

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

FORM 10-Q

(Mark One)

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

For the Quarterly Period Ended March 31, 2018

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

For the transition period from _____ to _____

Commission File Number: 000-55866

MONOPAR THERAPEUTICS INC.

(Exact name of registrant as specified in its charter)

DELAWARE

(State or other jurisdiction of
incorporation or organization)

32-0463781

(I.R.S. employer
identification number)

1000 Skokie Blvd., Suite 350, Wilmette, IL

(Address of principal executive offices)

60091

(zip code)

(847) 388-0349

(Registrant's telephone number, including area code)

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

Title of each class

N/A

Name of each exchange on which registered

N/A

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

Common Stock, \$0.001 par value

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

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

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

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

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

The number of shares outstanding with respect to each of the classes of our common stock, as of May 11, 2018, is set forth below:

<u>Class</u>	<u>Number of shares outstanding</u>
Common Stock, par value \$0.001 per share	9,291,420.614

MONOPAR THERAPEUTICS INC.
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Forward-Looking Statements

This Quarterly Report on Form 10-Q contains “forward-looking statements” within the meaning of Section 27A of the Securities Act of 1933, as amended (the “Act”) and Section 21E of the 34 Act. All statements other than statements of historical facts included in this Quarterly Report on Form 10-Q are forward-looking statements. The words “hopes,” “believes,” “anticipates,” “plans,” “seeks,” “estimates,” “projects,” “expects,” “intends,” “may,” “could,” “should,” “would,” “will,” “continue,” and similar expressions are intended to identify forward-looking statements. Forward-looking statements contained in this Quarterly Report on Form 10-Q include without limitation statements about the market for cancer products in general and statements about our:

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

Any forward-looking statements in this Quarterly Report reflect our current views with respect to future events or to our future financial performance and involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by these forward-looking statements. Information that is based on estimates, forecasts, projections, market research or similar methodologies is inherently subject to uncertainties and actual events or circumstances may differ materially from events and circumstances reflected in this information.

Although we believe that the expectations reflected in such forward-looking statements are appropriate, we can give no assurance that such expectations will be realized. Cautionary statements are disclosed in this Quarterly Report on Form 10-Q, addressing forward-looking statements. All subsequent written and oral forward-looking statements attributable to us or persons acting on our behalf are expressly qualified in their entirety by the cautionary statements. We undertake no obligation to update any statements made in this Quarterly Report on Form 10-Q or elsewhere, including without limitation any forward-looking statements, except as required by law.

PART I
FINANCIAL INFORMATION

Item 1. Financial Statements

Monopar Therapeutics Inc.

Condensed Consolidated Balance Sheets

	March 31, 2018	December 31, 2017*
Assets	<i>(unaudited)</i>	
Current assets:		
Cash and cash equivalents	\$ 8,173,045	\$ 8,981,894
Other current assets	175,100	149,342
Total current assets	8,348,145	9,131,236
Restricted cash	800,031	800,031
Total assets	<u>\$ 9,148,176</u>	<u>\$ 9,931,267</u>
Liabilities and Equity		
Current liabilities:		
Accounts payable and accrued expenses	\$ 290,597	\$ 311,867
Total current liabilities	290,597	311,867
Total liabilities	<u>290,597</u>	<u>311,867</u>
Commitments and contingencies (Note 7)		
Stockholders' equity:		
Common stock, par value of \$0.001 per share, 40,000,000 authorized, 9,291,421 shares issued and outstanding at March 31, 2018 and December 31, 2017	9,291	9,291
Additional paid-in capital	28,152,415	28,037,889
Accumulated deficit	(19,304,127)	(18,427,780)
Total stockholders' equity	8,857,579	9,619,400
Total liabilities and stockholders' equity	<u>\$ 9,148,176</u>	<u>\$ 9,931,267</u>

* Derived from the Company's audited financial statements.

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

Monopar Therapeutics Inc.

Condensed Consolidated Statements of Operations
(Unaudited)

	March 31,	
	2018	2017
Revenues	\$ —	\$ —
Operating expenses:		
Research and development	457,141	133,736
General and administrative	440,119	240,103
Total operating expenses	897,260	373,839
Loss from operations	(897,260)	(373,839)
Other income:		
Interest and other income	20,913	924
Net loss	\$ (876,347)	\$ (372,915)
Net loss per share:		
Basic and diluted	\$ (0.09)	\$ (0.04)
Weighted average shares outstanding:		
Basic and diluted	9,291,421	8,338,783 ⁽¹⁾

(1) The unaudited pro-forma net loss per share for the three months ended March 31, 2017 are presented after giving effect to the conversion of the Series A Preferred Stock and Series Z Preferred Stock into common stock at a conversion rate of 1.2 for 1 and 1 for 1, respectively, along with a concurrent common stock split of 70 for 1 as of the beginning of the period.

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

Monopar Therapeutics Inc.

Condensed Consolidated Statements of Cash Flows
(Unaudited)

	March 31,	
	2018	2017
Cash flows from operating activities:		
Net loss	\$ (876,347)	\$ (372,915)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock compensation expense (non-cash)	114,526	—
Changes in operating assets and liabilities, net		
Other current assets	(25,758)	7,570
Accounts payable and accrued expenses	(21,270)	53,859
Net cash used in operating activities	(808,849)	(311,486)
Cash flows from financing activities:		
Subscription for common stock, net of \$10,000 of issuance costs	-	990,002
Net cash provided by financing activities	-	990,002
Net increase (decrease) in cash, cash equivalents and restricted cash	(808,849)	678,516
Cash, cash equivalents and restricted cash at beginning of period	9,781,925	2,873,004
Cash, cash equivalents and restricted cash at end of period	\$ 8,973,076	\$ 3,551,520

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

MONOPAR THERAPEUTICS INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

March 31, 2018

Note 1 - Nature of Business and Liquidity

Nature of Business

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

The Company was originally formed in the State of Delaware on December 5, 2014 as a limited liability company ("LLC") and on December 16, 2015 converted to a C Corporation in a tax-free exchange at which time the Company effected a 1 for 10 reverse stock split. All references to preferred stock authorized, issued and outstanding and common stock authorized take into account the 1 for 10 reverse stock split. In March 2017, the Company's Series A Preferred Stock and Series Z Preferred Stock converted into common stock at a conversion rate of 1.2 for 1 and 1 for 1, respectively, along with a concurrent common stock split of 70 for 1 which eliminated all shares of Series A Preferred Stock and Series Z Preferred Stock. All references to common stock authorized, issued and outstanding and common stock options take into account the 70 for 1 stock split.

Liquidity

The Company has incurred an accumulated loss of approximately \$19.3 million as of March 31, 2018. To date, the Company has primarily funded its operations with the net proceeds from private placements of convertible preferred stock and common stock and from the cash provided in the MNPR-201 asset purchase transaction. Management believes that currently available resources will provide sufficient funds to enable the Company to meet its minimum obligations through June 2019. The Company's ability to fund its future operations, including the clinical development of Validive, is dependent primarily upon its ability to execute on its business strategy and obtain additional funding or execute collaboration research transactions. There can be no certainty that future financing or collaborative research transactions will occur.

Note 2 - Significant Accounting Policies

Basis of Presentation

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

In the opinion of management, the accompanying unaudited condensed consolidated financial statements contain all normal, recurring adjustments necessary to present fairly the Company's consolidated financial position as of March 31, 2018 and December 31, 2017, the Company's consolidated results of operations for the three months ended March 31, 2018 and 2017, and the Company's consolidated cash flows for the three months ended March 31, 2018 and 2017. The consolidated results of operations and cash flows for the periods presented are not necessarily indicative of the consolidated results of operations or cash flows which may be reported for the remainder of 2018 or in any future period. Certain information and footnote disclosures normally included in financial statements prepared in accordance with GAAP have been condensed or omitted. The accompanying unaudited interim condensed consolidated financial statements should be read in conjunction with the audited financial statements and notes thereto for the year ended December 31, 2017, included in the Company's Annual Report on Form 10-K filed with the United States Securities and Exchange Commission ("SEC") on March 26, 2018.

MONOPAR THERAPEUTICS INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

March 31, 2018

Comprehensive Loss

Comprehensive loss represents net loss plus any gains or losses not reported in the statements of operations, such as foreign currency translations gains and losses that are typically reflected on a company's statements of stockholders' equity. There were no differences between net loss for the three months ended March 31, 2018 and 2017, and comprehensive loss for those periods.

