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 September 30, 2019

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

For the transition period from_____ to _____

Commission File Number: 000-55866

MONOPAR THERAPEUTICS INC.

(Exact name of registrant as specified in its charter)

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

(847) 388-0349

(Registrant's telephone number, including area code)

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, $0.001 par value	**None**	**None**

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

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

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

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

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

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

The number of shares outstanding with respect to each of the classes of our common stock, as of November 12, 2019, is set forth below:

Class	Number of shares outstanding
Common Stock, par value $0.001 per share	9,291,420.614

MONOPAR THERAPEUTICS INC.
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Forward-Looking Statements

Unless the context otherwise requires, all references to "Monopar," "we," "us," "our," "our company," or "the Company" refer to Monopar Therapeutics Inc., a Delaware corporation, and its subsidiaries.

This Quarterly Report on Form 10-Q ("Quarterly Report") contains "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933, as amended (the "Act") and Section 21E of the Securities Exchange Act of 1934, as amended. All statements other than statements of historical facts included in this Quarterly Report are forward-looking statements. The words "hopes," "believes," "anticipates," "plans," "seeks," "estimates," "projects," "expects," "intends," "may," "could," "should," "would," "will," "continue," "potential," "possible," and similar expressions are intended to identify forward-looking statements. Forward-looking statements contained in this Quarterly Report 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;
- market opportunity, including without limitation the potential market acceptance of our technologies and products and the size of the market for our cancer products;
- future operating results;
- anticipated utility of our intellectual property portfolio;
- projected liquidity and capital expenditures; and
- development and expansion of strategic relationships, collaborations, and alliances.

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, 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 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

	September 30, 2019	December 31, 2018*
Assets	*(unaudited)*	
Current assets:		
Cash and cash equivalents	$ 4,494,540	$ 6,892,772
Deferred offering costs	529,203	344,936
Other current assets	84,878	80,247
Total current assets	5,108,621	7,317,955
Total assets	$ 5,108,621	$ 7,317,955
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable, accrued expenses and other current liabilities	$ 483,666	$ 399,551
Total current liabilities	483,666	399,551
Total liabilities	483,666	399,551
Commitments and contingencies (Note 7)		
Stockholders' equity:		
Common stock, par value of $0.001 per share, 40,000,000 shares authorized, 9,291,421 shares issued and outstanding at September 30, 2019 and December 31, 2018	9,291	9,291
Additional paid-in capital	29,301,586	28,567,221
Accumulated other comprehensive loss	(12,195)	(2,396)
Accumulated deficit	(24,673,727)	(21,655,712)
Total stockholders' equity	4,624,955	6,918,404
Total liabilities and stockholders' equity	$ 5,108,621	$ 7,317,955

* Derived from the Company's audited consolidated financial statements.

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

Monopar Therapeutics Inc.

Condensed Consolidated
Statements of Operations and Comprehensive Loss
(Unaudited)

	Three months ended September 30,		Nine months ended September 30,	
	2019	**2018**	**2019**	**2018**
Revenues	$ —	$ —	$ —	$ —
Operating expenses:				
Research and development	219,846	303,684	1,384,740	1,253,472
General and administrative	539,602	363,848	1,714,126	1,151,317
Total operating expenses	759,448	667,532	3,098,866	2,404,789
Loss from operations	(759,448)	(667,532)	(3,098,866)	(2,404,789)
Other income:				
Interest income	23,368	27,348	80,851	67,318
Net loss	(736,080)	(640,184)	(3,018,015)	(2,337,471)
Other comprehensive loss:				
Foreign currency translation loss	(8,739)	(806)	(9,799)	(2,385)
Comprehensive loss	$ (744,819)	$ (640,990)	$ (3,027,814)	$ (2,339,856)
Net loss per share:				
Basic and diluted	$ (0.08)	$ (0.07)	$ (0.32)	$ (0.25)
Weighted average shares outstanding:				
Basic and diluted	9,291,421	9,291,421	9,291,421	9,291,421

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

Monopar Therapeutics Inc.
Condensed Consolidated Statements of Stockholders' Equity
(Unaudited)

	Common Stock					
	Shares	**Amount**	**Additional Paid-in Capital**	**Accumulated Deficit**	**Accumulated Other Comprehensive Loss**	**Total Stockholders'Equity**
Balance at January 1, 2018	9,291,421	$ 9,291	$ 28,037,889	$ (18,427,780)	$ —	$ 9,619,400
Non-cash stock compensation	—	—	114,526	—	—	114,526
Net loss	—	—	—	(876,347)	—	(876,347)
Balance at March 31, 2018	9,291,421	9,291	28,152,415	(19,304,127)		8,857,579
Non-cash stock compensation	—	—	88,570	—	—	88,570
Net loss	—	—	—	(820,940)	—	(820,940)
Other comprehensive loss	—	—	—	—	(1,579)	(1,579)
Balance at June 30, 2018	9,291,421	9,291	28,240,985	(20,125,067)	(1,579)	8,123,630
Non-cash stock compensation	—	—	93,244	—	—	93,244
Net loss	—	—	—	(640,184)	—	(640,184)
Other comprehensive loss	—	—	—	—	(806)	(806)
Balance at September 30, 2018	9,291,421	9,291	28,334,229	(20,765,251)	(2,385)	7,575,884
Non-cash stock compensation	—	—	232,992	—	—	232,992
Net loss	—	—	—	(890,461)	—	(890,461)
Other comprehensive loss	—	—	—	—	(11)	(11)
Balance at December 31, 2018	9,291,421	9,291	28,567,221	(21,655,712)	(2,396)	6,918,404
Non-cash stock compensation	—	—	233,776	—	—	233,776
Net loss	—	—	—	(1,376,235)	—	(1,376,235)
Other comprehensive loss	—	—	—	—	(2,127)	(2,127)
Balance at March 31, 2019	9,291,421	9,291	28,800,997	(23,031,947)	(4,523)	5,773,818
Non-cash stock compensation	—	—	257,633	—	—	257,633
Net loss	—	—	—	(905,700)	—	(905,700)
Other comprehensive gain	—	—	—	—	1,067	1,067
Balance at June 30, 2019	9,291,421	9,291	29,058,630	(23,937,647)	(3,456)	5,126,818
Non-cash stock compensation	—	—	242,956	—	—	242,956
Net loss	—	—	—	(736,080)	—	(736,080)
Other comprehensive loss	—	—	—	—	(8,739)	(8,739)
Balance at September 30, 2019	9,291,421	$ 9,291	$ 29,301,586	$ (24,673,727)	$ (12,195)	$ 4,624,955

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

Monopar Therapeutics Inc.

