection. These cells express oral mucosa damaging cytokines in response to chemoradiation, and Validive exerts its effect by suppressing this expression.

The analysis of OPC patients in this study showed:

- The incidence of SOM (primary endpoint) was reduced by 26.3% (40% relative to placebo) in OPC patients treated with Validive 100 µg ($p=0.09^{(1)}$), a meaningful trend but not statistically significant). 65.2% of OPC patients on placebo experienced SOM compared to only 38.9% of OPC patients on Validive 100 µg.

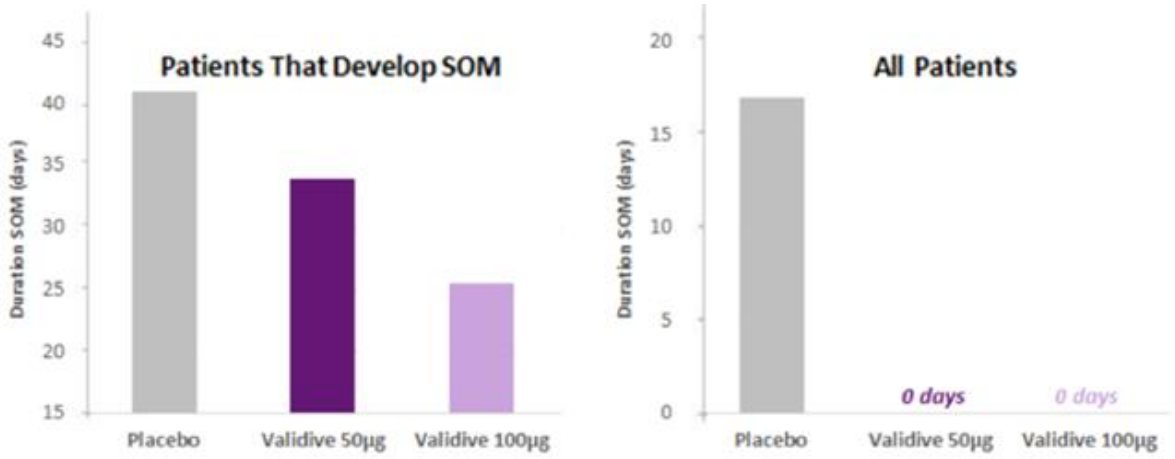
■ Incidence of SOM in OPC Patients



Validive has demonstrated reduced incidence of SOM in a Phase 2 clinical trial

- Patients on Validive experienced a delay in the time to onset of SOM. Patients receiving placebo experienced a median time to onset of SOM of 37 days; patients receiving Validive (50 µg one per day) experienced a 45 day median time to onset of SOM; and patients receiving Validive (100 µg once per day) did not reach a median time to onset. A comparison of hazards for time to onset demonstrated that patients that received Validive 100 µg had a hazard ratio (HR)=0.48 compared to placebo.
- Patients receiving Validive experienced a decrease in the median duration of SOM. In patients that developed SOM, a 15.5 day reduction (by 37.8%) in the median duration of SOM was observed in patients treated with Validive 100 µg (41 day median duration with placebo, 34 days in the Validive 50 µg group, and 25.5 days in the Validive 100 µg group). Median duration across all patients, inclusive of both those that did and did not develop SOM, was 17 days in the placebo group and 0 days in each of the Validive 50 and 100 µg groups.

■ Median Duration of SOM in OPC Patients



- Severe drinking, eating, and speaking limitations due to mouth and throat soreness ("MTS") score were also reduced in the Validive 100 µg treated cohort.
- Improvements in other indicators of clinical benefit, including decreased weight loss, decreased opiate use and increased cumulative dose of radiation received, strongly favored the Validive 100 µg treated group.
- 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.

(1) p-value is a conventional statistical method for measuring the statistical significance of experimental results. A p-value of less than 0.05 is generally considered to represent statistical significance, meaning that there is a less than five percent likelihood that the observed results occurred by chance.

Patients treated with Validive experienced less nausea and dysphagia compared to placebo. No clinically meaningful decreases in systolic blood pressure or diastolic blood pressure were noted between the placebo and Validive arms. There was no statistical difference in the number of patients having experienced at least one treatment emergent adverse event related to the study treatment between placebo and Validive. Additionally, patients in the Validive cohorts in the Phase 2 clinical trial demonstrated a safety profile similar to that of placebo. Two patients in the placebo group and 2 patients in the Validive 50 µg group experienced serious adverse events ("SAEs") that were assessed as treatment related. No patients in the Validive treated cohorts were discontinued due to study drug. The 2-year survival rate was similar between patients treated with placebo and Validive indicating that Validive did not interfere with primary disease treatment.

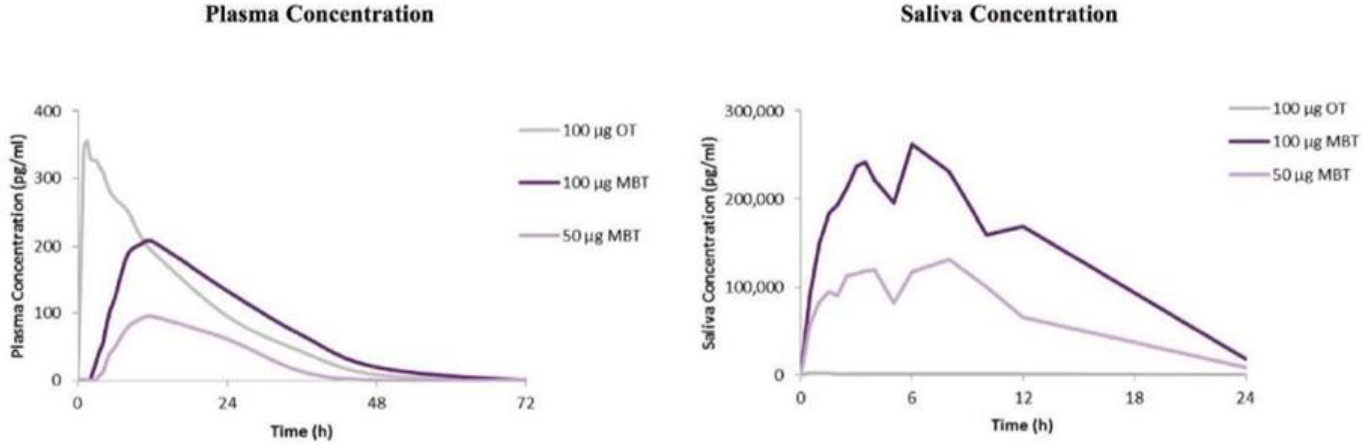
The mean overall patient compliance was approximately 90% across all treatment groups. Overall compliance according to patient diaries was similar in all treatment groups and consistent with the compliance according to the investigator's evaluation.

Our review of the Phase 2 clinical trial data suggests that the effect of Validive was much greater in OPC compared to non-OPC patients. We believe the Phase 2 data along with the mechanism of action of Validive provide 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 U.S. and Europe are patients with OPC, largely driven by HPV+ disease. 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 in the tumor. Evaluation of HPV status is part of the routine clinical assessment of patients with OPC prior to initiating treatment.

For the full 183 patient Phase 2 population, which included various types of head and neck cancer such as oral and laryngeal cancer in addition to OPC, the incidence of SOM was lower in patients treated with Validive (45.3% when the 50 and 100 µg dose groups were pooled together) than in patients receiving placebo (60.0%) ($p = 0.064$). Additionally, Validive was very well tolerated, with occurrence of adverse events of any type or grade being similar between placebo (98.4%) and Validive treated groups (90.8%).

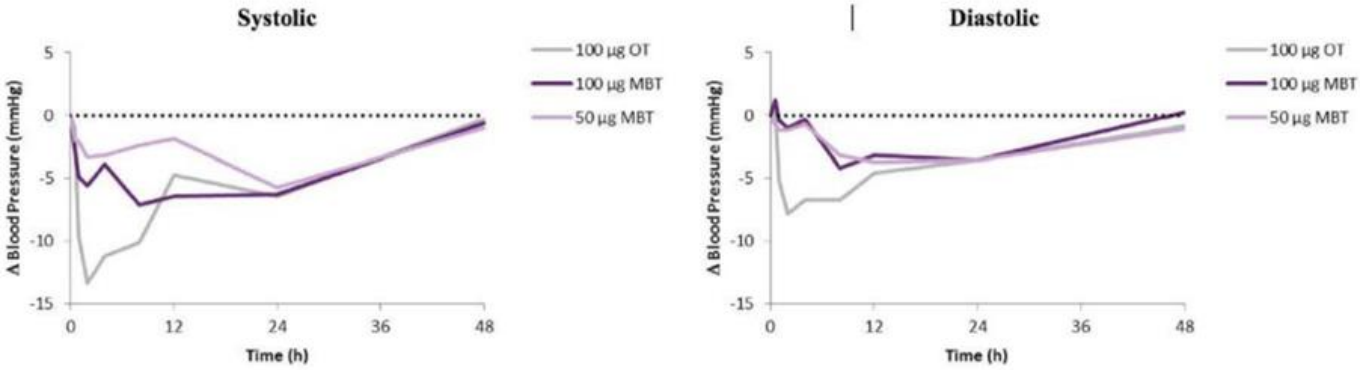
Validive Phase 1 Clinical Trial Data

A Phase 1 clinical trial in 36 healthy volunteers comparing the pharmacokinetics of the systemic (oral tablet) clonidine HCl with clonidine MBT (local delivery of clonidine to oral mucosa and oropharynx – Validive's formulation) was completed. This single-center, Phase 1, single-blind randomized, three-period, three-sequence, single-dose crossover study was conducted between August and November 2015. Healthy volunteers receiving Validive had far less systemic exposure to clonidine with the 50 µg and 100 µg clonidine MBTs (Validive) versus 100 µg clonidine HCl tablets (oral tablet). In contrast, levels of clonidine in saliva in volunteers receiving a single dose of 50 and 100 µg clonidine MBT (Validive) was much greater than saliva levels in volunteers receiving a single dose of 100 µg clonidine HCl tablets. These results are consistent with the hypothesis that the MBT formulation (Validive) is targeted in the mouth, as opposed to distributed systemically. Additionally, no significant effects on blood pressure were observed with the clonidine MBTs (Validive). Blood pressure effects were tested because clonidine is known to lower blood pressure when absorbed systemically.



Both Validive 50 µg and 100 µg showed high salivary exposure, with low systematic and blood pressure effect as seen below:

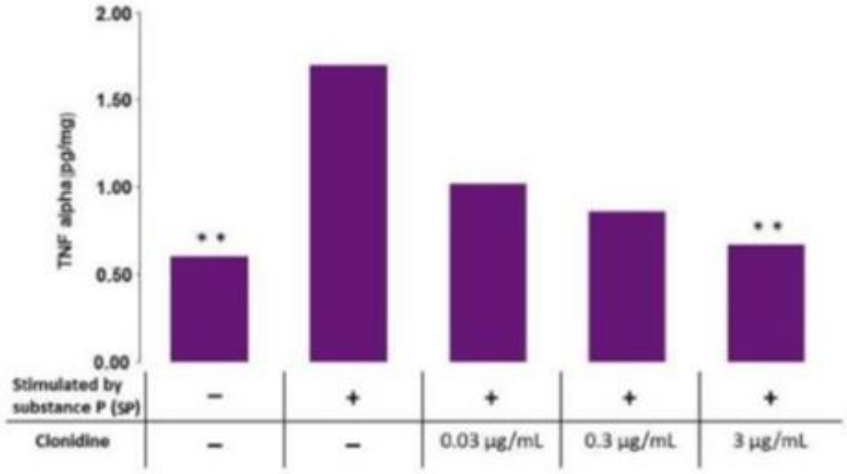
Change in Blood Pressure



Validive Preclinical Data

The anti-inflammatory properties of clonidine were studied in a human oral mucosa organotypic culture model, as pro-inflammatory cytokines are believed to drive the development of SOM. Samples of healthy non-keratinized human oral mucosa were obtained from patients undergoing surgery. The experimental oral mucosa pro-inflammatory process was mediated by the addition of neuropeptide substance P ("SP") to the culture medium. The addition of SP on human gingiva induced a significant increase in TNF-alpha, an important pro-inflammatory molecule involved in mucositis pathogenesis. Overall, on human gingiva stimulated by SP, a concentration dependent decrease in TNF-alpha production was observed with clonidine, which was statistically significant at 3 µg/ml clonidine; see below:

Clonidine Inhibits the Production of Pro-Inflammatory Cytokine Release from Oral Tissue



**** = different from SP treatment alone, p<0.01**

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

MNPR-201 (5-imino-13-deoxydoxorubicin) is a proprietary doxorubicin analog that is selective for topoisomerase II-alpha. Doxorubicin is used to treat adult and pediatric solid and blood (hematologic) cancers, including breast, gastric, ovarian and bladder cancers, soft tissue sarcomas, leukemias and lymphomas. A number of clinical studies have demonstrated the anti-cancer benefit of higher doses of doxorubicin administered for longer periods of time. The optimal clinical efficacy of doxorubicin, however, has historically been limited by the risk of patients developing irreversible, potentially life-threatening cardiotoxicity. For example, several clinical studies completed in the 1990s demonstrated that concurrent doxorubicin (60 mg/m2, 8 cycles) and paclitaxel gave a 94% overall response rate in patients with metastatic breast cancer but led to 18% of these patients developing congestive heart failure. Reduction of doxorubicin to 4-6 cycles of treatment decreased occurrence of congestive heart failure, but also reduced response rates to 45-55%.

MNPR-201 has been engineered specifically to retain the anticancer activity of doxorubicin while minimizing the toxic effects on the heart. We believe the results of these studies, along with the potential to combine a less or non-cardiotoxic analog of doxorubicin with other anticancer agents, offer the opportunity to develop a large market opportunity for MNPR-201 in a broad spectrum of cancer types.

The antitumor effects of MNPR-201 are mediated through the stabilization of the topoisomerase II complex after a DNA strand break and DNA intercalation leading to apoptosis (cell death) through a mechanism similar to doxorubicin and other anthracycline drugs. Inhibiting the topoisomerase II-alpha isoform is desired for the anti-cancer effect, while inhibiting the topoisomerase II-beta isoform has been demonstrated to mediate, at least in part, the cardiotoxicity associated with all anthracycline drugs currently used in the clinic. MNPR-201 is substantially more selective than doxorubicin for inhibiting topoisomerase II-alpha versus topoisomerase II-beta. This selectivity may at least partly explain the minimal cardiotoxicity that has been observed for MNPR-201 in preclinical and clinical studies to date.

MNPR-201 U.S. Market Opportunity

MNPR-201 is an analog of doxorubicin, the first anthracycline to gain FDA approval. Anthracyclines are a class of drugs that are among the most commonly used agents in the treatment of cancer. They have demonstrated efficacy in a wide variety of cancers, including breast cancer, lung cancer, ovarian cancer, sarcomas, and lymphomas. Although doxorubicin was approved decades ago, it is still widely used. According to Grand View Research, in 2015 the global Doxorubicin market was $809.6 million, with $349.7 million of those sales in the U.S. According to IMS Health (now known as IQVIA), in 2015 the European Union had over $270 million in sales between doxorubicin HCl and liposomal doxorubicin. Liposomal versions of doxorubicin (e.g. Doxil) demonstrated that a different formulation of doxorubicin with improved clinical benefits can command a significantly higher price premium compared to generic doxorubicin HCl.

MNPR-201 Development Strategy

We plan to initiate Phase 2 trial(s) that will evaluate MNPR-201 in cancer indications where doxorubicin has shown efficacy, but its utility is sub-optimal due to concerns over the potential for cardiotoxicity. The objective of these trial(s) would be to test for signals of efficacy with cumulative doses of MNPR-201 for which a comparable cumulative dose of doxorubicin would be expected to cause cardiotoxicity. A potential Phase 2 screening trial in patients with metastatic breast cancer would evaluate concurrent MNPR-201 plus paclitaxel to evaluate response rate vs. the 45-55% reported in historical controls as well as the incidence of irreversible cardiotoxicity. The absence of cardiotoxicity with concomitant administration of paclitaxel and MNPR-201 would provide a rationale for this combination in other clinical settings. Similar studies are also under consideration for the combination of MNPR-201 + trastuzumab in metastatic HER2+ breast cancer patients. Additional studies will evaluate cross-over to MNPR-201 in patients benefiting from doxorubicin that have reached their lifetime limit of doxorubicin exposure in soft tissue sarcoma ("STS") and other cancer indications including several pediatric cancer indications. The results of these Phase 2 clinical trials would be used to inform an initial registration strategy for MNPR-201, as well as to support collaborative clinical development efforts with cooperative groups and cancer-focused foundations.

MNPR-201 Clinical Data

Several clinical studies of MNPR-201 have been completed.

In January 2015, a multi-center open label single arm Phase 2 clinical trial was completed in doxorubicin-naïve patients with non-resectable or metastatic STS. Doxorubicin has historically been the standard of care for the treatment of leiomyosarcoma and other STS. This Phase 2 clinical trial enrolled 22 patients and was completed in August 2016. MNPR-201 was administered intravenously at 265 mg/m2 every 3 weeks for up to 16 doses and there was clear indication of anticancer activity at this well-tolerated dose and schedule. One patient went on compassionate use and received 20 cycles of MNPR-201, many more than the 6 to 8 cycles patients on doxorubicin are typically limited to. The progression free survival at 6 months was 38%, versus doxorubicin's 6-month progression free survival of 25%, 33%, and 23% in three separate studies in this patient. Progression free survival at 12 months was 12%, overall survival at 12 months was 45%, and 52.7% of patients experience stable disease or partial response. The median overall survival was 8 months.

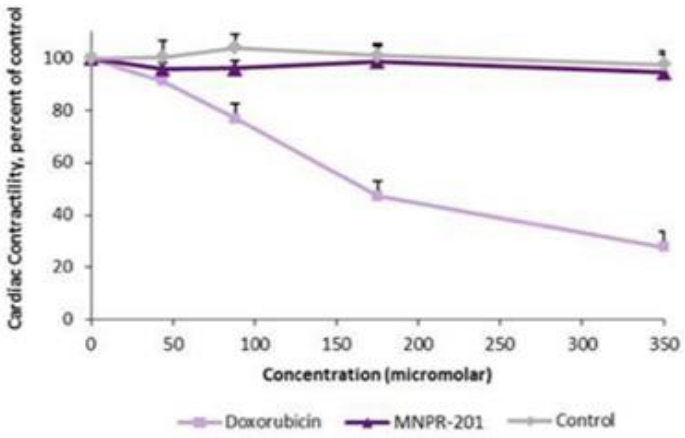
MNPR-201 was well tolerated. Apart from one patient that developed febrile neutropenia and severe leukopenia, there were no grade 4 toxicities reported and no grade 3 side effects other than from anemia. A transient decrease in left ventricular ejection fraction ("LVEF") was observed in four patients treated with MNPR-201. These decreases in LVEF in MNPR-201 treated patients were not serious adverse events and were transient, with LVEF subsequently returning to normal levels in all four subjects. Despite some subjects in this study receiving MNPR-201 for up to 20 cycles, effects on cardiac function were of no clinical significance and there was no evidence of irreversible heart failure in any subject.

In October 2013, a Phase 1 dose escalation study conducted at the University of Iowa completed enrolment of 24 patients who received one of 5 different dose levels of MNPR-201 ranging from 14 to 265 mg/m2. No evidence of irreversible cardiotoxicity was observed in any of these patients, including 4 patients who 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.

MNPR-201 Preclinical Data

In preclinical studies, MNPR-201 showed a lack of acute as well as chronic functional cardiotoxicity, and did not cause the cardiac histopathologic lesions observed with doxorubicin in a chronic rabbit model. Below is *in vitro* data showing the lack of altered contractility with acute exposure of rabbit atria to MNPR-201 even at increased concentrations:

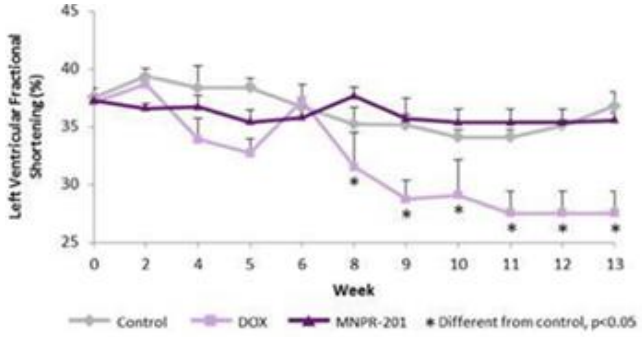
MNPR-201 Cardiac Contractility



MNPR-201 demonstrated limited effect on cardiac contractility, in-line with placebo.

Chronic administration of MNPR-201 two times per week through IV administration into New Zealand white rabbits over 13 weeks also showed a lack of cardiotoxicity of MNPR-201. Echocardiography was performed weekly to obtain left ventricular fractional shortening ("LVFS") measurements to assess cardiac function. At sacrifice, all six doxorubicin-treated rabbits showed cardiac dysfunction by echocardiography, and LVFS was significantly different from control values ($P < 0.001$). In contrast, none of the MNPR-201-treated rabbits exhibited cardiac dysfunction by echocardiography at any time during the study. Below is a graph of the results:

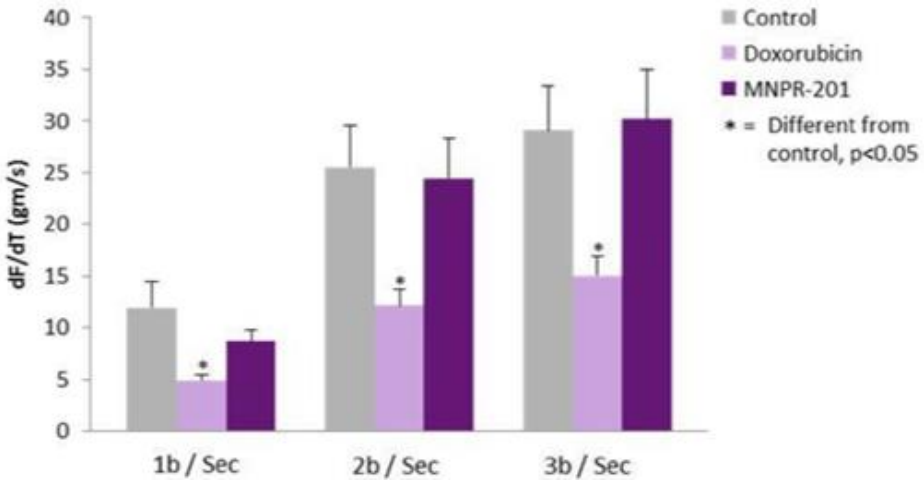
Weekly Cardiac Echos



None of the MNPR-201 treated rabbits showed significant cardiac dysfunction compared to the control, saline.