Use of Estimates

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

Going Concern Assessment

The Company adopted Accounting Standards Updates ("ASU") 2014-15, *Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern*, which the Financial Accounting Standards Board ("FASB") issued to provide guidance on determining when and how reporting companies must disclose going-concern uncertainties in their financial statements. The ASU requires management to perform interim and annual assessments of an entity's ability to continue as a going concern within one year of the date of issuance of the entity's financial statements (or within one year after the date on which the financial statements are available to be issued, when applicable). Further, a company must provide certain disclosures if there is "substantial doubt about the entity's ability to continue as a going concern." In April 2018, the Company analyzed its minimum cash requirements through June 2019 and has determined that, based upon the Company's current available cash, the Company has no substantial doubt about its ability to continue as a going concern.

Cash Equivalents

The Company considers all highly liquid investments purchased with an original maturity of 90 days or less to be cash equivalents. Cash equivalents as of March 31, 2018 and December 31, 2017 consist entirely of money market accounts.

Restricted Cash

On July 9, 2015, the Company entered into a Clinical Trial and Option Agreement ("CTOA") with Cancer Research UK. Pursuant to the CTOA, the Company deposited \$0.8 million into an escrow account to cover certain future indemnities, claims or potential termination costs incurred by Cancer Research UK. Restricted cash was \$0.8 million as of March 31, 2018 and December 31, 2017. In connection with a portfolio reprioritization review, on March 21, 2018, Cancer Research UK notified us it was terminating the CTOA and would work to transfer to us the data generated under the CTOA. Once termination is completed it is expected that these funds will be released from escrow.

Prepaid Expenses

Prepayments are expenditures for goods or services before the goods are used or the services are received and are charged to operations as the benefits are realized. Prepaid expenses include insurance premiums and software costs that are expensed monthly over the life of the contract and prepaid legal patent fees that will be expensed as incurred.

MONOPAR THERAPEUTICS INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

March 31, 2018

Concentration of Credit Risk

Financial instruments that potentially subject the Company to concentration of credit risk consist of cash and cash equivalents and restricted cash. The Company maintains cash and cash equivalents at one financial institution and restricted cash at another financial institution. As of March 31, 2018, and December 31, 2017, cash and cash equivalents and restricted cash balances at these two financial institutions were in excess of the \$250,000 Federal Deposit Insurance Corporation (“FDIC”) insurable limit.

Fair Value of Financial Instruments

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

The Company adopted Accounting Standard Codification (“ASC”) 820, *Fair Value Measurements and Disclosures*, as amended, addressing the measurement of the fair value of financial assets and financial liabilities. Under this standard, fair value is defined as the price that would be received to sell an asset or paid to transfer a liability (i.e., the “exit price”) in an orderly transaction between market participants at the measurement date.

In determining fair values of all reported assets and liabilities that represent financial instruments, the Company uses the carrying market values of such amounts. The standard establishes a hierarchy for inputs used in measuring fair value that maximizes the use of observable inputs and minimizes the use of unobservable inputs by requiring that the most observable inputs be used when available. Observable inputs reflect assumptions market participants would use in pricing an asset or liability based on market data obtained from independent sources. Unobservable inputs reflect a reporting entity’s pricing an asset or liability developed based on the best information available in the circumstances. The fair value hierarchy consists of the following three levels:

Level 1 - instrument valuations are obtained from real-time quotes for transactions in active exchange markets involving identical assets.

Level 2 - instrument valuations are obtained from readily-available pricing sources for comparable instruments.

Level 3 - instrument valuations are obtained without observable market values and require a high-level of judgment to determine the fair value.

Determining which category an asset or liability falls within the hierarchy requires significant judgment. The Company evaluates its hierarchy disclosures each reporting period. There were no transfers between Level 1, 2 or 3 of the fair value hierarchy during the three months ended March 31, 2018 and year ended December 31, 2017. The following table presents the assets and liabilities recorded that are reported at fair value on our balance sheets on a recurring basis.

Assets and Liabilities Measured at Fair Value on a Recurring Basis

	March 31, 2018	<u>Level 1</u>	<u>Level 2</u>	<u>Total</u>
Assets				
Cash equivalents(1)		\$ 8,151,365	\$ -	\$ 8,151,365
Restricted cash(2)		<u>31</u>	<u>800,000</u>	<u>800,031</u>
Total		<u>\$ 8,151,396</u>	<u>\$ 800,000</u>	<u>\$ 8,951,396</u>

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

(2) Restricted cash represents the fair value of the Company’s investments in an \$800,000 certificate of deposit and \$31 in a money market account at March 31, 2018.

MONOPAR THERAPEUTICS INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

March 31, 2018

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

(1) Cash equivalents represent the fair value of the Company's investments in two money market accounts at December 31, 2017.

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

Net Loss per Share

Net loss per share for the three months ended March 31, 2018 is calculated by dividing net loss by the weighted-average shares of common stock outstanding during the period. The unaudited pro-forma net loss per share for the three months ended March 31, 2017 are presented after giving effect to the conversion of the Series A Preferred Stock and Series Z Preferred Stock into common stock at a conversion rate of 1.2 for 1 and 1 for 1, respectively, along with a concurrent common stock split of 70 for 1 as of the beginning of the period. Diluted net loss per share for the three months ended March 31, 2018 is calculated by dividing net loss by the weighted-average shares of common stock outstanding and potential shares of common stock during the period. As of March 31, 2018, potentially dilutive securities included options to purchase up to 690,596 shares of the Company's common stock. As of March 31, 2017, potentially dilutive securities included stock options to purchase up to 555,520 shares of the Company's common stock. For all periods presented, potentially dilutive securities are excluded from the computation of fully diluted net loss per share as their effect is anti-dilutive.

Research and Development Expenses

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

The Company accrues and expenses the costs for clinical trial activities performed by third parties based upon estimates of the percentage of work completed over the life of the individual study in accordance with agreements established with contract research organizations and clinical trial sites. The Company determines the estimates through discussions with internal clinical personnel and external service providers as to progress or stage of completion of trials or services and the agreed upon fee to be paid for such services. Costs of setting up clinical trial sites for participation in the trials are expensed immediately as research and development expenses. Clinical trial site costs related to patient enrollment are accrued as patients are entered into the trial. During the three months ended March 31, 2018 and 2017, the Company had no clinical trials in progress.

In-process Research and Development

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

Collaborative Arrangements

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

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

MONOPAR THERAPEUTICS INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

March 31, 2018

Licensing Agreements

The Company has various agreements to license technology utilized in the development of its programs. The licenses contain success milestone obligations and royalties on future sales. During the three months ended March 31, 2018 and 2017, no milestones were met and no royalties were earned, therefore, the Company did not pay or accrue/expense any milestone or royalty payments under any of its license agreements.

Patent Costs

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

Income Taxes

From December 2014 to December 16, 2015, the Company was an LLC taxed as a partnership under the Internal Revenue Code, during which period the members separately accounted for their pro-rata share of income, deductions, losses, and credits of the Company. On December 16, 2015, the Company converted from an LLC to a C Corporation. Beginning on December 16, 2015, the Company uses an asset and liability approach for accounting for deferred income taxes, which requires recognition of deferred income tax assets and liabilities for the expected future tax consequences of events that have been recognized in its financial statements, but have not been reflected in its taxable income. Estimates and judgments occur in the calculation of certain tax liabilities and in the determination of the recoverability of certain deferred income tax assets, which arise from temporary differences and carry forwards. Deferred income tax assets and liabilities are measured using the currently enacted tax rates that apply to taxable income in effect for the years in which those tax assets and liabilities are expected to be realized or settled.

The Company regularly assesses the likelihood that its deferred income tax assets will be realized from recoverable income taxes or recovered from future taxable income. To the extent that the Company believes any amounts are more likely not to be realized, the Company records a valuation allowance to reduce the deferred income tax assets. In the event the Company determines that all or part of the net deferred tax assets are not realizable in the future, an adjustment to the valuation allowance would be charged to earnings in the period such determination is made. Similarly, if the Company subsequently realizes deferred income tax assets that were previously determined to be unrealizable are now realizable, the respective valuation allowance would be reversed, resulting in an adjustment to earnings in the period such determination is made.