Condensed Consolidated
Statements of Cash Flows
(Unaudited)

	Nine months ended September 30,	
	2019	**2018**
Cash flows from operating activities:		
Net loss	$ (3,018,015)	$ (2,337,471)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation (non-cash)	734,365	296,340
Changes in operating assets and liabilities, net		
Other current assets	(4,631)	(120,170)
Accounts payable, accrued expenses and other current liabilities	(60,695)	26
Net cash used in operating activities	(2,348,975)	(2,161,275)
Cash flows from financing activities:		
Deferred offering costs	(39,458)	—
Net cash used in financing activities	(39,458)	—
Effect of exchange rates on cash and cash equivalents	(9,799)	(2,385)
Net decrease in cash and cash equivalents	(2,398,232)	(2,163,660)
Cash and cash equivalents at beginning of period	6,892,772	9,781,925
Cash and cash equivalents at end of period	$ 4,494,540	$ 7,618,265

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

Note 1 - Nature of Business and Liquidity

Nature of Business

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

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

Liquidity

The Company has incurred an accumulated deficit of approximately $24.7 million as of September 30, 2019. To date, the Company has primarily funded its operations with the net proceeds from private placements of convertible preferred stock and of common stock and from the cash provided in the camsirubicin asset purchase transaction. Management believes that currently available resources will provide sufficient funds to enable the Company to meet its minimum obligations through December 2020. The Company's ability to fund its future operations, including the clinical development of Validive and camsirubicin, is dependent primarily upon its ability to execute its business strategy, to obtain additional funding and/or to 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 its wholly-owned Australian subsidiary, Monopar Therapeutics Australia Pty Ltd and have been prepared in accordance with accounting principles generally accepted in the United States ("GAAP") and include all disclosures required by GAAP for interim financial reporting. All intercompany accounts have been eliminated. 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 candidates, and raising capital to support and expand these activities.

Certain reclassifications have been made to the Company's condensed consolidated financial statements for the three and nine months ended September 30, 2018 to conform to the three and nine months ended September 30, 2019 presentation. The reclassifications had no impact on the Company's comprehensive loss, total assets, or stockholders' equity.

In the opinion of management, the accompanying unaudited condensed consolidated financial statements contain all normal, recurring adjustments necessary to present fairly the Company's condensed consolidated financial position as of September 30, 2019 and as of December 31, 2018, the Company's condensed consolidated results of operations and comprehensive loss for the three and nine months ended September 30, 2019 and 2018, and the Company's condensed consolidated cash flows for the nine months ended September 30, 2019 and 2018. The condensed 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 2019 or for 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, 2018, included in the Company's Annual Report on Form 10-K filed with the United States Securities and Exchange Commission (the "SEC") on February 26, 2019.

Functional Currency

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

Comprehensive Loss

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

Use of Estimates

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

Going Concern Assessment

The Company adopted Accounting Standards Updates ("ASU") 2014-15, *Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern,* which the Financial Accounting Standards Board ("FASB") issued to provide guidance on determining when and how reporting companies must disclose going-concern uncertainties in their financial statements. The ASU requires management to perform interim and annual assessments of an entity's ability to continue as a going concern within one year of the date of issuance of the entity's financial statements (or within one year after the date on which the financial statements are available to be issued, when applicable). Further, a company must provide certain disclosures if there is "substantial doubt about the entity's ability to continue as a going concern." In October 2019, the Company analyzed its minimum cash requirements through December 2020 and has determined that, based upon the Company's current available cash, the Company has no substantial doubt about its ability to continue as a going concern.

Cash Equivalents

The Company considers all highly liquid investments purchased with an original maturity of 90 days or less to be cash equivalents. Cash equivalents as of September 30, 2019 and December 31, 2018 consist entirely of a money market account.

Deferred Offering Costs

Deferred offering costs represent legal, auditing, and travel expenses related to fundraising efforts that have not yet been concluded.

Prepaid Expenses

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

Concentration of Credit Risk

Financial instruments that potentially subject the Company to concentration of credit risk consist of cash and cash equivalents. As of September 30, 2019 and December 31, 2018, the Company maintained cash and cash equivalents at two financial institutions. Balances at one financial institution for both periods presented 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, other current assets, accounts payable, accrued expenses and other current liabilities, the carrying amounts are reasonable estimates of fair value due to their relatively short maturities.

The Company adopted 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 amountsThe standard establishes a hierarchy for inputs used in measuring fair value that maximizes the use of observable inputs and minimizes the use of unobservable inputs by requiring that the most observable inputs be used when available. Observable inputs reflect assumptions market participants would use in pricing an asset or liability based on market data obtained from independent sources. Unobservable inputs reflect a reporting entity's pricing an asset or liability developed based on the best information available under the circumstances. The fair value hierarchy consists of the following three levels:

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

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

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

Determining which category an asset or liability falls within the hierarchy requires significant judgment. The Company evaluates its hierarchy disclosures each reporting period. There were no transfers between Level 1, 2 or 3 of the fair value hierarchy during the three and nine months ended September 30, 2019 and the year ended December 31, 2018. The following table presents the assets and liabilities recorded that are reported at fair value on our condensed consolidated balance sheets on a recurring basis. No values were recorded in Level 2 or Level 3 for the three and nine months ended September 30, 2019 and the year ended December 31, 2018.

Assets and Liabilities Measured at Fair Value on a Recurring Basis

September 30, 2019	Level 1	Total
Assets		
Cash equivalents(1)	$ 4,383,836	$ 4,383,836
Total	$ 4,383,836	$ 4,383,836

(1) Cash equivalents represent the fair value of the Company's investment in a money market account at September 30, 2019.

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

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

Net Loss per Share

Net loss per share for the three and nine months ended September 30, 2019 is calculated by dividing net loss by the weighted-average shares of common stock outstanding during the period. Diluted net loss per share for the three and nine months ended September 30, 2019 and 2018 is calculated by dividing net loss by the weighted-average shares of the sum of a) common stock outstanding (9,291,421 shares for all periods presented) and b) potentially dilutive shares of common stock (such as stock options and warrants) outstanding during the period. As of September 30, 2019, potentially dilutive securities included stock options to purchase up to 1,105,896 shares of the Company's common stock. As of September 30, 2018, potentially dilutive securities included stock options to purchase up to 661,429 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 R&D expenses include salaries and benefits paid to the Company's R&D staff, fees paid to consultants and to the entities that conduct certain R&D activities on the Company's behalf and materials and supplies which are used in R&D activities during the reporting period.

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 R&D expenses. Clinical trial site costs related to patient screening and enrollment are accrued as patients are screened/entered into the trial. During the three and nine months ended September 30, 2019 and 2018, the Company had no clinical trials in progress.

In-process Research and Development

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

Collaborative Arrangements

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

During the three and nine months ended September 30, 2019 and 2018, no milestones were met and no royalties were earned, therefore, the Company did not pay or accrue/expense any license or royalty payments.

Licensing Agreements

The Company has various agreements licensing technology utilized in the development of its product or technology programs. The licenses contain success milestone obligations and royalties on future sales. During the three and nine months ended September 30, 2019 and 2018, no milestones were met and no royalties were earned, therefore, the Company did not pay or accrue/expense any license or royalty payments under any of its license agreements.

Patent Costs

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

Leases

Effective January 1, 2019, the Company has adopted ASU 2016-02, *Leases*, which has been amended by ASU 2018-10, *Codification Improvements to Topic 842, Leases*, which for operating leases, requires a lessee to recognize a right-of-use asset and a lease liability, initially measured at the present value of the lease payments, in its balance sheet. ASU 2016-02 is intended to improve financial reporting of leasing transactions by requiring organizations that lease assets to recognize assets and liabilities for the rights and obligations created by leases on the balance sheet.

As a result, the Company has recorded on its condensed consolidated balance sheetthe unamortized present value of its lease payments as (a) a lease liability in other current liabilities and (b) a right-of-use asset in other current assets.

