

PROSPECTUS SUPPLEMENT (To prospectus dated January 13, 2020)

**\$19,700,000**



# Monopar Therapeutics

## Common Stock

In accordance with the terms of the Capital on Demand™ Sales Agreement entered into with JonesTrading Institutional Services LLC (“JonesTrading” or the “Agent”), dated January 13, 2020, which we refer to as the sales agreement, we may offer and sell under this prospectus supplement and accompanying prospectus shares of our Common Stock, \$0.001 par value per share, having an aggregate offering price of up to \$19,700,000 from time to time through or to the Agent, acting as sales agent or principal.

Our Common Stock is listed for trading on the Nasdaq Capital Market under the symbol “MNPR.” On January 10, 2020 the last reported sale price of our Common Stock was \$22.00 per share.

The aggregate market value of our outstanding Common Stock held by non-affiliates was approximately \$59.2 million based on 2,191,820 shares of outstanding Common Stock held by non-affiliates and a price per share of \$27.00, the closing price of our Common Stock on December 20, 2019. Pursuant to General Instruction I.B.6 of Form S-3, in no event will we sell securities pursuant to this prospectus supplement with a value more than one-third of the aggregate market value of our Common Stock held by non-affiliates in any 12-month period, so long as the aggregate market value of our Common Stock held by non-affiliates remains less than \$75.0 million. In the event that the aggregate market value of our outstanding Common Stock held by non-affiliates equals or exceeds \$75.0 million, then the one-third limitation on sales may not apply to additional sales made pursuant to this prospectus supplement. We have not sold any securities pursuant to General Instruction I.B.6 of Form S-3 during the 12 calendar months prior to, and including, the date of this prospectus supplement.

Sales of our Common Stock, if any, under this prospectus supplement will be made by any method permitted that is deemed an “at the market offering” as defined in Rule 415 under the Securities Act of 1933, as amended (the “Securities Act”). The Agent is not required to sell any specific amount of shares of our Common Stock, but will act as our sales agent using commercially reasonable efforts consistent with their normal trading and sales practices. There is no arrangement for funds to be received in any escrow, trust or similar arrangement.

The Agent will be entitled to compensation at a commission rate of up to 3.0% of the gross sales price per share of our Common Stock sold. In connection with the sale of our Common Stock on our behalf, the Agent will be deemed to be an “underwriter” within the meaning of the Securities Act and the compensation of the Agent will be deemed to be underwriting commission or discount. We have also agreed to provide indemnification and contribution to the Agent with respect to certain liabilities, including liabilities under the Securities Act.

We are an “emerging growth company” as that term is used in the Jumpstart Our Business Startups Act of 2012 and, as such, have elected to comply with certain reduced public company reporting requirements for this prospectus supplement and future filings.

**Investing in our Common Stock involves significant risks. See “Risk Factors” beginning on page S-9 of this prospectus supplement and in the documents incorporated by reference in this prospectus supplement for a discussion of the factors you should carefully consider before deciding to purchase our Common Stock.**

**Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or passed upon the accuracy or adequacy of this prospectus supplement. Any representation to the contrary is a criminal offense.**



The date of this Prospectus Supplement is January 13, 2020

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## ABOUT THIS PROSPECTUS SUPPLEMENT

This prospectus supplement is a supplement to the accompanying prospectus that is also a part of this document. This prospectus supplement and the accompanying prospectus, dated January 13, 2020, are part of a registration statement on Form S-3 (File No. 333-235791) that we filed with the Securities and Exchange Commission (the “SEC”), utilizing a “shelf” registration process. Under the shelf registration process, we may offer and sell from time to time in one or more offerings our Common Stock described in the accompanying prospectus.

This document is in two parts. The first part is this prospectus supplement, which describes our Common Stock we are offering and the terms of the offering and also adds to and updates information contained in the accompanying prospectus and the documents incorporated by reference into the accompanying prospectus. The second part is the accompanying prospectus, which provides more general information. Generally, when we refer to this “prospectus,” we are referring to both documents combined. To the extent there is a conflict between the information contained in this prospectus supplement, on the one hand, and the information contained in the accompanying prospectus or any earlier dated document incorporated by reference therein, on the other hand, you should rely on the information in this prospectus supplement. Additional prospectus supplements or documents filed after the date hereof that are deemed incorporated by reference herein may modify and supersede the information in this prospectus supplement. We urge you to carefully read this prospectus supplement and the accompanying prospectus and any related free writing prospectus, together with the information incorporated herein and therein by reference as described under the heading “Incorporation of Information by Reference,” before buying any of our Common Stock being offered.

You should rely only on the information that we have provided or incorporated by reference in this prospectus supplement and the accompanying prospectus and any related free writing prospectus that we may authorize to be provided to you. We have not, and Agent has not, authorized anyone to provide you with different information. No other dealer, salesperson or other person is authorized to give any information or to represent anything not contained in this prospectus supplement and the accompanying prospectus or any related free writing prospectus that we may authorize to be provided to you. You must not rely on any unauthorized information or representation. This prospectus supplement is an offer to sell only our Common Stock offered hereby and only under circumstances and in jurisdictions where it is lawful to do so. You should assume that the information in this prospectus supplement and the accompanying prospectus or any related free writing prospectus is accurate only as of the date on the front of the document and that any information we have incorporated by reference is accurate only as of the date of the document incorporated by reference, regardless of the time of delivery of this prospectus supplement and the accompanying prospectus or any related free writing prospectus, or any sale of our Common Stock.

This prospectus supplement contains summaries of certain provisions contained in some of the documents described herein, but reference is made to the actual documents for complete information. All of the summaries are qualified in their entirety by the actual documents. Copies of some of the documents referred to herein have been filed, will be filed or will be incorporated by reference as exhibits to the registration statement of which this prospectus supplement is a part, and you may obtain copies of those documents as described below under the heading “Where You Can Find More Information.”

As used in this prospectus supplement, the terms “we”, “us”, “our”, “Company”, “Monopar Therapeutics” and “Monopar” refer to Monopar Therapeutics Inc., a Delaware corporation.

We own or have rights to trademarks or trade names that we use in conjunction with the operation of our business. Each trademark, trade name or service mark of any other company appearing in this prospectus supplement or the accompanying prospectus belongs to its holder. Use or display by us of other parties’ trademarks, trade names or service marks is not intended to and does not imply a relationship with, or endorsement or sponsorship by us of, the trademark, trade name or service mark owner.

## SUMMARY

*This summary highlights certain information about us, this offering and selected information contained elsewhere in or incorporated by reference into this prospectus. This summary is not complete and does not contain all of the information that you should consider before deciding whether to invest in our Common Stock. For a more complete understanding of our Company and this offering, we encourage you to read and consider carefully the more detailed information in this prospectus, including the information incorporated by reference into this prospectus, and the information referred to under the heading "Risk Factors" in this prospectus beginning on page S-9, and in the documents incorporated by reference into this prospectus.*

### 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 the licensing and acquisition of oncology therapeutics in late preclinical and clinical development stages. We leverage our scientific and clinical experience to help de-risk and accelerate the clinical development of our drug product candidates.

On December 23, 2019, we completed our initial public offering. We sold 1,277,778 shares of our Common Stock at a public offering price of \$8.00 per share. Net proceeds were approximately \$9.3 million, after deducting underwriting discounts and offering expenses. Our Common Stock began trading on the Nasdaq Capital Market on December 19, 2019.

We are devoting a significant portion of the net proceeds from our initial public offering to prioritizing our camsirubicin Phase 2 clinical trial which we recently signed a collaboration agreement on, discussed in further detail below. We are aiming to enroll the first patient in a Phase 3 clinical development program for our lead product candidate, Validive (clonidine mucobuccal tablet; clonidine MBT) within a few months of raising sufficient funds. To do so, we will require additional funding in the millions or tens of millions of dollars (depending on if we have a collaboration or partnership or neither for Validive consummated), or find a suitable pharmaceutical partner, both of which we are planning to pursue in the coming months. There can be no assurance that the funds raised from the sale of our Common Stock pursuant to this prospectus supplement or other efforts will be sufficient.