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

Based on the available evidence, the Company believed it was not likely to utilize its minimal deferred tax assets in the future and as a result, the Company recorded a full valuation allowance as of March 31, 2018 and December 31, 2017. The Company intends to maintain the valuation allowance until sufficient evidence exists to support their reversal. The Company regularly reviews its tax positions and for a tax benefit to be recognized, the related tax position must be more likely than not to be sustained upon examination. Any amount recognized is generally the largest benefit that is more likely than not to be realized upon settlement. The Company's policy is to recognize interest and penalties related to income tax matters as an income tax expense. For the three months ended March 31, 2018 and 2017, the Company did not have any interest or penalties associated with unrecognized tax benefits.

The Company is subject to U.S. Federal, Illinois and California income taxes. Tax regulations within each jurisdiction are subject to the interpretation of the related tax laws and regulations and require significant judgment to apply. The Company was incorporated on December 16, 2015 and is subject to U.S. Federal, state and local tax examinations by tax authorities for the years ended December 31, 2017 and 2016 and for the short tax period December 16, 2015 to December 31, 2015. The Company does not anticipate significant changes to its current uncertain tax positions through March 31, 2018. The Company plans on filing its tax returns for the year ended December 31, 2017 prior to the filing deadlines in all jurisdictions.

MONOPAR THERAPEUTICS INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

March 31, 2018

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

Stock-Based Compensation

The Company accounts for stock-based compensation arrangements with employees, nonemployee directors and consultants using a fair value method, which requires the recognition of compensation expense for costs related to all stock-based payments, including stock options. The fair value method requires the Company to estimate the fair value of stock-based payment awards on the date of grant using an option pricing model.

Stock-based compensation costs for options granted to employees and nonemployee directors are based on the fair value of the underlying option calculated using the Black-Scholes option-pricing model on the date of grant for stock options and recognized as expense on a straight-line basis over the requisite service period, which is the vesting period. Determining the appropriate fair value model and related assumptions requires judgment, including estimating stock price volatility, forfeiture rates and expected term. The expected volatility rates are estimated based on the actual volatility of comparable public companies over the expected term. The Company selected these companies based on comparable characteristics, including market capitalization, stage of development and with historical share price information sufficient to meet the expected life of the stock-based awards. The expected term for options granted to date is estimated using the simplified method. Forfeitures are estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. The Company has not paid dividends and does not anticipate paying a cash dividend in the future vesting period and, accordingly, uses an expected dividend yield of zero. The risk-free interest rate is based on the rate of U.S. Treasury securities with maturities consistent with the estimated expected term of the awards. The measurement of consultant share-based compensation is subject to periodic adjustments as the underlying equity instruments vest and is recognized as an expense over the period over which services are rendered.

Recent Accounting Pronouncements

In January 2016, the FASB issued ASU 2016-01, *Recognition and Measurement of Financial Assets and Financial Liabilities*. The purpose is to enhance the reporting model for financial instruments to provide users of financial statements with more decision-useful information. The Company has adopted this ASU and determined that it does not have a material effect on its financial condition and results of operations for the three months ended March 31, 2018.

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

In January 2017, the FASB issued ASU No. 2017-01, *Business Combinations (Topic 805): Clarifying the Definition of a Business* ("ASU No. 2017-01"). The amendments in ASU No. 2017-01 clarify the definition of a business with the objective of adding guidance to assist entities with evaluating whether transactions should be accounted for as acquisitions (or disposals) of assets or businesses. The definition of a business affects many areas of accounting including acquisitions, disposals, goodwill and consolidation. For public companies, the amendments are effective for annual periods beginning after December 15, 2017, including interim periods within those periods. For all other companies and organizations, the amendments are effective for annual periods beginning after December 15, 2018, and interim periods within annual periods beginning after December 15, 2019. The Company has adopted this ASU and determined that it does not have a material effect on its financial condition and results of operations for the three months ended March 31, 2018.

MONOPAR THERAPEUTICS INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

March 31, 2018

In May 2017, the FASB issued ASU No. 2017-09, *Compensation-Stock Compensation (Topic 718): Scope of Modification Accounting*. The amendment amends the scope of modification accounting for share-based payment arrangements, provides guidance on the types of changes to the terms or conditions of share-based payment awards to which an entity would be required to apply modification accounting under ASC 718. This ASU is effective for all entities for annual periods, and interim periods within those annual periods, beginning after December 15, 2017. The Company has adopted this ASU and determined that it does not have a material effect on its financial condition and results of operations for the three months ended March 31, 2018.

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

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

In March 2018, the FASB issued ASU No. 2018-05, *Income Taxes (Topic 740): Amendments to SEC Paragraphs Pursuant to SEC Staff Accounting Bulletin No. 118*. This ASU amends certain SEC material on Topic 740 for the income tax accounting implications of the recently issued Tax Cuts and Jobs Act. ASU 2018-05 is effective upon inclusion in the FASB Codification. The Company is currently assessing the impact that adopting this new accounting standard will have on its financial statements and footnote disclosures.

Note 3 - Capital Stock

On December 16, 2015, the Company converted from an LLC to a C Corporation at which time the Company effected a 1 for 10 reverse stock split. All references to preferred stock authorized, issued and outstanding and common stock authorized take into account the 1 for 10 reverse stock split. In March 2017, the Company's Series A Preferred Stock and Series Z Preferred Stock converted to common stock at a conversion rate of 1.2 for 1 and 1 for 1, respectively, along with a simultaneous common stock split of 70 for 1 and the elimination all shares of Series A Preferred Stock and Series Z Preferred Stock (collectively, the "Conversion"). 100,000 shares of Series Z Preferred Stock were converted into 7,000,000 shares of common stock and 15,894 shares of Series A Preferred Stock were converted into 1,335,079 shares of common stock. All references to common stock authorized, issued and outstanding and common stock options take into account the 70 for 1 stock split.

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Holders of the common stock are entitled to receive such dividends as may be declared by the Board of Directors out of funds legally available therefor. Upon dissolution and liquidation of the Company, holders of the common stock are entitled to a ratable share of the net assets of the Company remaining after payments to creditors of the Company. The holders of shares of common stock are entitled to one vote per share for the election of directors and on all other matters submitted to a vote of stockholders.

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

Contribution to Capital

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

Sales of Common Stock

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

Issuance of Common Stock

In August 2017, the Company issued 3,055,394.12 shares of its common stock in exchange for cash and intellectual property related to MNPR-201.

As of March 31, 2018, the Company had 9,291,420.614 shares of common stock issued and outstanding. The Company no longer has any shares of preferred stock authorized or outstanding.

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

Note 4 - Stock Option Plan

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

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

In February 2017, the Board of Directors granted to certain Board members and the Company's acting chief financial officer stock options to purchase up to an aggregate 275,520 shares of the Company's common stock at an exercise price of \$0.001 par value based upon a third-party valuation of the Company's common stock. In September 2017, the Board of Directors represented by the designated Plan Administrator, granted options to purchase up to 21,024 shares of common stock to each of the three new Board members and in November 2017, the Company granted options to purchase up to 40,000 shares of common stock to an employee, these Board and employee options have an exercise price of \$6 per share based on the price per share at which common stock was sold in the Company's most recent private offering.

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In January 2018, the Company granted options to purchase up to 32,004 shares of common stock to its acting chief medical officer, at an exercise price of \$6 per share based on the price per share at which common stock was sold in the Company's most recent private offering.

Under the Plan, the per share exercise price for the shares to be issued upon exercise of an option shall be determined by the Plan administrator, except that the per share exercise price shall be no less than 100% of the fair market value per share on the grant date. Fair market value is established by the Company's Board of Directors, using third party valuation reports and recent financings. Options generally expire after ten years.

Stock option activity under the Plan was as follows:

	Options Available	Options Outstanding	
		Number of Options	Weighted-Average Exercise Price
Balances at January 1, 2017	420,000	280,000	\$ 0.001
Option pool increase (1)	900,000		
Granted (2)	(378,592)	378,592	1.63
Forfeited	—	—	—
Exercised	—	—	—
Balances at December 31, 2017	941,408	658,592	0.94
Granted (3)	(32,004)	32,004	6.00
Forfeited	—	—	—
Exercised	—	—	—
Balances at March 31, 2018	909,404	690,596	1.17

- (1) In October 2017, the Company's Board of Directors increased the option pool to 1,600,000 shares.
- (2) 336,544 options vest 6/48ths at the six-month anniversary of grant date and 1/48th per month thereafter; 21,024 options vest 6/24ths on the six-month anniversary of grant date and 1/24th per month thereafter; and 21,024 options vest 6/42nds on the six-month anniversary of grant date and 1/42nd per month thereafter.
- (3) The options vest as follows: options to purchase up to 12,000 shares of common stock vest at grant date, options to purchase up to 1,667 shares of common stock vest on the 1st of each month thereafter.