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. On December 16, 2015, the Company began using an asset and liability approach for accounting for deferred income taxes, which requires recognition of deferred income tax assets and liabilities for the expected future tax consequences of events that have been recognized in its financial statements, but have not been reflected in its taxable income. Estimates and judgments are required in the calculation of certain tax liabilities and in the determination of the recoverability of certain deferred income tax assets, which arise from temporary differences and 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 than not to be realized, the Company records a valuation allowance to reduce the deferred income tax assets. In the event the Company determines that all or part of the net deferred tax assets are not realizable in the future, an adjustment to the valuation allowance would be charged to earnings in the period such determination is made. Similarly, if the Company subsequently realizes deferred income tax assets that were previously determined to be unrealizable are now realizable, the respective valuation allowance would be reversed, resulting in a benefit 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 will limit the Company's usage of NOLs in the future.

Accounting Standards Codification ("ASC") 740, *Income Taxes*, requires that the tax benefit of net operating losses, temporary differences, and credit carryforwards be recorded as an asset to the extent that management assesses that realization is "more likely than not." Realization of the future tax benefits is dependent on the Company's ability to generate sufficient taxable income within the carryforward period. The Company has reviewed the positive and negative evidence relating to the realizability of the deferred tax assets and has concluded that the deferred tax assets are not more likely than not to be realized with the exception of its U.S. Federal R&D tax credits which will be utilized to reduce payroll taxes in future periods. The Company intends to maintain the valuation allowance until sufficient evidence exists to support its reversal. The Company regularly reviews its tax positions. For a tax benefit to be recognized, the related tax position must be more likely than not to be sustained upon examination. Any amount recognized is generally the largest benefit that is more likely than not to be realized upon settlement. The Company's policy is to recognize interest and penalties related to income tax matters as an income tax expense. For the three and nine months ended September 30, 2019 and 2018, the Company did not have any interest or penalties associated with unrecognized tax benefits.

The Company is subject to U.S. Federal, Illinois and California income taxes. Tax regulations within each jurisdiction are subject to the interpretation of the related tax laws and regulations and require significant judgment to apply. The Company was incorporated on December 16, 2015 and is subject to U.S. Federal, state and local tax examinations by tax authorities for the years ended December 31, 2018, 2017 and 2016 and for the short tax period December 16, 2015 to December 31, 2015. The Company does not anticipate significant changes to its current uncertain tax positions through September 30, 2019. The Company plans on filing its tax returns for the year ending December 31, 2019 prior to the extended filing deadlines in all jurisdictions.

Stock-Based Compensation

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

Stock-based compensation costs for options granted to employees and non-employee directors are based on the fair value of the underlying option calculated using the Black-Scholes option-pricing model on the date of grant for stock options and recognized as expense on a straight-line basis over the requisite service period, which is the vesting period. Determining the appropriate fair value model and related assumptions requires judgment, including estimating the future stock price volatility, forfeiture rates and expected terms. The expected volatility rates are estimated based on the actual volatility of comparable public companies over recent historical periods of the same length as the expected term. The Company selected these companies based on reasonably comparable characteristics, including market capitalization, stage of corporate development and with historical share price information sufficient to meet the expected term (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. Prior to January 1, 2019, the measurement of consultant stock-based compensation was subject to periodic adjustments as the underlying equity instruments vest. Since January 1, 2019, consultant stock-based compensation is valued on the grant date and is recognized as an expense over the period in which services are rendered.

Recent Accounting Pronouncements

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

Note 3 - Capital Stock

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

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

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

Contribution to Capital

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

Sales of Common Stock

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

Issuance of Common Stock

In August 2017, the Company issued 3,055,394 shares of its common stock in exchange for cash and intellectual property related to camsirubicin (MNPR-201).

As of September 30, 2019, the Company had 9,291,421 shares of common stock issued and outstanding. The Company no longer has any shares of preferred stock authorized or outstanding.

In April 2016, the Company adopted the 2016 Stock Incentive Plan and the Company's Board of Directors reserved 700,000 shares of common stock for issuances under the plan (as adjusted subsequent to the Conversion). In October 2017, the Company's Board of Directors voted to increase the stock-based award pool to 1,600,000 shares of common stock, which subsequently was approved by the Company's stockholders.

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 Amended and Restated Monopar Therapeutics Inc. 2016 Stock Incentive Plan, as amended (the "Plan"), allowing the Company to grant up to an aggregate 700,000 shares of stock awards, stock options, stock appreciation rights and other stock-based awards to employees, non-employee directors and consultants. Concurrently, the Board of Directors granted to certain Board members and the Company's then 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 to the Company's acting chief medical officer stock options to purchase up to 7,000 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 February 2017, the Board of Directors granted to certain Board members and to the Company's then 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 stock 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 stock options to purchase up to 40,000 shares of common stock to an employee. These Board and employee stock options have an exercise price of $6 per share based on the price per share at which common stock was sold in the Company's most recent private offering.

In January 2018, the Company granted stock options to purchase up to 32,004 shares of common stock to its acting chief medical officer, atan exercise price of $6 per share based on the price per share at which common stock was sold in the Company's most recent private offering. In May 2018 and August 2018, the Company granted stock options to two employees each to purchase up to 5,000 shares of common stock, at an exercise price of $6 per share based on the price per share at which common stock was sold in the Company's most recent private offering. Also in August 2018, the Company granted stock options to all four of its non-employee Board members, the Company's chief executive officer, chief scientific officer, and chief financial officer to purchase up to an aggregate 425,300 shares of the Company's common stock at an exercise price of $6 per share based on the price per share at which common stock was sold in the Company's most recent private offering; vesting of such stock options commenced on October 1, 2018.

In December 2018, the Company granted stock options to purchase up to 20,000 shares of common stock to its acting chief medical officer, at an exercise price of $6 per share based on the price per share at which common stock was sold in the Company's most recent private offering. Vesting of such stock options commenced on January 1, 2019.

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

Stock option activity under the Plan was as follows:

		Options Outstanding	
	Options Available	Number of Options	Weighted-Average Exercise Price
Balances at January 1, 2018	**941,408**	**658,592**	**$ 0.94**
Granted[1]	(487,304)	487,304	6.00
Forfeited[2]	40,000	(40,000)	6.00
Exercised	—	—	—
Balances at December 31, 2018	**494,104**	**1,105,896**	**2.99**
Granted	—	—	—
Forfeited	—	—	—
Exercised	—	—	—
Balances at September 30, 2019	**494,104**	**1,105,896**	**2.99**

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

(2) Forfeited options resulted from an employee termination.

A summary of options outstanding as of September 30, 2019 is shown below:

Exercise Prices	Number of Shares subject to Options Outstanding	Weighted Average Remaining Contractual Term	Number of Shares Subject to Options Fully Vested and Exercisable	Weighted Average Remaining Contractual Term
$0.001	555,520	7.0 years	457,940	6.9 years
6.00	550,376	8.8 years	232,341	8.7 years
	1,105,896		690,281	

During the three months ended September 30, 2019 and 2018, the Company recognized $154,906 and $29,383, respectively, of employee and non-employee director stock-based compensation expense as general and administrative expenses and $67,347 and $32,147, respectively, as research and development expenses. During the nine months ended September 30, 2019 and 2018, the Company recognized $470,232 and $81,896, respectively, of employee and non-employee director stock-based compensation expense as general and administrative expenses and $202,012 and $108,873, respectively, as research and development expenses. The stock-based 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 condensed consolidated statements of operations and comprehensive loss for stock-based compensation arrangements.

The Company recognizes as an expense the fair value of options granted to persons (currently consultants) who are neither employees nor non-employee directors. Stock-based compensation expense for consultants which was recorded as research and development expense for the three and nine months ended September 30, 2019 was $20,704 and $62,121, respectively. Stock-based compensation expense for consultants which was recorded as research and development expense for the three and nine months ended September 30, 2018 was $31,714 and $105,571, respectively.