At the conclusion of the 13 weeks of drug dosing, the rabbits were sacrificed and the left atria were studied to assess cardiac function *ex vivo*. Atria from the doxorubicin-treated rabbits had impaired cardiac contractility (dF/dt) compared to controls over the entire force-frequency range (1, 2 and 3 Hz). Cardiac contractility for the MNPR-201 treated cohort was not significantly different than the vehicle control. Below is a graph of the results:

MNPR-201 Cardiac Contractility



Cardiac contractility (dF/dt) of isolated atria at the three contraction rates (1, 2, and 3 contractions/sec) obtained from rabbits chronically infused with either DOX, MNPR-201 or saline vehicle (control). Values are mean, error bars are standard error of the mean (SEM). MNPR-201 demonstrated limited effect on cardiac contractility, in-line with placebo.

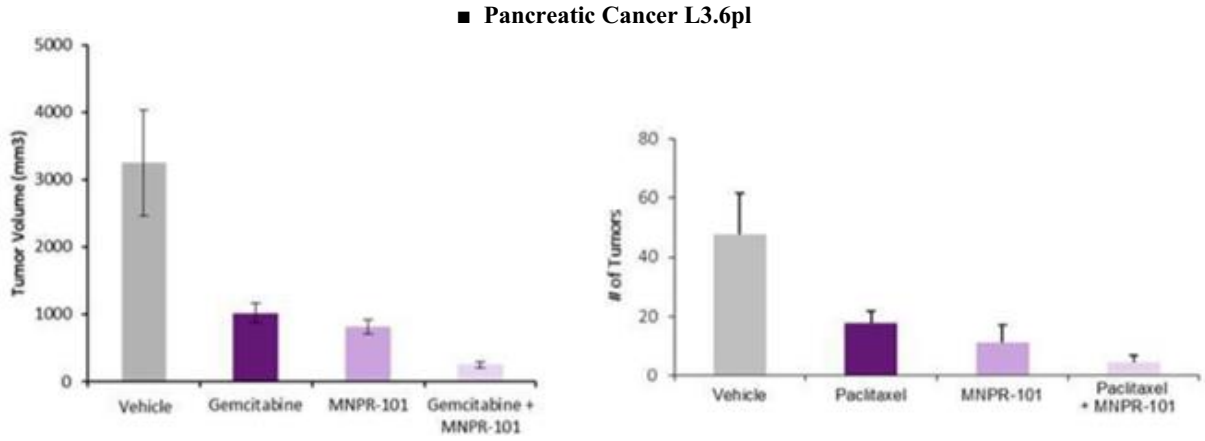
Finally**,** cardiac scoring by a histopathologist of the left ventricle walls obtained from the rabbits in this study showed increased microscopic injury in hearts from doxorubicin-treated rabbits compared to hearts from rabbits administered the vehicle control. Heart tissues from MNPR-201-treated rabbits were the same as the vehicle controls.

MNPR-101 (formerly huATN-658)

MNPR-101 is a humanized monoclonal antibody designed to bind a specific cell surface receptor found on cancer cells, the urokinase plasminogen activator receptor ("uPAR"), and to interrupt several pathways required for tumor growth and progression. MNPR-101 represents a novel approach for drug targeting of uPAR as it does not interfere with normal binding of uPA to uPAR. It blocks the CD11b (alpha-M)-uPAR interaction, a possible regulator of tumor immunity expressed by myeloid derived suppressor cells. MNPR-101 is believed to have potential activity against many different cancer types because it:

- is selectively expressed on metastatic tumor, tumor-associated immune and angiogenic endothelial cells, but not on most normal cells (several Phase 1 positron emission tomography (PET) 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, such as MAPK, AKT, MEK, and FAK, 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.

MNPR-101 Preclinical Studies



MNPR-101 has demonstrated significant anti-tumor activity as a monotherapy in numerous preclinical models of tumor growth as well as enhanced effect of multiple approved chemotherapeutics when used in combination in vivo.

MNPR-101 Development Strategy

Based upon the non-overlapping toxicity and distinct mechanism of action, we plan to develop MNPR-101 in combination with existing cancer therapies. The selective expression of uPAR in tumors underpins our expectation that MNPR-101 will be well-tolerated and amenable to a variety of combination treatment approaches. Published preclinical data have shown the ability of MNPR-101 to enhance the anti-tumor activity of chemotherapies such as paclitaxel and gemcitabine. The expression and targeting of uPAR, in general, also suggests that MNPR-101 may combine with other targeted agents that mediate 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 and may mediate resistance to immune checkpoint inhibitors.

Aside from manufacturing, we expect to conduct IND-enabling studies in order to file an IND with the FDA, depending on external funding and collaboration opportunities.

Partnerships, Licensing, and Acquisition

Since our inception, we have entered into three material business development agreements, one with Onxeo S.A., one with XOMA (US) LLC, and one with Cancer Research UK, which has since been terminated. None of the agreements have required any issuance of equity or any annual maintenance fee. See the summary of the two ongoing material agreements below.

Onxeo, S.A.

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 prevent and 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 a total of $108 million if we achieve all milestones, and in addition 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 3 clinical development program 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.

XOMA

To humanize our MNPR-101 antibody, we have taken a non-exclusive license to XOMA (US) LLC's humanization technology and know-how. Humanization involves replacing most of the non-critical parts of the mouse sequence of an antibody with the human sequence to minimize the ability of the human immune system to recognize this antibody as foreign. As such, MNPR-101 has been engineered to be 95% human sequence using the XOMA technology. Under the terms of the 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. The agreement does not require the payment of sales royalties. There can be no assurance that we will reach any milestones. The first milestone payment is payable upon first dosing of a human patient in a Phase 2 clinical trial.

Intellectual Property Portfolio and Exclusivity

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

Validive

We license all intellectual property related to Validive from Onxeo S.A., a French public company. See "Business - Partnerships, Licensing and Acquisition". Validive is covered by 31 issued patents in 30 jurisdictions, including the U.S., EU, Japan, and other Asian countries, and has orphan drug designation in the EU as well as Fast Track designation from the FDA. These patents are method 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 not accounting for possible extensions.

MNPR-201

MNPR-201 (GPX-150) is covered by manufacturing process patents. We have a patent for chemical synthesis technology that efficiently converts cardiotoxic "13-keto" anthracyclines such as doxorubicin, daunorubicin, epirubicin, and idarubicin into novel, patentable, and most likely less-cardiotoxic "5-imino-13-deoxy" analogs. A novel chemical composition of an intermediate for this synthesis is also patented. In addition, we have a patent covering the combination of MNPR-201 with paclitaxel for the treatment of cancer, plus covering the method of use of these two drugs for this purpose. Our MNPR-201 patent portfolio contains seven issued U.S. patents (two of which have expired) and one U.S. pending patent application. We have certain corresponding patents and applications in twenty-nine foreign jurisdictions, including the U.S., EU, Japan, and other Asian countries. The process patents for the synthesis of MNPR-201 intermediates will expires in 2024 and the patents covering the combination use of MNPR-201 and its analogs with taxanes will expire in 2026. We may pursue patent term extensions where appropriate. We have obtained patent protection around the intermediates and process used to manufacture MNPR-201 and we expect to obtain Hatch-Waxman exclusivity (applicable to new

chemical entities) for 5 years that will prevent generic competition. We have also obtained U.S. orphan drug status in soft tissue sarcoma with additional orphan cancer indications expected to follow. In addition, we have a pending International Nonproprietary Name ("INN") request with the World Health Organization for a non-proprietary (generic) name for MNPR-201.

MNPR-101

Our patent portfolio for our MNPR-101 antibody (huATN-658), as well as its epitope, consists of two issued U.S. composition of matter and their methods of use patents and corresponding (granted and pending) patents and patent applications in 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. Being a novel biologic, it is eligible for 12 years of exclusivity in the U.S. under the Biologics Price Competition and Innovation Act ("BPCI Act"), and in numerous other countries it will benefit from varying durations of similar exclusivity, as well.

Patent life determination depends on the date of filing of the application and other factors as promulgated under the patent laws. In most countries, including the U.S., the patent term is generally 20 years from the earliest claimed filing date (the priority date) of a non-provisional patent application in the applicable country, not taking into consideration any potential patent term adjustment that may be filed in the future or any regulatory extensions that may be obtained. Some of our patents are currently near expiration and we may pursue patent term extensions for these where appropriate. 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 Validive, MNPR-201, or MNPR-101, nor do we have plans to develop our own manufacturing operations in the foreseeable future. We presently depend on third party contract manufacturers for all our required raw materials, Active Pharmaceutical Ingredients ("API"), and finished drug products for our preclinical and clinical studies. We have executed a manufacturing agreement for the next clinical batch of drug product for Validive, which will provide sufficient drug to complete the Phase 3 trials. We have also secured a manufacturing agreement for MNPR-101, but we have not yet secured a manufacturing agreement for MNPR-201.

Sales and Marketing

In light of our stage of development, we have not yet established a commercial organization or distribution capabilities. We have retained worldwide commercial rights for our product candidates. If our product candidates receive marketing approval, we plan to commercialize them in the U.S. and potentially in Europe with our own focused, specialty sales force. We would expect to conduct most of the buildout of this organization following approval in the U.S. or following similar marketing authorizations in Europe of any of our product candidates. We expect to explore commercialization of Validive and potentially other product candidates in certain markets outside the U.S., including the EU, utilizing a variety of collaboration, distribution and other sales and marketing arrangements with one or more third parties.

Oncology Market Competition

The pharmaceutical industry in general, and the oncology therapeutics sector in particular, are characterized by intense competition. We face competition from pharmaceutical and biotechnology companies, many of which are larger and better financed than us. We also face competition in our efforts to develop and commercialize new oncology therapeutics from academic and government laboratories. The therapeutics that we are developing, if successfully commercialized, will have to compete with existing therapeutics already on the market and novel therapeutics currently in development, as well as new therapeutics that may be discovered and developed in the future. Our product candidates will also have to compete with alternate treatment modalities, such as 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."

There is no effective standard of care or FDA approved preventive or therapeutic treatments for patients that develop radiation-induced SOM. Only symptomatic treatments such as opioids and palliative mouthwashes are available but have no effect on the occurrence, time to onset, or duration of SOM. Our primary competitor is a dismutase mimetic entering Phase 3 clinical development, which is administered through a daily 60-minute intravenous ("IV") infusion to be completed within an hour before each radiation treatment. Validive, in comparison, acts locally at the sites of SOM and is a once a day self-administered oral/buccal tablet.

For our MNPR-201 program, we believe, if approved, it would compete with a number of currently available anthracycline-based drugs on the market. These are largely derivatives of doxorubicin, or reformulations of doxorubicin such as liposomal doxorubicin (e.g. Doxil, owned by Johnson & Johnson). All of these have the issue of cardiotoxicity. In addition to approved products, there are a number of product candidates in development, largely as new formulations or derivatives of doxorubicin.

For our MNPR-101 program, it is in the very early stages of development and the most susceptible to all of the competitive factors listed in the first paragraph of this section.

Government Regulation and Product Approval

Government authorities in the U.S., 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 product candidates that we develop must be approved by the FDA before they may be legally marketed in the U.S. See "Risk Factors – Risks Related to Clinical Development and Regulatory Approval".

U.S. Pharmaceutical Product Development Process

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

- Completion of preclinical laboratory tests, animal studies and formulation studies according to Good Laboratory Practices ("GLP"), 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") or Biologics License Application ("BLA"), for a new pharmaceutical product;
- Satisfactory completion of an FDA inspection of the manufacturing facility or facilities where the pharmaceutical product is produced to assess compliance with the FDA's current Good Manufacturing Practice standards ("cGMP:"), to assure that the facilities, methods and controls are adequate to preserve the pharmaceutical product's identity, strength, quality and purity;
- Potential FDA audit of the preclinical and clinical study sites that generated the data in support of the NDA or BLA; 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 2, and before an NDA or BLA is submitted. Meetings at other times may be requested. These meetings can provide an opportunity for the sponsor to share information about the data gathered to date, for the sponsor to ask specific questions to the FDA, for the FDA to provide advice, and for the sponsor and FDA to reach agreement on the next phase of development. Sponsors typically use the end of Phase 2 meeting to discuss their Phase 2 clinical results and present their plans for the pivotal Phase 3 clinical (registration) trial(s) that they believe will support approval of the new drug. A sponsor may be able to request a Special Protocol Assessment ("SPA"), the purpose of which is to reach agreement with the FDA on the Phase 3 clinical trial protocol design and analyses that will form the primary basis of an efficacy claim.

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

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

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

- Phase 1. The pharmaceutical product is initially introduced into healthy human subjects and tested for safety, dosage tolerance, absorption, metabolism, distribution and excretion.
- Phase 2. The pharmaceutical product is evaluated in a limited patient population to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the product for specific targeted diseases, to determine dosage tolerance, optimal dosage and dosing schedule and to identify patient populations with specific characteristics where the pharmaceutical product may be more effective.
- Phase 3. Clinical studies are undertaken to further evaluate dosage, clinical efficacy and safety in an expanded patient population at geographically dispersed clinical study sites. These clinical studies are intended to establish the overall risk/benefit ratio of the product and provide an adequate basis for product labeling. The studies must be well-controlled and usually include a control arm for comparison. One or two Phase 3 studies are required by the FDA for an NDA or BLA approval, depending on the disease severity and other available treatment options.
- Post-approval studies, or Phase 4 clinical studies, may be conducted after initial marketing approval. These studies are used to gain additional experience from the treatment of patients in the intended therapeutic indication.
- Progress reports detailing the results of the clinical studies must be submitted at least annually to the FDA and written IND safety reports must be submitted to the FDA and the investigators for serious and unexpected adverse events or any finding from tests in laboratory animals that suggests a significant risk for human subjects. Phase 1, Phase 2 and Phase 3 clinical studies may not be completed successfully within any specified period, if at all. The FDA or the sponsor or its data safety monitoring board may suspend a clinical study at any time on various grounds, including a finding that the research subjects or patients are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical study at its institution if the clinical study is not being conducted in accordance with the IRB's requirements or if the pharmaceutical product has been associated with unexpected serious harm to patients.

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

U.S. Review and Approval Processes

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

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

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

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

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

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

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

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. With a Fast Track designated product, the FDA may consider for review sections of the NDA or BLA 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 or BLA, if the FDA agrees to accept sections of the NDA or BLA 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 or BLA.

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.

Breakthrough Therapy Designation

The FDA is also required to expedite the development and review of the application for approval of drugs that are intended to treat a serious or life-threatening disease or condition where preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints. Under the breakthrough therapy program, the sponsor of a new product candidate may request that the FDA designate the product candidate for a specific indication as a breakthrough therapy concurrent with, or after, the filing of the IND for the product candidate. The FDA must determine if the product candidate qualifies for breakthrough therapy designation within 60 days of receipt of the sponsor's request. Validive and MNPR-101 may both be eligible for breakthrough therapy designation.

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.

PRIME Designation

The EMA launched its PRIME regulatory initiative to enhance support for the development of therapies that target an unmet medical need. The initiative focuses on drugs that may offer a major therapeutic advantage over existing treatments, or benefit patients with no treatment options. These therapies are considered priority medicines within the EU. Through PRIME, the EMA offers early, proactive and enhanced support to drug developers to optimize the generation of robust data on a therapy's benefits and risks and enable accelerated assessment of drug applications. MNPR-101 may be eligible for PRIME designation.

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 U.S. Department of Justice and/or U.S. 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 or BLA, 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 4 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.

U.S. Foreign Corrupt Practices Act

The U.S. 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 U.S. 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 Pharmaceutical Legislation

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.

Anti-Kickback Statute of 1972

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.

False Claims Act of 1986

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.

Health Insurance Portability and Accountability Act of 1996 ("HIPAA")

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".

Health Information Technology for Economic and Clinical Health Act of 2009 ("HITECH")

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, complicating compliance efforts. See "Risk Factors - Risks Related to Commercialization of Our Product Candidates".

The Medicare Prescription Drug, Improvement and Modernization Act of 2003 ("MMA")

In the U.S. 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 U.S. 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

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.

Physician Payments Sunshine Act of 2010

The federal Physician Payments Sunshine Act requires certain manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program, with specific exceptions, to report annually to the Centers for Medicare & Medicaid Services ("CMS") information related to payments or other transfers of value made to physicians and teaching hospitals, and applicable manufacturers and applicable group purchasing organizations to report annually to CMS ownership and investment interests held by the physicians and their immediate family members.

Patent Protection and Affordable Care Act of 2010 ("PPACA")

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:

- 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 U.S. 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.

Budget Control Act of 2011

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.

American Taxpayer Relief Act of 2012

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.

Proposals in Congress to repeal or replace parts of the PPACA

There have been a number of proposals in the U.S. Congress to repeal or replace parts of the PPACA. On December 22, 2017, the Tax Cuts and Jobs Act became law. One of its provisions repealed what is known as the individual mandate under PPACA, which could have the effect of negating such law. Other 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 or Private Sector 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 U.S. 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 or BLA plus the time between the submission date of an NDA or BLA 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 U.S. 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 U.S. 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 or BLA.

The Biologics Price Competition and Innovation Act (“BPCI Act”)

The Biologics Price Competition and Innovation Act, (“BPCI Act”), authorizes the FDA to license a biological product that is biosimilar to an FDA-licensed biologic through an abbreviated pathway. The BPCI Act establishes criteria for determining that a product is biosimilar to an already-licensed biologic, or reference product, and establishes a process by which an abbreviated BLA for a biosimilar product is submitted, reviewed and approved. The BPCI Act provides periods of exclusivity that protect a reference product from biosimilars competition. Under the BPCI Act, the FDA may not accept a biosimilar application for review until four years after the date of first licensure of the reference product, and the biosimilar may not be licensed until at least 12 years after the reference product’s approval. Additionally, the BPCI Act establishes procedures by which the biosimilar applicant provides information about its application and product to the reference product sponsor, and by which information about potentially relevant patents may be shared and litigation over patents may proceed in advance of approval. The BPCI Act also provides a period of exclusivity for the first biosimilar determined by the FDA to be interchangeable with the reference product.

We anticipate that the contours of the BPCI Act will continue to be defined as the statute is implemented over a period of years. This likely will be accomplished by a variety of means, including decisions related to the statute by the relevant federal courts, FDA issuance of guidance documents, and FDA decisions in the course of considering specific applications. The FDA has to date issued various guidance documents and other materials indicating the agency’s thinking regarding a number of issues implicated by the BPCI Act. Additionally, the FDA’s approval of several biosimilar applications in recent years has helped define the agency’s approach to certain issues.

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 U.S. 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 U.S. 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 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 U.S., 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 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 U.S. NDA and must be filed to obtain approval to market a pharmaceutical product in Canada. Marketing regulations and reimbursement are subject to national and provincial laws. In Japan, applications for approval to manufacture and market new drugs must be approved by the Ministry of Health, Labor and Welfare. Nonclinical and clinical studies must meet the requirements of Japanese laws. Results from clinical studies conducted outside of Japan must be supplemented with at least a bridging clinical study conducted in Japanese patients.

In addition to regulations in Europe, Canada, Japan and the U.S., there are a variety of foreign regulations governing clinical studies, commercial distribution and reimbursement of future product candidates which we may be subject to as we pursue regulatory approval and commercialization of Validive, MNPR-201, MNPR-101, or any future product candidates internationally.

Employees

Our operations are currently managed (including our executive chairman and Acting Chief Medical Officer) by five individuals, of whom three have a PhD, two have an MD, one has an MBA, one has an MSc in health economics and policy, and one was a former CPA. They have worked at industry leading companies such as BioMarin Pharmaceutical Inc., Raptor Pharmaceuticals, Abbott Laboratories, and Onyx Pharmaceuticals. As of February 26, 2019, we had five employees; four of them were full-time. We anticipate hiring additional employees in clinical operations and regulatory to help manage our clinical studies, regulatory submissions, and manufacturing to support Validive program development. In addition, to complement our internal expertise, we have contracts with medical and scientific

consultants, manufacturers, laboratories, and contract research organizations that specialize in various aspects of drug development including clinical development, preclinical development, manufacturing and regulatory affairs. For information regarding our executive officers, see the section entitled "Executive Officers and Board Members."

Compliance with Environmental Laws

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

Available Information

Our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Exchange Act may be accessed through the SEC's website at www.sec.gov and on our website at www.monopartx.com free of charge. Such filings are placed on our website as soon as reasonably practicable after they are filed with the SEC. Our Code of Business Conduct and Ethics and our Audit Committee Charter are also posted on the Investor Highlight page on our website.

Item 1A. Risk Factors

RISK FACTORS

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

Risks Related to Our Financial Condition and Capital Requirements

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

We commenced operations in December 2014 and have a limited operating history of less than five years. Therefore, there is limited historical financial or operational information upon which to evaluate our performance. Our prospects must be considered in light of the uncertainties, risks, expenses, and difficulties frequently encountered by companies in their early stages of operations. Many if not most companies in our industry at our stage of development never become profitable and are acquired or go out of business before successfully developing any product that generates revenue from commercial sales or enables profitability.