A summary of options outstanding as of March 31, 2018 is shown below:

Exercise Prices	Number of Shares Outstanding	Weighted Average Remaining Contractual Term	Number of Shares Fully Vested and Exercisable	Weighted Average Remaining Contractual Term
\$ 0.001	555,520	8.5 years	354,620	8.2 years
6.00	135,076	9.6 years	27,348	9.6 years
	<u>690,596</u>		<u>381,968</u>	

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During the three months ended March 31, 2018 and 2017, the Company recognized \$26,152 and \$0 of employee and non-employee director stock-based compensation expense as general and administrative expenses, respectively, and \$39,748 and \$0 as research and development expenses, respectively. The compensation expense is allocated on a departmental basis, based on the classification of the option holder. No income tax benefits have been recognized in the statements of operations for stock-based compensation arrangements.

The Company recognizes as an expense the fair value of options granted to persons who are neither employees nor directors. Stock-based compensation expense for consultants for the three months ended March 31, 2018 and 2017 was \$48,627 and \$0, respectively, which was recorded as research and development expenses.

The fair value of expensed options was based on the Black-Scholes option-pricing model assuming the following factors: 6.1 to 5.3 years expected term, 57% volatility, 2.6% to 1.2% risk free interest rate and zero dividends. The expected term for options granted to date is estimated using the simplified method. For the three months ended March 31, 2018 and 2017: the weighted average grant date fair value was \$3.20 and \$0.00 per share, respectively; and the fair value of shares vested were \$66,574 and nominal, respectively. At March 31, 2018, the aggregate intrinsic value was approximately \$3.3 million of which approximately \$2.1 million was vested and approximately \$1.2 million is expected to vest and the weighted average exercise price in aggregate was \$1.17 which includes \$0.43 for fully vested stock options and \$2.09 for stock options expected to vest. At March 31, 2018, unamortized unvested balance of stock base compensation was approximately \$0.8 million to be amortized over 3.0 years.

Note 5 - Development and Collaboration Agreements

Onxeo SA

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

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

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

The Company plans to internally develop Validive with the near-term goal of commencing a Phase 3 clinical program, which, if successful, may allow the Company to apply for marketing approval within the next few years. The Company will need to raise significant funds to support the further development of Validive.

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Cancer Research UK

In May 2015, the Company entered into a CTOA with Cancer Research UK and Cancer Research Technology Limited, a wholly-owned subsidiary of Cancer Research UK. As part of the CTOA, the Company was obligated to submit \$0.8 million in escrow to cover certain potential future claims, intellectual property infringement costs or termination costs incurred by Cancer Research UK. Pursuant to this agreement Cancer Research UK conducted preclinical work, improved manufacturing processes and yields, and planned to conduct a Phase 1a/1b clinical trial in cancer patients. As part of a portfolio reprioritization review, on March 21, 2018 Cancer Research UK notified the Company that it was terminating the CTOA and would work to transfer to the Company the data generated under the CTOA. The Company is currently reviewing potential alternative collaboration opportunities for MNPR-101 and continues to maintain the program's intellectual property portfolio.

XOMA Ltd.

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

Note 6 - Related Party Transactions

During the three months ended March 31, 2018 and 2017, the Company was advised by four members of its Board of Directors, who were Managers of the LLC prior to the Company's conversion to a C Corporation. The four former Managers are also current common stockholders (owning approximately an aggregate 3% of the common stock outstanding as of March 31, 2018). Three of the former Managers are also Managing Members of Tactic Pharma the Company's largest and controlling stockholder (beneficially owning 46% of the Company at March 31, 2018 and together with Gem through TacticGem owning 77%). Monopar paid Managing Members of Tactic Pharma and the Manager of CDR Pharma, LLC, which is the Manager of TacticGem the following during the three months ended March 31, 2018 and 2017: Chandler D. Robinson, the Company's Co-Founder, Chief Executive Officer, common stockholder, Managing Member of Tactic Pharma, former Manager of the predecessor LLC, and the Manager of CDR Pharma, LLC, which is the Manager of TacticGem: \$99,230 and \$80,500, respectively; and Andrew P. Mazar, the Company's Co-Founder, Chief Scientific Officer, common stockholder, Managing Member of Tactic Pharma and former Manager of the predecessor LLC, \$93,462 and \$75,000, respectively. The Company also paid Christopher M. Starr, the Company's Co-Founder, Executive Chairman of the Board of Directors, common stockholder and former Manager of the predecessor LLC \$25,224 and \$25,224 during the three months ended March 31, 2018 and 2017, respectively.

The Company reimbursed Tactic Pharma, a *de minimis* amount in monthly storage fees during the three months ended March 31, 2017. In March 2017, Tactic Pharma wired \$1 million to the Company in advance of the sale of the Company's common stock at \$6 per share under a private placement memorandum. In April, the Company issued to Tactic Pharma 166,667 shares in exchange for the \$1 million at \$6 per share once the Company began selling stock to unaffiliated parties under the private placement memorandum. In August 2017, Tactic Pharma surrendered 2,888,727 shares of common stock back to the Company as a contribution to the capital of the Company. This resulted in reducing Tactic Pharma's ownership in Monopar from 79.5% to 69.9%. Following the surrender of the common stock, Tactic Pharma contributed 4,111,272.88 shares of its holdings in Monopar's common stock to TacticGem pursuant to the Gem Transaction discussed in detail in the Company's Annual Report on Form 10-K filed with the SEC on March 26, 2018. As of March 31, 2018, Tactic Pharma beneficially owned 46% of Monopar's common stock, and TacticGem owned 77% of Monopar's common stock.

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During the three months ended March 31, 2018 and 2017, the Company paid or accrued legal fees to a large national law firm, in which a family member of the Company's Chief Executive Officer is a law partner, approximately \$53,000 and \$30,000, respectively. The family member personally billed a *de minimis* amount of time on the Company's legal engagement with the law firm in these periods.

Note 7 – Commitments and Contingencies

Development and Collaboration Agreements

The intellectual property rights contributed by Tactic Pharma, LLC to the Company included the non-exclusive license agreement with XOMA Ltd. for the humanization technology used in the development of MNPR-101. Pursuant to such license agreement, the Company is obligated to pay XOMA Ltd. clinical, regulatory and sales milestones for MNPR-101 and zero royalties. As of March 31, 2018, the Company has not reached any milestones and has not been required to pay XOMA Ltd. any funds under this license agreement.

Leases

The Company leases office space at 500 Mercer St., Seattle, WA. The lease commenced on November 1, 2017 and is extendable on a month-to-month basis. Commencing January 1, 2018, the Company entered into a lease for its executive headquarters at 1000 Skokie Blvd., Suite 350, Wilmette, IL. The lease term is January 1, 2018 through December 31, 2019. The future lease commitments as presented below include amounts for the lease in Wilmette only, as the Seattle lease is on a month-to-month basis.

2018 (Q2-Q4)	\$	22,676
2019		30,234
Total future lease payments	\$	<u>52,910</u>

Legal Contingencies

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

Indemnification

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

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

Note 8 - Subsequent Events

The Company has evaluated all events occurring from March 31, 2018 through May 11, 2018, the date which these condensed consolidated financial statements were available to be issued, and did not identify any additional material disclosable subsequent events.

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations.