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 in response to chemoradiation. The majority of patients receiving CRT to treat their OPC develop SOM, which remains one of the most common and devastating 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 promising 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 immune tissue at the back of the tongue and throat, which comprise the oropharynx, and consists of acute severe tissue damage and pain that prevents patients from swallowing, eating and drinking. Validive stimulates the alpha-2 adrenergic receptor on macrophages (white blood cells present in 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 to reduce treatment discontinuation and/or treatment delays potentially leading to improved survival outcomes, and reducing or eliminating these 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 new cases of OPC in the alone in 2019. The growth in OPC is driven by the increasing prevalence of oral human papilloma virus ("HPV") infections in the U.S. and around the world. Despite the availability of a pediatric/adolescent HPV vaccine, the rate of OPC incidence in adults is not anticipated to be materially reduced for many decades due to low adoption of the vaccine to date. 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 CRT-induced SOM in patients with OPC since CRT is the standard of care treatment.

A pre-Phase 3 meeting with the FDA was held and 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 have 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). Based on comments and guidance provided by FDA and EMA, subject to our ability to raise additional funding from the sale of our Common Stock pursuant to this prospectus supplement, we are aiming to enroll the first patient in our Phase 3 randomized trial for our lead product candidate, Validive, within a few months of raising sufficient funds. The Validive 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, camsirubicin, is a novel analog of doxorubicin which has been designed to reduce the cardiotoxic side effects generated by doxorubicin while retaining anti-cancer activity. Camsirubicin is not metabolized to the derivatives that are believed to be responsible for doxorubicin’s cardiotoxic effects. A Phase 2 clinical trial for camsirubicin has been completed in patients with advanced (e.g. unresectable or metastatic) soft tissue sarcoma (“ASTS”). Average life expectancy for these patients is 12-15 months. In this study, 52.6% of patients evaluable for tumor progression demonstrated clinical benefit (partial response or stable disease), which was proportional to dose and consistently observed at higher cumulative doses of camsirubicin (>1000 mg/m2). Camsirubicin was very well tolerated in this study and underscored the ability to potentially administer camsirubicin without restriction for cumulative dose in patients with ASTS. Doxorubicin is limited to a lifetime cumulative dose maximum of 450 mg/m2. Even if a patient is responding, they are pulled off of doxorubicin treatment once this cumulative dose has been reached.

Based on encouraging clinical results to date, we plan to continue the development of camsirubicin as first line treatment in patients with ASTS, where the current first line treatment is doxorubicin. The aim is to administer camsirubicin without restricting cumulative dose, thereby potentially improving efficacy by keeping patients on treatment who are responding. In June 2019, we entered into a clinical collaboration with Grupo Español de Investigación en Sarcomas (“GEIS”). GEIS will lead a multi-country, randomized, open-label Phase 2 clinical trial evaluating camsirubicin head-to-head against doxorubicin in patients with ASTS. GEIS is an internationally renowned non-profit organization focused on the research, development and management of clinical trials for sarcoma that has worked with many of the leading biotech and global pharmaceutical companies. Enrollment of the trial is currently expected to begin in the first half of 2020 and to include approximately 170 ASTS patients, an interim analysis, and take around two years to enroll. The primary endpoint of the trial will be progression-free survival, with secondary endpoints including overall survival and incidence of treatment-emergent adverse events. In November 2019, the European Commission granted orphan drug designation for camsirubicin for the treatment of soft tissue sarcoma in the EU.

Our third program, MNPR-101, is 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.

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 biopharmaceutical 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 an 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 outside of the patient's upper gum 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 in response to chemoradiation therapy. Patients receiving CRT to treat their OPC often develop SOM, which remains one of the most common and devastating 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 comorbidities 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.

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

Camsirubicin 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 soft tissue sarcomas, breast, gastric, ovarian and bladder cancers, leukemias and lymphomas. The 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 1990's demonstrated that concurrent doxorubicin (60 mg/m<sup>2</sup>, 8 cycles) and paclitaxel gave a 94% overall response rate in patients with metastatic breast cancer but led to 18% of these patients developing congestive heart failure. Reduction of doxorubicin to 4-6 cycles of treatment decreased the incidence of congestive heart failure, but also reduced response rates to 45-55%.

Camsirubicin has been engineered specifically to retain the anticancer activity of doxorubicin while minimizing the toxic effects on the heart. Similar to doxorubicin, the antitumor effects of camsirubicin are mediated through the stabilization of the topoisomerase II complex after a DNA strand break and DNA intercalation leading to tumor cell apoptosis (cell death). Inhibiting the topoisomerase II-alpha isoform is desired for the anti-cancer effect, while inhibiting the topoisomerase II-beta isoform has been demonstrated to mediate, at least in part, the cardiotoxicity associated with doxorubicin. Camsirubicin is 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 camsirubicin in preclinical and clinical studies to date. We believe these attributes provide a strong rationale to develop camsirubicin without restriction on cumulative dose, in a broad spectrum of cancer types.

Development of camisirubicin is being pursued initially in patients with advanced soft tissue sarcoma (ASTS). Currently, these patients receive doxorubicin in the 1<sup>st</sup> line and camisirubicin will be evaluated in a randomized Phase 2 trial head to head against doxorubicin. Although doxorubicin has been the standard of care treatment for over 40 years for patients with ASTS, patients are pulled off treatment to limit irreversible heart failure once the cumulative dose reaches 450 mg/m<sup>2</sup>, even if they are experiencing clinical benefit. As a result, median progression free survival for ASTS patients is approximately 6 months, with median overall survival of 12-15 months. Thus, there is a significant unmet opportunity to develop a replacement for doxorubicin that retains anti-cancer activity while reducing or eliminating the risk for irreversible heart failure.

### ***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 is detected selectively in the tumor.

In normal cells, uPAR is transiently expressed as part of a highly regulated process required for the breakdown of the extracellular matrix during normal tissue remodeling. In cancer, however, uPAR is constitutively overexpressed 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 uPAR expression increases in high grade and metastatic disease.

MNPR-101 has demonstrated significant antitumor 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 five key elements of our strategy to achieve this goal are to:

- **Advance the clinical development of camisirubicin, by pursuing clinical indications where doxorubicin has demonstrated efficacy.** ASTS will be the first indication, which will allow camisirubicin to go head-to-head against doxorubicin, the current 1<sup>st</sup> line treatment. In this indication, camisirubicin previously demonstrated clinical benefit (stable disease or partial response) in 52.6% of patients evaluable for tumor progression in a single arm Phase 2 study. Clinical benefit was proportional to dose and consistently observed at higher cumulative doses of camisirubicin (>1000 mg/m<sup>2</sup>). Camisirubicin was very well tolerated in this Phase 2 study and underscored the ability to potentially administer camisirubicin without restriction for cumulative dose (doxorubicin is limited to 450 mg/m<sup>2</sup> cumulative dose due to heart toxicity).
- **Leverage data generated from the Phase 2 Validive clinical trial to position us well for a successful Phase 3 clinical 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 currently 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.
- **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*

**Our business is subject to numerous risks and uncertainties, including those highlighted in the section titled “Risk Factors” immediately following this prospectus summary. These risks include, among others, the following:**

- We are a clinical stage biopharmaceutical company with a history of losses. We expect to continue to incur significant losses for the foreseeable future and may never achieve or maintain profitability, which could result in a decline in the market value of our common stock.
- Funds raised in our recent initial public offering of our Common Stock are not sufficient to start our Phase 3 clinical development of Validive, and require that we raise significant additional funds from the sale of our Common Stock pursuant to this prospectus supplement or other financing efforts. If we are unable to raise enough funds in the coming months from the sale of our Common Stock pursuant to this prospectus supplement or other financing efforts, we may have to consider strategic options such as out-licensing Validive, entering into a clinical partnership, or terminating the program there can be no assurance that we can find a suitable partner on satisfactory terms.
- We have a limited operating history, no revenues from operations, and are dependent upon raising capital to continue our drug development programs.
- 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 would 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.
- 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, but are not limited to:

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

We 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 our 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 elected to take advantage of certain of the reduced disclosure obligations in the registration statement, of which this prospectus is a part, and may elect to take advantage of other reduced reporting requirements in future filings. As a result, the information that we provide to our stockholders may be different than you might receive from other public reporting companies in which you hold equity interests.

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 avoiding the 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](http://www.monopartx.com). Any information contained in, or that can be accessed through our website, is not incorporated by reference in this prospectus.