From inception in December 2014 through December 31, 2018, we have incurred losses of approximately $21.7 million, which includes $13.5 million of non-cash in-process research and development. We expect to continue to incur substantial operating losses over the next several years for the clinical development of our current and future licensed or purchased product candidates.

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. 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.

As a recently established public reporting company, we are subject to SEC 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 will be unable to advance our development programs, complete our clinical trials, or bring products to market, or may be forced to reduce or cease operations entirely. In addition, any capital obtained by us may be obtained on terms that are unfavorable to us, our investors, or both.

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

- receiving less funding than we require;
- higher than expected costs to manufacture our active pharmaceutical ingredient and our product candidates;
- higher than expected costs for preclinical testing;
- an increase in the number, size, duration, and/or complexity of our clinical trials;
- slower than expected progress in developing Validive, MNPR-201, MNPR-101, or other product candidates, including without limitation, additional costs caused by program delays;
- higher than expected costs associated with attempting to obtain regulatory approvals, including without limitation additional costs caused by additional regulatory requirements or larger clinical trial requirements;
- higher than expected personnel, consulting or other costs, such as adding personnel or industry expert consultants or pursuing the licensing/acquisition of additional assets; and
- higher than expected costs to protect our intellectual property portfolio or otherwise pursue our intellectual property strategy.

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 operational and/or financial performance, investor confidence in us and the biopharmaceutical industry, credit availability from banks and other financial institutions, the status of current projects, and our prospects for obtaining any necessary regulatory approvals. Potential investors' capital investments may have shifted to other opportunities with perceived greater returns and/or lower risk thereby reducing capital available to us, if available at all.

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

Our current cash and cash equivalents are not sufficient to complete our Phase 3 clinical development of Validive, which requires that we raise additional funds. If we raise additional funds in the future to complete our Phase 3 clinical program for Validive, it may not be at favorable terms. If we are unable to raise enough funds in the future, we may have to discontinue or delay our operations.

In order to be commercially viable, we must successfully research, develop, obtain regulatory approval for, manufacture, introduce, market and distribute Validive and, if applicable, any current and future product candidates we may develop. The estimated required capital and time-frames necessary to achieve these developmental milestones as described in this Annual Report on Form 10-K or as we may state from time to time is subject to inherent risks, many of which may be beyond our control. Clinical development of Validive will require significant funds. We cannot be certain the amount we raise in the near-term will be sufficient to fund our Validive Phase 3 clinical program to completion. When we raise additional funds in the future to be able to complete our Validive Phase 3 clinical program, it may be on terms that are unfavorable to us, and if we are unable to raise sufficient funds, we may have to discontinue or delay our operations.

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

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

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 U.S. and international governmental agencies and will be severely harmed if we are not granted approval to manufacture and sell our product candidates.

In order for us to commercialize any treatment for chemoradiation-induced SOM or for any other disease 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 will prove to be safe and effective, that our clinical trials will demonstrate the necessary safety and effectiveness of our product candidates, or that we will succeed in obtaining regulatory approval for any treatment we develop even if such safety and effectiveness are demonstrated.

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

- Clinical trials may not yield sufficiently conclusive results for regulatory agencies to approve the use of our products.
- Our products may fail to be more effective than current therapies, or to be effective at all.
- We may discover that our products have adverse side effects, which could cause our products to be delayed or precluded from receiving regulatory approval or 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 suffer severe adverse side effects even up to death, whether as a result of treatment with our products, the withholding of such treatment, or other reasons (whether within or outside of our control).
- We may fail to be able 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 or patient population.
- We may be unable to produce sufficient quantities of product to complete the clinical trials.
- Even if we are successful in our clinical trials, 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 will cause a substantial increase in costs and which we might not succeed in performing or completing.
- If granted, approval may be withdrawn or limited if problems with our products emerge or are suggested by the data arising from their use or if there is a change in law or regulation.

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

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

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

Even if we complete the clinical trials we discussed with the FDA, there is no guarantee that at the time of submission the FDA will accept our new drug application ("NDA").

The FDA provided helpful guidance on our proposed Validive adaptive design trial and confirmatory second trial, informing us it might be an acceptable pathway for NDA submission, but the FDA is not bound by the guidance they give, and can change their position in the future, even if a company gets a special protocol assessment ("SPA") in place. Any future decision by the FDA will be driven largely by the data generated from the Validive clinical trials.

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

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

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

We may seek fast track designation for one or more of our current and future product candidates, but we might not receive such designation, and even if we do, such designation may not actually lead to a faster development or regulatory review or approval process.

Our lead product candidate, Validive, has been given fast track designation from the FDA. Fast track designation does not ensure that we will receive marketing approval or that approval will be granted within any particular timeframe. We may not experience a faster development, regulatory review or approval process with fast track designation compared to conventional FDA procedures. Additionally, the FDA may withdraw fast track designation, for reasons such as it comes to believe a drug candidate no longer adequately addresses an unmet medical need. Fast track designation alone does not guarantee qualification for the FDA's priority review procedures. If we seek fast track designation for other product candidates, we may not receive such a designation from the FDA.

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

Validive has been granted orphan drug designation for the treatment of SOM in the EU. MNPR-201 has been granted orphan drug designation for the treatment of soft tissue sarcoma in the U.S. We may seek additional orphan drug designations or regulatory incentives for our pipeline product candidates, for other indications or for future product candidates. There can be no assurances that we will be able to obtain such designations.

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

drug is clinically superior in that it is shown to be safer, more effective or makes a major contribution to patient care compared to our product.

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

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

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

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

With regard to our lead product candidate, Validive, unforeseen side effects from Validive could arise either during clinical development or, if approved, after Validive has been marketed. This could cause regulatory approvals for, or market acceptance of, Validive harder and costlier to obtain.

To date, no difference in the frequency of serious adverse events ("SAEs") has been observed in patients treated with Validive compared to placebo. In the Phase 2 clinical trial, two patients in the placebo group and 2 patients in the Validive 50 µg group experienced SAEs that were assessed as treatment related. No patients in the Validive treated cohorts were discontinued due to study drug. Clonidine, the active ingredient of Validive, has been used for over 50 years as an orally swallowed systemic treatment for high blood pressure. Validive administration leads to very low, but still detectable exposure of clonidine outside the oral cavity. Thus, there is some risk that patients may experience side effects due to this systemic exposure, which could include a reduction in blood pressure, irregular heartbeat, drowsiness or dry mouth.

The results of our planned or any future clinical trials may show that the side effects of Validive are unacceptable or intolerable, which could interrupt, delay or halt clinical trials, and result in delay of, or failure to obtain, marketing approval from the FDA or EMA and other regulatory authorities, or result in marketing approval from the FDA or EMA and other regulatory authorities with restrictive label warnings.

If Validive receives marketing approval and we or others later identify undesirable or unacceptable side effects caused by the use of Validive:

- regulatory authorities may withdraw their approval of the prouct, which would force us to remove Validive from the market;
- regulatory authorities may require the addition of labeling statements, specific warnings, a contraindication, or field alerts to physicians and pharmacies;
- we may be required to change instructions regarding the way the product is administered, conduct additional clinical trials or change the labeling of the product;
- we may be subject to limitations on how we may promote the product;
- sales of the product may decrease significantly;
- we may be subject to litigation or product liability claims; and
- our reputation may suffer.

Any of these events could prevent us or our potential future collaborators from achieving or maintaining market acceptance of Validive and/or could substantially increase commercialization costs and expenses, which in turn could delay or prevent us from generating significant revenues from the sale of Validive.

Our Phase 3 development program for Validive entails significant risk.

The Phase 3 development program for Validive has been designed based on an analysis of the 64 oropharyngeal cancer ("OPC") patients included in the Phase 2 trial (n= 24 in the placebo group, n= 21 Validive 50 µg group, and n= 19 Validive 100 µg group). While a dose response was observed in the Validive treated OPC cohorts compared to placebo across multiple clinically meaningful endpoints, the ability to establish statistical significance was limited by the relatively small sample size. This increases the risk of the Phase 3 trials. Given the large unmet medical need for the prevention of radiotherapy-induced SOM in OPC patients, we have decided to pursue an adaptive design Phase 3 clinical development strategy in an effort to mitigate this risk. Our adaptive design approach will allow us to confirm or reject our hypothesis based off the Phase 2 data that the optimal patient population for Validive is likely either all OPC patients or HPV+ OPC patients, and then run a confirmatory second trial should it be warranted.

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

Identifying, screening and enrolling patients to participate in clinical trials of our product candidates is critical to our success, and we may not be able to identify, recruit, enroll and dose a sufficient number of patients with the required or desired characteristics to complete our clinical trials in a timely manner. The timing of our clinical trials depends on our ability to recruit patients to participate as well as to subsequently dose these patients and complete required follow-up periods. In particular, because our planned clinical trials of Validive and MNPR-201 are focused on indications with relatively small patient populations, our ability to enroll eligible patients may be limited or may result in slower enrollment than we anticipate.

In addition, we may experience enrollment delays related to increased or unforeseen regulatory, legal and logistical requirements at certain clinical trial sites. These delays could be caused by reviews by regulatory authorities and contractual discussions with individual clinical trial sites. Any delays in enrolling and/or dosing patients in our planned clinical trials could result in increased costs, delays in advancing our product candidates, delays in testing the effectiveness of our product candidates or in termination of the clinical trials altogether.

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

- coordination with clinical research organizations to enroll and administer the clinical trials;
- coordination and recruitment of collaborators and investigators at individual sites;
- size of the patient population and process for identifying patients;
- design of the clinical trial protocol;
- eligibility and exclusion criteria;
- perceived risks and benefits of the product candidates under study;
- availability of competing commercially available therapies and other competing products' clinical trials;
- time of year in which the trials are initiated or conducted;
- severity of the diseases under investigation;
- ability to obtain and maintain subject consents;
- ability to enroll and treat patients in a timely manner;
- risk that enrolled subjects will drop out before completion of the trials;
- proximity and availability of clinical trial sites for prospective patients;
- ability to monitor subjects adequately during and after treatment; and
- patient referral practices of physicians.

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

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

Completion of our clinical trials and commercialization of our product candidates require access to, or development of, facilities to manufacture a sufficient supply of our product candidates. We currently plan to contract with third parties to manufacture Validive, MNPR-201, and MNPR-101. We have an agreement in place with a manufacturer for Validive and MNPR-101. We are in negotiations with manufacturers for MNPR-201.

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

Before we can begin to commercially manufacture Validive, MNPR-201, 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 current Good Manufacturing Practices requirements, commonly known as "cGMP." The cGMP requirements govern quality control and documentation policies and procedures. Complying with cGMP and non-U.S. regulatory requirements will require that we expend time, money, and effort in production, recordkeeping, and quality control to ensure that the product meets applicable specifications and other requirements. We, or our contracted manufacturing facility, must also pass a pre-approval inspection prior to FDA 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 and will lose time to market and potential revenues.

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

Clinical research involves the testing of new drugs on human volunteers pursuant to a clinical trial protocol. Such testing involves a risk of liability for personal injury to or death of patients due to, among other causes, adverse side effects, improper administration of the new drug, or improper volunteer behavior. Claims may arise from patients, clinical trial volunteers, consumers, physicians, hospitals, companies, institutions, researchers, or others using, selling, or buying our products, as well as from governmental bodies. 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 product liability insurance (at the clinical stage and/or commercial stage) 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 (including lack of effective actions) to delay, prevent, or undermine the success of our products.

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

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

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

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

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

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

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

Our Validive manufacturer is in the United Kingdom ("UK"), and it is unknown how they will be impacted by Brexit; however, if they are negatively impacted, this could increase our manufacturing costs and adversely impact our financial condition.

The UK's referendum to leave the EU or "Brexit," has caused and may continue to cause disruptions to capital and currency markets worldwide. The full impact of the Brexit decision, however, remains uncertain. A process of negotiation will determine the future terms of the UK's relationship with the EU. During this period of negotiation, our Validive manufacturer may be negatively affected by interest rate, exchange rate and other market and economic volatility, as well as regulatory and political uncertainty. The tax consequences of the UK's withdrawal from the EU are uncertain as well. If Brexit has a detrimental effect on our Validive manufacture, it could, in turn, adversely impact our manufacturing costs and financial condition.

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

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

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

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

Risks Related to Commercialization of Our Product Candidates

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

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

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

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

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

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

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

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

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

Comparative superiority of the effectiveness and safety in the treatment of the disease indication compared to alternative treatments;

- Less prevalence and severity of adverse side effects;
- Potential advantages over alternative treatments;
- Cost effectiveness;
- Convenience and ease of administration;
- Sufficient third-party coverage and/or reimbursement;
- Strength of sales, 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, payers, and patients, we may generate insufficient, 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 do not achieve adequate reimbursement, then the number of physician prescriptions of our products may not be sufficient to make our products profitable.

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

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

The effects of economic and political pressure to lower pharmaceutical prices are a major threat to the economic viability of new research-based pharmaceutical products, and any development along these lines could materially and adversely affect our prospects.

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.

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. Fraud and abuse laws are expected to increase in breadth and in detail, which will likely increase our operating costs and the complexity of our programs to insure compliance with such enhanced laws.

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

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

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

Negotiated prices for our products covered by a Part D prescription drug plan 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 have licensed all intellectual property related to Validive from Onxeo S.A., a French public company. See "Business - Partnerships, Licensing and Acquisition". The assignment and transfer of the MNPR-201 (GPX-150) patent portfolio from TacticGem, LLC ("TacticGem") to us has been completed. We filed and have been granted in the U.S. and various countries around the world patents for antibodies that target uPAR for our MNPR-101 program. We have also been granted in the U.S. and various countries around the world patents to a specific sequence of amino acids on uPAR, to which our MNPR-101 antibody binds. We are currently prosecuting this patent in other countries around the world to further protect MNPR-101. 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 "Item I Business - Intellectual Property Portfolio and Exclusivity". These risks and uncertainties include without limitation the following:

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

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

In addition to patents, we also rely on trade secrets and proprietary know-how. While we take measures to protect this information by entering into confidentiality and invention agreements with our 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.

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

We may be subject to competition despite the existence of intellectual property we license or own. We can give no assurances that our intellectual property claims will be sufficient to prevent third parties from designing around patents we own or license and developing and commercializing competitive products. The existence of competitive products that avoid our intellectual property could materially adversely affect our operating results and financial condition. Furthermore, limitations, or perceived limitations, in our intellectual property may limit the interest of third parties to partner, collaborate or otherwise transact with us, if third parties perceive a higher than acceptable risk to commercialization of our products or future products. When looking at our Validive patents' ability to block competition, the protection offered by our patents may be, to some extent, more limited than the protection provided by patents claiming the composition of matter of entirely new chemical structures previously unknown. If a competitor were able to successfully design around any method of use and formulation patents we may have now or in the future, our business and competitive advantage could be adversely affected.

Patent terms may be inadequate to protect our competitive position on our product candidates for an adequate amount of time.

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

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

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

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

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

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

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

If we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed.

In addition to seeking patent protection, we also rely on trade secrets, including unpatented know-how, technology and other proprietary information, to maintain our competitive position. We seek to protect these trade secrets, in part, by entering into non-disclosure and confidentiality agreements with parties who have access to them. Despite these efforts, these parties may breach the

agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts inside and outside the U.S., including in foreign jurisdictions, are less willing or unwilling to protect trade secrets. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent them from using that technology or information to compete with us. If any of our trade secrets were to be disclosed to or independently developed by a competitor, our competitive position would be harmed.

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

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

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

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

Risks Related to Our Business Operations and Industry

As a recently established entity, we have a limited operating history.

As of February 15, 2019, we have engaged exclusively in acquiring pharmaceutical product candidates, licensing rights to product candidates and entering into collaboration agreements with respect to key services or technologies for our drug product development, and have not completed any clinical trials, received any governmental approvals, brought any product to market, manufactured products in clinical or commercial quantities or sold any pharmaceutical products. As a company we have limited experience in negotiating, establishing, and maintaining strategic relationships, conducting clinical trials, and managing the regulatory approval process, all of which will be necessary if we are to be successful. Our lack of experience in these critical areas makes it difficult for a prospective investor to evaluate our abilities and increases the risk that we will fail to successfully execute our strategies.

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

In the normal course of business, we have evaluated and expect to evaluate potential acquisitions and/or licenses of patents, compounds, and technologies that our management believes could complement or expand our business. 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 current business development.

If we lose key management leadership, and/or scientific personnel, and if we cannot recruit qualified employees, managers, directors, officers, or other significant personnel, we may experience program delays and increases in compensation costs, and 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, Christopher M. Starr, our Executive Chairman of the Board of Directors (referred to as the "Board" or the "Board of Directors"), 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 product development and commercialization of our product candidates. We have employment agreements with Dr. Robinson and Dr. Mazar which have no term but are for at-will employment, meaning the executives have the ability to terminate their employment at any time. We do not have an employment agreement with Dr. Starr.

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

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

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

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

We are an emerging growth company. Under the Jumpstart Our Business Startups Act of 2012 (the "JOBS Act"), emerging growth companies can delay adopting new or revised accounting standards until such time as those standards apply to private companies. 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, if and when our stock becomes publicly traded, there may be less liquidity for our common stock and our stock price may be more volatile.

We will remain an emerging growth company until the earliest of (1) the last day of the year (a) following the fifth anniversary of the completion of a public offering, (b) in which we have total annual gross revenue of at least $1.07 billion or (c) in which we are deemed to be a large accelerated filer, which means the market value of our common stock that is held by non-affiliates exceeds $700 million as of the prior June 30th, and (2) the date on which we have issued more than $1.0 billion in non-convertible debt securities during the prior three-year period.

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

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

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

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

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

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

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

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

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, including a possibility in some states for product liability claims being made based on generic copies of our drugs. Since we currently are not sponsoring any clinical trials, 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, assuming the coverage is available at a commercially reasonable cost, if available at all. Regardless of their merit or eventual outcome, product liability claims may result in:

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

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

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

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, good business judgement, 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 of members of our Board (each a "Member"), if such 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 or private sector actions may increase the difficulty and cost for us to commercialize our products and affect the prices obtained for such products.

There have been several attempts made to repeal or modify the Patient Protection and Affordable Care Act (the "PPACA"), and modification and partial or complete repeal of the Affordable Care Act in the future is possible. On December 22, 2017, the Tax Cuts and Jobs Act became law – one of its provisions repealed what is known as the individual mandate under PPACA, which may have the effect of negating PPACA. Healthcare reform measures that may be adopted in the future may result in more rigorous coverage criteria resulting in lower reimbursement, and in additional downward pressure on the price that may be charged for any of our product candidates, if approved.

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

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

Legislative actions, as well as various governmental policies and political actions can impact the FDA posing a risk to the successful development of new pharmaceutical products in the U.S. and our business may be negatively impacted.

Executive Orders and policy statements issued by President Trump, as well as legislative actions have increased the uncertainty regarding the FDA's interpretation and implementation of requirements under the Federal Food, Drug and Cosmetic Act ("FDCA"). Some of these actions may also negatively affect the FDA's exercise of regulatory oversight and ability to timely review and approve industry submissions and applications in connection with the drug development and approval processes. For example, due to the absence of a fiscal year 2019 appropriation or continuing resolution for the FDA, beginning on December 22, 2018 and continuing for a 35-day period, the FDA's operations were limited to those permitted by law. These activities were limited to such activities necessary to address imminent threats to the safety of human life and activities funded by carryover user fee funds. During this period, the FDA did not have legal authority to accept user fees assessed for fiscal year 2019 until a fiscal year 2019 appropriation or a continuting resolution was enactedAn under-resourced 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. If executive or legislative actions impose restrictions on the FDA's ability to engage in oversight and implementation activities over human drugs and biologics in the normal course, our business may be negatively impacted.

Effective collaboration with the FDA's Center for Drug Evaluation and Research ("CDER") for the approval of drug candidates is a highly demanding process which can result in increased time and expense to gain approvals.

Our lead drug development program, Validive, will be reviewed by CDER. Efficient and professional collaboration with the FDA's CDER is essential for the timely clinical testing, test evaluations, analysis and approval of our drug candidates in the CDER is arguably the most qualified organization for the review and approval and continued monitoring of prescription pharmaceuticals. Financial resources available to CDER have increased every year from fiscal year 2015 to fiscal year 2018 and are projected to increase in 2019. At the program level, which combines budget authority and industry user fees, the total fiscal year 2019 President's Budget is approximately $1,853 million and is an increase of approximately $198 million. CDER portion of the budget is approximately $1,651 million. The sources of the Budget funding is 30% from budget authority and 70% from industry user fees. Industry user fees have been extended to 2022. CDER has an outstanding record of drug approvals and substantial funds to operate a highly professional organization, but is also very demanding as to the quality of clinical research and applications for marketing approvals for drug candidates.

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

Future tax reform measures may negatively impact our financial position.

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, on December 22, 2017, the Tax Cuts and Jobs Act of 2017 was signed into law that significantly revises the Internal Revenue Code of 1986, as amended (the "Code"). The newly enacted federal income tax law, among other things, contains significant changes to corporate taxation, including reduction of the corporate tax rate from a top marginal rate of 35% to a flat rate of 21%, limitation of the tax deduction for interest expense to 30% of adjusted earnings (except for certain small businesses), limitation of the deduction for net operating losses to 80% of current year taxable income and elimination of net operating loss carrybacks, treatment of proceeds from the sale of "self-created" patents as ordinary income, and modifying or repealing many business deductions and credits (including reducing the business tax credit for certain clinical testing expenses incurred in the testing of orphan drugs from 50% to 25%). Notwithstanding the reduction in the corporate income tax rate, the overall impact of the new federal tax law is uncertain and our business and financial condition could be adversely affected. In addition, it is uncertain if and to what extent various states will conform to the newly enacted federal tax law. The impact of this tax reform on holders of our common stock is also uncertain. We urge our stockholders to consult with their legal and tax advisors with respect to this legislation and the potential tax consequences of investing in or holding our common stock. It is difficult to predict what future 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 and capital expenditures over the next year are based upon our management's estimates of possible future events. Actual amounts and the cost of new conditions could differ materially from those estimated by our management.