You should read the following discussion and analysis of our financial condition and results of operations together with our financial statements and related notes contained in this Quarterly Report on Form 10-Q. Some of the information contained in this discussion and analysis or set forth elsewhere in this Quarterly Report on Form 10-Q, including information with respect to our plans and strategy for our business and related financing, includes forward-looking statements that involve risks and uncertainties. *Statements in the following discussion and throughout this report that are not historical in nature are "forward-looking statements." You can identify forward-looking statements by the use of words such as "expect," "anticipate," "estimate," "may," "will," "should," "intend," "believe," and similar expressions, although not all forward-looking statements contain these identifying words. Although we believe the expectations reflected in these forward-looking statements are reasonable, such statements are inherently subject to significant risks and uncertainties and we can give no assurances that our expectations will prove to be correct. Actual results could differ materially from those described in this report because of numerous factors, many of which are beyond our control. We undertake no obligation to update these forward-looking statements to reflect events or circumstances after the date of this report or to reflect actual outcomes.*

Overview

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

Our lead product candidate Validive[®] (clonidine mucobuccal tablet; clonidine MBT), is an orally delivered molecule ready to go into Phase 3 clinical trials for the prevention and treatment of severe oral mucositis ("SOM") in patients undergoing radiotherapy for oropharyngeal cancer ("OPC"). The mucobuccal tablet ("MBT") formulation is a novel delivery system for clonidine that allows for prolonged local delivery and enhanced local concentrations of drug in the area of radiation damage in patients with OPC. Validive is one of the only non-IV drug candidates in late stage development. Phase 1 and Phase 2 clinical trials of Validive demonstrated a safety profile similar to placebo and a reduction in the incidence of SOM in OPC patients by 26.3% (65.2% in placebo, 38.9% in the Validive 100µg group). Validive has been granted fast track designation in the U.S., orphan drug designation in Europe, and has global intellectual property protection through at least mid-2029.

OPC typically arises in the immune tissue at the back of the tongue and throat, which is characterized by a high localization of macrophages. Studies have indicated that SOM in patients with OPC is likely to result from an increased expression of pro-inflammatory cytokines by macrophages. Macrophages express the receptor for clonidine (alpha₂-adrenergic receptor), which regulates cytokine expression in these cells. Validive works through agonizing the alpha₂-adrenergic receptor on macrophages, resulting in a suppression of pro-inflammatory cytokine expression. Because of its unique MBT formulation, Validive exerts this effect locally and over a prolonged period of time at the sites of radiation and macrophage concentration in the back of the tongue and throat.

Currently, there are no U.S. Food and Drug Administration ("FDA")-approved preventive or therapeutic treatments for patients that develop radiotherapy-induced SOM. An estimated 50,000 new cases of OPC occur each year in the U.S. alone, and this number is rising. Almost all of these patients will receive radiotherapy, the majority of whom will experience SOM. SOM is excruciatingly painful and frequently leads to complications that negatively affect clinical outcomes, such as the inability to eat or swallow (both short-term and long-term), increased hospitalizations due to infections, and termination or interruption of treatment which can reduce survival rates. Some of these complications like pain and the inability to swallow may become irreversible and negatively affect quality of life.

The OPC target population for Validive is the most rapidly growing segment of head and neck cancer ("HNC"). The alarming growth in OPC is being driven by the human papilloma virus ("HPV") epidemic and the high prevalence of oral HPV infections, which continues to increase despite the availability of an HPV vaccine that continues to be underutilized in the U.S. This vaccine is only useful if given prior to infection. As a result, the incidence of HPV-driven OPC is predicted to increase for many years to come and will drive an increase in the market for Validive for the prevention of radiotherapy-induced SOM in patients with OPC.

A pre-Phase 3 meeting with the FDA was held in early May 2018, and once we receive the meeting minutes, we intend to initiate a Phase 3 development program for registration in late 2018 or early 2019. One of the two Phase 3 trials will be an adaptive design, with an interim analysis planned for approximately twelve months after the first patient is dosed. The second Phase 3 will be a conventional design trial.

Our second product candidate MNPR-201 is a novel doxorubicin analog engineered to eliminate the cardiotoxic side effects typically generated by doxorubicin and other anthracycline-based cancer drugs. The structure of MNPR-201 has been modified to prevent its metabolism to cardiotoxic forms while maintaining anti-cancer activity. MNPR-201 has completed a Phase 2 clinical trial in patients with unresectable or metastatic sarcoma, showing 6-month progression free survival (“PFS”) of 38%, compared to doxorubicin historical values of 23-33%. We plan to initiate further development of MNPR-201 in the first half of 2019, focused around additional Phase 2 trial(s) we can conduct which would leverage existing doxorubicin data and have a clear path towards registration.

In addition, we plan to advance development of MNPR-101, a novel first-in-class humanized monoclonal antibody to the urokinase plasminogen activator receptor (“uPAR”) for the treatment of advanced cancers. The IND-enabling work is nearly completed and we anticipate requesting a pre-IND meeting with the FDA in the second half of 2018.

Critical Accounting Policies and Use of Estimates

Our significant accounting policies are described in more detail in Note 2 of our condensed consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q.

Use of Estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the U.S. (“GAAP”) requires our management to make estimates and assumptions that affect the reported amounts of assets and liabilities, disclosure of contingent assets and liabilities, and reported amounts of revenues and expenses in the financial statements and accompanying notes. Actual results could differ from those estimates.

Revenue

We are an emerging growth company, have no approved drugs and have not generated any revenues. To date, we have engaged in acquiring pharmaceutical drug product candidates, licensing rights to drug product candidates, entering into collaboration agreements for testing and clinical development of our drug product candidates and providing the infrastructure to support the clinical development of our drug product candidates. We do not anticipate revenues from operations until we complete testing and development of one of our drug product candidates and obtain marketing approval or we sell or out-license one of our drug product candidates to another party. See “Liquidity and Capital Resources”.

Research and Development Expenses

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

We accrue and expense the costs for clinical trial activities performed by third parties based upon estimates of the percentage of work completed over the life of the individual study in accordance with agreements established with contract research organizations and clinical trial sites. We determine the estimates through discussions with internal clinical personnel and external service providers as to progress or stage of completion of trials or services and the agreed upon fee to be paid for such services. Costs of setting up clinical trial sites for participation in the trials are expensed immediately as research and development expenses. Clinical trial site costs related to patient enrollment are accrued as patients are entered into the trial. During the three months ended March 31, 2018 and 2017, we had no clinical trials in progress.

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

- receiving less funding than we require;
- slower than expected progress in developing Validive, MNPR-201, MNPR-101 or other drug product candidates;
- higher than expected costs to produce our current and future drug product candidates;
- higher than expected costs for preclinical testing of our future and current acquired and/or in-licensed programs;
- future clinical trial costs, including an increase in the number, size, duration, or complexity of future clinical trials;
- future clinical trial results;
- higher than expected costs associated with attempting to obtain regulatory approvals, including without limitation additional costs caused by delays;
- higher than expected personnel or other costs, such as adding personnel or pursuing the acquisition or licensing of additional assets;
- higher than expected costs to protect our intellectual property portfolio or otherwise pursue our intellectual property strategy;
- the potential benefits of our product candidates over other therapies; and
- our ability to market, commercialize and achieve market acceptance for any of our product candidates that we are developing or may develop in the future.

A change in the outcome of any of these variables with respect to the development of a drug product candidate could mean a significant change in the costs and timing associated with the development of that drug product candidate. We expect that research and development expenses will increase in future periods as a result of increased personnel, increased consulting, future preclinical studies and clinical trial costs, including clinical drug product manufacturing and related costs.

In-process Research and Development

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

General and Administrative Expenses

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

Collaborative Arrangements

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

In May 2015, we entered into a Clinical Trial and Option Agreement (“CTOA”) with Cancer Research UK with respect to our drug product candidate MNPR-101 (formerly huATN-658). Pursuant to this agreement Cancer Research UK conducted preclinical work, improved the manufacturing, and planned to conduct a Phase 1a/1b clinical trial in cancer patients. Under this agreement, Cancer Research UK was to cover all costs through Phase 1a/1b clinical studies, including manufacturing. As part of a portfolio reprioritization review, on March 21, 2018 Cancer Research UK notified us it was closing its project related to MNPR-101 and would work to make arrangements to formally terminate the agreement. We are currently reviewing potential alternative collaboration opportunities for MNPR-101 and continue to maintain the program’s intellectual property portfolio.

In addition, we have a non-exclusive license with XOMA Ltd. for its humanization technology and know-how utilized in the development of MNPR-101. Under the terms of the license, we are required to pay developmental and sales milestones which could reach up to \$14.925 million if we achieve all milestones. The agreement does not require the payment of sales royalties. There can be no assurance that we will reach any milestones.

From inception in December 2014 through May 1, 2018, no milestones were met and no royalties were earned, therefore, we did not pay or accrue/expense any milestone or royalty payments under the CTOA and XOMA Ltd. license agreement.