***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 prospectus are the property of their respective owners. We have omitted the ® and ™ designations, as applicable, for the trademarks used herein.

## THE OFFERING

<b>Common Stock Offered By Us</b>	Shares of our Common Stock having an aggregate offering price up to \$19,700,000
<b>Manner of Offering</b>	“At the market offering” that may be made from time to time on Nasdaq through or to the Agent, as sales agent or principal. See the section entitled “Plan of Distribution” below.
<b>Common Stock to be Outstanding After This Offering<sup>(1)</sup></b>	Up to 11,483,087 shares, assuming sales price at a price of \$22.00 per share, which was the closing price of our Common Stock on Nasdaq on January 11, 2020. The actual number of shares issued will vary depending on the sales price under this offering.
<b>Use of Proceeds</b>	We intend to use the net proceeds of this offering for our operations, including, but not limited to, general corporate purposes, which may include research and development expenditures, clinical trial expenditures, manufacture and supply of product and working capital. See the section entitled “Use of Proceeds” below.
<b>Nasdaq Capital Market Symbol</b>	MNPR
<b>Risk Factors</b>	See “Risk Factors” beginning on page S-9 and the other information included in, or incorporated by reference into, this prospectus for a discussion of certain factors you should carefully consider before deciding to invest in our Common Stock.

(1) The Common Stock outstanding after the offering is based on approximately 10,587,632 shares of our Common Stock outstanding as of January 11, 2020 and the sale of 895,455 shares of our Common Stock at an assumed offering price of \$22.00 per share, the last reported sale price of our Common Stock on Nasdaq on January 11, 2020, and excludes the following:

- 1,096,463 shares of our Common Stock issuable upon the exercise of outstanding stock options (weighted-average exercise price of \$3.06; 758,685 shares vested); and
- 485,104 shares of our Common Stock reserved for issuance under our 2016 Stock Incentive Plan.

Except as otherwise indicated, all information in this prospectus assumes:

- All shares referenced above and throughout this prospectus take into account a 70-for-1 stock split of our Common Stock effected in March 2017.

## RISK FACTORS

*Investing in our Common Stock involves a high degree of risk. Before deciding to invest in our Common Stock, you should consider carefully the risks and uncertainties described below, together with all of the other information in our Annual Report on Form 10-K for the year ended December 31, 2018, including the consolidated financial statements and the related notes, as well as the risks and uncertainties in our subsequent quarterly reports on Form 10-Q, as updated by our subsequent filings under the Securities Exchange Act of 1934, as amended (the "Exchange Act") and other information set forth in our reports filed with the SEC, all of which are incorporated by reference into this prospectus in its entirety, together with other information in this prospectus, and the information and documents incorporated by reference in this prospectus, any prospectus supplement and any free writing prospectus that we have authorized for use in connection with this offering before you make a decision to invest in our Common Stock. If any of the following risks or the risk factors incorporated by reference hereto were to materialize, our business, financial condition, results of operations, and future growth prospects could be materially and adversely affected. In that event, the market price of our Common Stock could decline, and you could lose part of or all of your investment in our Common Stock.*

### ***Risks Associated to our Common Stock and this Offering***

***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 1,096,463 shares of our common stock have already been granted (758,685 stock options are exercisable) and are outstanding as of January 13, 2020. The issuance of such equity and/or the exercise of such options will dilute both our existing and our new investors. As of January 13, 2020, 18,433 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 of Directors ("Board"). Our Stockholders are entitled to vote only on actions that require a Stockholder vote under federal or state law. Stockholder approval requires the consent and approval of holders of a majority or more of our outstanding stock. Shares of stock do not have cumulative voting rights and therefore, holders of a majority of the shares of our outstanding stock will be able to elect all Board Members. TacticGem LLC ("TacticGem") owns 7,166,667 shares of common stock (68%). The limited liability company agreement of TacticGem provides that the manager will vote its shares of Monopar to elect to the Board 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 and participant in our initial public offering, holds an approximately 42% beneficial interest in us and together with Gem's beneficial ownership of approximately 29%, 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.

***Our failure to meet the continued listing requirements of The Nasdaq Capital Market could result in a de-listing of our Common Stock.***

If we fail to satisfy the continued listing requirements of The Nasdaq Capital Market, such as the corporate governance requirements or the minimum closing bid price requirement, the Nasdaq Stock Market ("Nasdaq") may take steps to de-list our Common Stock. Such a de-listing or the announcement of such de-listing will have a negative effect on the price of our Common Stock and would impair your ability to sell or purchase our Common Stock when you wish to do so. In the event of a de-listing, we would take actions to restore our compliance with the Nasdaq listing requirements, but we can provide no assurance that any such action taken by us would allow our Common Stock to become listed again, stabilize the market price or improve the liquidity of our Common Stock, prevent our Common Stock from dropping below the Nasdaq minimum bid price requirement or prevent future non-compliance with the Nasdaq listing requirements.

***The stock price of our Common Stock may be volatile or may decline regardless of our operating performance.***

The market prices for securities of biotechnology and pharmaceutical companies have historically been highly volatile, and the market has from time to time experienced significant price and volume fluctuations that are unrelated to the operating performance of particular companies. Our Common Stock has only been trading on the Nasdaq Capital Market since December 19, 2019 and has experienced significant volatility in market prices to date. Our small public float and relatively low trading volumes exacerbate volatility.

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

- announcements concerning the progress and success of our clinical trials, our ability to obtain regulatory approval for and commercialize our product candidates, including any requests we receive from the FDA 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 clinical success, NDA approval or 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 or annual operating results, and concerns by investors that such fluctuations may occur in the future and are symbolic of internal problems;
- deviations in our operating results from the estimates of securities analysts or other analyst comments;
- additions or departures of key personnel;
- healthcare reform legislation, including measures directed at controlling the pricing of pharmaceutical products, and third-party coverage and reimbursement policies;
- developments concerning current or future strategic collaborations; and
- discussion of us, our stock price or our potential future market value by the financial and scientific press and in online investor communities.

***Investors in this Offering will suffer immediate and substantial dilution of their investment.***

The offering price per share in this offering may exceed the net tangible book value per share of our Common Stock. Assuming that an aggregate of 895,455 shares of our Common Stock are sold at a price of \$22.00 per share pursuant to this prospectus, which was the last reported sale price of our Common Stock on Nasdaq on January 11, 2020, for aggregate net proceeds of \$19,069,000 after deducting commissions and estimated aggregate offering expenses payable by us, you would experience immediate dilution of \$19.12 per share, representing a difference between our as adjusted net tangible book value per share as of September 30, 2019 after giving effect, our recent initial public offering, stock option exercises and this offering and the assumed offering price. The exercise of outstanding stock options and warrants may result in further dilution of your investment. See the section entitled “Dilution” on page S-38 of this prospectus for a more detailed illustration of the dilution you would incur if you participate in this offering.

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

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

***Substantial amounts of our outstanding shares may be sold into the market 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.***

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. We have 10,587,632 outstanding shares of our Common Stock as of the date of this prospectus supplement. The overwhelming majority of all of our outstanding shares of Common Stock are currently restricted from resale as a result of market standoff and “lock-up” agreements. These shares will become available to be sold after June 16, 2020. Shares held by directors, executive officers and other affiliates will 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 will have rights, subject to some conditions, to require us to file registration statements covering their shares or to include their shares in registration statements that we may file for ourselves or our stockholders, subject to market standoff and lock-up agreements. We have also registered shares of Common Stock that we have issued and may issue under our employee equity incentive plans. These shares are able to be sold freely in the public market upon issuance, subject to existing market standoff or lock-up agreements or internal practices which prohibit sales under certain circumstances. 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.



***We have broad discretion in the use of the net proceeds from this offering, and our use of those proceeds may not yield a favorable return on your investment.***

We intend to use the net proceeds of this offering for our operations, including, but not limited to, general corporate purposes, which may include research and development expenditures, clinical trial expenditures, manufacture and supply of product and working capital. We have not specifically allocated the amount of net proceeds that will be used for these purposes, and our management will have broad discretion over how these proceeds are used and could spend the proceeds in ways with which you may not agree. In addition, we may not use the proceeds of this offering effectively or in a manner that increases our market value or enhances our profitability. We have not established a timetable for the effective deployment of the proceeds, and we cannot predict how long it will take to deploy the proceeds.