The fair value of options granted from inception toSeptember 30, 2019 was based on the Black-Scholes option-pricing model assuming the following factors: 4.7 to 6.2 years expected term, 55% to 85% volatility, 1.2% to 2.9% risk free interest rate and zero dividends. The expected term for options granted to date was estimated using the simplified method. There were no stock option grants during the three and nine months ended September 30, 2019. For the three and nine months endedSeptember 30, 2018 the weighted average grant date fair value was $4.34 per share and $4.25 per share, respectively. For the three months ended September 30, 2019 and 2018, the fair value of shares vested was $210,889 and $79,069, respectively. For the nine months ended September 30, 2019 and 2018, the fair value of shares vested was $639,365 and $316,263, respectively. At September 30, 2019, the aggregate intrinsic value of outstanding stock options was approximately $3.3 million of which approximately $2.7 million was vested and approximately $0.6 million is expected to vest and the weighted average exercise price in aggregate was $2.99 which includes $2.02 for fully vested stock options and $4.59 for stock options expected to vest. At September 30, 2019, the unamortized unvested balance of stock-based compensation was approximately $1.5 million to be amortized over 2.5 years.

Note 5 - Development and Collaboration Agreements

Onxeo S.A.

In June 2016, the Company executed an option and license agreement with Onxeo S.A. (“Onxeo”), a public French company, which gave Monopar the exclusive option to license (on a world-wide exclusive basis) Validive to pursue treating severe oral mucositis in patients undergoing chemoradiation treatment for head and neck cancers. 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% to 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 development program, which, if successful, may allow the Company to apply for marketing approval within the next several years. The Company will need to raise significant funds to support the further development of Validive. As of September 30, 2019, the Company had not reached any of the pre-specified milestones and has not been required to pay Onxeo any funds under this license agreement other than the one-time license fee.

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 September 30, 2019, the Company had not reached any milestones and has not been required to pay XOMA Ltd. any funds under this license agreement.

Note 6 - Related Party Transactions

In March 2017, Tactic Pharma, the Company's largest shareholder at that time, wired $1 million to the Company in advance of the sale of the Company's common stock at $6 per share under a private placement memorandum. In April, the Company issued to Tactic Pharma 166,667 shares in exchange for the $1 million at $6 per share once the Company began selling stock to unaffiliated parties under the private placement memorandum.

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

In August 2017, the Company executed definitive agreements with Gem Pharmaceuticals, LLC ("Gem"), pursuant to which Tactic Pharma and Gem formed a limited liability company, TacticGem LLC ("TacticGem"). Tactic Pharma contributed 4,111,273 shares of its holdings in Monopar's common stock to TacticGem and Gem contributed cash and assets to TacticGem. TacticGem then contributed cash and assets to the Company in exchange for stock. The Gem Transaction is discussed in detail in the Company's Annual Report on Form 10-K filed with the SEC on February 26, 2019. As of September 30, 2019, Tactic Pharma beneficially owned 46% of Monopar's common stock, and TacticGem owned 77% of Monopar's common stock.

During the three and nine months ended September 30, 2019 and 2018, the Company was governed by four members of its Board of Directors, who were Managers of the LLC prior to the Company's conversion to a C Corporation. The four former Managers are also current common stockholders (owning approximately an aggregate 3% of the common stock outstanding as of September 30, 2019). Three of the former Managers are also Managing Members of Tactic Pharma. Monopar paid or accrued payments for Managing Members of Tactic Pharma and the Manager of CDR Pharma, LLC, which is the Manager of TacticGem the following: Chandler D. Robinson, the Company's Co-Founder, Chief Executive Officer, common stockholder, board member of Monopar as a C Corporation, Managing Member of Tactic Pharma, former Manager of the predecessor LLC, and the Manager of CDR Pharma, LLC: $112,010 and $107,500 for the three months ended September 30, 2019 and 2018, respectively; and $340,091 (including $7,500 bonus paid on March 8, 2019) and $322,500 for the nine months ended September 30, 2019 and 2018, respectively; Andrew P. Mazar, the Company's Co-Founder, Chief Scientific Officer, common stockholder, board member of Monopar as a C Corporation, Managing Member of Tactic Pharma and former Manager of the predecessor LLC: $105,473 and $101,250 for the three months ended September 30, 2019 and 2018, respectively; and $318,783 (including $5,600 bonus paid on March 8, 2019) and $303,750 for the nine months ended September 30, 2019 and 2018, respectively. The Company also paid or accrued payments for Christopher M. Starr, the Company's Co-Founder, Executive Chairman of Monopar's Board of Directors as a C Corporation, common stockholder and former Manager of the predecessor LLC $30,000 and $25,224 for the three months ended September 30, 2019 and 2018; and $90,000 and $75,673 for the nine months ended September 30, 2019 and 2018, respectively. Michael Brown, as a managing member of Tactic Pharma (with no voting power as it relates to the Company commencing February 1, 2019), a previous managing member of Monopar as an LLC and common stockholder and board member of Monopar as a C Corporation was paid or accrued for $15,500 and $10,000 in board fees for the three months ended September 30, 2019 and 2018; and $46,500 and $30,000 for the nine months ended September 30, 2019 and 2018, respectively.

During the three and nine months ended September 30, 2018, 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 was a law partner through January 31, 2019, approximately $38,774 and $131,358, 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

Onxeo S.A.

The Onxeo license agreement for Validive includes clinical, regulatory, developmental and sales milestones that could reach up to $108 million if the Company achieves all milestones, and escalating royalties on net sales from 5% to 10%. During the three and nine months ended September 30, 2019, the Company had not reached any of these milestones and has not been required to pay Onxeo any funds under this license agreement other than the $1 million one-time license fee.

Grupo Español de Investigación en Sarcomas ("GEIS")

In June 2019, the Company executed a clinical collaboration with GEIS for the development of camsirubicin in patients with advanced soft tissue sarcoma ("ASTS"). GEIS will be the study sponsor and will lead a multi-country, randomized, open-label Phase 2 clinical trial to evaluate camsirubicin head-to-head against the current 1st line treatment for ASTS, doxorubicin. Enrollment of the trial is expected to begin in the first quarter of 2020 and will include approximately 170 ASTS patients. The Company will provide study drug and supplemental financial support for the clinical trial averaging approximately $1 million to $2 million per year. During the three and nine months ended September 30, 2019, the Company provided a nominal amount of financial support. The Company can terminate the agreement by providing GEIS with advance notice, and without affecting the Company's rights and ownership to any intellectual property or clinical data.

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 but is not required to pay royalties on product sales. During the three and nine months ended September 30, 2019, the Company had not reached any milestones and has not been required to pay XOMA Ltd. any funds under this license agreement.

Operating Leases

Commencing January 1, 2018, the Company entered into a lease for its executive headquarters at 1000 Skokie Blvd., Suite 350, Wilmette, Illinois. The lease term is January 1, 2018 through December 31, 2019. In addition, effective February 2019, the Company leases on a month-to-month basis additional office space in the same building.

During the three and nine months ended September 30, 2019, the Company recognized operating lease expense of $13,462 and $38,427, respectively. During the three and nine months ended September 30, 2018, the Company recognized operating lease expense of $10,451 and $33,036, respectively.