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

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

The projections that we provide herein or our management may provide from time to time (including, but not limited to, the cost and timing of our Phase 3 clinical trials, clinical and regulatory timelines, production and supply matters, commercial launch dates, and other financial or operational matters) reflect numerous assumptions made by our management, including assumptions with respect to our specific as well as general business, regulatory, economic, market and financial conditions and other matters, all of which are difficult to

predict and many of which are beyond our control. Accordingly, there is a risk that the assumptions made in preparing the projections, or the projections themselves, will prove inaccurate. There may be differences between actual and projected results, and actual results may be materially different from those contained in the projections. The inclusion of the projections in this Annual Report on Form 10-K should not be regarded as an indication that we consider the projections to be a guaranteed prediction of future events, and the projections should not be relied upon as such. See “Special Cautionary Notice Regarding Forward-Looking Statements”.

Risks Related to our Common Stock

Existing and new investors will experience dilution as a result of future sales or issuances of our common stock and future option exercises under our stock option plan.

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 1,105,896 shares of our common stock have already been granted and are outstanding as of February 26, 2019. 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 February 26, 2019, 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 of decisions on major transactions.

Our business and affairs are managed by or under the direction of our Board. Our Stockholders are entitled to vote only on actions that require a Stockholder vote under federal or state law. Stockholder approval requires the consent and approval of holders of a majority or more of our outstanding stock. Shares of stock do not have cumulative voting rights and therefore, holders of a majority of the shares of our outstanding stock will be able to elect all Board Members. TacticGem owns 7,166,667 shares of common stock (77.1%). The limited liability company agreement of TacticGem provides that the manager will vote its shares of Monopar to elect to the Board of Directors those persons nominated by Tactic Pharma plus one person nominated by Gem Pharmaceuticals, LLC ("Gem"). 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 our common stock and elect over a majority of our Board of Directors. See "Principal Stockholders".

There has been no prior public market for our common stock, if our stock becomes publicly tradable in the future, the future stock price of our common stock may be volatile or may decline regardless of our operating performance and limited trading volume could adversely affect your ability to resell your shares.

There has been no public market for our common stock up to and including the filing date of this Annual Report on Form 10-K. If our stock becomes publicly tradable in the future, the future stock price of our common stock may be volatile or may decline regardless of our operating performance and limited trading volume could adversely affect your ability to resell your shares. An active or liquid market in our common stock may not develop or, if it does develop, it may not be sustainable.

The market prices for securities of biotechnology and pharmaceutical companies have historically been highly volatile, and the market has from time to time experienced significant price and volume fluctuations that are unrelated to the operating performance of particular companies.

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

- announcements concerning the progress and success of our clinical trials, our ability to obtain regulatory approval for and commercialize our product candidates, including any requests we receive from the FDA for additional studies or data that result in delays in obtaining regulatory approval or launching our product candidates, if approved;
- market conditions in the pharmaceutical and biotechnology sectors or the economy as a whole;
- price and volume fluctuations in the overall stock market;
- the failure of our product candidates, if approved, to achieve commercial success;
- announcements of the introduction of new products by us or our competitors;
- developments concerning product development results or intellectual property rights of others;
- litigation or public concern about the safety of our potential products;
- actual fluctuations in our quarterly operating results, and concerns by investors that such fluctuations may occur in the future;
- deviations in our operating results from the estimates of securities analysts or other analyst comments;
- additions or departures of key personnel;
- healthcare reform legislation, including measures directed at controlling the pricing of pharmaceutical products, and third-party coverage and reimbursement policies;
- developments concerning current or future strategic collaborations; and

- discussion of us or our stock price by the financial and scientific press and in online investor communities.

If our stock becomes publicly tradable in the future, we may become involved in securities class action litigation that could divert management's attention and harm our business.

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

If our stock becomes publicly tradable in the future, substantial amounts of our outstanding shares may be sold into the market, when lock-up or market standoff periods end. If there are substantial sales of shares of our common stock, the price of our common stock could decline.

If our stock becomes publicly tradable in the future, the price of our common stock could decline if there are substantial sales of our common stock, particularly sales by our directors, executive officers and significant stockholders, or if there is a large number of shares of our common stock available for sale and the market perceives that sales will occur. The overwhelming majority of all of our outstanding shares of common stock may be restricted from resale as a result of market stand-off and "lock-up" agreements. Shares held by directors, executive officers and other affiliates would be subject to volume limitations under Rule 144 under the Securities Act of 1933, as amended (Securities Act), and various vesting agreements.

Certain of our stockholders have rights, subject to certain conditions, to require us to file registration statements covering their shares or to include their shares in registration statements that we may file for ourselves or our stockholders, subject to market standoff and lockup agreements. We also would likely intend to register shares of common stock that we have issued and may issue under our employee equity incentive plans. Once we register these shares, they would be able to be sold freely in the public market upon issuance, subject to existing market standoff or lock-up agreements. The market price of the shares of our common stock could decline as a result of the sale of a substantial number of our shares of common stock in the public market or the perception in the market that the holders of a large number of shares intend to sell their shares.

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

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

If our stock becomes publicly tradable, at such time, if securities or industry analysts do not publish research or publish inaccurate or unfavorable research about our business, our stock price and trading volume could decline.

If our stock becomes publicly tradable in the future, the trading market for our common stock would depend in part on the research and reports that securities or industry analysts publish about us or our business. Securities and industry analysts do not currently, and may never, publish research on our Company. If securities or industry analysts do not commence coverage of our Company, the trading price for our stock would likely be negatively impacted. In the event securities or industry analysts initiate coverage, if one or more of the analysts who covers us downgrades our stock or publishes inaccurate or unfavorable research about our business, our stock price may decline. If one or more of these analysts ceases coverage of our Company or fails to publish reports on us regularly, demand for our stock could decrease, which might cause our stock price and trading volume to decline.

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

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

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

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

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

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

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

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

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

Item 2. Properties

We lease approximately 1,202 square feet of space in the Village of Wilmette, Illinois for our corporate offices, under a lease which runs through the end of 2019. In February 2019, on a month-to-month basis, we leased additional office space at our corporate offices. We believe that we will lease additional office space within the next 12 months as we begin to hire additional personnel.

Item 3. Legal

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

PART II

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

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 February 26, 2019, 9,291,421 shares of our common stock are eligible for sale under Rule 144.

We cannot estimate the number of shares of our common stock that our existing stockholders will elect to sell under Rule 144.

Holders

As of February 26, 2019, there were 9,291,421 shares of our common stock outstanding held by 43 holders. In addition, there were 11 holders of stock options to purchase up to 1,105,896 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.

Registration Rights

We are subject to an agreement with TacticGem (pursuant to the Gem Transaction as discussed later in this document), 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.

Recent Sales of Unregistered Securities.

Set forth below is information regarding shares of common stock issued and options granted by us in the year ended December 31, 2018, 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) 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.

(b) On May 21, 2018, we granted options for 5,000 shares of common stock to an employee in exchange for services. The exercise price of the options was $6.00 per share and the options expire on May 20, 2028.

(c) On August 6, 2018, we granted options for 5,000 shares of common stock to an employee in exchange for services. The exercise price of the options was $6.00 per share and the options expire on August 5, 2028.

(d) On August 28, 2018, we granted options for 320,900 shares of common stock to our officers for services. The exercise price of the options was $6.00 per share and the options expire on August 27, 2028.

(e) On August 28, 2018, we granted options for 104,400 shares of common stock to our non-employee directors for services. The exercise price of the options was $6.00 per share and the options expire on August 27, 2028.

(f) On December 30, 2018, we granted options for 20,000 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 29, 2028.

The offers, sales and issuances of the securities described in paragraphs (a) through (e) 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, non-employee directors, 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.

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations.

You should read the following discussion and analysis of our financial condition and results of operations together with our financial statements and related notes appearing at the end of this Annual Report on Form 10-K. Some of the information contained in this discussion and analysis or set forth elsewhere in this Annual Report on Form 10-K, including information with respect to our plans and strategy for our business and related financing, includes forward-looking statements that involve risks and uncertainties. You should read the "Risk Factors" section of this Annual Report on Form 10-K, Item 1A, for a discussion of important factors that could cause actual results to differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis.

Overview

Our mission is to develop innovative drugs and 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.

Validive is being developed for the treatment of radiation-induced 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 treatment complications. Many affected patients require hospitalization and the SOM symptoms can force patients to stop cancer treatments early, which reduces the success of treatments. Validive is designed to deliver the active ingredient, clonidine, to the at-risk oropharyngeal mucosa. Clonidine reduces the production of cytokines, the molecules that cause ulcerations and pain in patients that develop SOM. Preclinical studies and a Phase 2 clinical trial have demonstrated that Validive has the potential for reducing the incidence of SOM in addition to improving its symptoms, as compared to a placebo. Additionally, patients in the Validive cohorts in the Phase 2 clinical trial demonstrated a safety profile similar to that of placebo. On September 8, 2017, we exercised our exclusive option to license Validive in order to advance its development with the near-term goal of commencing a Phase 3 clinical program. If successful, this Phase 3 clinical program may allow us to apply for marketing approval both in the U.S. and internationally. See "Item I - Business - Partnerships, Licensing and Acquisition" and "Strategy".

In August 2017, we acquired MNPR-201 (GPX-150; 5-imino-13-deoxydoxorubicin) from TacticGem, LLC. MNPR-201 is a proprietary analog of doxorubicin that is selective for topoisomerase II-alpha, and has been engineered specifically to retain the anticancer activity of doxorubicin while minimizing toxic effects on the heart. It has completed a small Phase 2 clinical trial in soft tissue sarcoma patients, with no irreversible cardiotoxicity events observed.

MNPR-101 is our product candidate designed to reduce tumor growth by targeting a specific 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. Preclinical models have shown that MNPR-101 is effective at reducing tumor growth, both used alone and in combination with existing therapies. We are currently reviewing potential clinical development opportunities for MNPR-101.

Over the next three years, we plan to execute our Phase 3 clinical program for Validive, continue clinical development of MNPR-201, pursue collaboration opportunities for MNPR-101 for initial clinical development, raise additional capital to fund our drug development programs, acquire or in-license additional 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 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 our drug development. See "Item 1-A - Risk Factors – Risks Related to our Reliance on Third Parties". Additionally, if we do not raise enough funds in our next offering to cover the Phase 3 clinical program, we will need to raise significant additional funds in the next 12–24 months to continue our clinical development of Validive and potential approval and commercialization plans. We believe that we will have better access to capital as a public reporting company and if a trading market develops for our stock. This would increase corporate visibility, provide increased liquidity for our stockholders, and create a market value for our pipeline of oncology product candidates. Therefore, we became a public reporting company under the Securities Exchange Act of 1934 (the "34 Act") through the filing of a Form 10 registration statement with the SEC. We intend to list on the Nasdaq Stock Market ("Nasdaq") as soon as we are able to meet the shareholder number, capitalization and other requirements for such a listing. There can be no assurance that we will be successful in including our stock for trading on Nasdaq or that a market will develop for our stock. See "Item 1-A - Risk Factors – Risks Related to Our Financial Condition and Capital Requirements", and "Risks Related to Our Business Operations and Industry".

Revenues

We are an emerging growth company, have no approved drugs and have not generated any revenues.

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 were converted into 7,000,000 shares of common stock and 15,894 shares of Series A Preferred Stock were converted into 1,335,079 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 consolidated financial statements included elsewhere in this Annual Report on Form 10-K, we believe the following accounting policies to be critical to the judgments and estimates used in the preparation of our consolidated financial statements.

Recently Issued and Adopted Accounting Pronouncements

A description of recently issued accounting pronouncements that may potentially impact our financial position and consolidated results of operations is disclosed in Note 2 to our consolidated financial statements appearing elsewhere in this Annual Report on Form 10-K.

Research and Development Expenses

Research and development ("R&D") costs are expensed as incurred. Major components of research and development expenses include salaries and benefits of R&D staff, fees paid to consultants and to the entities that conduct certain development activities on our behalf and materials and supplies.

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 years, we had no clinical trials in progress.

The successful development of our product pipeline is 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 product candidates or the period, if any, in which material net cash inflows from our product candidates may commence. This is due to the numerous risks and uncertainties associated with developing product candidates, including:

- receiving less funding than we require;
- slower than expected progress in developing Validive, MNPR-201, MNPR-101 or other product candidates;
- higher than expected costs to produce our current and future 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 of patients, clinical sites, 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 and additional clinical testing mandated by regulatory authorities;
- higher than expected personnel or other costs, such as adding personnel or engaging consultants or pursuing the acquisition or licensing of additional assets; and
- lower potential benefits of our product candidates compared to other therapies.

There are other risks described in “Item 1-A - Risk Factors”. A change in the outcome of any of these variables with respect to the development of a product candidate could mean a significant change in the costs and timing associated with the development of that product candidate. We expect that research and development expenses will increase in future periods as a result of additional product programs under development which will require increased personnel, increased consulting, future preclinical and clinical trial costs, including clinical drug product manufacturing and related costs.

General and Administrative Expenses

General and administrative expenses consist primarily of compensation and expenses for our executive personnel who perform corporate and administrative functions, 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 personnel or engagement of consultants in the areas of finance, human resources, information technology, business, legal, compliance, investor relations and business development, 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 personnel, expanded infrastructure, increased consulting, legal, accounting, investor relations and other expenses associated with being a public company and costs incurred to seek and establish collaborations with respect to any of our product candidates.

Stock-Based Compensation

We account for stock-based compensation arrangements with employees, non-employee directors and consultants using a fair value method, which requires the recognition of compensation expense for costs related to all stock-based 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 non-employee 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 selecting methods for 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 recent historical periods. We selected these companies based on comparable characteristics, including market capitalization, risk profiles, stage of development and with historical share price information sufficient to meet the expected term of the stock-based awards. The expected term for options granted during the years ended December 31, 2018 and 2017 was 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. We have not paid dividends and do not anticipate paying a cash dividend in future vesting periods and, accordingly, use an expected dividend yield of zero. The risk-free interest rate is based on the rate of U.S. Treasury securities with maturities consistent with the estimated expected term of the awards. 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, 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 our employees, non-employee directors and consultants. In October 2017, our Board increased the stock option pool to 1,600,000 shares after the increase was approved by stockholders. Through February 2017, our Board granted to Board Members, our Chief Financial Officer, and our Acting Chief Medical Officer stock options to purchase up to an aggregate 555,520 shares of our common stock at an exercise price of $0.001per share par value, based upon third party valuations of our common stock.

In September 2017, we granted options to purchase up to 21,024 shares of our common stock to each of the three new Board Members and in November 2017, we granted options to purchase up to 40,000 shares of our common stock to an employee. These Board and employee options have an exercise price of $6 per share based on the price per share at which our common stock was sold in our most recent private offering.

In January 2018, we granted options to purchase up to 32,004 shares of our common stock to our acting Chief Medical Officer 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. In May 2018, we granted options to purchase up to 5,000 shares of our common stock to an employee 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. In August 2018, we granted options to purchase up to 5,000 shares of our common stock to an employee 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. Also in August 2018, the Company granted stock options to all of its non-employee Board Members, the Company's chief executive officer, chief scientific officer, and chief financial officer to purchase up to an aggregate 425,300 shares of the Company's common stock 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. Vesting of such options commenced on October 1, 2018. In December 2018, the Company granted options to purchase up to 20,000 shares of common stock to its acting chief medical officer, 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. Vesting of such options commenced on January 1, 2019.

Under the Plan, the per share exercise price for the shares to be issued upon exercise of an option is determined by a committee of our Board, 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, November 2017, January 2018, May 2018 and August 2018 fair market value was established by our Plan Administrator Committee based on the price per share at which common stock was sold in our most recent private offering. Options generally expire after ten years.

During the years ended December 31, 2018 and 2017, we recognized $232,625 and $26,864 of employee and non-employee director stock-based compensation expense as general and administrative expenses, respectively, and $171,238 and $26,499 as research and development expenses, respectively. 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 consolidated statements of operations and comprehensive loss for stock-based compensation arrangements.

We recognize as an expense the fair value of options granted to persons who are neither employees nor directors. Stock-based compensation expense for non-employees for the years ended December 31, 2018 and 2017 was $125,469 and $251,842, respectively, of which $125,469 and $199,769, respectively was recorded as research and development expenses and $0 and $52,073, respectively, as general and administrative expenses.

The fair value of options granted from inception to December 31, 2018 was based on the Black-Scholes option-pricing model assuming the following factors: 4.7 to 6.2 years expected term, 55% to 85% volatility, 1.2% to 2.9% risk free interest rate and zero dividends. The expected term for options granted to date is estimated using the simplified method. For the years ended December 31, 2018 and 2017: the weighted-average grant date fair value was $2.05 and $0.88 per share, respectively; and the fair value of shares vested was $0.4 million and $0.3 million, respectively. At December 31, 2018, the aggregate intrinsic value was approximately $3.3 million of which approximately $2.4 million was vested and approximately $0.9 million is expected to vest and the weighted-average exercise price in aggregate was $2.99 which includes $0.76 for fully vested stock options and $4.60 for stock options expected to vest. At December 31, 2018, unamortized unvested balance of stock based compensation was $2.2 million, to be amortized over 2.9 years.

Stock option activity under the Plan for the year ended December 31, 2018 was as follows:

		Options Outstanding	
	Options Available	Number of Options	Weighted-Average Exercise Price
Balances, January 1, 2017	420,000	280,000	$ 0.001
Increase in option pool(1)	900,000		
Granted(2)	(378,592)	378,592	1.63
Forfeited	-	-	-
Exercised	-	-	-
Balances, January 1, 2018	941,408	658,592	0.94
Granted(3)	(487,304)	487,304	6.00
Forfeited(4)	40,000	(40,000)	6.00
Exercised	-	-	-
Balances, December 31, 2018	494,104	1,105,896	2.99

(1) In October 2017, our Board of Directors increased the option pool from 700,000 to 1,600,000 shares after such increase was approved by stockholders.

(2) 336,544 options vest 6/48ths at the six-month anniversary of grant date and 1/48th per month thereafter; 21,024 options vest 6/24ths on the six-month anniversary of grant date and 1/24th per month thereafter; and 21,024 options vest 6/42nds on the six-month anniversary of grant date and 1/42nd per month thereafter.

(3) 32,004 options vest as follows: options to purchase up to 12,000 shares of common stock vest on the grant date, options to purchase up to 1,667 shares of common stock vest on the 1st of each month thereafter. 5,000 options vest 6/48ths on the grant date and 1/48th per month thereafter. 5,000 options vest 6/48ths on the six-month anniversary of grant date and 1/48th per month thereafter. 320,900 options vest 6/51 at the six-month anniversary of vesting commencement date and 1/51 per month thereafter, with vesting commencing on October 1, 2018. 104,400 options vest quarterly over 5 quarters, with the first quarter commenced October 1, 2018. 20,000 options vest as follows: options to purchase up to 1,667 shares of common stock vest on January 31, 2019 and the last day of each month thereafter.

(4) Forfeited options resulted from an employee termination.

A summary of options outstanding as of December 31, 2018 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	7.7 years	406,280	7.6 years
6.00	550,376	9.5 years	58,910	8.9 years
	1,105,896		465,190	

Results of Operations

Comparison of the Years Ended December 31, 2018 and December 31, 2017

The following table summarizes the results of our operations for the years ended December 31, 2018 and 2017:

(in thousands)	Year Ended December 31, 2018	2017	Increase (Decrease)
Revenue	$ -	$ -	$ -
Research and development expenses	1,775	935	840
In-process research and development expenses	-	14,502	(14,502)
General and administrative expenses	1,628	1,166	462
Total operating expenses	3,403	16,603	(13,200)
Operating loss	(3,403)	(16,603)	13,200
Interest income	103	48	55
Loss before income tax benefit	(3,300)	(16,555)	13,255
Income tax benefit	72	-	72
Net loss	$ (3,228)	$ (16,555)	$ 13,327

R&D Expenses

R&D expenses for the year ended December 31, 2018 were approximately $1,774,000, compared to approximately $935,000 for the year ended December 31, 2017, an increase of approximately $840,000. This increase was primarily attributed to:

R&D Expenses (in thousands)	Year ended December 31, 2018 versus year ended December 31, 2017
Net increase in salaries and benefits due to CSO and VP of Clinical Development hired in November 2017, previously recorded as consultants, plus new hires in Q3 2018	$ 541
Increase in clinical research organization fees, clinical consulting fees and clinical materials manufactured Q3 2018 in preparation for the Validive Phase 3 clinical trial	264
Increase in employee stock compensation for CSO and VP of Clinical Development hired in November 2017	145
Increase in CEO's salary allocated to R&D expenses due to increase in the CEO salary	16
Decrease in R&D consulting fees related to the termination of two consulting contracts obtained in the Gem Transaction	(51)
Decrease in consultants stock compensation due to CSO's stock options classified as employee stock compensation commencing in November 2017	(74)
Other, net	(1)
Net increase in R&D expenses	$ 840

In-process Research and Development Expenses

There were no in-process research and development ("IPR&D") expenses for the year ended December 31, 2018. IPR&D expenses for the year ended December 31, 2017 of approximately $14,502,000 represent the $1,000,000 license fee for Validive and approximately $13,502,000 represent the value of MNPR-201, including transaction costs, acquired from TacticGem in August 2017. IPR&D represents the costs of acquiring or licensing technologies that have not reached technological feasibility and have no alternative future use.