License Option Agreement

In June 2016, we executed an agreement with Onxeo S.A., a French public company, which gave us the option to license Validive (clonidine mucobuccal tablet), a mucoadhesive tablet of clonidine based on the Lauriad mucoadhesive technology to potentially treat severe oral mucositis in patients undergoing treatment for head and neck cancers. The pre-negotiated license terms included as part of the option agreement included clinical, regulatory, developmental and sales milestones that could reach up to \$108 million if we achieve all milestones, and escalating royalties on net sales from 5 - 10%. On September 8, 2017, we exercised the option to license Validive in order to commence the clinical development of the drug product candidate in exchange for a one-time option fee payment of \$1 million.

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

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

From the execution of the agreement through May 1, 2018, no milestones were met and no royalties were earned, therefore, we did not pay or accrue/expense any milestone or royalty payments under the Onxeo option agreement.

Stock-Based Compensation

We account for stock-based compensation arrangements with employees, nonemployee directors and consultants using a fair value method, which requires the recognition of compensation expense for costs related to all stock-based payments, including stock options. The fair value method requires us to estimate the fair value of stock-based payment awards on the date of grant using an option pricing model.

Stock-based compensation costs for options granted to our employees and nonemployee directors are based on the fair value of the underlying option calculated using the Black-Scholes option-pricing model on the date of grant for stock options and recognized as expense on a straight-line basis over the requisite service period, which is the vesting period. Determining the appropriate fair value model and related assumptions requires judgment, including estimating stock price volatility, forfeiture rates and expected term. The expected volatility rates are estimated based on the actual volatility of comparable public companies over the expected term. We selected these companies based on comparable characteristics, including market capitalization, risk profiles, stage of development and with historical share price information sufficient to meet the expected life of the stock-based awards. The expected term for options granted during the three months ended March 31, 2018 and 2017 is estimated using the simplified method. Forfeitures are estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. We have not paid dividends and do not anticipate paying a cash dividend in the future vesting period and, accordingly, use an expected dividend yield of zero. The risk-free interest rate is based on the rate of U.S. Treasury securities with maturities consistent with the estimated expected term of the awards. The measurement of consultant share-based compensation is subject to periodic adjustments as the underlying equity instruments vest and is recognized as an expense over the period over which services are rendered.

Stock Option Plan

In April 2016, our Board and the preferred stockholders representing a majority in interest of our outstanding stock approved the Amended and Restated Monopar Therapeutics Inc. 2016 Stock Incentive Plan (the "Plan"), allowing us to grant up to an aggregate 700,000 shares of stock awards, stock options, stock appreciation rights and other stock-based awards to our employees, non-employee directors and consultants. In October 2017, our Board increased the stock option pool up to 1,600,000 shares. Through March 31, 2018, our Board granted to Board Members, our Chief Financial Officer, our Acting Chief Medical Officer, and our Senior Vice President of Clinical Development stock options to purchase up to an aggregate 555,520 shares of our common stock at an exercise price of \$0.001 par value based upon third party valuations of our common stock and stock options to purchase up to an aggregate 135,076 shares of our common stock at an exercise price of \$6.00 based on the price per share at which common stock was sold in our most recent private offering.

Under the Plan, the per share exercise price for the shares to be issued upon exercise of an option is determined by a committee of our Board, except that the per share exercise price cannot be less than 100% of the fair market value per share on the grant date. There were no options granted to employees or non-employee directors during the three months ended March 31, 2018. We granted options to purchase up to 32,004 to a consultant on January 1, 2018 which vested as follows: options to purchase up to 12,000 shares of our common stock on the grant date and options to purchase up to 1,667 shares of our common stock on the 1st of each month thereafter.

Stock based compensation for employees and non-employee directors totaled \$65,900 during the three months ended March 31, 2018 of which \$26,152 was recorded as general and administrative expenses and \$39,748 was recorded as research and development expenses.

Stock based compensation for the three months ended March 31, 2017 was nominal due to the \$0.001 par value valuation of our common stock.

We recognize as an expense the fair value of options granted to persons who are neither employees nor directors. Stock-based compensation expense for a consultant for the three months ended March 31, 2018 and 2017 was \$48,627 and \$0, respectively, and was recorded as research and development expenses.

The fair value of expensed options was based on the Black-Scholes option-pricing model assuming the following factors: 6.1 to 5.3 year expected term, 57% volatility, 2.6% to 1.2% risk free interest rate and zero dividends. For the three months ended March 31, 2018 and 2017: the weighted average grant date fair value was \$3.20 and \$0.00 per share, respectively; and the fair value of shares vested were \$66,574 and nominal, respectively. At March 31, 2018, the aggregate intrinsic value was approximately \$3.3 million of which approximately \$2.1 million was vested and approximately \$1.2 million is expected to vest and the weighted average exercise price in aggregate was \$1.17 which includes \$0.43 for fully vested stock options and \$2.09 for stock options expected to vest. At March 31, 2018, unamortized unvested balance of stock base compensation was approximately \$0.8 million to be amortized over 3.0 years. Stock option activity under the Plan for the three months ended March 31, 2018 was as follows:

	Options Available	Options Outstanding	
		Number of Options	Weighted-Average Exercise Price
Balances, January 1, 2018	941,408	658,592	\$ 0.94
Granted ⁽¹⁾	(32,004)	32,004	6.00
Forfeited	-	-	-
Exercised	-	-	-
Balances, March 31, 2018	<u>909,404</u>	<u>690,596</u>	1.17

(1) The options vest as follows: options to purchase up to 12,000 shares of common stock vest at grant date, options to purchase up to 1,667 shares of common stock vest on the 1st of each month thereafter.

A summary of options outstanding as of March 31, 2018 is shown below:

Exercise Prices	Number of Shares Subject to Options Outstanding	Weighted Average Remaining Contractual Term	Number of Shares Subject to Options Fully Vested and Exercisable	Weighted Average Remaining Contractual Term
\$0.001	555,520	8.5 years	354,620	8.2 years
6.00	135,076	9.6 years	27,348	9.6 years
	<u>690,596</u>		<u>381,968</u>	

No income tax benefits have been recognized in the statements of operations for stock-based compensation arrangements.

Results of Operations

Comparison of the Three Months Ended March 31, 2018 and March 31, 2017

The following table summarizes the results of our operations for the three months ended March 31, 2018 and 2017:

(in thousands)	Three Months Ended March 31, (Unaudited)		Increase (Decrease)
	2018	2017	
Revenue	\$ -	\$ -	\$ -
Research and development expenses	457	134	323
General and administrative expenses	440	240	200
Total operating expenses	897	374	523
Operating loss	(897)	(374)	(523)
Interest and other income	21	1	20
Net loss	<u>\$ (876)</u>	<u>\$ (373)</u>	<u>\$ (503)</u>

R&D Expenses

R&D expenses for the three months ended March 31, 2018 were approximately \$457,000, compared to approximately \$134,000 for the three months ended March 31, 2017, an increase of approximately \$323,000. This increase was primarily attributed to:

	Three months ended March 31, 2018 versus three months ended March 31, 2017
Research and Development Expense (in thousands)	
Salaries and benefits for R&D staff hired in Q4 2017	\$ 179
Stock-based compensation (non-cash) for consultants in Q1 2018	49
Increased consulting to support the clinical development of Validive	47
Stock-based compensation (non-cash) for R&D employees hired in Q4 2017	40
Other, net	8
Net increase in R&D expenses	<u>\$ 323</u>

General and Administrative (“G&A”) Expenses

G&A expenses for the three months ended March 31, 2018 were approximately \$440,000, compared to approximately \$240,000 for the three months ended March 31, 2017, an increase of approximately \$200,000. This increase was primarily attributed to:

	Three months ended March 31, 2018 versus three months ended March 31, 2017
General and Administrative Expense (in thousands)	
Increase in CEO’s salary plus new hires in Q4 2017	\$ 96
Fees and expenses for new Board members	32
Intellectual property legal costs for MNPR-201 purchased in August 2017	24
Audit and legal services related to being a public reporting company starting in Q1 2018	20
Stock-based compensation (non-cash) for new Board members	17
Increase in leased space for headquarters in Q1 2018 and initial lease of offices in Seattle for clinical development in Q4 2017	9
Other, net	<u>2</u>
Net increase in G&A expenses	<u>\$ 200</u>

Interest Income

Interest income for the three months ended March 31, 2018 increased by approximately \$20,000 versus the three months ended March 31, 2017 due to higher bank balances resulting from funds raised in 2017. Interest income was the result of interest earned on our cash equivalent investments in a money market account and on our escrow account.