As a result of the adoption of ASU 2016-02, as amended by ASU 2018-10, as of September 30, 2019, the Company's condensed consolidated balance sheet includes (a) a lease liability of $7,559 in other current liabilities, and (b) a right-of-use asset of $7,559 in other current assets. Due to the adoption of the standard using the retrospective cumulative-effect adjustment method, there are no changes to our previously reported results prior to January 1, 2019. The effect on the operating lease expense was nominal as a result of the adoption of ASU 2016-02, as amended by ASU 2018-10.

The future lease commitments as presented below represent amounts for the Company's lease of its executive headquarters.

2019 (October 1 to December 31)	$7,559
Thereafter	-
Total future lease payments	$7,559

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 nor been required to defend any action related to its indemnification obligations. However, the Company may record charges in the future as a result of future claims against these indemnification obligations.

In accordance with its 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 capacities. There have been no claims to date.

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 condensed consolidated financial statements and related notes contained in this Quarterly Report.

Overview

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

We are aiming to start a Phase 3 clinical development program for our lead product candidate Validive® (clonidine mucobuccal tablet; clonidine MBT), in the first quarter of 2020. Validive is designed to be used prophylactically to reduce the incidence, delay the time to onset, and decrease the duration of severe oral mucositis ("SOM") in patients undergoing chemoradiotherapy for oropharyngeal cancer ("OPC"). Our mucobuccal tablet ("MBT") formulation is a novel delivery system for clonidine that allows for prolonged and enhanced local concentrations of clonidine in the regions of mucosal radiation damage in patients with OPC. Validive has been granted fast track designation in the U.S., orphan designation in the EU, and has global intellectual property patent protection through mid-2029 not accounting for possible extensions.

SOM typically arises in the immune tissue at the back of the tongue and throat, which comprise the oropharynx, and consists of acute severe tissue damage and pain that prevents patients from swallowing, eating and drinking. Validive stimulates the alpha-2 adrenergic receptor on macrophages (white blood cells that comprise the immune tissues of the oropharynx) suppressing pro-inflammatory cytokine expression. Validive exerts its effects locally in the mouth over a prolonged period of time through its unique MBT formulation. Patients who develop SOM are also at increased risk of developing late onset toxicities, including trismus (jaw, neck and throat spasms), dysphagia, and lung complications, which are often irreversible and lead to increased hospitalization and the need for further interventions sometimes years after completion of chemoradiotherapy. We believe that a reduction in the incidence and duration of SOM by Validive will have the potential to reduce treatment discontinuation and/or treatment delays potentially leading to improved survival outcomes and reducing or eliminating the long-term morbidities.

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

A pre-Phase 3 meeting with the FDA was held and based on the meeting discussion, a Phase 3 clinical protocol and accompanying statistical analysis plan ("SAP") was submitted to the FDA for review and comments. We have also received protocol assistance and advice on our Phase 3 protocol and SAP from the European Medicines Agency Committee on Human Medicinal Products ("EMA/CHMP"/"SAWP"). Based on comments and guidance provided by the FDA and EMA, we are aiming to start a Phase 3 clinical development program in the first quarter of 2020 to support registration. This program will consist of an adaptive design trial with an interim analysis planned for approximately twelve months after the first patient is dosed, and a confirmatory second trial planned to commence shortly after completion of this interim analysis.

Our second product candidate, camsirubicin (generic name for MNPR-201, GPX-150; 5-imino-13-deoxydoxorubicin), is a novel analog of doxorubicin which has been designed to reduce the cardiotoxic side effects generated by doxorubicin while retaining anti-cancer activity. Camsirubicin is not metabolized to the derivatives that are believed to be responsible for doxorubicin's cardiotoxic effects. A Phase 2 clinical trial for camsirubicin has been completed in patients with advanced (e.g. unresectable or metastatic) soft tissue sarcoma ("ASTS"). Average life expectancy for these patients is 12-15 months. In this study, 52.6% of patients demonstrated clinical benefit (partial response or stable disease), which was proportional to dose and consistently observed at higher cumulative doses of camsirubicin (>1000 mg/m^2). Camsirubicin was very well tolerated in this study and underscored the ability to potentially administer camsirubicin without restriction for cumulative dose in patients with ASTS. Doxorubicin is limited to a lifetime cumulative dose maximum of 450 mg/m^2, to minimize irreversible heart damage. Even if a patient is responding, they are pulled off doxorubicin treatment once this cumulative dose has been reached.

Based on encouraging clinical results to date, we plan to continue the development of camsirubicin in patients with ASTS in the first line setting, where the current first line treatment is doxorubicin. The aim is to administer camsirubicin without restricting cumulative dose, thereby potentially improving efficacy by keeping patients on treatment who are responding. In June 2019, we entered into a clinical collaboration with Grupo Español de Investigación en Sarcomas ("GEIS"). GEIS will lead a multi-country, randomized, open-label Phase 2 clinical trial evaluating camsirubicin head-to-head against doxorubicin as first line therapy in patients with ASTS. GEIS is an internationally renowned non-profit organization focused on the research, development and management of clinical trials for sarcoma, that has worked with many of the leading biotech and global pharmaceutical companies. Enrollment of the trial is expected to begin in the first quarter of 2020 and will include approximately 170 ASTS patients. The primary endpoint of the trial will be progression-free survival, with secondary endpoints including overall survival and incidence of treatment-emergent adverse events. In October 2019, the EMA's Committee for Orphan Medicinal Products adopted a positive opinion to grant orphan drug designation for camsirubicin for the treatment of soft tissue sarcoma in the EU.

MNPR-101 is a novel first-in-class humanized monoclonal antibody to the urokinase plasminogen activator receptor ("uPAR") for the treatment of advanced cancers. The IND-enabling work is nearly completed.

Revenues

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 commercial revenues from operations until we complete testing and development of one of our drug product candidates and obtain marketing approval or we sell, enter into a collaborative marketing arrangement, or out-license one of our drug product candidates to another party. See "Liquidity and Capital Resources".

Conversion of Preferred Stock to Common Stock

In March 2017, holders of a majority in interest of our Series A Preferred Stock and holders of a majority in interest of our Series Z Preferred Stock voted to adopt the Second Amended and Restated Certificate of Incorporation of the Company (the "Certificate of Incorporation"). When the Certificate of Incorporation took effect, each share of Series A Preferred Stock was automatically converted into 84 shares of common stock of the Company (a 1.2 for 1 conversion to common stock concurrent with a 70 for 1 stock split) and each share of Series Z Preferred Stock was automatically converted into 70 shares of common stock of the Company (a 1 for 1 conversion to common stock concurrent with a 70 for 1 stock split) and Series A Preferred Stock and Series Z Preferred Stock were eliminated (the "Conversion"). 100,000 shares of Series Z Preferred Stock were converted into 7,000,000 shares of common stock and 15,894 shares of Series A Preferred Stock were converted into 1,335,079 shares of common stock. All references in this "Management's Discussion and Analysis of Financial Conditions and Results of Operations" to common stock authorized, issued and outstanding and common stock options take into account the stock split that occurred as part of the Conversion.

Recently Issued and Adopted Accounting Pronouncements

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

Critical Accounting Policies and Use of Estimates

While 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, we believe the following accounting policies to be critical to the judgments and estimates used in the preparation of our condensed consolidated financial statements.