General and Administrative Expenses

General and administrative ("G&A") expenses for the year ended December 31, 2018 were approximately $1,628,000, compared to approximately $1,166,000 for the year ended December 31, 2017, an increase of approximately $462,000. This increase was primarily attributed to:

G&A Expenses (in thousands)	**Year ended December 31, 2018 versus year ended December 31, 2017**
Increase in salaries and benefits for two new hires in November 2017 and increase in CEO salary in October 2017	$ 326
Increase in Board stock-based compensation (non-cash) due to new stock grants to Board Members in September 2017	131
Increase in Board fees and expenses due to compensation to three non-employee Board Members commencing in September 2017	85
Increase in employee stock-based compensation due to two new hires in November 2017	75
Increase in audit and legal fees due to the public reporting company status commenced in January 2018	49
Increase in Delaware franchise tax due to increase in the Company's tax basis	19
Increase in rent and related telephone due to the increase in facilities space commencing in January 2018	15
Increase in CEO salary allocated to R&D due to salary increase	(16)
Decrease in consulting fees due to the CFO hired as employee in November 2017, previously recorded as consulting	(46)
Decrease in stock-based compensation (non-cash) for consultants due to the CFO hired as employee in November 2017, previously recorded as consulting	(52)
Decrease in patent legal fees in 2018	(97)
Other, net	(27)
Net increase in G&A expenses	$ 462

Interest Income

Interest income for the year ended December 31, 2018 increased by approximately $55,000 versus the year ended December 31, 2017 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 which closed in September 2018.

Income Tax Benefit

Income tax benefit for the year ended December 31, 2018 represents federal R&D credits expected to be applied towards federal payroll tax expenses in 2019.

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 December 31, 2018 we had an accumulated deficit of approximately $21.7 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 February 26 2019, we have financed our operations primarily through private placements of our preferred stock and common stock, the $4.8 million received (net of transaction costs) in the Gem Transaction (as defined below), and our previous Cancer Research UK collaboration. As of February 26, 2019, we have received net proceeds of approximately $4.7 million (net of issuance costs) from the sale of our preferred stock which have been converted into common stock and we sold 789,674 shares of our common stock for net proceeds of approximately $4.7 million. We anticipate that the funds raised to date will fund our minimal operations through March 2020.

We invest our cash equivalents in a money market account.

Contribution to Capital

In August 2017, our largest stockholder, Tactic Pharma, surrendered 2,888,727 shares of common stock back to us as a contribution to the capital of the Company. This resulted in reducing Tactic Pharma's ownership in us at that time from 79.5% to 69.9%.

The Gem Transaction

On August 25, 2017, Tactic Pharma and Gem formed a limited liability company, TacticGem with Tactic Pharma contributing 4,111,273 shares of our common stock and Gem contributing assets and $5 million in cash before transaction costs. TacticGem then contributed the Gem assets (the "Gem Assets") and cash to us in exchange for 3,055,394 shares of our common stock (the "Gem Transaction"). This has resulted in TacticGem owning 77.1% of our outstanding common stock as of February 26, 2019. The contribution by TacticGem, made in conjunction with contributions from outside investors in a private offering, was intended to qualify for tax-free treatment.

During the year ended December 31, 2018, the Company's annual cash burn increased by approximately $100,000 due to the addition of the Gem Assets, and future cash burn will be significantly higher when the Company chooses to conduct clinical trials with the Gem drug candidate programs.

The Gem Transaction was recorded on our financial statements for the year ended December 31, 2017 as follows:

Cash recorded on our Balance Sheet	$ 5,000,000
Assembled Workforce recorded as In-process Research and Development Expense on our Statement of Operations	9,886
MNPR-201 (GPX-150) recorded as In-process Research and Development Expense on our Statement of Operations	13,491,736
Total Gem Transaction	$ 18,501,622

Cash Flows

The following table provides information regarding our cash flows for the years ended December 31, 2018 and 2017.

(in thousands)	Year ended December 31,		Variance year ended December 31, 2018 over December 31, 2017
	2018	2017	
Cash used in operating activities	$ (2,887)	$ (2,627)	$ (260)
Cash provided by financing activities	-	9,536	(9,536)
Effect of exchange rates on cash and cash equivalents	(2)	-	(2)
Net change in cash, cash equivalents and restricted cash	$ (2,889)	$ 6,909	$ (9,798)

During the years ended December 31, 2018 and 2017, we had net cash outflows of $(2,889,000) and net cash inflows of $6,909,000, respectively.

Cash Flow Used in Operating Activities

The increase to cash used in operating activities during the year ended December 31, 2018 compared to the year ended December 31, 2017 of approximately $260,000 was primarily due the increase in clinical development expenses related to planning our Phase 3 clinical trial for Validive. Cash used in operating activities of approximately $(2,887,000) for the year ended December 31, 2018 was primarily a result of our approximately $(3,200,000) net loss offset by $529,000 of non-cash stock-based compensation less changes in operating assets and liabilities of approximately $(116,000). Cash used in operating activities of approximately $(2,627,000) for the year ended December 31, 2017 was primarily a result of our approximately $(16,555,000) net loss, offset by non-cash in-process research and development of $13,502,000, non-cash stock-based compensation of $305,000 and changes in operating assets and liabilities of approximately $121,000.

Cash Flow Used in Investing Activities

There was no cash provided by or used in investing activities for the years ended December 31, 2018 and 2017.

Cash Flow Provided by Financing Activities

The decrease of cash provided by financing activities during the year ended December 31, 2018 compared to the year ended December 31, 2017 of approximately $9,536,000 was due to the sale of common stock during the year ended December 31, 2017 at $6.00 per share for aggregate net proceeds of approximately $4.7 million plus approximately $4.8 million of net proceeds from the Gem Transaction. There was no cash flow provided by financing activities during the year ended December 31, 2018.

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 another party. At the same time, we expect our expenses to increase in connection with our ongoing development activities, particularly as we continue the research, development, future preclinical and clinical trials of, and seek regulatory approval for, our current and future drug product candidates. If we are able to list on Nasdaq or another national stock exchange, we expect to incur additional costs associated with operating as a listed public company. In addition, if we obtain regulatory approval of any of our current and future drug product candidates, we will need substantial additional funding in connection with our future 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:

- advance the clinical development and execute the regulatory strategy of Validive;
- continue the clinical development of MNPR-201;
- continue the preclinical and clinical development of MNPR-101;
- acquire and/or license additional pipeline drug product candidates and pursue the future preclinical and/or clinical development of such drug product candidates;
- seek regulatory approvals for any of our current and future drug product candidates that successfully complete registration 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 minimal operations through at least 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 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 regulatory interactions and clinical development of Validive;
- the progress of clinical development of MNPR-201;
- the progress of preclinical and clinical development of MNPR-101;
- 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 international 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 or payment to or from others of any milestone or royalty payments under these arrangements.

See “Item 1A - Risk Factors”. In the second quarter of 2019, expenditures are expected to increase to support the planning and implementation of our Phase 3 clinical trial of Validive, including the addition of clinical staff, 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 2019 and 2020 if additional product candidates 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 2019 through 2020 are expected to be primarily driven by the funding of our planned Validive Phase 3 clinical program. Office space rent in 2019 and 2020 will also likely increase as a result of requiring additional space as we hire additional employees.

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 Item 1A - “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 other 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 others to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

Contractual Obligations and Commitments

Development and Collaboration Agreements

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 pursue treating 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 February 26, 2019, 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 2 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.

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 The agreement does not require the payment of sales royalties. There can be no assurance that we will achieve any milestones. As of February 26, 2019, we had not reached any milestones and had not been required to pay XOMA Ltd. any funds under this license agreement.

Service Providers

In the normal course of business, we contract with service providers to assist in the performance of 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 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

Effective January 1, 2018, we leased office space in the Village of Wilmette for $2,379 per month for 24 months. This office space houses our current headquarters. In February 2019, we commenced leasing additional offices on a month-to-month basis and we anticipate that we will lease additional permanent space in the future as we hire additional personnel.

Legal Contingencies

We are currently not, and to date have never been, a party to any 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 Item 1A - “Risk Factors - We have limited the liability of and indemnified our directors and officers.”

Off-Balance Sheet Arrangements

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

Item 8. Financial Statements and Supplementary Data

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

Documents filed as part of this Annual Report on Form 10-K:

PART II – FINANCIAL INFORMATION

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

None.

Item 9a: Controls and Procedures

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

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

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

This annual report does not include a report of management's assessment regarding internal controls over financial reporting or an attestation report of the Company's registered public accounting firm due to a transition period established by SEC rules for newly public companies.

(b) Disclosure Controls and Procedures

We carried out an evaluation, under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, of the effectiveness of our disclosure controls and procedures as of December 31, 2018, pursuant to Rules 13a15(e) and 15d15(e) under the Exchange Act. Based on that evaluation, our Chief Executive Officer and Chief Financial Officer have concluded that our disclosure controls and procedures, as of such date, were effective.

(c) Changes in Internal Control over Financial Reporting

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

There have been no changes in our internal control over financial reporting during the fourth quarter and the year ended December 31, 2018 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART III

Item 10. Directors and Executive Officers and Corporate Governance.

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, PhD	66	Executive Chairman, Director	December 2014
Chandler D. Robinson, MD MBA MSc	35	Chief Executive Officer, Director	December 2014
Andrew P. Mazar, PhD	57	Executive Vice President of Research and Development, Chief Scientific Officer, Director	December 2014
Kim R. Tsuchimoto	56	Chief Financial Officer	-
Patrice Rioux, MD, PhD	68	Acting Chief Medical Officer	-
Raymond W. Anderson, MBA	77	Director, Chair of the Audit Committee, Chair of the Compensation Committee and Member of the Corporate Governance and Nominating Committee	April 2017
Michael J. Brown, MSc	60	Director, Member of the Audit Committee, Member of the Compensation Committee, Member of the Corporate Governance and Nominating Committee	December 2014
Arthur Klausner, MBA	58	Director, Chair of the Corporate Governance and Nominating Committee, Member of the Audit Committee, Member of the Compensation Committee	August 2017

Backgrounds of our executive officers and Board Members are discussed below.

Executive Officers and Board Members

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

Dr. Starr is a co-founder and has been our Executive Chairman and a Board Member of ours and our predecessor, Monopar Therapeutics, LLC, since its inception in December 2014. Dr. Starr was the co-founder and served as the chief executive officer ("CEO") at Raptor Pharmaceuticals ("Raptor") (Nasdaq: RPTP), 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 was the development and commercialization of treatments for rare diseases. Dr. Starr was also a co-founder of BioMarin Pharmaceutical ("BioMarin") (Nasdaq: BMRN) in 1997 where he last served as Vice President of Research and Development until 2006. BioMarin is a fully-integrated multinational biopharmaceutical company. Dr. Starr earned a B.S. from Syracuse University and a Ph.D. in Biochemistry and Molecular Biology from the State University of New York Health Science Center, in Syracuse, New York.

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

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

Dr. Robinson is a co-founder and has been our CEO and a Board Member of ours and our predecessor, Monopar Therapeutics, LLC, since its inception in December 2014. Since 2010, Dr. Robinson has been, and continues to be, a manager of Tactic Pharma, which he co-founded and led as CEO until it became a holding company in April 2014. Tactic Pharma acquired and developed preclinical and clinical stage biopharmaceutical compounds. From 2009 to 2010 Dr. Robinson conducted research at Northwestern University on a drug candidate currently being developed to treat Wilson's disease, which was acquired by Tactic Pharma in 2010 and sold in 2014. Among his

previous experiences, Dr. Robinson in 2008 worked at Onyx Pharmaceuticals, an oncology biopharmaceutical company, in their Nexavar marketing division, from 2008 to 2009 as a co-manager of a healthcare clinic in San Jose CA, from 2004 to present as Founder and President of an undergraduate research focused non-profit now in its 15th 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 (acquired by Alexion Pharmaceuticals Inc.), a biopharmaceutical company, and is currently on the board of Northwestern University's Chemistry of Life Processes Institute. Dr. Robinson graduated summa cum laude from Northwestern University, earned a master's degree in International Health Policy and Health Economics from the London School of Economics on a Fulbright Scholarship, an MBA from Cambridge University on a Gates Scholarship through Bill Gates' Trust, and an MD from Stanford University.

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

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

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 its inception in December 2014. Dr. Mazar became our Executive Vice President of Research and Development effective as of November 1, 2017. Dr. Mazar has founded or co-founded eight start-up companies to commercialize new drug discoveries, including Tactic Pharma, formerly a biopharmaceutical company, where he worked since 2010, and which acquired and developed preclinical and clinical stage compounds. Dr. Mazar has founded or advised several start-up companies over the past five years including Tactic Pharma, Valence Therapeutics (a biopharmaceutical company), Wilson Therapeutics (a biopharmaceutical company), Panther Biotechnology (a biopharmaceutical company), Lung Therapeutics Inc. (a biopharmaceutical company), Actuate Therapeutics (an oncology biopharmaceutical company), AvidTox (a biopharmaceutical company) and Tempus (a biopharmaceutical company). Prior to joining Tactic Pharma in 2010 and the Chemistry of Life Processes Institute at Northwestern University in 2009, Dr. Mazar was the Chief Scientific Officer at Attenuon, LLC, a biopharmaceutical company in San Diego from 2000 to 2009. Dr. Mazar is the previous Chair of the National Cancer Institute Nanotechnology Alliance Animal Model working group (2011-2015) and has been a member of the National Heart, Lung and Blood Institute Scientific Review Board (SRB) for the SMARTT program since 2011. Dr. Mazar is currently a member of the editorial board of Clinical Cancer Research and the External Advisory Board for NewCures at Northwestern University. Dr. Mazar earned a Ph.D. in biochemistry at the University of Illinois College of Medicine.

Dr. Mazar's extensive experience in leadership positions in the biopharmaceutical industry led to the conclusion that he should serve as a member of our Board of Directors.

Kim R. Tsuchimoto – Chief Financial Officer

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

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

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

Michael J. Brown, MSc – Board Member

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

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

Raymond W. Anderson, MBA MS – Board Member

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

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

Arthur Klausner, MBA – Board Member

Mr. Klausner has been a Board Member of Monopar since August 2017. Since 2018 Mr. Klausner has served as President, CEO, and a Director of the start-up drug development company Goldilocks Therapeutics, Inc. Mr. Klausner has been a consultant to the biopharmaceutical industry since 2009. He served as Chief Executive Officer of Gem from September 2012 until Gem's drug development assets were acquired by us in 2017. In addition to his role at Gem, Mr. Klausner served as CEO of 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. Mr. Klausner currently serves on the board of directors of Cennerv Pharma (S) Pte. Ltd. (Singapore), and on the life science investment review board for the New York University Innovation Venture Fund. He received his M.B.A. from the Stanford University Graduate School of Business and his B.A. in biology from Princeton University.

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

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 plus one person designated by Gem to our Board. The Gem board nomination right terminates at such time as we achieve a listing on a national stock exchange. Gem's initial designee for election to our Board is 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 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 and Risk Oversight

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 Executive 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 help set our strategic direction and provide guidance to, and oversight of our Chief Executive Officer. Our Executive Chairman sets the agenda for Board meetings and presides over them.

Pursuant to our Audit Committee Charter, which was approved by our Board on March 22, 2018 and amended on December 4, 2018, our Audit Committee is responsible for the oversight of our risk management programs, and specifically:

- Risk assessment and risk management. The Audit Committee shall review (at least annually or as needed due to specific circumstances) with the Company's management and the independent registered public accounting firm the Company's policies, procedures and current status with respect to risk assessment and risk management including steps taken by management to monitor, mitigate and manage risk exposures; and
- The Audit Committee review shall also include the Company's major financial risk exposures and other major risk exposures as assigned by the Board to the Audit Committee for oversight. The Audit Committee shall review with the Company's senior management our overall anti-fraud programs and controls. The Audit Committee shall consider the risk of the Company's management's ability to override the Company's internal controls.

Audit Committee

Our Board formed an Audit Committee in October 2017 and appointed Mr. Anderson, Dr. Starr, Mr. Klausner and Mr. Brown to serve as independent members. Mr. Anderson was appointed to serve as chair of the Audit Committee. Mr. Anderson is a financial expert as defined by Nasdaq and the SEC and is an independent board member as contemplated by Rule 10A-3 under the Exchange Act. Dr. Starr served on the Audit Committee until August 2018.

The functions of our Audit Committee include, among other duties and responsibilities:

- to assist the Board of Directors in its oversight responsibilities for the integrity of the Company's financial statements;
- to assure the quality of the accounting and financial reporting processes of the Company;
- to assure the effectiveness of the Company's internal controls over financial reporting;
- to assist with the Company's compliance with legal and regulatory requirements;
- to review and discuss with management and the independent registered public accounting firm the Company's annual and quarterly SEC reports including the audit of the annual financial statements and the reviews of the quarterly financial statements and related disclosures;
- to be directly responsible for the appointment, compensation, retention, and oversight of the work of the independent registered public accounting firm and any other independent registered public accounting firm performing other audit, review, or attest services for the Company;
- to review and discuss with the Company's management the risk assessment and risk management policies of the Company;
- to oversee systems and procedures for the receipt, retention and resolution of complaints received by the Company regarding accounting, internal financial controls or auditing matters and for the confidential and anonymous submission by Company employees of concerns regarding potential fraud or questionable financial, accounting, internal financial controls or auditing matters;
- to periodically review and update the financial-related sections of the Company's Code of Business Conduct and Ethics and review programs established to monitor compliance with and to improve employees' knowledge of the Code;
- to review and approve or disapprove any transaction required to be disclosed according to SEC regulations between the Company and any related party and to oversee the Company's policies and procedures for judgments as to related party transactions; and
- to prepare the Audit Committee's report required by SEC rules, when such requirement becomes applicable to the Company.

The Audit Committee is governed by a written charter adopted by the Board in May 2018 and updated in December 2018. The Audit Committee Charter can be found in the Corporate Governance section of the Investors section of our website at www.monopartx.com. Information on our website is NOT incorporated by reference in this Annual Report on Form 10-K. The Audit Committee Charter complies with the guidelines established by Nasdaq.

As required by its Charter, the Audit Committee conducts a self-evaluation at least annually. The Audit Committee also periodically reviews and assesses the adequacy of its Charter, including the Audit Committee's role and responsibilities, and recommends any proposed changes to the Board for its consideration.

Corporate Governance and Nominating Committee

Our Board formed a Corporate Governance and Nominating ("CG&N") Committee in October 2017 and appointed Mr. Brown, Dr. Starr, Mr. Anderson and Mr. Klausner as independent members. Mr. Klausner was appointed to serve as the chair of the CG&N Committee in August 2018. Dr. Starr served on the CG&N Committee until August 2018.

The functions of our corporate governance and nominating committee include, among other things:

- overseeing the composition of the Board to ensure that qualified individuals meeting the criteria of applicable rules and regulations serve as members of the Board and its committees
- identifying, reviewing and evaluating individuals qualified to serve on the Board consistent with criteria approved by the Board as vacancies arise, and seeking out nominees to enhance the diversity, expertise and independence of the Board;
- considering and assessing the independence of directors, including whether a majority of the Board continue to be independent from management in both fact and appearance, as well as within the meaning prescribed by the listing standards of Nasdaq;
- recommending to our Board the persons to be nominated for election as directors and to each of the Board's committees;
- considering proposals appropriately submitted by our stockholders;
- 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.

The CG&N Committee is governed by a written charter adopted by the Board in May 2018. The CG&N Committee Charter can be found in the Corporate Governance section of the Investors section of our website at www.monopartx.com. Information on our website is NOT incorporated by reference in this Annual Report on Form 10-K. The CG&N Committee Charter complies with the guidelines established by Nasdaq. The Charter of the CG&N Committee grants the CG&N Committee full access to all of our books, records, facilities and personnel, as well as authority to obtain, at our expense, advice and assistance from internal and external legal, accounting or other advisors and consultants and other external resources that the CG&N Committee considers necessary or appropriate in the performance of its duties.

As required by its Charter, the CG&N Committee conducts a self-evaluation at least annually. The CG&N Committee also periodically reviews and assesses the adequacy of its Charter, including the CG&N Committee's role and responsibilities, and recommends any proposed changes to the Board for its consideration.

Compensation Committee

Our Board also formed a Compensation Committee in October 2017 and appointed Mr. Brown, Dr. Starr, Mr. Anderson and Mr. Klausner as independent members. Mr. Anderson was appointed to serve as the chair of the Compensation Committee in August 2018. Dr. Starr served on the Compensation Committee until August 2018.

During the year ended December 31, 2018, the Compensation Committee did not engage an independent third-party compensation expert.

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

- annually reviewing and approving corporate goals and objectives relevant to our CEO's compensation;
- determining our CEO'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, when such requirement becomes applicable to us.

The Compensation Committee is governed by a written charter adopted by the Board in May 2018. The Compensation Committee Charter can be found in the Corporate Governance section of the Investors section of our website at www.monopartx.com. Information on our website is NOT incorporated by reference in this Annual Report on Form 10-K. The Compensation Committee Charter complies with the guidelines established by Nasdaq.

As required by its Charter, the Compensation Committee conducts a self-evaluation at least annually. The Compensation Committee also periodically reviews and assesses the adequacy of its Charter, including the Compensation Committee’s role and responsibilities, and recommends any proposed changes to the Board for its consideration.

Plan Administrator Committee

Our Board formed a Plan Administrator Committee in 2018 and appointed Dr. Starr, Mr. Brown and Mr. Anderson to serve as independent members. The Plan Administrator Committee does not have a charter but the functions of the Plan Administrator Committee include, among other things:

- appointing individuals responsible for the day-to-day administration of the Plan including the issuance and routing of stock option grant agreements based upon Plan Administrator Committee approved grants and related recordkeeping and accounting functions;
- pursuant to the Plan, granting "performance based" and "time based" options or stock awards to our directors, officers, employees and consultants;
- determining the number of shares of common stock and the type of awards granted under the Plan to optionees; and
- determining restrictions and terms of awards including modifications or amendments to awards under the Plan.