Liquidity and Capital Resources

Sources of Liquidity

We have incurred losses and cumulative negative cash flows from operations since our inception in December 2014 resulting in an accumulated deficit of approximately \$19.3 million as of March 31, 2018. We anticipate that we will continue to incur losses for the foreseeable future. We expect that our research and development and general and administrative expenses will increase, and, as a result, we anticipate that we will need to raise additional capital to fund our operations, which we may seek to obtain through a combination of equity offerings, debt financings, strategic collaborations and grant funding. From our inception, through May 1, 2018, we have financed our operations primarily through private placements of our preferred stock and of our common stock, the \$4.8 million received (net of transaction costs) received related to the purchase of MNPR-201, and our Cancer Research UK collaboration. As of May 1, 2018, we have received net proceeds of approximately \$4.70 million (net of issuance costs) from the sale of our preferred stock which have been converted into common stock and we sold 789,674.33 shares of our common stock for net proceeds of approximately \$4.71 million. We anticipate that the funds raised to-date will fund our minimal operations through June 2019.

We invest our cash equivalents in a money market account.

Contribution to Capital

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

Cash Flows

The following table provides information regarding our cash flows for the three months ended March 31, 2018 and 2017.

(in thousands)	Three months ended March 31, (Unaudited)		Increase (decrease) three months ended March 31, 2018 versus three months ended March 31, 2017
	2018	2017	
Cash used in operating activities	\$ (809)	\$ (311)	\$ (497)
Cash provided by financing activities	-	990	(990)
Net change in cash, cash equivalents and restricted cash	<u>\$ (809)</u>	<u>\$ 679</u>	<u>\$ (1,487)</u>

During the three months ended March 31, 2018 we had a net cash outflow of approximately \$(809,000), compared to net cash inflow of approximately \$679,000 during three months ended March 31, 2017.

Cash Flow Used in Operating Activities

The increase to cash used in operating activities during the three months ended March 31, 2018 compared to the three months ended March 31, 2017 of approximately \$497,000 was primarily a result of the increase of net loss.

Cash Flow Used in Investing Activities

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

Cash Flow Provided by Financing Activities

There was no cash provided by financing activities during the three months ended March 31, 2018. The cash provided by financing activities during the three months ended March 31, 2017 of approximately \$990,000 was due to the \$1 million wire received from Tactic Pharma in advance of the sale of our common stock (subscribed capital) at \$6 per share under a private placement memorandum, net of issuance costs.

Future Funding Requirements

We have not generated any revenue from product sales. We do not know when, or if, we will generate any revenue from product sales. We do not expect to generate any revenue from product sales unless and until we obtain regulatory approval of and commercialize any of our current or future drug product candidates or we out-license or sell a drug product candidate to another party. At the same time, we expect our expenses to increase in connection with our ongoing development activities, particularly as we continue the research, development, future preclinical studies and clinical trials of, and seek regulatory approval for, our current and future drug product candidates. Our goal is to list our common stock on Nasdaq or another national stock exchange and we expect to incur additional costs associated with operating as a listed public company. In addition, if we obtain regulatory approval of any of our current and future drug product candidates, we will need substantial additional funding in connection with our future continuing operations.

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

- advance the clinical development and execute the regulatory strategy of Validive;
- continue the clinical development of MNPR-201;
- continue the preclinical and clinical development of MNPR-101;
- acquire and/or license additional pipeline drug product candidates and pursue the future preclinical and/or clinical development of such drug product candidates;
- seek regulatory approvals for any of our current and future drug product candidates that successfully complete registration trials;
- establish a sales, marketing and distribution infrastructure and increase, contract for, or develop internal manufacturing and quality capabilities to commercialize any products for which we may obtain regulatory approval; and
- add research and development, operational, administrative, and other specialized experts to support our drug product candidate development and planned commercialization efforts.

We anticipate that the funds raised to-date will fund our minimal operations through at least the next 12 months. We have based this estimate on assumptions that may prove to be wrong, and we could use our available capital resources sooner than we currently expect. Because of the numerous risks and uncertainties associated with the development and commercialization of our drug product candidates, and the extent to which we enter into collaborations with third parties to participate in the development and commercialization of our drug product candidates, we are unable to estimate the amounts of increased capital outlays and operating expenditures associated with our current and anticipated drug product candidate development programs. Our future capital requirements will depend on many factors, including:

- the progress of regulatory interactions and clinical development of Validive;
- the progress of clinical development of MNPR-201;
- the progress of preclinical and clinical development of MNPR-101;
- the number and characteristics of other drug product candidates that we may pursue;
- the scope, progress, timing, cost and results of research, preclinical development and clinical trials;
- the costs, timing and outcome of seeking and obtaining FDA and international regulatory approvals;
- the costs associated with manufacturing and establishing sales, marketing and distribution capabilities;
- our ability to maintain, expand and defend the scope of our intellectual property portfolio, including the amount and timing of any payments we may be required to make in connection with the licensing, filing, defense and enforcement of any patents or other intellectual property rights;
- our need and ability to hire additional management, scientific and medical personnel;
- the effect of competing products that may limit market penetration of our drug product candidates;
- our need to implement additional internal systems and infrastructure; and
- the economic and other terms, timing and success of our existing collaboration and licensing arrangements and any collaboration, licensing or other arrangements into which we may enter in the future, including the timing of receipt of or payment to or from others of any milestone or royalty payments under these arrangements

Expenditures are expected to increase in 2018 in employee compensation and consulting fees as a result of hiring various employees and consultants to support the planning of our Phase 3 clinical program of Validive, and in adjusting employee compensation to align with comparable public companies. There can be no assurance that any such events will occur. We intend to continue evaluating drug product candidates for the purpose of growing our pipeline. Identifying and securing high quality compounds usually takes time; however, our spending could be significantly accelerated in 2018 or 2019 if additional product candidates are acquired and enter clinical development. In this event, we may be required to expand our management team, and pay much higher insurance rates, contract manufacturing costs, contract research organization fees or other clinical development costs that are not currently anticipated. We, under this scenario, would plan to pursue raising additional capital in the next 12 months. The anticipated operating cost increases from 2018 through 2019 are expected to be primarily driven by the funding of our planned Validive Phase 3 clinical program. Office space rent in 2018 and 2019 will also likely increase as a result of requiring additional space as we hire additional employees.

Until we can generate a sufficient amount of product revenue to finance our cash requirements, we expect to finance our future cash needs primarily through a combination of equity offerings, debt financings, strategic collaborations and grant funding. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interest of our stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect our stockholders' rights. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise additional funds through marketing and distribution arrangements or other collaborations, strategic alliances or licensing arrangements with other parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate our pipeline product development or commercialization efforts or grant rights to others to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

Contractual Obligations and Commitments

Development and Collaboration Agreements

Onxeo SA

In June 2016, we executed an agreement with Onxeo S.A., a French public company, which gave us the exclusive option to license (on a world-wide exclusive basis) Validive (clonidine mucobuccal tablet; clonidine MBT a mucoadhesive tablet of clonidine based on the Lauriad mucoadhesive technology) to pursue treating severe oral mucositis in patients undergoing chemoradiation treatment for head and neck cancers. The agreement includes clinical, regulatory, developmental and sales milestones that could reach up to \$108 million if we achieve all milestones, and escalating royalties on net sales from 5 - 10%. In September 2017, we exercised the option to license Validive from Onxeo for \$1 million, but as of May 1, 2018, we have not been required to pay Onxeo any other funds under the agreement. We fully anticipate the need to raise significant funds to support the completion of clinical development of Validive.