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

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

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

The trading market for our common stock will depend in part on the research and reports that securities or industry analysts publish about us or our business. 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. Accordingly, investors must rely on sales of their common stock after price appreciation, which may never occur, as the only way to realize any future gains as a return on their investments.

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

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

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

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

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

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

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

## ***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 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 September 30, 2019, we have incurred losses of approximately \$24.7 million, which includes \$13.5 million of non-cash in-process research and development, which was incurred in connection with our acquisition of camsirubicin. We expect to continue to incur substantial operating losses over the next several years for the clinical development of our current and future licensed or purchased product candidates.

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.

***The funds raised from the recent initial public offering of our Common Stock should enable us to obtain topline results for the camsirubicin Phase 2 clinical trial and ramp up the initiation of Validive's Phase 3 clinical program, but are not sufficient for us to start our Validive Phase 3 clinical program, which require that we raise significant additional funds from the sale of our Common Stock pursuant to this prospectus supplement or other financing efforts. If we are able to raise additional funds from the sale of our Common Stock pursuant to this prospectus supplement, to start our Phase 3 clinical trial for Validive, it may not be on 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 camsirubicin, 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 prospectus 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 camsirubicin and Validive will require significant funds. Proceeds from the recent initial public offering of our Common Stock should enable us to obtain topline results for the camsirubicin Phase 2 clinical trial and ramp up the initiation of Validive's Phase 3 clinical program, but are not sufficient for us to start our Validive Phase 3 clinical program, which require that we raise significant additional funds from the sale of our Common Stock pursuant to this prospectus supplement or other financing efforts. If we are unable to raise enough funds in the future, we may have to discontinue or delay our operations.

***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, camsirubicin, 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.



When we attempt to raise additional financing, there can be no assurance that we will be able to secure such additional financing in sufficient quantities or at all. We may be unable to raise additional capital for reasons including, without limitation, our operational and/or financial performance, investor confidence in us and the biopharmaceutical industry, credit availability from banks and other financial institutions, the status of current projects, and our prospects for obtaining any necessary regulatory approvals. 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 will 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.

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

#### ***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 safe and effective.
- Patients involved in our clinical trials may suffer severe adverse side effects, even up to death, whether as a result of treatment with our products, the withholding of such treatment, or other reasons (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 or other regulatory organizations approval.

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

Outside the U.S., our ability to market a product is contingent upon receiving clearances from appropriate non-U.S. regulatory authorities. 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. 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. Camsirubicin has been granted orphan drug designation for the treatment of soft tissue sarcoma in the U.S. and in the EU. We may seek additional orphan drug designations or regulatory incentives for our pipeline product candidates, for other indications or for future product candidates. There can be no assurances that we will be able to obtain such designations.

Even if we obtain orphan drug designation for a product candidate, we may not be able to maintain orphan drug exclusivity for that drug. For example, 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 product, 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 camsirubicin 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 will utilize third parties to manufacture Validive, camsirubicin, and MNPR-101. We currently have manufacturing agreements in place for Validive and MNPR-101. We are in negotiations with manufacturers for camsirubicin.

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, camsirubicin, 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.

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

Our understanding of the number of people who suffer from SOM resulting from chemoradiotherapy for the treatment of OPC, whom Validive may have the potential to treat, is based upon estimates. These estimates may prove to be incorrect, and new studies may demonstrate or suggest a lower estimated incidence or prevalence of this condition. The number of patients in the U.S. or elsewhere may turn out to be lower than expected, may not be otherwise amenable to Validive treatment, or treatment-amenable patients may become increasingly difficult to identify and access, all of which would adversely affect our business prospects and financial condition. In particular, the treatable population for Validive may further be reduced if our estimates of addressable populations are erroneous or sub-populations of patients within the addressable population do not derive benefit from Validive.

#### ***Risks Related to Our Reliance on Third Parties***

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

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

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

We 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 and afterwards, 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 manufacturer, 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, or contract for, 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 or capabilities, upon drug approval, our product launch and subsequent revenues could be delayed and /or fail to reach their commercial potential.

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

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

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

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

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

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

Any product candidate that we may develop may not gain market acceptance among physicians 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 or earn appropriate returns on the investment of product development costs 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 and government price controls in the U.S. has increased and we expect this will continue to increase the pressure on pharmaceutical pricing. Coverage policies and third-party reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained for one or more products for which we receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.



Any development along these lines could materially and adversely affect our prospects. We are unable to predict what 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 and other government programs will be lower than the prices we might otherwise obtain.***

Government payment for some of the costs of prescription drugs may increase demand for our products for which we receive marketing approval; however, any negotiated prices for our products covered by a Part D prescription drug plan and other government programs will be lower than the prices we might otherwise obtain.

#### ***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 camsirubicin (formerly GPX-150) patent portfolio from TacticGem, LLC ("TacticGem") to us has been completed. We filed and have been granted in the U.S. and various countries around the world patents for antibodies that target uPAR for our MNPR-101 program. We have also been granted in the U.S. and various countries around the world patents to a specific sequence of amino acids on uPAR, to which our MNPR-101 antibody binds. We are currently prosecuting this patent in other countries around the world to further protect MNPR-101. The patent process is subject to numerous risks and uncertainties, and there can be no assurance that we will be successful in obtaining and defending patents. See "Business - Intellectual Property Portfolio and Exclusivity". These risks and uncertainties include without limitation the following:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

#### ***Risks Related to Our Business Operations and Industry***

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

As of January 13, 2020, 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"), 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.

***We will incur increased costs as a result of operating as a stock trading public company, and our management will be required to devote substantial time to new compliance initiatives and corporate governance practices.***

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

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

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

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

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

For as long as we continue to be an emerging growth company, we 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 our 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 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 will require us to incur non-recurring or other charges, may increase our near- and long-term expenditures and may pose significant integration challenges or disrupt our management or business, which could adversely affect our operations and financial results. For example, these transactions may entail numerous operational and financial risks, including:

- exposure to unknown 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 claims.

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

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

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

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

In addition, California recently enacted the California Consumer Privacy Act (“CCPA”), which creates new individual privacy rights for California consumers (as defined in the law) and places increased privacy and security obligations on entities handling personal data of consumers or households. The CCPA will require covered companies to provide new disclosure to consumers about such companies’ data collection, use and sharing practices, provide such consumers new ways to opt-out of certain sales or transfers of personal information, and provide consumers with additional causes of action. The CCPA goes into effect on January 1, 2020, and the California Attorney General may bring enforcement actions for violations beginning July 1, 2020. The CCPA was amended on September 23, 2018, and it remains unclear what, if any, further modifications will be made to this legislation or how it will be interpreted. As currently written, the CCPA may impact our business activities and exemplifies the vulnerability of our business to the evolving regulatory environment related to personal data and protected health information.

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

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

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

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

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

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

Although our directors and officers are accountable to us and must exercise good faith, good business judgement, and integrity in handling our affairs, our Second Amended and Restated Certificate of Incorporation (the “Certificate of Incorporation”), 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.***

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

Some of the provisions of the ACA have yet to be fully implemented, and there have been legal and political challenges to certain aspects of the ACA. Since January 2017, President Trump has signed two executive orders and other directives designed to delay, circumvent, or loosen certain requirements mandated by the ACA. Concurrently, Congress has considered legislation that would repeal or repeal and replace all or part of the ACA. While Congress has not passed comprehensive repeal legislation, two bills affecting the implementation of certain taxes under the ACA have been signed into law. The Tax Cuts and Jobs Act of 2017 (the “Tax Act”), includes a provision that repealed, effective January 1, 2019, the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying healthcare coverage for all or part of a year, that is commonly referred to as the “individual mandate.” Additionally, on January 22, 2018, President Trump signed a continuing resolution on appropriations for fiscal year 2018 that delayed the implementation of certain ACA-mandated fees, including the so-called “Cadillac” tax on certain high cost employer-sponsored insurance plans, the annual fee imposed on certain health insurance providers based on market share, and the medical device excise tax on non-exempt medical devices. Further, the Bipartisan Budget Act of 2018 (“BBA”), among other things, amended the ACA, effective January 1, 2019, to close the coverage gap in most Medicare drug plans, commonly referred to as the “donut hole.” In July 2018, Centers for Medicare & Medicaid Services (“CMS”) published a final rule permitting further collections and payments to and from certain ACA-qualified healthcare plans and healthcare insurance issuers under the ACA risk adjustment program in response to the outcome of federal district court litigation regarding the method CMS uses to determine this risk adjustment. On December 14, 2018, a U.S. District Court Judge in the Northern District of Texas ruled that the individual mandate is an inseparable feature of the ACA, and therefore, because it was repealed as part of the Tax Act, the remaining provisions of the ACA are invalid as well. While the Texas U.S. District Court Judge, as well as the Trump Administration and CMS have stated that the ruling will have no immediate effect, it is unclear how this decision, subsequent appeals, and other efforts to repeal and replace the ACA will impact the ACA and our business.