Research and Development Expenses

Research and development ("R&D") costs are expensed as incurred. Major components of R&D expenses include salaries and benefits of R&D staff, stock-based compensation expense related to stock options granted to our R&D team, fees paid to consultants and to the entities that conduct certain development activities on our behalf, and materials and supplies 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 R&D expenses. Clinical trial site costs related to patient enrollment are accrued and expensed as patients are entered into the trial. During the three and nine months ended September 30, 2019 and 2018, we had no clinical trials in progress.

The successful development of our product pipeline is uncertain. We cannot precisely or accurately 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 the product programs require;
- slower than expected progress in developing Validive, camsirubicin, MNPR-101 or other drug product candidates;
- higher than expected costs to produce, test, package, warehouse, and distribute our current and future drug product candidates;
- higher than expected costs for preclinical testing of our current or future acquired and/or in-licensed programs;
- increased future clinical trial costs, including requirements for increases in the number of patients, clinical sites, size, duration, testing requirements, or complexity of future clinical trials;
- future clinical trial results;
- higher than expected costs associated with attempting to obtain regulatory approvals, including without limitation additional costs caused by delays and additional clinical testing mandated by regulatory authorities;
- higher than expected personnel or other costs, such as adding personnel and engaging consultants;
- higher than expected costs in 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;
- lower benefits of our drug product candidates compared to other competitive therapies; and
- our ability to market, commercialize and achieve market acceptance sufficient to provide financial returns acceptable for future requirements and financial returns for our investors for any of our drug product candidates that we are developing or may develop in the future.

A change in the outcome of any of these and other additional 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 R&D expenses will increase in future periods as a result of current product candidates entering more expensive stages of development and additional current and future product candidate programs under development which will require increased personnel, increased consulting, future preclinical studies and clinical trial costs, including clinical drug product manufacturing and related costs.

General and Administrative Expenses

General and administrative expenses consist primarily of compensation and expenses for our executive personnel who perform corporate and administrative functions, stock-based compensation expense related to stock options granted to our executive team, legal and audit expenses, general and administrative consulting, board fees and expenses, patent legal and application fees, and facilities and related expenses. Future general and administrative expenses may also include: compensation and expenses related to the employment of personnel or the engagement of consultants in the areas of finance, human resources, information technology, business development, legal, compliance, investor relations and others, depreciation and amortization of general and administrative fixed assets, investor relations and annual meeting expense, and stock-based compensation granted to personnel who perform corporate and administrative functions. 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/auditing, investor relations and other expenses associated with being a public reporting company, costs incurred to seek and establish collaborations with respect to any of our drug product candidates, and costs required to find and acquire or license additional product candidates to expand our product pipeline.

Stock-Based Compensation

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

Stock-based compensation costs for stock options granted to our employees and non-employee directors are based on the fair value of the underlying option calculated using the Black-Scholes option-pricing model on the date of grant for stock options and recognized as expense on a straight-line basis over the requisite service period, which is the vesting period. Determining the appropriate fair value model and related assumptions requires judgment, including selecting methods for estimating the Company's future stock price volatility, forfeiture rates and expected term. The expected volatility rates are estimated based on the actual volatility of comparable public companies over recent historical periods of the same length as the expected term. We generally selected these companies based on reasonably comparable characteristics, including market capitalization, risk profiles, stage of corporate development and with historical share price information sufficient to meet the expected term of the stock-based awards. The expected term for stock options granted during the three and nine months ended September 30, 2019 and 2018 was estimated using the simplified method. Forfeitures are estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. We have not paid dividends and do not anticipate paying a cash dividend in future vesting periods and, accordingly, use an expected dividend yield of zero. The risk-free interest rate is based on the rate of U.S. Treasury securities with maturities consistent with the estimated expected term of the awards. Prior to January 1, 2019, the measurement of consultant stock-based compensation was subject to periodic adjustments as the underlying equity instruments vest. Since January 1, 2019, consultant stock-based compensation is valued on the grant date and is recognized as an expense over the period during which services are rendered.

Stock Option Plan

In April 2016, our Board and the preferred stockholders representing a majority in interest of our outstanding stock approved the Amended and Restated Monopar Therapeutics Inc. 2016 Stock Incentive Plan, as subsequently amended (the "Plan"), allowing us to grant up to an aggregate 700,000 shares of stock awards, stock options, stock appreciation rights and other stock-based awards to our employees, non-employee directors and consultants. In October 2017, our Board voted to increase the stock option pool to 1,600,000 shares, which subsequently was approved by our stockholders. Through February 2017, our Board granted to Board Members, our then acting chief financial officer, and our acting chief medical officer stock options to purchase up to an aggregate 555,520 shares of our common stock at an exercise price of $0.001 par value based upon third party valuations of our common stock.

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

In January 2018, we granted stock options to purchase up to 32,004 shares of our common stock to our acting chief medical officer at an exercise price of $6 per share based on the price per share at which our common stock was sold in our most recent private offering. In May 2018 and August 2018, we granted stock options to purchase up to 5,000 shares of our common stock each to two employees at an exercise price of $6 per share based on the price per share at which common stock was sold in the Company's most recent private offering.

In August 2018, we granted stock options to all four of our non-employee Board members, our chief executive officer, our chief scientific officer, and our chief financial officer to purchase up to an aggregate 425,300 shares of our common stock at an exercise price of $6 per share based on the price per share at which our common stock was sold in our most recent private offering. Vesting of such stock options commenced on October 1, 2018.

In December 2018, we granted stock options to purchase up to 20,000 shares of our common stock to our acting chief medical officer, at an exercise price of $6 per share based on the price per share at which our common stock was sold in our most recent private offering. Vesting of such stock options commenced on January 1, 2019.

Under the Plan, the per share exercise price for the shares to be issued upon exercise of an option is determined by a committee of our Board, except that the per share exercise price cannot be less than 100% of the fair market value per share on the grant date. In connection with our stock options issued in April 2016, December 2016, and February 2017, fair market value was established by our Plan Administrator using recently obtained third party valuation reports. In connection with our stock options issued in September 2017, November 2017, January 2018, May 2018, August 2018 and December 2018, fair market value was established by our Plan Administrator Committee based on the price per share at which common stock was sold in our most recent private offering. Options generally expire after ten years.

During the three months ended September 30, 2019 and 2018, we recognized $154,906 and $29,383, respectively, of employee and non-employee director stock-based compensation expense as general and administrative expenses and $67,347 and $32,147, respectively, as research and development expenses. During the nine months ended September 30, 2019 and 2018, we recognized $470,232 and $81,896, respectively, of employee and non-employee director stock-based compensation expense as general and administrative expenses and $202,012 and $108,873, respectively, as research and development expenses. The stock-based compensation expense is allocated on a departmental basis, based on the classification of the option holder. No income tax benefits have been recognized in our condensed consolidated statements of operations and comprehensive loss for stock-based compensation arrangements.

We recognize as an expense the fair value of options granted to persons (currently consultants) who are neither employees nor non-employee directors. Stock-based compensation expense for consultants which were recorded as research and development expense for the three and nine months ended September 30, 2019 was $20,704 and $62,121, respectively. Stock-based compensation expense for consultants which were recorded as research and development expense for the three and nine months ended September 30, 2018 was $31,714 and $105,571, respectively.