Code of Business Conduct and Ethics

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

Section 16(A) Beneficial Ownership Reporting Compliance

Under Section 16(a) of the Exchange Act and SEC rules, our directors, executive officers and beneficial owners of more than 10% of any class of equity security are required to file periodic reports of their ownership, and changes in that ownership, with the SEC. To our knowledge, based solely on the review of copies of the reports filed with the SEC and any written representations that no other reports were required, all reports required to be filed by our executive officers, directors and beneficial owners of more than 10% of our common stock were timely filed during the year ended December 31, 2018, except that Forms 4 reporting the grants of stock options on August 28, 2018 were filed on September 27, 2018 for the following directors and officers: Dr. Robinson, Dr. Mazar, Dr. Starr, Ms. Tsuchimoto, Mr. Brown, Mr. Anderson and Mr. Klausner.

Item 11. Executive Compensation.

Summary Compensation Table

The following table sets forth for the years ended December 31, 2018, 2017 and 2016, the compensation of our Chief Executive Officer and our two highest compensated executive officers whose compensation exceeded $100,000 during our last fiscal year and our Chief Financial Officer.

Name and Positions	Fiscal Year	Salary ($)	Bonus ($)	Option Awards ($)[1] [2]	All Other Compensation ($)[3]	Total ($)
Chandler D. Robinson M.D., Chief Executive Officer and Director	2018	375,000	-	640,928	55,000	1,070,928
	2017	330,545	-	46	70,000	400,591
	2016	300,000	-	42	75,000	375,042
Andrew P. Mazar, Ph.D.[4] Executive Vice President of Research and Development and Chief Scientific Officer and Director	2018	350,000	-	591,592	55,000	996,592
	2017	75,731	-	46	238,750	314,527
	2016	-	-	42	197,500	197,542
Kim R. Tsuchimoto[5] Chief Financial Officer	2018	125,991	-	181,046	18,000	325,037
	2017	11,370	-	13	50,000	61,383
	2016	-	-	11	79,500	79,511
Kirsten Anderson Former Senior Vice President, Clinical Development[6]	2018	123,000	-	-	80,618	203,618
	2017	43,000	25,000	132,041	78,550	278,591
	2016	-	-	-	-	-

(1) The amounts in this column represent the aggregate grant date fair value of stock options awarded during the applicable year to the named executive officers, computed in accordance with FASB ASC Topic 718. The fair value of stock options is estimated on the date of grant using the Black-Scholes option pricing model for employees and on each remeasurement date for consultants. For a discussion of valuation assumptions, see Note 4 to our consolidated financial statements included in this Annual Report on Form 10-K.

(2) In 2016, each of Dr. Robinson and Dr. Mazar were granted options to purchase up to 84,000 shares of our common stock and Ms. Tsuchimoto was granted options to purchase up to 21,000 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 and Dr. Mazar’s stock options was $ 42 and the value of Ms. Tsuchimoto’s stock options was $ 11. 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 and Ms. Tsuchimoto was granted options to purchase up to 23,520 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, Dr. Mazar's and Ms. Tsuchimoto's stock options was $46, $46, and $13, respectively. The options granted to Dr. Robinson, Dr. Mazar and Ms. Tsuchimoto in 2017 vested 6/48ths on the six-month anniversary of grant date (August 20, 2017) and 1/48th per month thereafter.

In 2018, Dr. Robinson, Dr. Mazar and Ms. Tsuchimoto were granted options to purchase up to 145,500, 134,300 and 41,000 shares of our common stock, respectively, 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, Dr. Mazar's and Ms. Tsuchimoto's stock options was $640,928, $591,592, and $181,046, respectively. The options granted in 2018 to Dr. Robinson, Dr. Mazar and Ms. Tsuchimoto commenced vesting on October 1, 2018 and vested 6/48ths on the six-month anniversary of vesting commencement date (March 31, 2019) and 1/48th per month thereafter.

(3) For 2016, All Other Compensation consisted of the following: for Dr. Robinson, an employer funded 401(k) in the amount of $53,000 plus $22,000 representing amounts paid in lieu of insurance and other medical benefits ("Benefits"); for Dr. Mazar $197,500 of consulting fees earned prior to becoming an employee on November 1, 2017; and for Ms. Tsuchimoto $79,500 of consulting fees earned prior to becoming an employee on November 1, 2017.

For 2017, All Other Compensation consisted of the following: for Dr. Robinson, an employer funded 401(k) in the amount of $54,000 plus $16,000 in lieu of Benefits; for Dr. Mazar $225,000 of consulting fees earned prior to becoming an employee on November 1, 2017 plus $13,750 in lieu of Benefits as an employee; and for Ms. Tsuchimoto $50,000 of consulting fees earned prior to becoming an employee on November 1, 2017.

For 2018, All Other Compensation consisted of the following: for Dr. Robinson, Dr. Mazar and Ms. Tsuchimoto in lieu of Benefits of $55,000, $55,000 and $18,000, respectively.

(4) 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 an amount 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.

(5) Until November 1, 2017, Ms. Tsuchimoto was a consultant acting as chief financial officer for $50,000 and $79,500 in consulting fees in 2017 and 2016, respectively. As of November 1, 2017, Ms. Tsuchimoto became employed as our Chief Financial Officer initially at ¼ of full-time at an annual base salary of $68,750 and as of March 1, 2018, Ms. Tsuchimoto commenced working ½ of full time at an annual base salary of $137,500 and an amount in lieu of Benefits of $21,600. In 2018, a pro rata amount of in lieu of Benefits of $18,000 is included in All Other Compensation.

(6) 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 was $132,041. The options vested 6/48ths on the six-month anniversary of grant date (May 1, 2018) and 1/48th per month thereafter. As of June 20, 2018, Ms. Anderson was no longer with the Company, at which time options to purchase up to 34,167 shares of our common stock were forfeited and options to purchase up to 5,833 shares of our common stock expired unexercised on September 20, 2018. For 2018, All Other Compensation for Ms. Anderson consisted of the following: $4,818 in lieu of Benefits from April 1, 2018 to June 20, 2018; $65,000 representing three months of base salary severance; and $10,800 representing six months in lieu of Benefits.

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). The agreement was amended on March 1, 2018. Under her employment agreement, Ms. Tsuchimoto receives a $137,500 per year base salary to reflect 50% time, which may be adjusted from time to time in accordance with normal business practice and in our sole discretion. Ms. Tsuchimoto is entitled to an additional salary of up to $1,800 per month in lieu of medical, dental and vision benefits until such time the Company has such benefit plans in place. 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 was for an indefinite term (for at-will employment). Under her employment agreement, Ms. Anderson received 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 included a $25,000 sign-on bonus. As of June 20, 2018, Ms. Anderson was no longer with the Company. Pursuant to Ms. Anderson's termination agreement, she received a lump sum representing three months of base salary totaling $65,000 plus six months of taxable fringe benefits to cover healthcare insurance totaling $10,800.

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, 2018. There were no outstanding stock awards as of December 31, 2018.

Name	*Number of securities underlying unexercised options (#) exercisable*		*Number of securities underlying unexercised options (#) unexercisable*		*Option exercise price ($)*	*Option expiration date*
Chandler D. Robinson, M.D., Chief Executive Officer and Director	-	(1)	145,500	(1)	$ 6.00	August 27, 2028
	38,500	(2)	45,500	(2)	$0.001	February 19, 2027
	84,000	(3)	-	(3)	$0.001	April 3, 2026
Andrew P. Mazar, Ph.D., Executive Vice President of Research and Development and Chief Scientific Officer and Director	-	(1)	134,300	(1)	$ 6.00	August 27, 2028
	38,500	(2)	45,500	(2)	$0.001	February 19, 2027

	84,000	(3)	-	(3)	$0.001	April 3, 2026
Kim R. Tsuchimoto, Chief Financial Officer	-	(1)	41,100	(1)	$ 6.00	August 27, 2028
	10,780	(2)	12,740	(2)	$0.001	February 19, 2027
	21,000	(3)	-	(3)	$0.001	April 3, 2026
Kirsten Anderson Former Senior Vice President, Clinical Development	-	(4)	-	(4)	N/A	N/A

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

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

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

(4) On November 1, 2017, Ms. Anderson was granted options to purchase up to 40,000 shares of our common stock. As of June 20, 2018, Ms. Anderson was no longer with the Company, at which time options to purchase up to 34,167 shares of our common stock were forfeited and options to purchase up to 5,833 shares of our common stock expired unexercised on September 20, 2018.

Potential Payments upon Termination or Change in Control

Each of Dr. Robinson's, Dr. Mazar's and Ms. Tsuchimoto's employment agreements provides that upon execution and effectiveness of a release of claims, Dr. Robinson, Dr. Mazar and Ms. Tsuchimoto will be entitled to severance payments if their employment with us terminates under certain circumstances. If we terminate their employment without "cause," or if Dr. Robinson, Dr. Mazar or Ms. Tsuchimoto resigns for "good reason," in each case absent a "change in control," Dr. Mazar and Dr. Robinson would receive, (1) base salary continuation for 12 months, (2) to provide that any equity awards will continue vesting, (3) payment of or reimbursement for COBRA continuation coverage until the earlier of 12 months following termination or the date the executive become eligible for coverage under an employer's plan 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. Ms. Tsuchimoto would receive, (1) base salary continuation for 3 months, (2) to provide that any equity awards will continue vesting, (3) if Ms. Tsuchimoto is full-time, payment of or reimbursement for COBRA continuation coverage until the earlier of 12 months following termination or the date the executive become eligible for coverage under an employer's plan 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 Dr. Robinson's or Dr. Mazar's employment is terminated without cause or for good reason within 12 months following a change in control, they would be entitled to (1) a lump sum payment in an amount equal to 1.5 times his respective base salary plus target annual bonus for the year in which the termination occurs, (2) payment of or reimbursement for COBRA continuation coverage until the earlier of 18 months following termination or the date the executive becomes eligible for coverage under an employer's plan and (3) full vesting acceleration of all outstanding equity awards. If either of Dr. Mazar's or Dr. Robinson's employment is terminated because of death or permanent disability, we will be obligated to provide base salary continuation and COBRA payment or reimbursement for a period of three months.

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

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

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

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").

Share Reserve

The Plan originally allowed us to grant up to an aggregate 10,000 shares of stock awards, stock options, stock appreciation rights and other stock-based awards to employees, non-employee directors and consultants. In March 2017, at the time of the conversion of the then outstanding preferred stock to our common stock and a concurrent 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, 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.

Administration

The Plan provides that the administrator of the Plan will be our Board, a committee designated by our Board, or an individual designee (the "Administrator"). On February 28, 2018, our independent Directors approved the appointment of a committee (the "Plan Administrator Committee") consisting of three independent, non-employee Directors (Dr. Starr, Mr. Brown, and Mr. Anderson) to serve as the Administrator of the Plan. The Plan Administrator Committee will require a quorum of at least two of the three Directors on all decisions. 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. Prior to the formation of the Plan Administrator Committee, Mr. Brown was the Board-representative Administrator of the Plan.

Eligibility

Under the Plan, awards may be granted only to our directors, employees and consultants or any of our affiliates; provided, however, that Incentive Stock Options may be granted only to our employees and our subsidiaries (within the meaning of Section 424(f) of the Code).

Options

The per share exercise price for the shares to be issued upon exercise of an option shall be determined by the 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, except with respect to conversion awards. Subject to Section 15 of the Plan, the exercise price of an option may not be reduced without shareholder approval, nor may outstanding options be cancelled in exchange for cash, other awards or options with an exercise price that is less than the exercise price of the original option without shareholder approval. Options granted under the Plan shall vest and/or be exercisable at such time and in such installments during the period prior to the expiration of the option's term as determined by the Administrator and as specified in the option agreement. The Administrator shall have the right to make the timing of the ability to exercise any option granted under this Plan subject to continued active employment (or retention in the case of a consultant or director), the passage of time and/or such performance requirements as deemed appropriate by the Administrator. At any time after the grant of an option, the Administrator may reduce or eliminate any restrictions surrounding any participant's right to exercise all or part of the option. Fair market value is established by our Board, using third party valuation reports and recent financings. Stock options generally expire after ten years.

Stock Appreciation Rights

A Stock Appreciation Right is a right that entitles the awardee to receive, in cash or shares (as determined by the Administrator), value equal to or otherwise based on the excess of (i) the fair market value of a specified number of shares at the time of exercise over (ii) the aggregate exercise price of the right, as established by the Administrator on the grant date. Stock Appreciation Rights may be granted to awardees either alone ("freestanding") or in addition to or in tandem with other awards granted under the Plan and may, but need not, relate to a specific option granted under the Plan. To date, we have not granted any Stock Appreciation Rights under the Plan.

Stock Awards

Each Stock Award agreement shall contain provisions regarding (i) the number of shares subject to such stock award or a formula for determining such number, (ii) the purchase price of the shares, if any, and the means of payment for the shares, (iii) the performance criteria, if any, and level of achievement versus these criteria that shall determine the number of shares granted, issued, retainable and/or vested, (iv) such terms and conditions on the grant, issuance, vesting and/or forfeiture of the shares as may be determined from time to time by the Administrator, (v) restrictions on the transferability of the Stock Award, and (vi) such further terms and conditions, in each case not inconsistent with the Plan, as may be determined from time to time by the Administrator. To date, we have not granted any Stock Awards under the Plan.

Other Stock-Based Awards

An "Other Stock-Based Award" means any other type of equity-based or equity-related award not otherwise described by the terms of the Plan (including the grant or offer for sale of unrestricted shares), as well as any cash bonus based on the attainment of qualifying performance criteria, in such amount and subject to such terms and conditions as the Administrator shall determine. Such awards may involve the transfer of actual shares to participants, or payment in cash or otherwise of amounts based on the value of shares or pursuant to attainment of a performance goal. To-date, we have not granted any Other Stock-Based Awards under the Plan.

Limited Transferability

Unless determined otherwise by the Administrator, an award may not be sold, pledged, assigned, hypothecated, transferred or disposed of in any manner other than by beneficiary designation, will or by the laws of descent or distribution, including but not limited to any attempted assignment or transfer in connection with the settlement of marital property or other rights incident to a divorce or dissolution, and any such attempted sale, assignment or transfer shall be of no effect prior to the date an Award is vested and settled. The Administrator may only make an award transferable to an awardee's family member or any other person or entity provided the awardee does not receive consideration for such transfer. If the Administrator makes an award transferable, either as of the grant date or thereafter, such award shall contain such additional terms and conditions as the Administrator deems appropriate, and any transferee shall be deemed to be bound by such terms upon acceptance of such transfer.

Change of Control

In the event of a change of control, unless otherwise determined by the Administrator as of the grant date of a particular award (or subsequent to the grant date), the following acceleration, exercisability and valuation provisions shall apply: (i) on the date that such change of control occurs, any or all options and Stock Appreciation Rights awarded under the Plan not previously exercisable and vested shall become fully exercisable and vested; (ii) except as may be provided in an individual severance or employment agreement (or severance plan) to which an awardee is a party, in the event of an awardee's termination of employment within two (2) years after a change of control for any reason other than because of the awardee's death, retirement, disability or termination for cause, each option and Stock Appreciation Right held by the awardee (or a transferee) that is vested shall remain exercisable until the earlier of the third (3rd) anniversary of such termination of employment (or any later date until which it would remain exercisable under such circumstances by its terms) or the expiration of its original term; (iii) on the date that such change of control occurs, the restrictions and conditions applicable to any or all Stock Awards and Other Stock-Based Awards shall lapse and such awards shall be fully vested. Unless otherwise provided in an award at the grant date, upon the occurrence of a change of control, any performance-based award shall be deemed fully earned at the target amount as of the date on which the change of control occurs. All Stock Awards, Other Stock-Based Awards and cash awards shall be settled or paid within thirty (30) days of vesting hereunder; (iv) the Administrator, in its discretion, may determine that, upon the occurrence of a change of control of the Company, each option and Stock Appreciation Right outstanding shall terminate within a specified number of days after notice to the participant, and/or that each participant shall receive, with respect to each share subject to such option or Stock Appreciation Right, an amount equal to the excess of the fair market value of such share immediately prior to the occurrence of such change of control over the exercise price per share of such option and/or Stock Appreciation Right; such amount to be payable in cash, in one or more kinds of stock or property (including the stock or property, if any, payable in the transaction) or in a combination thereof, as the Administrator, in its discretion, shall determine, and if there is no excess value, the Administrator may, in its discretion, cancel such awards.

Adjustments

In the event of (i) a stock dividend, extraordinary cash dividend, stock split, reverse stock split, share combination, or recapitalization or similar event affecting our capital structure or (ii) a merger, consolidation, acquisition of property or shares, separation, spin-off, reorganization, liquidation, disaffiliation, or similar event affecting us or any of our subsidiaries, the Administrator or our Board may in its discretion make such substitutions or adjustments as it deems appropriate and equitable. In the case of share changes, such adjustments shall be mandatory in order to avoid material impairment of any outstanding award; provided, however, the Administrator or the Board shall retain discretion to determine the appropriate and equitable substitutions and adjustments that will be made to avoid such material impairment.

Amendment and Termination

Our Board may amend, alter or discontinue the Plan or any award agreement, but any such amendment shall be subject to approval of our stockholders in the manner and to the extent required by applicable law.

Option Grants Under the Plan

In April 2016, our Board granted to non-employee 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 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 monthly over six months from the grant date. In February 2017, our Board granted to its 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 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. On January 1, 2018, our Board granted to our acting chief medical officer options to purchase up to 32,004 shares of our common stock at an exercise price of $6 per share, and such options vest 12,000 on the date of grant and 1,667 options on the 1st of each month thereafter. On May 21, 2018, our Board granted to an employee options to purchase up to 5,000 shares of our common stock at an exercise price of $6 per share, and such options vest 6/48ths on the grant date ant 1/48th per month thereafter. On August 6, 2018, our Board granted to an employee options to purchase up to 5,000 shares of our common stock at an exercise price of $6 per share, and such options vest 6/48ths on the six month anniversary of grant date ant 1/48th per month thereafter. In August 2018, stock options to purchase up to an aggregate 425,300 shares of our common stock were granted at an exercise price of $6.00. 104,400 options vests commencing on October 1, 2018 quarterly over five quarters. 320,900 options vest commencing on October 1, 2018 6/51 on the six month anniversary of vesting commencement date and 1/51 per month thereafter. In December 2018, stock options to purchase up to an aggregate 20,000 shares of our common stock were granted at an exercise price $6.00. The exercise price of the stock options granted in 2018 are based upon the price per share at which our common stock was sold in our most recent private offering. In 2018, 40,000 options expired related to an employment termination. All outstanding stock options have a ten-year term. 1,105,896 stock options were outstanding as of December 31, 2018.

401(k) Plan

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

The 401(k) plan provides that each participant may contribute up to 100% of his or her pre-tax compensation, up to a statutory limit, which is $18,500 for 2018, a $500 rise from 2017 and 2016 limits. Participants who are at least 50 years old can also make “catch-up” contributions, which in 2018 may be up to an additional $6,000 above the statutory limit.

Employees become eligible to participate in the 401(k) plan after four months of active employment with the Company.

Under the 401(k) plan, each employee is fully vested in his or her deferred salary contributions. Employee contributions are held and invested by the plan’s trustee. The 401(k) plan also permits us to make discretionary profit sharing contributions and discretionary matching contributions, subject to established limits and a vesting schedule. To date, we have not made any discretionary profit sharing or discretionary matching contributions to the plan on behalf of participating employees.

During the period between January 2016 and October 2017, we maintained an individual defined contribution employee retirement plan (“i401(k)”) for Dr. Robinson, our only employee during that period. Under the i401(k) plan we contributed for the benefit of Dr. Robinson up to the statutory limit under Section 415(c)(1)(A) of the Code, which was $54,000 in 2017 and $53,000 in 2016.

Director Compensation for Fiscal Year Ended December 31, 2018

The following table sets forth the compensation of our non-employee Board of Directors during the year ended December 31, 2018.

Name	*Fees earned or paid in cash ($)*	*Option Awards ($) (1)*	*All Other Compensation ($)*	*Total ($)*
Christopher M. Starr, Ph.D.	105,673	109,523	-	215,196
Michael J. Brown	45,500	109,523	-	155,023
Raymond W. Anderson	55,625	109,523	-	165,148
Arthur Klausner	46,125	109,523	-	155,648

(1) Based upon the Black-Scholes valuation model for stock option compensation expense, Option Awards represents the following:

For each of Dr. Starr, Mr. Brown, Mr. Anderson and Mr. Klausner, stock option s to purchase up to 26,100 shares of our common stock were awarded on August 28, 2018; these options commenced vesting on October 1, 2018, vest quarterly over five quarters and was valued at $109,523 for each individual.

As of December 31, 2018, our directors held the following number of stock options:

Name	*Aggregate Number of Shares Subject to Stock Options*
Christopher M. Starr, Ph.D.	194,100
Michael J. Brown	47,124
Raymond W. Anderson	47,124
Arthur Klausner	47,124

Options Exercised and Stock Vested

None of our executive officers or non-employee directors exercised any options during the years ended December 31, 2018 and 2017.

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

Securities Authorized for Issuance Under Equity Compensation Plans

The following table provides information as of December 31, 2018, with respect to shares of our common stock that may be issued under existing equity compensation plans. All of our equity compensation plans have 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)	1,105,896	$ 2.99	494,104

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

Principal Stockholders

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 February 26, 2019 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 February 26, 2019, 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. Beneficial ownership is based upon 9,291,421 shares of our common stock outstanding as of February 26, 2019.