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

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

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

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

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

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

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

A relevant example of dysfunctional government was the 35-day government shutdown that ended February 15, 2019 which limited the FDA to activities necessary to address imminent threats to human life and to activities funded by carry-over user fees. Future government shutdowns or other activities which limit the financial resources available to the FDA (and in particular to the Center for Drug Evaluation and Research) will delay the processing of new product drug development submissions, reviews, and approvals and other required regulatory actions. Such delays will adversely impact our business and financial condition.

***Effective collaboration with the FDA'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. 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 in our drug approval process; however, there is a meaningful risk that discussions and interactions inherent in the drug approval process and future developments or new improvements will result in delays, added expenses and new scientific/medical requirements which will cause adverse financial results and will likely impact the price of the Company's stock.

***Future tax reform measures may negatively impact our financial position.***

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

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

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

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

Development of pharmaceuticals and cancer drugs is extremely risky and unpredictable. We have estimated operating expenses and capital expenditures over the next year based on certain assumptions. Any change in the assumptions could 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 prospectus supplement. 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 prospectus should not be regarded as an indication that we, our management, the underwriters or their respective representatives considered or consider the projections to be a guaranteed prediction of future events, and the projections should not be relied upon as such. See “Cautionary Statement Concerning Forward-Looking Statements.”

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

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

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

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

***Our future growth may depend, in part, on our ability to operate in foreign markets, where we would be subject to additional regulatory burdens and other risks and uncertainties.***

Our future growth may depend, in part, on our ability to develop and commercialize drug candidates in foreign markets for which we may rely on partnering with third parties. We will not be permitted to market or promote any drug candidate before we receive regulatory approval from the applicable regulatory authority in a foreign market, and we may never receive such regulatory approval for any drug candidate. To obtain separate regulatory approval in foreign countries, we generally must comply with numerous and varying regulatory requirements of such countries regarding safety and efficacy and governing, among other things, clinical trials and commercial sales, pricing and distribution of a drug candidate, and we cannot predict success in these jurisdictions. If we obtain approval of any of our current or potential future drug candidates and ultimately commercialize any such drug candidate in foreign markets, we would be subject to risks and uncertainties, including the burden of complying with complex and changing foreign regulatory, tax, accounting and legal requirements and the reduced protection of intellectual property rights in some foreign countries.

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

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

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



## FORWARD-LOOKING STATEMENTS

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

- our ability to raise sufficient funds in the coming months in order for us to start our Validive Phase 3 clinical trial;
- our ability to find a suitable pharmaceutical partner to further our development of Validive, if we are unable to raise sufficient additional financing;
- risks and uncertainties associated with our research and development activities, including our clinical trials;
- estimated timeframes for our clinical trials and regulatory reviews for approval to market products;
- plans to research, develop and commercialize our current and future product candidates;
- the rate and degree of market acceptance and clinical utility of any products for which we receive marketing approval;
- commercialization, marketing and manufacturing capabilities and strategy;
- intellectual property position and strategy;
- future financial performance;
- estimates regarding expenses, capital requirements and need for additional financing;
- the impact of government laws and regulations;
- ability to attract and retain key personnel; and
- financial and operational projections.

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. 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 above and made elsewhere in this prospectus and future supplemental prospectuses. We undertake no obligation to update any statements made in this Prospectus or elsewhere, including without limitation any forward-looking statements, except as required by law.

You should read this prospectus and the documents that we reference in this prospectus with the understanding that our actual future results, levels of activity, performance and events and circumstances may be materially different from what we expect.

## USE OF PROCEEDS

The amount of proceeds from this offering will depend upon the number of shares of our Common Stock sold and the market price at which they are sold. There can be no assurance that we will be able to sell any shares under or fully utilize the sales agreement with the Agent as a source of financing.

We intend to use the net proceeds of this offering for our operations, including, but not limited to, general corporate purposes, which may include research and development expenditures, clinical trial expenditures, manufacture and supply of product and working capital. The precise amount, use, and timing of the application of such proceeds will depend upon our funding requirements and the availability and cost of other capital. Pending application of the net proceeds as described above, we intend to invest the net proceeds of the offering in short-term, investment-grade, interest-bearing securities and/or savings accounts.

We will need to raise significant additional funds or find a suitable pharmaceutical partner to start the Validive clinical trial program, to complete it and take Validive through potential approval and, if approved, through commercialization, to support further development of camsirubicin, MNPR-101 and any additional product candidates.

## DILUTION

Our historical net tangible book value as of September 30, 2019, was \$4.6 million, or \$0.50 per share of our Common Stock.

After giving effect to the sale of our Common Stock in the aggregate amount of \$19.7 million at an assumed price of \$22.00 per share, the last reported sale price of our Common Stock on Nasdaq on January 10, 2020, and after deducting estimated offering commissions and expenses payable by us, after giving effect to the issuance of 18,433 shares of common stock pursuant to a stock option exercise on November 25, 2019 for \$109,998 and our issuance and sale of 1,277,778 shares of our Common Stock in our initial public offering price at \$8.00 per share, after deducting underwriting discounts and commissions and estimated offering expenses payable by us, our as adjusted net tangible book value as of September 30, 2019, would have been \$33.1 million, or \$2.88 per share. This represents an immediate increase in net tangible book value per share of \$2.38 to existing stockholders and immediate dilution of \$19.12 in net tangible book value per share to new investors purchasing our Common Stock in this offering.

Dilution per share to new investors is determined by subtracting as adjusted net tangible book value per share after this offering from the assumed price per share paid by new investors. The following table illustrates this dilution on a per share basis.

Assumed Price Per Share		\$	22.00
Historical Net Tangible Book Value Per Share as of September 30, 2019		\$	0.50
Increase in Net Tangible Book Value Per Share Attributable to New Investors			2.38
As Adjusted Net Tangible Book Value Per Share After this Offering			2.88
Dilution Per Share to New Investors		\$	19.12

The foregoing table is based on an aggregate 10,587,632 shares of our Common Stock outstanding as of January 10, 2020 and excludes:

- 1,096,463 shares of our Common Stock issuable upon the exercise of outstanding stock options (weighted-average exercise price of \$3.06; 758,685 shares vested); and
- 485,104 shares of our Common Stock reserved for issuance under our 2016 Stock Incentive Plan.

Except as otherwise indicated, all information in this prospectus assumes:

- All shares referenced above and throughout this prospectus take into account a 70-for-1 stock split of our Common Stock effected in March 2017.

All of the foregoing is illustrative only. There can be no assurance we will sell all, or any, of the shares offered by this prospectus, when any such sales will occur or what the sales prices will be.

#### **DIVIDEND POLICY**

We have never declared or paid cash dividends on our capital stock. We currently intend to retain all available funds and future earnings, if any, for use in the operation of our business and do not anticipate paying any cash dividends on our Common Stock in the foreseeable future. Any future determination to declare and pay dividends will be made at the discretion of our Board and will depend on various factors, including applicable laws, our results of operations, our financial condition, our capital requirements, general business conditions, our future prospects and other factors that our Board may deem relevant. Additionally, our ability to pay dividends on our capital stock could be limited by terms and covenants of any future indebtedness. Investors should not purchase our Common Stock with the expectation of receiving cash dividends.

## PLAN OF DISTRIBUTION

On January 13, 2020 we entered into a Sales Agreement (the “Sales Agreement”) with JonesTrading Institutional Services LLC (the “Agent”) under which we may issue and sell our Common Stock having an aggregate gross sales price of up to \$19,700,000 from time to time through or to the Agent, acting as agent or principal. A copy of the Sales Agreement is filed as an exhibit herein.