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

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

Cancer Research UK

In July 2015, we entered into a Clinical Trial and Option Agreement (“CTOA”) with Cancer Research UK and Cancer Research Technology Limited, a wholly-owned subsidiary of Cancer Research UK. As part of the CTOA, we were obligated to deposit \$0.8 million in escrow to cover certain potential future claims, intellectual property infringement costs or termination costs incurred by Cancer Research UK. Pursuant to this agreement Cancer Research UK conducted preclinical work, improved the manufacturing, and planned to conduct a Phase 1a/1b clinical trial in cancer patients. Under this agreement, Cancer Research UK was to cover all costs through Phase 1a/1b clinical studies, including manufacturing. As part of a portfolio reprioritization review, on March 21, 2018, Cancer Research UK notified us it was closing its project related to MNPR-101 and would work to make arrangements to formally terminate the agreement. We are currently reviewing potential alternative collaboration opportunities for MNPR-101 and continue to maintain the program’s intellectual property portfolio.

XOMA Ltd.

The intellectual property rights contributed by Tactic Pharma, LLC to us included the non-exclusive license agreement with XOMA Ltd. for the humanization technology used in the development of MNPR-101. Pursuant to such license agreement, we are obligated to pay XOMA Ltd. clinical, regulatory and sales milestones which could reach up to \$14.925 million if we achieve all milestones for MNPR-101. The agreement does not require the payment of sales royalties. There can be no assurance that we will achieve any milestones. As of May 1, 2018, we had not reached any milestones and had not been required to pay XOMA Ltd. any funds under this license agreement.

Service Providers

In the normal course of business, we contract with service providers to assist in the performance of research and development, financial strategy, audit, tax and legal support. We can elect to discontinue the work under these agreements at any time. We could also enter into collaborative research, contract research, manufacturing and supplier agreements in the future, which may require upfront payments and/or long-term commitments of cash.

Office Lease

Effective January 1, 2018, we leased office space in the Village of Wilmette for \$2,379 per month for 24 months. This office space houses our current headquarters. On November 1, 2017, we executed a month-to-month office lease in Seattle, Washington for \$1,249 per month for the first three months, but which tiers up to \$2,495 on the last month.

Legal Contingencies

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

Indemnification

In the normal course of business, we enter into contracts and agreements that contain a variety of representations and warranties and provide for general indemnification. Our exposure under these agreements is unknown because it involves claims that may be made against us in the future, but that have not yet been made. To date, we have not paid any claims or been required to defend any action related to our indemnification obligations. However, we may record charges in the future as a result of these indemnification obligations.

In accordance with our Second Amended and Restated Certificate of Incorporation and Amended and Restated Bylaws we have indemnification obligations to our officers and Board Members for certain events or occurrences, subject to certain limits, while they are serving at our request in such capacity. There have been no claims to date.

Off-Balance Sheet Arrangements

To date, we have not had any off-balance sheet arrangements, as defined under the U.S. Securities and Exchange Commission (“SEC”) rules.

Item 4. Controls and Procedures

Our Chief Executive Officer and Chief Financial Officer have provided certifications filed as Exhibits 31.1 and 32.1, and 31.2, respectively. Such certifications should be read in conjunction with the information contained in this Item 4 for a more complete understanding of the matters covered by those certifications.

(a) Disclosure Controls and Procedures

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

(b) Changes in Internal Control over Financial Reporting

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

There have been no changes in our internal control over financial reporting during the three months ended March 31, 2018 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

Item 1. Legal Proceedings

We are not party to any material legal proceedings.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds

Set forth below is information regarding options granted by us in the three months ended March 31, 2018, that were not registered under the Securities Act. Also included is the consideration, if any, received by us, for such options and information relating to the Securities Act, or rule of the SEC, under which exemption from registration was claimed. No underwriters were involved in this issuance of securities. Below this description of recent sales of unregistered securities is a description of the exemptions from registration which were applicable to each sale or grant.

On January 1, 2018, we granted options for the purchase of up to 32,004 shares of our common stock to Dr. Patrice Rioux in exchange for services as our Acting Chief Medical Officer. The exercise price of the option was \$6.00 per share and the options expire on December 31, 2027.

The issuance of the securities described in above were deemed to be exempt from registration under the Securities Act in reliance on both Section 4(a)(2) of the Act and Rule 701 in that the transactions were under compensatory benefit plans and contracts relating to compensation as provided under Rule 701. The recipient of such securities was our bona fide consultant and received the securities under our Plan. Appropriate legends were affixed to the securities issued in these transactions. The recipient of securities in this transaction had adequate access, through employment, business or other relationships, to information about us and had knowledge and experience to make the decision to accept the stock options.

Item 6. Exhibits

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

Exhibit	Document	Incorporated by Reference From:
3.1	Second Amended and Restated Certificate of Incorporation	Form 10-K filed on March 26, 2018
3.2	Amended and Restated Bylaws	Form 10-K filed on March 26, 2018
10.1*	Clinical Trial and Option Agreement with Cancer Research UK	Form 10-K filed on March 26, 2018
10.2*	License Agreement with XOMA Ltd.	Form 10-K filed on March 26, 2018
10.3*	Option and License Agreement with Onxeo S.A.	Form 10-K filed on March 26, 2018
10.4*	Contribution Agreement (351) – Containing Registration Rights Agreement with TacticGem	Form 10-K filed on March 26, 2018
10.5	Amended and Restated 2016 Stock Incentive Plan	Form 10-K filed on March 26, 2018
10.6	Employment Agreement of Chandler D. Robinson – terminated October 31, 2017	Form 10-K filed on March 26, 2018
10.7	Employment Agreement of Chandler D. Robinson – effective November 1, 2017	Form 10-K filed on March 26, 2018
10.8	Consulting Agreement of Kim Tsuchimoto – terminated October 31, 2017	Form 10-K filed on March 26, 2018
10.9	Employment Agreement of Kim Tsuchimoto – effective November 1, 2017	Form 10-K filed on March 26, 2018
10.10	Consulting Agreement of Andrew P. Mazar – terminated October 31, 2017	Form 10-K filed on March 26, 2018
10.11	Employment Agreement of Andrew P. Mazar – effective November 1, 2017	Form 10-K filed on March 26, 2018
10.12	Consulting Agreement of pRx Consulting (Patrice Rioux) – terminated December 31, 2017	Form 10-K filed on March 26, 2018
10.13	Employment Agreement of Kirsten Anderson	Form 10-K filed on March 26, 2018
10.14	Consulting Agreement of pRx Consulting (Patrice Rioux) - effective January 1, 2018	Form 10-K filed on March 26, 2018
10.15	Amendment One to Employment Agreement of Kim Tsuchimoto – effective March 1, 2018	Form 10-K filed on March 26, 2018
10.16	Cancer Research UK Letter Dated March 21, 2018	Form 10-K filed on March 26, 2018
11	Statement Regarding Computation of Per Share Earnings	Form 10-K filed on March 26, 2018
31.1	Certification of Chandler Robinson, Chief Executive Officer	
31.2	Certification of Kim Tsuchimoto, Chief Financial Officer	
32.1	Certification of Chandler Robinson, Chief Executive Officer and Kim Tsuchimoto, Chief Financial Officer	
101.INS	XBRL Instance Document	
101.SCH	XBRL Taxonomy Extension Schema	
101.CAL	XBRL Taxonomy Extension Calculation Linkbase	
101.DEF	XBRL Taxonomy Extension Definition Linkbase	
101.LAB	XBRL Taxonomy Extension Label Linkbase	
101.PRE	XBRL Taxonomy Extension Presentation Linkbase	

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

SIGNATURES

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

MONOPAR THERAPEUTICS INC.

Dated: May 11, 2018

By: /s/ Chandler D. Robinson

Chandler D. Robinson
Chief Executive Officer and Director (Principal
Executive Officer)

Dated: May 11, 2018

By: /s/ Kim R. Tsuchimoto

Kim R. Tsuchimoto
Chief Financial Officer (Principal Financial
Officer)

CERTIFICATION

I, Chandler D. Robinson, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Monopar Therapeutics Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the condensed consolidated financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:
 - a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 11, 2018

/s/ CHANDLER D. ROBINSON

Chandler D. Robinson

Chief Executive Officer

CERTIFICATION

I, Kim R. Tsuchimoto, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Monopar Therapeutics Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the condensed consolidated financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:
 - a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 11, 2018

/s/ KIM R. TSUCHIMOTO

Kim R. Tsuchimoto

Chief Financial Officer

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

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

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

/s/ CHANDLER D. ROBINSON

Chandler D. Robinson

Chief Executive Officer

May 11, 2018

/s/ KIM R. TSUCHIMOTO

Kim R. Tsuchimoto

Chief Financial Officer

May 11, 2018

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