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

Name and Address of Beneficial Owner *Unless otherwise noted, addresses are: 1000 Skokie Blvd., Suite 350, Wilmette, IL 60091	Shares of Common Stock Beneficially Owned	Percent of Class Held
TacticGem, LLC[1]	7,166,667	77.10%
Tactic Pharma LLC[1]	4,277,940	46.00%
Gem Pharmaceutical LLC[1] 941 Lake Forest Cir., Birmingham, AL 35244	3,055,394	32.90%
Chandler D. Robinson, Chief Executive Officer and Director[2]	160,614	1.70%
Christopher M. Starr, Executive Chairman and Director[3]	189,340	2.00%
Andrew P. Mazar, Executive Vice President of Research and Development, Chief Scientific Officer and Director[4]	159,297	1.70%
Michael J. Brown, Director[5]	237,084	2.50%
Raymond W. Anderson, Director[6]	20,952	*
Arthur Klausner, Director[7]	23,762	*
Kim R. Tsuchimoto, Chief Financial Officer[8]	38,573	*
Patrice P. Rioux, Acting Chief Medical Officer[9]	44,005	*
Named executive officers and directors as a group (8 persons)[10]	8,040,294	81.40%

(1)Tactic Pharma shares voting and investment power over 4,111,273 shares of our common stock owned by TacticGem, and Gem shares voting and investment power over 3,055,394 shares of our common stock owned by TacticGem, because pursuant to the TacticGem limited liability company agreement all votes of our common stock (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. Dr. Mazar and Dr. Robinson are managers of Tactic Pharma; because of this, they control voting and dispositive power over 4,111,273 shares of our common stock owned by TacticGem, and over our common stock owned by Tactic Pharma. Gem is controlled by Pharma Investments, LLC, which is in turn controlled by Diane M. Hendricks.

(2)Includes 146,611 common stock options that vest within 60 days after February 26, 2019.

(3)Includes 139,940 common stock options that vest within 60 days after February 26, 2019.

(4)Includes 145,294 common stock options that vest within 60 days after February 26, 2019.

(5)Includes 27,084 common stock options that vest within 60 days after February 26, 2019.

(6)Includes 19,952 common stock options that vest within 60 days after February 26, 2019.

(7)Includes 18,762 common stock options that vest within 60 days after February 26, 2019.

(8)Includes 38,573 common stock options that vest within 60 days after February 26, 2019.

(9)Includes 44,005 common stock options that vest within 60 days after February 26, 2019.

(10)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 (until we achieve listing on a national stock exchange) to our Board, and acting together the directors are able to control Tactic Pharma and how it selects its nominees for our Board of Directors.

* Less than 1%

Item 13. 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 immediate 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.

During the years ended December 31, 2018 and 2017, the we paid or accrued legal fees to Baker & Hostetler, LLP, a large national law firm, in which a family member of the Company's Chief Executive Officer is a law partner, approximately $152,094 and $289,175, respectively. The family member billed a *de minimis* amount of time on our legal engagement with Baker & Hostetler, LLP.

Contributions by Tactic Pharma

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 of MNPR- 101 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". We reimbursed Tactic Pharma, a *de minimis* amount in monthly storage fees during the year ended December 31, 2017 and nothing during the year ended December 31, 2018. In March 2017, Tactic Pharma wired $1,000,000 to us in advance of the sale of our common stock at $6 per share under a private placement memorandum. In April 2017, we issued to Tactic Pharma 166,667 shares in exchange for the $1,000,000 at $6 per share once we began selling our common stock to unaffiliated parties under the private placement memorandum. In August 2017, Tactic Pharma surrendered 2,888,727.12 shares of our common stock back to us as a contribution to the capital of the Company. This resulted in reducing Tactic Pharma's ownership in us 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 our common stock to TacticGem pursuant to the Gem Transaction discussed in detail in below. As of February 26, 2019, Tactic Pharma beneficially owned 46% of our common stock, and TacticGem owned 77% of our common stock.

Gem Transaction

On June 27, 2017, we signed a term sheet with Gem pursuant to which Gem was to transfer assets related to certain of its 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, our largest stockholder at that time. Gem contributed certain of Gem's product candidates' intellectual property and agreements associated primarily with Gem's GPX-150 (renamed MNPR-201) 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. 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 Pharma 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. Gem submitted an IND in February 2007, for MNPR-201, formerly known as GPX-150, for the treatment of cancer. The IND remains open and was transferred to us in February 2018.

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.

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 and directors (taking into account the Conversion).

Name	Related Person Status	Year	# Shares of Common Stock	Purchase Price Per Share	Transaction Value (and Related Person's Interest) ($)
Christopher M. Starr, Ph.D.	Executive Chairman	2016 2017	29,400 20,000	$ 3.57 6.00	105,000 120,000
Chandler D. Robinson, M.D.	Director, Chief Executive Officer	2016	14,002.3	$ 3.57	50,010
Andrew P. Mazar, Ph.D.	Director, Executive Vice President of Research and Development, Chief Scientific Officer	2016	14,002.3	$ 3.57	50,010
Michael J. Brown	Director	2016	210,000	$ 3.57	750,000
Raymond W. Anderson	Director	2017	1,000	$ 6.00	6,000
Arthur Klausner	Director	2017	5,000	$ 6.00	30,000

Promoters and Certain Control Persons

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

Majority Stockholders

Prior to the Gem Transaction, Tactic Pharma was our majority stockholder, having a controlling interest in us. After the Gem Transaction, TacticGem became our majority stockholder, and currently has a 77.1% controlling interest in us. See "Contributions by Tactic Pharma, LLC" and "Gem Transaction".

Director Independence

We have decided to follow the Nasdaq listing standards, which require that a majority of the members of 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 years ended December 31, 2018 and 2017, we were advised by four members of our Board of Directors, who were managers of our predecessor LLC prior to our conversion to a C Corporation. The four former Managers are also current holders of our common stock (owning an aggregate 3.1% of our common stock outstanding as of December 31, 2018). As of December 31, 2018, three of the former Managers were also Managing Members of Tactic Pharma, which was, prior to the Gem Transaction, our largest and controlling stockholder (owning a 46.0% beneficial interest in us at December 31, 2018 and in partnership with Gem through TacticGem owning 77.1%). We paid the Managing Members of Tactic Pharma, LLC the following during the years ended December 31, 2018 and 2017: Chandler D. Robinson, our Co-Founder, Chief Executive Officer, common stockholder, Managing Member of Tactic Pharma, and former Manager of our predecessor LLC, $430,000 and $346,545, respectively; Andrew P. Mazar, our Co-Founder, Chief Scientific Officer, common stockholder, Managing Member of Tactic Pharma, and former Manager of our predecessor LLC, $405,000 and $300,731, respectively; and Michael Brown, Board Member, common stockholder, a Managing Member of Tactic Pharma, LLC until February 1, 2019 and former Manager of our predecessor LLC, Board of Directors fees of $45,500 and $20,000, respectively. We also paid Christopher M. Starr, our Co-Founder, Executive Chairman of the Board of Directors, common stockholder and former Manager of our predecessor LLC, Board of Director fees $105,673 and $100,897 during the years ended December 31, 2018 and 2017, respectively. On February 1, 2019 Mr. Brown entered into an agreement with Tactic Pharma whereby it was agreed that he would become a non-managing member of Tactic Pharma with respect to any votes, decisions or matters relating to Monopar and not exercise any manager votes or decisions of Tactic Pharma related to Monopar. As a non-managing member of Tactic Pharma in connection with any decisions relating to Monopar, Mr. Brown is an independent board member of Monopar as contemplated by Rule 10A-3 under the Exchange Act.

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

Item 14. Principal Accounting Fees and Services

The following is a summary of the fees billed and services provided by our independent registered public accounting firm, BPM LLP during the years ended December 31, 2018 and 2017, respectively.

	For the Year Ended December 31,	
Description of Services Provided by BPM LLP	**2018**	**2017**
Audit Fees	$ 110,993	$ 83,815
Audit-Related Fees: These services relate to assurance and services reasonably related to the performance of the audit or review of financial statements not included above.	28,510	28,325
Tax Compliance Fees: These services relate to the preparation of federal, state and foreign tax returns and other filings.	6,437	3,150
Tax Consulting and Advisory Services: These services primarily relate to the area of tax strategy and minimizing Federal, state, local and foreign taxes.	-	1,250
All Other Fees	-	-

PART IV

Item 15. Exhibits, Financial Statement Schedule

1. **Financial Statements**

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2. **Financial Statements Schedules**

(b) Exhibits

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

Exhibit	Document	Incorporated by Reference From:
3.1	Second Amended and Restated Certificate of Incorporation	Form 10-K filed on March 26, 2018
3.2	Amended and Restated Bylaws	Form 10-K filed on March 26, 2018
10.1*	License Agreement with XOMA Ltd.	Form 10-K filed on March 26, 2018
10.2*	Option and License Agreement with Onxeo S.A.	Form 10-K filed on March 26, 2018
10.3*	Contribution Agreement (351) – Containing Registration Rights Agreement with TacticGem	Form 10-K filed on March 26, 2018
10.4	Amended and Restated 2016 Stock Incentive Plan	Form 10-K filed on March 26, 2018
10.5	Employment Agreement of Chandler D. Robinson – effective November 1, 2017	Form 10-K filed on March 26, 2018
10.6	Employment Agreement of Kim Tsuchimoto – effective November 1, 2017	Form 10-K filed on March 26, 2018
10.7	Employment Agreement of Andrew P. Mazar – effective November 1, 2017	Form 10-K filed on March 26, 2018
10.8	Consulting Agreement of pRx Consulting (Patrice Rioux) - effective January 1, 2018	Form 10-K filed on March 26, 2018
10.9	Amendment One to Employment Agreement of Kim Tsuchimoto – effective March 1, 2018	Form 10-K filed on March 26, 2018
11	Statement Regarding Computation of Per Share Earnings	
24.1	Power of Attorney (included in the signature page hereto)	
31.1	Certification of Chandler Robinson, Chief Executive Officer	
31.2	Certification of Kim Tsuchimoto, Chief Financial Officer	
32.1	Certification of Chandler Robinson, Chief Executive Officer and Kim Tsuchimoto, Chief Financial Officer	
101.INS	XBRL Instance Document	
101.SCH	XBRL Taxonomy Extension Schema	
101.CAL	XBRL Taxonomy Extension Calculation Linkbase	
101.DEF	XBRL Taxonomy Extension Definition Linkbase	
101.LAB	XBRL Taxonomy Extension Label Linkbase	
101.PRE	XBRL Taxonomy Extension Presentation Linkbase	

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

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

MONOPAR THERAPEUTICS INC.

Dated: February 26, 2019

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

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

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

Signatures	Title	Date
/s/ Chandler Robinson		February 26, 2019
Chandler Robinson	Chief Executive Officer and Director (Principal Executive Officer)	
/s/ Kim Tsuchimoto		February 26, 2019
Kim Tsuchimoto	Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)	
/s/ Andrew Mazar		February 26, 2019
Andrew Mazar.	Chief Scientific Officer and Director	
/s/ Christopher Starr		February 26, 2019
Christopher Starr	Executive Chairman of the Board and Director	
/s/ Raymond W. Anderson		February 26, 2019
Raymond W. Anderson	Director	
/s/ Michael Brown		February 26, 2019
Michael Brown	Director	
/s/ Arthur Klausner		February 26, 2019
Arthur Klausner	Director	

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated balance sheets of Monopar Therapeutics Inc. and its subsidiaries (the "Company") as of December 31, 2018 and 2017, the related consolidated statements of operations and comprehensive loss, stockholders' equity and cash flows, for each of the two years in the period ended December 31, 2018, and the related notes and the financial statement schedule listed in the Index to this Annual Report on Form 10-K at Part IV Item 15.2 (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2018 and 2017, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2018, in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

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

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

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

/s/ BPM LLP

We have served as the Company's auditor since 2015.

San Francisco, California

February 26, 2019

Monopar Therapeutics Inc.

Consolidated Balance Sheets

	December 31,	
Assets	**2018**	**2017**
Current assets:		
Cash and cash equivalents	$ 6,892,772	$ 8,981,894
Prepaid expenses and other current assets	425,183	149,342
Total current assets	7,317,955	9,131,236
Restricted cash	-	800,031
Total assets	$ 7,317,955	$ 9,931,267
Liabilities and Equity		
Current liabilities:		
Accounts payable and accrued expenses	$ 399,551	$ 311,867
Total current liabilities	399,551	311,867
Long term liabilities	—	—
Total liabilities	399,551	311,867
Commitments and contingencies (Note 9)		
Stockholders' equity:		
Common stock, par value of $0.001 per share, 40,000,000 authorized, 9,291,421 shares issued and outstanding at December 31, 2018 and 2017	9,291	9,291
Additional paid-in capital	28,567,221	28,037,889
Accumulated deficit	(21,655,712)	(18,427,780)
Accumulated other comprehensive loss	(2,396)	-
Total stockholders' equity	6,918,404	9,619,400
Total liabilities and stockholders' equity	$ 7,317,955	$ 9,931,267

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

Monopar Therapeutics Inc.

Consolidated Statements of Operations and Comprehensive Loss

	December 31,	
	2018	**2017**
Revenues	$ —	$ —
	—	—
Operating expenses:		
Research and development	1,774,454	935,319
In-process research and development	-	14,501,622
General and administrative	1,628,308	1,166,186
Total operating expenses	3,402,762	16,603,127
Loss from operations	(3,402,762)	(16,603,127)
Other income:		
Interest and other income	103,215	48,255
Loss before income tax benefit	(3,299,547)	(16,554,872)
Income tax benefit	71,615	-
Net loss	(3,227,932)	(16,554,872)
Other comprehensive income (loss):		
Foreign currency translation loss	(2,396)	-
Comprehensive loss	$ (3,230,328)	$(16,554,872)
Net loss per share:		
Basic and diluted	$ (0.35)	$ (1.89)
Weighted-average shares outstanding:		
Basic and diluted	9,291,421	8,782,037

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

Monopar Therapeutics Inc.
Consolidated Statements of Stockholders' Equity

	Series A and Z Preferred Stock		Common Stock		Additional Paid-In	Accumulated	Other Comprehensive	Total
	Shares	Amount	Shares	Amount	Capital	Deficit	Loss	Equity
Balance at January 1, 2017	115,894	$ 116	—	$ —	$4,703,848	$(1,872,908)	$ —	$2,831,056
Conversion of preferred stock to common stock	(115,894)	(116)	8,335,080	8,335	(8,219)	—	—	—
Issuance of common stock at $6 per share for cash, net of $32,400 issuance costs	—	—	789,674	790	4,704,856	—	—	4,705,646
Tactic Pharma shares surrendered	—	—	(2,888,727)	(2,889)	2,889	—	—	—
Shares issued in Gem transaction, net of issuance costs of $169,257	—	—	3,055,394	3,055	18,329,310	—	—	18,332,365
Non-cash stock compensation	—	—	—	—	305,205	—	—	305,205
Net loss	—	—	—	—	—	(16,554,872)	—	(16,554,872)
Balance at January 1, 2018	—	—	9,291,421	9,291	28,037,889	(18,427,780)	—	9,619,400
Non-cash stock compensation	—	—	—	—	529,332	—	—	529,332
Net loss	—	—	—	—	—	(3,227,932)	—	(3,227,932)
Accumulated other comprehensive loss	—	—	—	—	—	—	(2,396)	(2,396)
Balance at December 31, 2018	—	$ —	9,291,421	$9,291	$28,567,221	$(21,655,712)	$ (2.396)	$6,918,404

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

Monopar Therapeutics Inc.

Consolidated Statements of Cash Flows

	December 31,	
	2018	**2017**
Cash flows from operating activities:		
Net loss	$ (3,227,932)	$(16,554,872)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock compensation expense (non-cash)	529,332	305,205
In process research and development (non-cash)	-	13,501,622
Changes in operating assets and liabilities, net		
Prepaid expenses and other current assets	(275,841)	(126,780)
Accounts payable and accrued expenses	87,684	247,357
Net cash used in operating activities	(2,886,757)	(2,627,468)
Cash flows from financing activities:		
Cash received from Gem, net of $169,257 of transaction costs	—	4,830,743
Proceeds from the sale of common stock, net of $32,400 of issuance costs	—	4,705,646
Net cash provided by financing activities	—	9,536,389
Effect of exchange rates on cash, cash equivalents, and restricted cash	(2,396)	—
Net increase (decrease) in cash, cash equivalents and restricted cash	(2,889,153)	6,908,921
Cash, cash equivalents and restricted cash at beginning of period	9,781,925	2,873,004
Cash, cash equivalents and restricted cash at end of period	$ 6,892,772	$ 9,781,925
Supplemental disclosure of non-cash items for cash flow information:		
Value of shares issued in Gem transaction	-	18,332,365

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

MONOPAR THERAPEUTICS INC.

NOTES TO FINANCIAL STATEMENTS

December 31, 2018

Note 1 - Nature of Business and Liquidity

Nature of Business

Monopar Therapeutics Inc. ("Monopar" or the "Company") is an emerging biopharmaceutical company focused on developing innovative drugs and drug combinations to improve clinical outcomes in cancer patients. Monopar currently has three compounds in development: Validive® (clonidine mucobuccal tablet; clonidine MBT), a Phase 3-ready, first-in-class mucoadhesive buccal anti-inflammatory tablet for the prevention and treatment of radiation-induced severe oral mucositis ("SOM") in oropharyngeal cancer patients; MNPR-201 (GPX-150; 5-imino-13-deoxydoxorubicin), a proprietary Phase 2 clinical-stage topoisomerase II-alpha targeted analog of doxorubicin engineered specifically to retain anticancer activity while minimizing toxic effects on the heart; and MNPR-101 (formerly huATN-658), a pre-IND stage humanized monoclonal antibody, which targets the urokinase plasminogen activator receptor ("uPAR"), for the treatment of advanced solid cancers.

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 at which time the Company effected a 1 for 10 reverse stock split. All references to preferred stock 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 into common stock at a conversion rate of 1.2 for 1 and 1 for 1, respectively, which eliminated all shares of Series A Preferred Stock and Series Z Preferred Stock along with a concurrent common stock split of 70 for 1. 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 $21.7 million as of December 31, 2018. To date, the Company has primarily funded its operations with the net proceeds from private placements of convertible preferred stock and of common stock and from the cash provided in the MNPR-201 asset purchase transaction. Management believes that currently available resources will provide sufficient funds to enable the Company to meet its minimum obligations through March 2020. 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 and/or execute collaboration research transactions. There can be no certainty that future financing or collaborative research transactions will occur.

Note 2 - Significant Accounting Policies

Basis of Presentation

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

Certain reclassifications have been made to the Company's consolidated financial statements for the year ended December 31, 2018 to conform to the year ended December 31, 2017 presentation. The reclassifications had no impact on the Company's net loss, total assets, or stockholders' equity.

Functional Currency

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

Comprehensive Loss

Comprehensive loss represents net loss plus any gains or losses not reported in the statements of operations, such as foreign currency translations gains and losses that are typically reflected on a company's statements of stockholders' equity.

Use of Estimates

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

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 February 2019, the Company analyzed its minimum cash requirements through March 2020 and has determined that, based upon the Company's current available cash, the Company has no substantial doubt about its ability to continue as a going concern.

Cash Equivalents

The Company considers all highly liquid investments purchased with an original maturity of 90 days or less to be cash equivalents. Cash equivalents as of December 31, 2018 and 2017 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 as of December 31, 2018 and $0.8 million as of December 31, 2017. In connection with a portfolio reprioritization review, on March 21, 2018, Cancer Research UK notified us that it was terminating the CTOA and transferred to us the data generated under the CTOA. These funds were released from escrow in September 2018 and were deposited into a money market account and reclassified as cash equivalents.

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.

Concentration of Credit Risk

Financial instruments that potentially subject the Company to concentration of credit risk consist of cash and cash equivalents. The Company maintains cash and cash equivalents at one financial institution. As of December 31, 2018, cash and cash equivalents 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, deferred offering costs, 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.

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, 2018 and 2017. The following table presents the assets and liabilities recorded that are reported at fair value on our consolidated balance sheets on a recurring basis.

Assets and Liabilities Measured at Fair Value on a Recurring Basis

December 31, 2018	Level 1	Level 2	Total
Assets			
Cash equivalents(1)	$ 6,788,333	$ -	$ 6,788,333
Total	$ 6,788,333	$ -	$ 6,788,333

(1) Cash equivalents represent the fair value of the Company's investments in a money market account at December 31, 2018.

December 31, 2017	Level 1	Level 2	Total
Assets			
Cash equivalents(1)	$ 8,872,982	$ -	$ 8,872,982
Restricted cash(2)	31	800,000	800,031
Total	$ 8,873,013	$ 800,000	$ 9,673,013

(1) Cash equivalents represent the fair value of the Company's investments in two money market accounts at December 31, 2017.
(2) Restricted cash represents the fair value of the Company's investments in an $800,000 certificate of deposit and $31 in a money market account at December 31, 2017.

Net Loss per Share

Net loss per share for the year ended December 31, 2018 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 year ended December 31, 2018 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 December 31, 2018, potentially dilutive securities included 1,105,896 options to purchase common stock. As of December 31, 2017, potentially dilutive securities included stock options to purchase up to 658,592 shares of the Company's common stock. For all periods presented, potentially dilutive securities are excluded from the computation of fully diluted net loss per share as their effect is anti-dilutive.

Research and Development Expenses

Research and development ("R&D") costs are expensed as incurred. Major components of research and development expenses include salaries and benefits paid to the Company's R&D staff, fees paid to consultants and to the entities that conduct certain development activities on the Company's behalf and materials and supplies.

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, 2018 and 2017, the Company had no clinical trials in progress.

In-process Research and Development

In-process research and development ("IPR&D") expense represents the costs to acquire technologies to be used in research and development that have not reached technological feasibility, have no alternative future uses and thus are expensed as incurred. IPR&D expense also includes upfront license fees and milestones paid to collaborators for technologies with no alternative use.

Collaborative Arrangements

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

During the years ended December 31, 2018 and 2017, no milestones were met and no royalties were earned, therefore, the Company did not pay or accrue/expense any milestone or royalty payments.

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 years ended December 31, 2018 and 2017, no milestones were met and no royalties were earned, therefore, the Company did not pay or accrue/expense any milestone or royalty payments under any of its license agreements.

Patent Costs

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

Income Taxes

From December 2014 to December 16, 2015, the Company was 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 carryforwards. Deferred income tax assets and liabilities are measured using the currently enacted tax rates that apply to taxable income in effect for the years in which those tax assets and liabilities are expected to be realized or settled.