Each time that we wish to issue and sell shares of our Common Stock under the Sales Agreement, if any, we will provide the Agent with a placement notice describing the amount of shares to be sold or the gross proceeds to be raised in a given time period, the time period during which sales are requested to be made, any limitation on the amount of shares of Common Stock that may be sold in any single day, any minimum price below which sales may not be made or any minimum price requested for sales in a given time period and any other instructions relevant to such requested sales. Upon delivery of a placement notice and subject to the terms and conditions of the Sales Agreement, the Agent may sell our Common Stock by any method permitted by law deemed to be “at the market offerings” as defined in Rule 415 under the Securities Act. We may instruct the Agent not to sell our Common Stock if the sales cannot be effected at or above the price designated by us from time to time. We or the Agent may suspend the offering of our Common Stock upon notice and subject to other conditions.

We will pay the Agent commissions, in cash, for its services in acting as an agent in the sale of our Common Stock. The Agent will be entitled to compensation of up to 3.0% of the gross proceeds from each sale of our Common Stock. Because there is no minimum offering amount required as a condition to this offering, the actual total public offering amount, commissions and proceeds to us, if any, are not determinable at this time. We have also agreed to reimburse the Agent for certain specified expenses, including the fees and disbursements of their legal counsel in an amount not to exceed \$40,000. Additionally, pursuant to the terms of the sales agreement, we agreed to reimburse the Agent for the documented fees and costs of its legal counsel reasonably incurred in connection with the Agent’s ongoing diligence in an amount not to exceed \$5,000 per year. We estimate that the total expenses for the offering, excluding compensation and reimbursements payable to the Agent under the terms of the Sales Agreement, will be approximately \$40,000.

Settlement for sales of our Common Stock will occur on the second business day following the date on which any sales are made, or on some other date that is agreed upon by us and the Agent in connection with a particular transaction, in return for payment of the net proceeds to us. Sales of our Common Stock as contemplated in this prospectus will be settled through the facilities of The Depository Trust Company or by such other means as we and the Agent may agree upon. There is no arrangement for funds to be received in an escrow, trust or similar arrangement.

The Agent will use their commercially reasonable best efforts, consistent with its sales and trading practices, to solicit offers to purchase our Common Stock under the terms and subject to the conditions set forth in the Sales Agreement. In connection with the sale of our Common Stock on our behalf, the Agent will be deemed to be an “underwriter” within the meaning of the Securities Act and the compensation of the Agent will be deemed to be an underwriting commission or discount. We have agreed to provide indemnification and contribution to the Agent against certain civil liabilities, including liabilities under the Securities Act.

The offering of our Common Stock pursuant to the Sales Agreement will terminate upon the termination of the Sales Agreement as permitted therein. We and the Agent may terminate the Sales Agreement at any time upon five days’ prior notice or by the Agent at any time in certain circumstances, including the occurrence of a material and adverse change in our business or financial condition that makes it impractical or inadvisable to market our Common Stock or to enforce contracts for the sale of our Common Stock.

The Agent and its respective affiliates have in the past and may in the future provide various investment banking, commercial banking and other financial services for us, for which services they may in the future receive customary fees.

This prospectus in electronic format may be made available on a website maintained by the Agent who may distribute this prospectus electronically.

## LEGAL MATTERS

Certain legal matters will be passed upon for us by Baker & Hostetler, LLP, Columbus, Ohio. Certain legal matters in connection with this offering will be passed upon for the Agent by Duane Morris LLP, New York, New York.

## EXPERTS

The financial statements as of December 31, 2018 and 2017, and for the years then ended, included in this Prospectus have been so included in reliance on the report of BPM LLP, an independent registered public accounting firm, given on the authority of said firm as experts in auditing and accounting.

## WHERE YOU CAN FIND MORE INFORMATION

We have filed with the SEC a shelf registration statement on Form S-3 under the Securities Act with respect to the Common Stock we are offering by this prospectus. This prospectus does not contain all of the information included in the registration statement. For further information pertaining to us and our Common Stock, you should refer to the registration statement and to its exhibits. Whenever we make reference in this prospectus to any of our contracts, agreements or other documents, the references are not necessarily complete, and you should refer to the exhibits attached to the registration statement for copies of the actual contract, agreement or other document.

We file annual, quarterly and current reports, information statements and proxy statements and other information with the SEC. You can read our SEC filings, including the registration statement, at the SEC's website at [www.sec.gov](http://www.sec.gov). You may also read and copy any document we file with the SEC at its public reference facility at 100 F Street, N.E., Room 1580, Washington, D.C. 20549. We also maintain a website at <http://www.monopartx.com>. You may access, free of charge, 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 as soon as reasonably practicable after such material is electronically filed with, or furnished to, the SEC. The information contained on, or that can be accessed through, our website is not a part of, and should not be construed as being incorporated by reference into, this prospectus or the accompanying prospectus supplement.

You may also obtain copies of the documents at prescribed rates by writing to the Public Reference Section of the SEC at 100 F Street, N.E., Washington, D.C. 20549. Please call the SEC at 1-800-SEC-0330 for further information on the operation of the public reference facilities.

## INCORPORATION OF DOCUMENTS BY REFERENCE

The SEC allows us to incorporate by reference the information we file with it, which means that we can disclose important information to you by referring you to another document that we have filed separately with the SEC. You should read the information incorporated by reference because it is an important part of this prospectus. Information in this prospectus supersedes information incorporated by reference that we filed with the SEC prior to the date of this prospectus, while information that we file later with the SEC will automatically update and supersede the information in this prospectus. We incorporate by reference into this prospectus and the registration statement of which this prospectus is a part the information and documents listed below that we have filed with the SEC:

- our Quarterly Report on [Form 10-Q](#) for the quarter ended September 30, 2019, filed with the SEC on November 12, 2019;
- our Quarterly Report on [Form 10-Q](#) for the quarter ended June 30, 2019, filed with the SEC on August 8, 2019;
- our Quarterly Report on [Form 10-Q](#) for the quarter ended March 31, 2019, filed with the SEC on May 10, 2019;
- our Information Statement regarding our Annual Meeting of Stockholders on June 27, 2019, on [DEF14C](#), filed with the SEC on May 22, 2019;
- our Annual Report on [Form 10-K](#) for the year ended December 31, 2018, filed with the SEC on February 26, 2019;
- our Current Reports on Form 8-K, filed with the SEC on January 7, 2020 and [June 27, 2019](#), to the extent the information in such reports is filed and not furnished; and
- the description of our Common Stock contained in our Registration Statement on [Form 8-A](#), registering our Common Stock under Section 12(b) under the Exchange Act, filed with the SEC on September 30, 2019, as supplemented by the "Description of Capital Stock" beginning on page 5 of this prospectus and including any amendments or reports filed for the purpose of updating such description.

We also incorporate by reference any future filings (other than Current Reports furnished under Item 2.02 or Item 7.01 of Form 8-K and exhibits filed on such form that are related to such items unless such Form 8-K expressly provides to the contrary) made with the SEC pursuant to Sections 13(a), 13(c), 14 or 15(d) of the Exchange Act until we file a post-effective amendment that indicates the termination of the offering of the common stock made by this prospectus and will become a part of this prospectus from the date that such documents are filed with the SEC. Information in such future filings updates and supplements the information provided in this prospectus. Any statements in any such future filings will automatically be deemed to modify and supersede any information in any document we previously filed with the SEC that is incorporated or deemed to be incorporated herein by reference to the extent that statements in the later filed document modify or replace such earlier statements.

We will furnish without charge to each person, including any beneficial owner, to whom a prospectus is delivered, upon written or oral request, a copy of any or all of the documents incorporated by reference into this prospectus but not delivered with the prospectus, including exhibits that are specifically incorporated by reference into such documents. You should direct any requests for documents to Monopar Therapeutics, Inc., Attention: Corporate Secretary, 1000 Skokie Blvd., Suite 350, Wilmette, IL 60091. Our phone number is (847) 388-0349. You may also view the documents that we file with the SEC and incorporate by reference in this Prospectus on our corporate website at [www.monopartrx.com](http://www.monopartrx.com). The information on our website is not incorporated by reference and is not a part of this prospectus.