The fair value of options granted from inception toSeptember 30, 2019 was based on the Black-Scholes option-pricing model assuming the following factors: 4.7 to 6.2 years expected term, 55% to 85% volatility, 1.2% to 2.9% risk free interest rate and zero dividends. The expected term for options granted to date was estimated using the simplified method. There were no stock option grants during the three and nine months ended September 30, 2019. For the three and nine months ended September30, 2018 the weighted average grant date fair value was $4.34 per share and $4.25 per share, respectively. For the three months ended September 30, 2019 and 2018, the fair value of shares vested was $210,889 and $79,069, respectively. At September 30, 2019, the aggregate intrinsic value was approximately $3.3 million of which approximately $2.7 million was vested and approximately $0.6 million is expected to vest and the weighted average exercise price in aggregate was $2.99 which includes $2.02 for fully vested stock options and $4.59 for stock options expected to vest. At September 30, 2019, the unamortized unvested balance of stock-based compensation was approximately $1.5 million to be amortized over 2.5 years.

Stock option activity under the Plan for the nine months endedSeptember 30, 2019 was as follows:

		Options Outstanding	
	Options Available	Number of Options	Weighted-Average Exercise Price
Balances, January 1, 2019	494,104	1,105,896	$ 2.99
Granted	—	—	—
Exercised	—	—	—
Balances, September 30, 2019	494,104	1,105,896	2.99

A summary of options outstanding as ofSeptember 30, 2019 is shown below:

Exercise Prices	Number of Shares Subject to Options Outstanding	Weighted Average Remaining Contractual Term	Number of Shares Subject to Options Fully Vested and Exercisable	Weighted Average Remaining Contractual Term
$ 0.001	555,520	7.0 years	457,940	6.9 years
6.00	550,376	8.8 years	232,341	8.7 years
	1,105,896		690,281	

Results of Operations

Comparison of the Three and Nine Months Ended September 30, 2019 and September 30, 2018

The following table summarizes the results of our operations for the three and nine months ended September 30, 2019 and 2018:

	Three Months Ended September 30,			Nine Months Ended September 30,		
	(Unaudited)			*(Unaudited)*		
(in thousands)	**2019**	**2018**	**Variance**	**2019**	**2018**	**Variance**
Revenues	$ —	$ —	$ —	$ —	$ —	$ —
Research and development expenses	220	304	(84)	1,385	1,253	132
General and administrative expenses	539	364	175	1,714	1,151	563
Total operating expenses	759	668	91	3,099	2,404	695
Loss from operations	(759)	(668)	(91)	(3,099)	(2,404)	(695)
Interest income	23	28	(5)	81	67	14
Net loss	$ (736)	$ (640)	$ (96)	$ (3,018)	$ (2,337)	$ (681)

Research and Development Expenses

Research and Development ("R&D") expenses for the three and nine months ended September30, 2019 were approximately $220,000 and $1,385,000, compared to approximately $304,000 and $1,253,000, for the three and nine months ended September 30, 2018. This represents a decrease of approximately ($84,000) for the three-month variance, and an increase of approximately $132,000 for the nine-month variance detailed as follows:

	Three months ended September 30, 2019 versus three months ended September 30, 2018
R&D Expenses (in thousands)	
Increase in R&D consulting related to Validive and camsirubicin clinical trial preparation and related research	$ 52
Increase in employee stock-based compensation (non-cash) due to August 2018 stock option grant to officer	35
Reduction of previous accrual related to clinical materials manufacturing for Validive	(172)
Other, net	1
Net decrease in R&D expenses	$ (84)

	Nine months ended September 30, 2019 versus nine months ended September 30, 2018
R&D Expenses (in thousands)	
Increase in CRO and related fees in Q1 2019 in preparation for Validive Phase 3 clinical trial	$ 368
Increase in employee stock-based compensation (non-cash) due to August 2018 stock option grant to officer	93
Decrease in stock-based compensation (non-cash) to the Acting Chief Medical Officer due to longer vesting of stock options granted for 2019	(43)
Decrease in R&D compensation primarily due to the departure of our VP of Clinical Development in June 2018	(116)
Decrease in consulting fees for regulatory consultants utilized in 2018 in preparation for our meeting with the FDA regarding Validive planning not repeated in 2019	(169)
Other, net	(1)
Net increase in R&D expenses	$ 132

General and Administrative Expenses

General and Administrative ("G&A") expenses for the three and nine months ended September30, 2019 were approximately $539,000 and $1,714,000, compared to approximately $364,000 and $1,151,000, for the three and nine months ended September 30, 2018, which represent increases of approximately $175,000 and $563,000, for the for the three-month variance and nine-month variance, respectively. These increases were primarily attributed to:

	Three months ended September 30, 2019 versus three months ended September 30, 2018
G&A Expenses (in thousands)	
Increase in Board stock-based compensation (non-cash) due to August 2018 stock option grants to Board Members	$ 79
Increase in employee stock-based compensation (non-cash) due to August 2018 stock option grants to officers	46
Increase in Board fees for 2019 committee services	23
Increase in audit fees due to increased scope and accounting complexity	20
Other, net	7
Net increase in G&A expenses	$ 175

	Nine months ended September 30, 2019 versus nine months ended September 30, 2018
G&A Expenses (in thousands)	
Increase in Board stock-based compensation (non-cash) due to August 2018 stock option grants to Board Members	$ 244
Increase in employee stock-based compensation (non-cash) due to August 2018 stock option grants to officers	145
Increase in audit fees due to increased scope and accounting complexity	96
Increase in Board fees for 2019 committee services	66
Increase in G&A salaries and benefits due to 2019 cost of living adjustments and 2018 bonuses	40
Other, net	(28)
Net increase in G&A expenses	$ 563

Interest Income

Interest income for the three months ended September 30, 2019 compared to the three months ended September30, 2018 decreased by approximately $5,000 due to the decrease in bank balances resulting from the use of cash in operating activities. For the nine months ended September 30, 2019 compared to the nine months ended September 30, 2018 interest income increased by approximately $14,000, due to higher bank interest rates on our money market 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 $24.7 million as of September 30, 2019. 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 to enable the execution of our strategic plan. As a result, we anticipate that we will need to raise additional capital to fund our operations. We will seek to obtain needed capital through a combination of equity offerings, debt financings, strategic collaborations and grant funding. From our inception, through November 12, 2019, 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) related to the purchase of camsirubicin, and the shared expenses of our former Cancer Research UK collaboration. As of November 12, 2019, we have received net proceeds of approximately $4.7 million (net of issuance costs) from the sale of our preferred stock which have been converted into common stock and we have sold 789,674 shares of our common stock for net proceeds of approximately $4.7 million. We anticipate that the available funds as of November 12, 2019 will fund our minimal required operations through December 2020.

We invest our cash equivalents in a money market account.

Contribution to Capital

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

Cash Flows

The following table provides information regarding our cash flows for the nine months ended September30, 2019 and 2018.

Cash Flows (in thousands)	**Nine months ended September 30, *(Unaudited)***		
	2019	**2018**	**Nine months ended September 30, 2019 versus nine months ended September 30, 2018**
Cash used in operating activities	$ (2,349)	$ (2,161)	$ (188)
Cash used in financing activities	(39)	—	(39)
Effect of exchange rates on cash and cash equivalents	(10)	(3)	(7)
Net change in cash and cash equivalents	$ (2,398)	$ (2,164)	$ (234)

During the nine months ended September 30, 2019, we had a net cash outflow of approximately $(2,398,000) primarily due to operating activities compared to net cash outflow of approximately $(2,164,000) due primarily to operating activities during the nine months ended September 30, 2018.

Cash Flow Used in Operating Activities

The increase of approximately $188,000 in cash flow used in operating activities during the nine months ended September 30, 2019, compared to the nine months ended September 30, 2018, was primarily a result of increased R&D and G&A cash operating expenses (excludes non-cash stock compensation) as discussed above.