The Company regularly assesses the likelihood that its deferred income tax assets will be realized from recoverable income taxes or recovered from future taxable income. To the extent that the Company believes any amounts are 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 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 December 31, 2018 and 2017. The Company intends to maintain the valuation allowance until sufficient evidence exists to support their 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 years ended December 31, 2018 and 2017, 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 years ended December 31, 2018, 2017 and 2016 and for 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 December 31, 2018. The Company plans on filing its tax returns for the year ending December 31, 2018 prior to the filing deadlines in all jurisdictions.

On December 22, 2017, the Tax Cuts and Jobs Act of 2017 was enacted. The Tax Reform Bill was effective as of January 1, 2018. In accordance with ASC guidance, deferred tax assets/liabilities in the Company's financial statements for the years ended December 31, 2018 and 2017, were reflected at the tax rate in which the deferred tax assets/liabilities are anticipated to be realized. As a result, the Company changed the tax rate for tax provision purposes commencing on December 31, 2017 from 34% to 21%.

Stock-Based Compensation

The Company accounts for stock-based compensation arrangements with employees, non-employee directors and consultants using a fair value method, which requires the recognition of compensation expense for costs related to all stock-based 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 non-employee 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 market capitalization, 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 future vesting period and, accordingly, uses an expected dividend yield of zero. The risk-free interest rate is based on the rate of U.S. Treasury securities with maturities consistent with the estimated expected term of the awards. 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 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. The Company has adopted this ASU and determined that it does not have a material effect on its financial condition and consolidated results of operations and comprehensive loss for the year ended December 31, 2018.

In February 2016, the FASB issued ASU 2016-02, *Leases*, which has been amended by ASU No. 2018-10, *Codification Improvements to Topic 842, 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. This ASU was further amended by ASU No. 2018-11, *Leases (Topic 842): Targeted Improvements*, issued in July 2018. The ASU 2018-11 is intended to reduce costs and ease implementation of the *Leases* standard for financial statement preparers. ASU 2018-11 provides a new transition method and a practical expedient for separating components of a contract. 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 consolidated financial statements and footnote disclosures.

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 has adopted this ASU and determined it does not have a material impact on its financial condition and consolidated statements of operations and comprehensive loss for the year ended December 31, 2018.

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. The Company has adopted this ASU and determined that it does not have a material effect on its financial condition and consolidated results of operations and comprehensive loss for the year ended December 31, 2018.

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 consolidated financial statements and footnote disclosures.

In February 2018, the FASB issued ASU No. 2018-03, *Technical Corrections and Improvements to Financial Instruments – Overall (Subtopic 825-10): Recognition and Measurement of Financial Assets and Financial Liabilities*, that clarifies the guidance in ASU No. 2016-01, *Financial Instruments – Overall (Subtopic 825-10)*. For public business entities, ASU 2018-03 is effective for fiscal years beginning after June 15, 2018. Public business entities with fiscal years beginning between December 15, 2017, and June 15, 2018, are not required to adopt ASU 2018-03 until the interim period beginning after June 15, 2018. The Company has early adopted this ASU and determined that it does not have a material effect on its financial condition and consolidated results of operations and comprehensive loss for the year ended December 31, 2018.

In March 2018, the FASB issued ASU No. 2018-05, *Income Taxes (Topic 740): Amendments to SEC Paragraphs Pursuant to SEC Staff Accounting Bulletin No. 118.* This ASU amends certain SEC material on Topic 740 for the income tax accounting implications of the recently issued Tax Cuts and JOBS Act. ASU 2018-05 is effective upon inclusion in the FASB Codification. The Company has adopted this ASU and determined it does not have a material impact on its financial condition and consolidated results of operations and comprehensive loss for the year ended December 31, 2018.

In June 2018, the FASB issued ASU No. 2018-07, *Compensation-Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting*. The ASU is intended to reduce the cost and complexity and to improve financial reporting for nonemployee share-based payments. The ASU expands the scope of Topic 718, *Compensation—Stock Compensation* (which currently only includes share-based payments to employees) to include share-based payments issued to nonemployees for goods or services. Consequently, the accounting for share-based payments to nonemployees and employees will be substantially aligned. The ASU supersedes Subtopic 505-50, *Equity—Equity-Based Payments to Non-Employees.* The amendments in this ASU are effective for public companies for fiscal years beginning after December 15, 2018, including interim periods within that fiscal year. For all other companies, 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, but no earlier than a company's adoption date of Topic 606, *Revenue from Contracts with Customers*. The Company is currently assessing the impact that adopting this new accounting standard will have on its consolidated financial statements and footnote disclosures.

In August 2018, the FASB issued ASU No. 2018-13, *Fair Value Measurement (Topic 820): Disclosure Framework—Changes to the Disclosure Requirements for Fair Value Measurement.* The ASU modifies, and in certain cases eliminates, the disclosure requirements on fair value measurements in Topic 820. The amendments in ASU No. 2018-13 are effective for all entities for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2019. Early adoption is permitted. An entity is permitted to early adopt any removed or modified disclosures upon issuance of ASU No. 2018-13 and delay adoption of the additional disclosures until their effective date. The Company is currently assessing the impact that adopting this new accounting standard will have on its consolidated financial statements and footnote disclosures.

Note 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 15,894 shares of Series A Preferred Stock were converted into 1,335,079 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.

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 shares of common stock back to the Company as a contribution to the capital of the Company. This resulted at that time 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 shares of its common stock in exchange for cash and intellectual property related to GPX-150 (renamed MNPR-201).

As of December 31, 2018, 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.

Note 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.

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 and in November 2017, the Company granted options to purchase up to 40,000 shares of common stock to an employee. These Board and employee options have 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.

In January 2018, the Company granted options to purchase up to 32,004 shares of common stock to its acting chief medical officer, 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. In May 2018 and August 2018, the Company granted options to two employees to each purchase up to 5,000 shares of common stock, 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. Also in August 2018, the Company granted stock options to all of its non-employee Board members, the Company's chief executive officer, chief scientific officer, and chief financial officer to purchase up to an aggregate 425,300 shares of the Company's common stock 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. Vesting of such options commenced on October 1, 2018. In December 2018, the Company granted options to purchase up to 20,000 shares of common stock to its acting chief medical officer, 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. Vesting of such options commenced on January 1, 2019.

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 was as follows:

		Options Outstanding	
	Options Available	Number of Options	Weighted-Average Exercise Price
Balances at January 1, 2017	**420,000**	**280,000**	**$0.001**
Board-approved increase in option pool[1]	900,000	—	—
Granted [2]	(378,592)	378,592	1.63
Forfeited	—	—	—
Exercised	—	—	—
Balances at December 31, 2017	**941,408**	**658,592**	**0.94**
Granted[3]	(487,304)	487,304	6.00
Forfeited[4]	40,000	(40,000)	6.00
Exercised	—	—	—
Balances at December 31, 2018	**494,104**	**1,105,896**	**2.99**

(1) In October 2017, the Company's Board of Directors increased the option pool from 700,000 to 1,600,000 shares.

(2) 336,544 options vest 6/48ths at the six-month anniversary of grant date and 1/48th per month thereafter; 21,024 options vest 6/24ths on the six-month anniversary of grant date and 1/24th per month thereafter; and 21,024 options vest 6/42nds on the six-month anniversary of grant date and 1/42nd per month thereafter.

(3) 32,004 options vest as follows: options to purchase up to 12,000 shares of common stock vest on the grant date, options to purchase up to 1,667 shares of common stock vest on the 1st of each month thereafter. 5,000 options vest 6/48ths on the grant date and 1/48th per month thereafter. 5,000 options vest 6/48ths on the six-month anniversary of grant date and 1/48th per month thereafter. 320,900 options vest 6/51 at the six-month anniversary of vesting commencement date and 1/51 per month thereafter, with vesting commencing on October 1, 2018. 104,400 options vest quarterly over 5 quarters, with the first quarter commenced on October 1, 2018. 20,000 options vest as follows: options to purchase up to 1,667 shares of common stock vest on January 31, 2019 and the last day of each month thereafter.

(4) Forfeited options resulted from an employee termination.

A summary of options outstanding as of December 31, 2018 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	7.7 years	406,280	7.6 years
$ 6.00	550,376	9.5 years	58,910	8.9 years
	1,105,896		465,190	

During the years ended December 31, 2018 and 2017, the Company recognized $232,625 and $26,864 of employee and non-employee director stock-based compensation expense as general and administrative expenses, respectively, and $171,238 and $26,499 as research and development expenses, respectively. 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 consolidated statements of operations and comprehensive loss 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. Stock-based compensation expense for non-employees for the years ended December 31, 2018 and 2017 was $125,469 and $251,842, respectively, of which $125,469 and $199,769, respectively, was recorded as research and development expenses and $0 and $52,073, respectively, as general and administrative expenses.

The fair value of options granted from inception to December 31, 2018 was based on the Black-Scholes option-pricing model assuming the following factors: 4.7 to 6.2 years expected term, 55% to 85% volatility, 1.2% to 2.9% risk free interest rate and zero dividends. The expected term for options granted to date is estimated using the simplified method. For the years ended December 31, 2018 and 2017: the weighted-average grant date fair value was $2.05 and $0.88 per share, respectively; and the fair value of shares vested was $0.4 million and $0.3 million, respectively. At December 31, 2018, the aggregate intrinsic value was approximately $3.3 million of which approximately $2.4 million was vested and approximately $0.9 million is expected to vest and the weighted-average exercise price in aggregate was $2.99 which includes $0.76 for fully vested stock options and $4.60 for stock options expected to vest. At December 31, 2018 unamortized unvested balance of stock base compensation was $2.2 million, to be amortized over 2.9 years.

Note 5 - Development and Collaboration Agreements

Onxeo SA

The pre-negotiated Onxeo license agreement for Validive 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 the Company's royalty payment obligations with respect to such product have expired. The agreement may also be terminated early for cause if either the Company or Onxeo materially breach the agreement, or if either the Company or Onxeo become insolvent. The Company may also choose to terminate the agreement, either in its entirety or as to a certain product and a certain country, by providing Onxeo with advance notice.

The Company plans to internally develop Validive with the near-term goal of commencing a Phase 3 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. As of December 31, 2018, the Company had not reached any of the pre-specified milestones and has not been required to pay Onxeo any funds under this license agreement.

XOMA Ltd.

The intellectual property rights contributed by Tactic Pharma to the Company included the non-exclusive license agreement with XOMA Ltd. for the humanization technology used in the development of MNPR-101. Pursuant to such license agreement, the Company is obligated to pay XOMA Ltd. clinical, regulatory and sales milestones for MNPR-101 that could reach up to $14.925 million if the Company achieves all milestones. The agreement does not require the payment of sales royalties. There can be no assurance that the Company will reach any milestones. As of December 31, 2018, the Company has not reached any milestones and has not been required to pay XOMA Ltd. any funds under this license agreement.

Note 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 (renamed MNPR-201) 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 4,111,273 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 newly issued shares of common stock of the Company (31.4% 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 December 31, 2018.

The transaction was recorded as an asset acquisition on 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 and Comprehensive Loss	9,886
MNPR-201 (GPX-150) recorded as In-process Research and Development Expense on the Company's Statement of Operations and Comprehensive Loss	13,491,736
Total Gem Transaction	$ 18,501,622

Within 90 days of the effective date of the transaction, the Company was required to use its best efforts to file a Form 10 to register its common stock under the Securities Exchange Act of 1934. The Company filed its Form 10 on November 9, 2017. Additionally, 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 plus one person designated by Gem to our Board. The Gem board nomination right terminates at such time as we achieve a listing on a national stock exchange. Gem's initial designee for election to our Board is Arthur Klausner, former CEO of Gem. Also, Richard Olson and Gerald Walsh, former CSO and former President of Gem, respectively, had been retained with one-year consulting agreements to aid in an efficient transfer of Gem's GPX-150 (renamed MNPR-201) and associated programs.

During the year ended December 31, 2018, the Company's annual cash burn increased by approximately $100,000 due to the addition of the Gem Assets, and future cash burn will be significantly higher when the Company chooses to conduct clinical trials with the Gem drug candidate programs.

Note 7 - Related Party Transactions

In March 2017, Tactic Pharma, the Company's largest shareholder at that time, 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 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 at the time from 79.5% to 69.9%.

In August 2017, the Company executed definitive agreements with Gem, pursuant to which Tactic Pharma and Gem formed a limited liability company, TacticGem. Tactic Pharma contributed 4,111,273 shares of its holdings in Monopar's common stock to TacticGem and Gem contributed cash and assets to TacticGem. TacticGem then contributed cash and assets to the Company in exchange for stock. As of December 31, 2018, Tactic Pharma beneficially owned 46% of Monopar's common stock, and TacticGem owned 77% of Monopar's common stock.

During the years ended December 31, 2018 and 2017, 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 December 31, 2018). Three of the former Managers are also Managing Members of Tactic Pharma as of December 31, 2018. Monopar paid Managing Members of Tactic Pharma and the Manager of CDR Pharma, LLC, which is the Manager of TacticGem the following: Chandler D. Robinson, the Company's Co-Founder, Chief Executive Officer, common stockholder, Managing Member of Tactic Pharma, former Manager of the predecessor LLC, and the Manager of CDR Pharma, LLC: $430,000 and $346,545 for the years ended December 31, 2018 and 2017, respectively; and Andrew P. Mazar, the Company's Co-Founder, Chief Scientific Officer, common stockholder, Managing Member of Tactic Pharma and former Manager of the predecessor LLC, $405,000 and $89,481 for the years ended December 31, 2018 and 2017, respectively. In addition, Dr. Mazar was paid $225,000 in consulting fees for the year ended December 31, 2017. 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 $105,673 and $100,897 in board fees for the years ended December 31, 2018 and 2017, respectively. Michael Brown, as a managing member of Tactic Pharma until February 1, 2019, a previous managing member of Monopar as an LLC and common stockholder and board member of Monopar as a C Corporation was paid $45,500 and $20,000 for the years ended December 31, 2018 and 2017, respectively.

For the year ended December 31, 2018, $102,760 of fees paid to or accrued for a large national law firm, in which a family member of the Company's Chief Executive Officer is a law partner, were recorded as deferred offering costs and $49,334 as legal expense for a total of $152,094. For the year ended December 31, 2017, $110,341 of fees accrued for, or paid to, this law firm was recorded as deferred offering costs, $13,076 as legal expense, $31,500 as fundraising costs (contra equity) and $134,258 as Gem transaction cost recorded as in-process research and development expense for a total of $289,175. The family member personally billed a *de minimis* amount of time on the Company's legal engagement with the law firm in these periods.

Note 8 – 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 not more likely than not to be realized with the exception of $75,973 and $4,358 of U.S. Federal R&D tax credits for the years ended December 31, 2018 and 2017, respectively. The 2018 tax credit of $71,615 will be utilized to reduce payroll taxes in 2019. The tax credit generated in 2017 in the amount of $4,358 will also be claimed to offset payroll taxes in 2019. Accordingly, the valuation allowance has not been released related to these assets with the exception of $75,973 and $4,358 in U.S. Federal R&D tax credits for the years ended December 31, 2018 and 2017, respectively. The valuation allowance increased by approximately $690,000 and $466,000 during the years ended December 31, 2018 and 2017, respectively.

The provision for income taxes for December 31, 2018 and 2017 consists of the following:

	As of December 31, 2018	2017
Current:		
Federal	$ -	$ -
State	-	-
Total current	-	-
Deferred:		
Federal	(71,615)	-
State		
Total deferred	(71,615)	-
Full valuation allowance		
Total provision	$ (71,615)	$ -

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

	%
Federal income tax	21.00%
State income taxes, less federal benefit	0.78%
Tax Credits	1.87%
Permanent differences	-0.13%
Change in valuation allowances	-20.92%
Other	-0.43%
Effective Tax Rate Benefit (expense)	2.17%

Deferred tax assets and liabilities consist of the following:

	As of December 31,	
	2018	2017
Deferred tax assets:		
Net operating loss carryforwards	$ 467,186	$ 186,019
Tax credit carryforwards	107,969	30,143
Stock compensation	138,111	58,536
Intangible asset basis differences	1,053,518	730,647
Gross deferred tax assets	1,766,784	1,005,345
Valuation allowance	(1,690,811)	(1,000,987)
Total deferred tax assets, net of valuation allowance	75,973	4,358
Deferred tax liabilities:		
Net deferred tax liability	—	—
Net deferred taxes	$ 75,973	$ 4,358

As of December 31, 2018, Company had total federal net operating loss carryforwards of approximately $2,132,000. The $820,000 will begin to expire in 2035, and the $1,312,000 will carry forward indefinitely for federal tax purposes. At December 31, 2018, the Company had state net operating loss carryforwards of approximately $259,000 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, 2018, Company had R&D credit carryforwards of approximately $76,000 and $40,000 available to reduce future taxable income, if any, for both federal and state income tax purposes, respectively. The federal credit of $76,000 may be able to reduce future payroll taxes. The federal R&D credit carryforwards expire beginning 2035 and Illinois R&D credit carryforwards expire beginning 2020. The federal credit has been recorded as a deferred tax asset included as a component of prepaid expenses and other current assets in our consolidated balance sheet.

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 Accounting Standards Codification (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, 2018. 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 related to uncertain tax positions is recorded on the financial statements related to uncertain tax positions. There are no unrecognized tax benefits as of December 31, 2018. The Company does not expect that uncertain tax benefits will materially change in the next 12 months.

Company files U.S. federal, California and Illinois State tax returns. Company is subject to California State minimum franchise taxes. All tax returns will remain open for examination by the federal and state taxing authorities for three and four years, respectively, from the date of utilization of any net operating loss carryforwards or R&D credits. In addition, due to the new operations in certain foreign countries, the Company became subject to local tax laws of such countries. Nonetheless, as of December 31, 2018, due to the insignificant expenditures in such countries, there was no material tax effect to the Company’s 2018 consolidated financial statements.

On December 22, 2017, the Tax Cuts and Jobs Act (“TCJA”) of 2017 was enacted by the U.S. President. The Tax Cuts and Jobs Act of 2017 is effective as of January 1, 2018. In accordance with ASC guidance, deferred tax assets/liabilities in the Company’s financial statements are to be reflected at the tax rate in which the deferred tax assets/liabilities are anticipated to be realized. As a result, the Company changed the tax rate for tax provision purposes commencing on December 31, 2017 from 34% to 21%. This resulted in a reduction of the value of the Company’s deferred tax asset balances in the amount of approximately $176,000. The Company completed the accounting for revaluation of deferred taxes at the new corporate tax rate and did not make any adjustment to the tax impact reported in 2017. The Company appropriately reflected any tax effects by the provisions included in the TCJA. Such effects are immaterial to the Company’s 2018 consolidated financial statement.

Note 9 – Commitments and Contingencies

Development and Collaboration Agreements

Onxeo S.A.

The Onxeo license agreement for Validive includes clinical, regulatory, developmental and sales milestones that could reach up to $108 million if the Company achieves all milestones, and escalating royalties on net sales from 5% to 10%. During the years ended December 31, 2018 and 2017, the Company had not reached any milestones and has not been required to pay Onxeo any funds under this license agreement.

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 and zero royalties. During the years ended December 31, 2018 and 2017, the Company had not reached any milestones and has not been required to pay XOMA Ltd. any funds under this license agreement.

Leases

Commencing January 1, 2018, the Company entered into a lease for its executive headquarters at 1000 Skokie Blvd., Suite 350, Wilmette, Illinois. The lease term is January 1, 2018 through December 31, 2019. The Company also leased office space in Seattle, Washington, from November 1, 2017 to July 31, 2018. The future lease commitments as presented below represent amounts for the Company's lease of its executive headquarters.

2019	$	30,234
Thereafter		-
Total future lease payments	$	30,234

Legal Contingencies

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

Indemnification

In the normal course of business, the Company enters into contracts and agreements that contain a variety of representations and warranties and provide for general indemnification. The Company's exposure under these agreements is unknown because it involves claims that may be made against the Company in the future, but that have not yet been made. To date, the Company has not paid any claims 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.

Schedule II: Valuation and Qualifying Accounts

Valuation Allowance for Deferred Tax Assets

	Year Ended December 31,	
(In thousands)	**2018**	**2017**
Balance at beginning of year	$ 1,000,987	$ 535,254
Additions charged to expenses/other accounts	689,824	465,733
Balance at end of year	$ 1,690,811	$ 1,000,987

Exhibit 11

Statement Regarding Computation of Per Share Earnings

The statement regarding computation of per share earnings is set forth in Note 2 of the Notes to the Consolidated Financial Statements of the Company for the years ended December 31, 2018 and 2017.

Exhibit 31.1

CERTIFICATION

I, Chandler D. Robinson, certify that:

1. I have reviewed this Annual Report on Form 10-K of Monopar Therapeutics Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: February 26, 2019

/s/ Chandler D. Robinson

Chandler D. Robinson

Chief Executive Officer

Exhibit 31.2

CERTIFICATION

I, Kim R. Tsuchimoto, certify that:

1. I have reviewed this Annual Report on Form 10-K of Monopar Therapeutics Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: February 26, 2019

/s/ Kim R. Tsuchimoto

Kim R. Tsuchimoto

Chief Financial Officer

Exhibit 32.1

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report on Form 10-K of Monopar Therapeutics Inc. (the Company) for the year ended December 31, 2018, as filed with the Securities and Exchange Commission on the date hereof (the Report), we, Chandler D. Robinson, and Kim R. Tsuchimoto, hereby certify, pursuant to 18 U.S.C. §1350, as adopted pursuant to §906 of the Sarbanes-Oxley Act of 2002, that:

(1) the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
(2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ Chandler D. Robinson

Chandler D. Robinson

Chief Executive Officer

February 26, 2019

/s/ Kim R. Tsuchimoto

Kim R. Tsuchimoto

Chief Financial Officer

February 26, 2019

This certification accompanies the Form 10-K to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of Monopar Therapeutics Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Form 10-K), irrespective of any general incorporation language contained in such filing.