PROSPECTUS

\$75,000,000



# Monopar Therapeutics

## Common Stock

We may offer and sell an indeterminate number of shares of our Common Stock from time to time under this prospectus. You should read this prospectus and any prospectus supplement carefully before you invest.

We may offer our Common Stock in one or more offerings in amounts, at prices, and on terms determined at the time of the offering. We may sell our Common Stock through agents we select or through underwriters and dealers we select. If we use agents, underwriters or dealers, we will name them and describe their compensation in a prospectus supplement.

This prospectus provides a general description of our Common Stock that we may offer. Each time we sell our Common Stock, we will provide specific terms of the Securities offered in a supplement to this prospectus. The prospectus supplement may also add, update or change information contained in this prospectus. You should read this prospectus and the applicable prospectus supplement carefully before you invest in our Common Stock. This prospectus may not be used to consummate a sale of our Common Stock unless accompanied by the applicable prospectus supplement.

Our Common Stock is listed for trading on the Nasdaq Capital Market under the symbol "MNPR." On January 2, 2020 the last reported sale price of our Common Stock was \$17.27 per share. As of that date, and based on that price, the aggregate market value of our voting and non-voting common equity held by non-affiliates was approximately \$37.9 million.

We have not offered and sold any securities pursuant to General Instruction I.B.6 of Form S-3 during the 12 calendar months prior to and including the date of this prospectus.

**Investing in our Common Stock involves significant risks. See "Risk Factors" included in any accompanying prospectus supplement and in the documents incorporated by reference in this prospectus for a discussion of the factors you should carefully consider before deciding to purchase our Common Stock.**

**Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or passed upon the accuracy or adequacy of this prospectus. Any representation to the contrary is a criminal offense.**

The date of this Prospectus is January 13, 2020

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## SUMMARY

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 the licensing and acquisition of oncology therapeutics in late preclinical and clinical development stages. We leverage our scientific and clinical experience to help reduce the risk and accelerate the clinical development of our drug product candidates. We currently have three compounds in development: Validive® (clonidine mucobuccal tablet; clonidine MBT), a Phase 3-ready, first-in-class mucoadhesive buccal tablet for the prevention and treatment of radiation-induced severe oral mucositis in oropharyngeal cancer patients; camsirubicin (generic name for 5-imino-13-deoxydoxorubicin; previously known as MNPR-201, GPX-150), a proprietary Phase 2 clinical stage topoisomerase II-alpha selective 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.

Our principal executive offices are located at 1000 Skokie Blvd, Suite 350, Wilmette, IL 60091. Our telephone number is (847) 388-0349.

## **RISK FACTORS**

You should consider carefully the risks discussed under the section captioned “Risk Factors” contained in our annual report on Form 10-K for the year ended December 31, 2018 and in our subsequent quarterly reports on Form 10-Q, as updated by our subsequent filings under the Securities Exchange Act of 1934, as amended (the “Exchange Act”), each of which is incorporated by reference in this prospectus in its entirety, together with other information in this prospectus, and the information and documents incorporated by reference in this prospectus, any prospectus supplement and any free writing prospectus that we have authorized for use in connection with this offering before you make a decision to invest in our securities. If any of these events actually occur, our business, operating results, prospects or financial condition could be materially and adversely affected. This could cause the trading price of our common stock to decline and you may lose all or part of your investment.

## IMPORTANT INFORMATION ABOUT THIS PROSPECTUS

In this prospectus, unless the context suggests otherwise, references to “Monopar Therapeutics,” “Monopar,” the “Company,” “we,” “us” and “our” refer to Monopar Therapeutics Inc.

This prospectus is part of a “shelf” registration statement. By using a shelf registration statement, we may sell our Common Stock, as described in this prospectus, from time to time in one or more offerings. Each time we sell our Common Stock, we will provide a prospectus supplement to this prospectus that contains specific information about the terms of such offering. The prospectus supplement may also add, update or change information contained in this prospectus. Before purchasing our Common Stock, you should carefully read both this prospectus and any prospectus supplement, together with the additional information incorporated into this prospectus or described under the heading “*Where You Can Find More Information.*”

You should rely only on the information contained or incorporated by reference in this prospectus and any prospectus supplement. We have not authorized any other person to provide you with different information. If anyone provides you with different or inconsistent information, you should not rely on it. We will not make an offer to sell our Common Stock in any jurisdiction where the offer or sale is not permitted. You should assume that the information appearing in this prospectus, and have incorporated by reference, is accurate only as of the date on the front cover of this prospectus, or when such document was filed with the Securities and Exchange Commission (“SEC”). Our business, financial condition, results of operations and prospects may have changed since the relevant date.

Neither we, nor any of our officers, directors, agents, representatives or underwriters, make any representation to you about the legality of an investment. You should not interpret the contents of this prospectus, any prospectus supplement, or any free writing prospectus to be legal, business, investment or tax advice. You should consult with your own advisors for that type of advice and consult with them about the legal, tax, business, financial and other issues that you should consider before investing in our Common Stock.

We will not use this prospectus to offer and sell our Common Stock unless it is accompanied by a prospectus supplement that more fully describes the terms of the offering.

## FORWARD-LOOKING STATEMENTS

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

- our ability to raise sufficient funds in the coming months in order for us to start our Validive Phase 3 clinical trial;
- our ability to find a suitable pharmaceutical partner to further our development of Validive, if we are unable to raise sufficient additional financing;
- risks and uncertainties associated with our research and development activities, including our clinical trials;
- estimated timeframes for our clinical trials and regulatory reviews for approval to market products;
- plans to research, develop and commercialize our current and future product candidates;
- the rate and degree of market acceptance and clinical utility of any products for which we receive marketing approval;
- commercialization, marketing and manufacturing capabilities and strategy;
- intellectual property position and strategy;
- future financial performance;
- estimates regarding expenses, capital requirements and need for additional financing;
- the impact of government laws and regulations;
- ability to attract and retain key personnel;  
and
- financial and operational projections.

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. 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 above and made elsewhere in this prospectus and future supplemental prospectuses. We undertake no obligation to update any statements made in this Prospectus or elsewhere, including without limitation any forward-looking statements, except as required by law.

You should read this prospectus and the documents that we reference in this prospectus with the understanding that our actual future results, levels of activity, performance and events and circumstances may be materially different from what we expect.

## DESCRIPTION OF CAPITAL STOCK

We have the authority to issue 40,000,000 shares of Common Stock, \$0.001 par value. As of January 3, 2020, there were 10,587,632 shares of our Common Stock issued and outstanding.

We have reserved 1,600,000 shares of our Common Stock for issuance under our 2016 Stock Incentive Plan, as subsequently amended (the "Plan"), and as of January 3, 2020, we have outstanding stock options to purchase up to 1,087,463 shares of our Common Stock and 494,104 shares of our Common Stock available for future stock awards under the Plan.

### **Common Stock**

#### *Voting Rights*

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

#### *Dividends*

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

#### *Liquidation*

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

#### *Rights and Preferences*

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

### **Preferred Stock**

We have no preferred stock authorized or outstanding.

### **Anti-Takeover Provisions**

#### *Delaware Law*

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

#### *Authorized but Unissued Shares*

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

### ***Election of Director by Plurality of Shares; Vacancies***

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

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

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

Our Amended and Restated By-laws provide that, except as otherwise required by law, special meetings of the stockholders can only be called by our Board. Stockholders at a special meeting may only consider matters set forth in the notice of the meeting. These provisions could have the effect of delaying until the next stockholder meeting stockholder actions that may be favored by the holders of a majority of our outstanding voting securities.

### ***Super Majority Voting***

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

### **Registration Rights**

We are subject to an agreement with TacticGem, LLC (“TacticGem”), our largest stockholder, which obligates us to file a Form S-3 or other appropriate form of registration statement covering the resale of any of our Common Stock by TacticGem, or its members Gem Pharmaceuticals, LLC, or Tactic Pharma, LLC, upon direction by TacticGem at any time after we have been subject to the reporting requirements of the 1934 Act for at least twelve months (the “Initial Holding Period”). We are required to use our best efforts to have such registration statement declared effective as soon as practical after it is filed. In the event that such registration statement for resale is not approved by the SEC, and TacticGem submits a written request, we are required to prepare and file a registration statement on Form S-1 registering such Common Stock for resale and to use our best efforts to have such registration statement declared effective as soon as practical thereafter. After registration, pursuant to these rights, these shares will become freely tradable without restriction under the Securities Act other than pursuant to restrictions on affiliates under Rule 144. TacticGem has agreed to enter into a lock-up agreement and to not exercise any rights of resale for 180 days after the date of our initial public offering which was December 18, 2019.