Cash Flow Used in Investing Activities

There was no cash flow used in investing activities for the nine months ended September30, 2019 and 2018.

Cash Flow Used in Financing Activities

The increase of approximately $39,000 in cash flow used in financing activities for the nine months ended September30, 2019 compared to the nine months ended September 30, 2018, was primarily a result of deferred offering costs incurred in 2019 related to a future financing.

Future Funding Requirements

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

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

- advance the clinical development and execute the regulatory strategy for Validive;
- continue the clinical development of camsirubicin;
- continue the preclinical and potentially enter 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 clinical trials;
- establish or purchase the services of a sales, marketing and distribution infrastructure to commercialize any products for which we may obtain marketing approval;
- develop our manufacturing capabilities or establish a reliable, high quality supply chain sufficient to support our clinical requirements and to provide sufficient capacity to launch and grow the sales of any product for which we obtain marketing approval; and
- add or contract for required operational, financial and management information systems and capabilities and other specialized expert personnel to support our drug product candidate development and planned commercialization efforts.

We anticipate that the funds available as of November 12, 2019 will fund our minimal operations through at least December 2020. We have based this estimate on assumptions that may prove to be wrong, and we could use our available capital resources sooner than we currently expect. Because of the numerous risks and uncertainties associated with the development and commercialization of our drug product candidates, and the extent to which we enter into collaborations with third parties to participate in the development and commercialization of our drug product candidates, we are unable to accurately estimate with high reliability the amounts and timing required for increased capital outlays and operating expenditures associated with our current and anticipated drug product candidate development programs. Our future capital requirements will depend on many factors, including:

- the progress of regulatory interactions and clinical development of Validive;
- the progress of clinical development and regulatory outcomes of camsirubicin;
- the progress of preclinical and clinical development of MNPR-101;
- the number and characteristics of other drug product candidates that we may license, acquire or otherwise pursue;
- the scope, progress, timing, cost and results of research, preclinical development and clinical trials of current and future drug product candidates;
- the costs, timing and outcomes of seeking and obtaining FDA and international regulatory approvals;
- the costs associated with manufacturing/quality requirements 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 or contract for additional management, administrative, scientific, medical, sales and marketing, and manufacturing/quality and other specialized personnel or external expertise;
- the effect of competing products or new therapies that may limit market penetration or prevent the introduction of our drug product candidates or reduce the commercial potential of our product portfolio;
- our need to implement additional 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 the first quarter of 2020 onward for: CRO and clinical site fees for the Validive Phase 3 clinical trial; process development and manufacturing costs of camsirubicin in preparation for the GEIS Phase 2 clinical trial; collaboration milestone fees; employee compensation and consulting fees as a result of hiring additional employees and consultants to support the planning and initiation of our Validive Phase 3 clinical development program; 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 and related expenses; however, our spending could be significantly accelerated in the first quarter of 2020 and onward if additional drug product candidates are acquired and enter clinical development. In this event, we may be required to expand our management team, and pay much higher contract manufacturing costs, contract research organization fees, other clinical development costs or insurance costs that are not currently projected. We, under this scenario, plan to pursue raising additional capital over the next 12 – 24 months. The anticipated operating cost increases in the first quarter of 2020 onward are expected to be primarily driven by the funding of our planned Validive Phase 3 clinical development program and in support of the GEIS Phase 2 clinical trial of camsirubicin.

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 current stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect our current stockholders' rights. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise additional funds through marketing and distribution arrangements or other collaborations, strategic alliances or licensing arrangements with other parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or drug product candidates or grant licenses on terms that may not be favorable to us, which will reduce our future returns and affect our future operating flexibility. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate our pipeline product development or commercialization efforts or grant rights to others to develop and market drug product candidates that we would otherwise prefer to develop and market ourselves.

Contractual Obligations and Commitments

Development and Collaboration Agreements

Onxeo S.A.

In June 2016, we executed an agreement with Onxeo S.A., a French public company, which gave us the exclusive option to license (on a world-wide exclusive basis) Validive (clonidine 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 from 5% to 10% on net sales. In September 2017, we exercised the option to license Validive from Onxeo for $1 million, but as of November 12, 2019, we have not been required to pay Onxeo any other funds under the agreement. We anticipate the need to raise significant funds to support the completion of clinical development and marketing approval 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.

Grupo Español de Investigación en Sarcomas ("GEIS")

In June 2019, we executed a clinical collaboration with GEIS for the development of camsirubicin in patients with advanced soft tissue sarcoma ("ASTS"). GEIS will be the study sponsor and will lead a multi-country, randomized, open-label Phase 2 clinical trial to evaluate camsirubicin head-to-head against doxorubicin in patients with ASTS. Enrollment of the trial is expected to begin in the first quarter of 2020 and will include approximately 170 ASTS patients. We will provide study drug and supplemental financial support for the clinical trial averaging approximately $1 million to $2 million per year. As of November 12, 2019, we have only paid a nominal amount of financial support. We can terminate the agreement by providing GEIS with advance notice, and without affecting the Company's rights and ownership to any intellectual property or clinical data.

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 November 12, 2019, we had not reached any milestones and had not been required to pay XOMA Ltd. any funds under this license agreement.

Service Providers

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

Office Lease

Effective January 1, 2018, we leased office space in the Village of Wilmette, Illinois for $2,519.50 per month for 24 months. This office space houses our current headquarters. In February 2019, we leased additional office spaces on a month-to month basis at our headquarters and we anticipate that we will lease additional permanent space in the future as we hire additional personnel.

Legal Contingencies

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

Indemnification

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

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

Off-Balance Sheet Arrangements

To date, we have not had any off-balance sheet arrangements, as defined under the 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 September 30, 2019, 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 comprehensive loss and cash flows as of, and for, the periods presented.

There have been no changes in our internal control over financial reporting during the nine months ended September 30, 2019 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 1A. Risk Factors

There have been no material changes in information regarding our risk factors as described in Item 1A of our Annual Report on Form 10-K as filed with the SEC on February 26, 2019.

Item 6. Exhibits

The following exhibits are filed as part of this Quarterly Report.

Exhibit	Document	Incorporated by Reference From:
31.1	Certification of Chandler Robinson, Chief Executive Officer	Filed herewith
31.2	Certification of Kim Tsuchimoto, Chief Financial Officer	Filed herewith
32.1	Certification of Chandler Robinson, Chief Executive Officer and Kim Tsuchimoto, Chief Financial Officer	Filed herewith
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	

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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: November 12, 2019

By: /s/ Chandler D. Robinson
Name: Chandler D. Robinson
Title: Chief Executive Officer and Director
(Principal Executive Officer)

MONOPAR THERAPEUTICS INC.

Dated: November 12, 2019

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

Exhibit 31.1

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 financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

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

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

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

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

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

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

Date: November 12, 2019

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

Exhibit 31.2

CERTIFICATION

I, Kim R. Tsuchimoto, certify that:

1. I have reviewed this 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 financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

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

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

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

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

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

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

Date: November 12, 2019

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

Exhibit 32.1

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

AS ADOPTED PURSUANT TO

SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report on Form 10-Q of Monopar Therapeutics Inc. (the Company) for the three and nine months ended September 30, 2019, 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
November 12, 2019

/s/ Kim R. Tsuchimoto
Kim R. Tsuchimoto
Chief Financial Officer
November 12, 2019

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.