### **Listing**

Our Common Stock is listed on the Nasdaq Capital Market under the symbol “MNPR.”

### **Transfer Agent and Registrar**

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

## PLAN OF DISTRIBUTION

We may sell our Common Stock covered in this prospectus in any of three ways (or in any combination):

- through underwriters or dealers;
- directly to a limited number of purchasers or to a single purchaser; or
- through agents.

The distribution of our Common Stock may be effected from time to time in one or more transactions:

- at market prices prevailing at the time of sale;
- at prices related to such prevailing market prices; or
- at negotiated prices.

Each time that we use this prospectus to sell our Common Stock, we will also provide a prospectus supplement that contains the specific terms of the offering. The prospectus supplement will set forth the terms of the offering of our Common Stock, including:

- the name or names of any underwriters, dealers or agents and the amounts of any of our Common Stock underwritten or purchased by each of them; and
- the public offering price of our Common Stock and the proceeds to us and any discounts, commissions or concessions allowed or reallowed or paid to dealers.

Any public offering price and any discounts or concessions allowed or reallowed or paid to dealers may be changed from time to time.

If underwriters are used in the sale of our Common Stock, our Common Stock will be acquired by the underwriters for their own account and may be resold from time to time in one or more transactions, including negotiated transactions, at a fixed public offering price or at varying prices determined at the time of sale. Our Common Stock may be either offered to the public through underwriting syndicates represented by managing underwriters, or directly by underwriters. Generally, the underwriters' obligations to purchase our Common Stock will be subject to certain conditions precedent. The underwriters may be obligated to purchase all of our Common Stock if they purchase any of our Common Stock.

We may sell the securities through agents from time to time. The prospectus supplement will name any agent involved in the offer or sale of our Common Stock and any commissions we pay to them. Generally, any agent will be acting on a best efforts basis for the period of its appointment.

We may authorize underwriters, dealers or agents to solicit offers by certain purchasers to purchase our Common Stock from us at the public offering price set forth in the prospectus supplement pursuant to delayed delivery contracts providing for payment and delivery on a specified date in the future. The contracts will be subject only to those conditions set forth in the prospectus supplement, and the prospectus supplement will set forth any commissions we pay for solicitation of these contracts.

Agents and underwriters may be entitled to indemnification by us against certain civil liabilities, including liabilities under the Securities Act of 1933, as amended, or to contribution with respect to payments which the agents or underwriters may be required to make in respect thereof. Agents and underwriters may be customers of, engage in transactions with, or perform services for us in the ordinary course of business.

We may enter into derivative transactions with third parties, or sell our Common Stock not covered by this prospectus to third parties in privately negotiated transactions. If the applicable prospectus supplement indicates, in connection with those derivatives, the third parties may sell our Common Stock covered by this prospectus and the applicable prospectus supplement, including in short sale transactions. If so, the third party may use our Common Stock pledged by us or borrowed from us or others to settle those sales or to close out any related open borrowings of our Common Stock, and may use our Common Stock received from us in settlement of those derivatives to close out any related open borrowings of our Common Stock. The third party in such sale transactions will be an underwriter and will be identified in the applicable prospectus supplement (or a post-effective amendment).



## LEGAL MATTERS

Certain legal matters will be passed upon for us by Baker & Hostetler, LLP, Columbus, Ohio.

## EXPERTS

The financial statements as of December 31, 2018 and 2017, and for the years then ended, included in this Prospectus have been so included in reliance on the report of BPM LLP, an independent registered public accounting firm, given on the authority of said firm as experts in auditing and accounting.

## WHERE YOU CAN FIND MORE INFORMATION

We have filed with the SEC this shelf registration statement on Form S-3 under the Securities Act with respect to our Common Stock we are offering by this prospectus. This prospectus does not contain all of the information included in the registration statement. For further information pertaining to us and our Common Stock, you should refer to the registration statement and to its exhibits. Whenever we make reference in this prospectus to any of our contracts, agreements or other documents, the references are not necessarily complete, and you should refer to the exhibits attached to the registration statement for copies of the actual contract, agreement or other document.

We file annual, quarterly and current reports, information statements and proxy statements and other information with the SEC. You can read our SEC filings, including the registration statement, at the SEC's website at [www.sec.gov](http://www.sec.gov). You may also read and copy any document we file with the SEC at its public reference facility at 100 F Street, N.E., Room 1580, Washington, D.C. 20549. We also maintain a website at <http://www.monopartx.com>. You may access, free of charge, 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 as soon as reasonably practicable after such material is electronically filed with, or furnished to, the SEC. The information contained on, or that can be accessed through, our website is not a part of, and should not be construed as being incorporated by reference into, this prospectus or the accompanying prospectus supplement.

You may also obtain copies of the documents at prescribed rates by writing to the Public Reference Section of the SEC at 100 F Street, N.E., Washington, D.C. 20549. Please call the SEC at 1-800-SEC-0330 for further information on the operation of the public reference facilities.

## INCORPORATION OF DOCUMENTS BY REFERENCE

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- our Quarterly Report on [Form 10-Q](#) for the quarter ended September 30, 2019, filed with the SEC on November 12, 2019;
- our Quarterly Report on [Form 10-Q](#) for the quarter ended June 30, 2019, filed with the SEC on August 8, 2019;
- our Quarterly Report on [Form 10-Q](#) for the quarter ended March 31, 2019, filed with the SEC on May 10, 2019;
- our Information Statement regarding our Annual Meeting of Stockholders on June 27, 2019, on [DEF14C](#), filed with the SEC on May 22, 2019;
- our Annual Report on [Form 10-K](#) for the year ended December 31, 2018, filed with the SEC on February 26, 2019;
- our Current Reports on Form 8-K, filed with the SEC on [June 27, 2019](#), [June 5, 2018](#), and [July 2, 2018](#), to the extent the information in such reports is filed and not furnished; and
- the description of our Common Stock contained in our Registration Statement on [Form 8-A](#), registering our Common Stock under Section 12(b) under the Exchange Act, filed with the SEC on September 30, 2019, as supplemented by the "Description of Capital Stock" beginning on page 5 of this prospectus and including any amendments or reports filed for the purpose of updating such description.

We also incorporate by reference any future filings (other than Current Reports furnished under Item 2.02 or Item 7.01 of Form 8-K and exhibits filed on such form that are related to such items unless such Form 8-K expressly provides to the contrary) made with the SEC pursuant to Sections 13(a), 13(c), 14 or 15(d) of the Exchange Act, including those made after the date of the initial filing of the registration statement of which this prospectus is a part and prior to effectiveness of such registration statement, until we file a post-effective amendment that indicates the termination of the offering of the common stock made by this prospectus and will become a part of this prospectus from the date that such documents are filed with the SEC. Information in such future filings updates and supplements the information provided in this prospectus. Any statements in any such future filings will automatically be deemed to modify and supersede any information in any document we previously filed with the SEC that is incorporated or deemed to be incorporated herein by reference to the extent that statements in the later filed document modify or replace such earlier statements.

We will furnish without charge to each person, including any beneficial owner, to whom a prospectus is delivered, upon written or oral request, a copy of any or all of the documents incorporated by reference into this prospectus but not delivered with the prospectus, including exhibits that are specifically incorporated by reference into such documents. You should direct any requests for documents to Monopar Therapeutics, Inc., Attention: Corporate Secretary, 1000 Skokie Blvd., Suite 350, Wilmette, IL 60091. Our phone number is (847) 388-0349. You may also view the documents that we file with the SEC and incorporate by reference in this Prospectus on our corporate website at [www.monopartx.com](http://www.monopartx.com). The information on our website is not incorporated by reference and is not a part of this prospectus.

**\$19,700,000**



**Monopar Therapeutics**

**Common Stock**

**PROSPECTUS SUPPLEMENT**

**JonesTrading**

**January 13, 2020**