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 June 30, 2020

☐ **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: : 001-39070

MONOPAR THERAPEUTICS INC.

(Exact name of registrant as specified in its charter)

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

(847) 388-0349

(Registrant's telephone number, including area code)

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

Title of each class	**Trading Symbol(s)**	**Name of each exchange on which registered**
Common Stock, $0.001 par value	**MNPR**	**The Nasdaq Stock Market LLC (Nasdaq Capital Market)**

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

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 July 31, 2020, is set forth below:

Class	Number of shares outstanding
Common Stock, par value $0.001 per share	10,736,396

MONOPAR THERAPEUTICS INC.
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Forward-Looking Statements

This Quarterly Report on Form 10-Q contains "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933, as amended (the "Act") and Section 21E of the Securities Exchange Act of 1934, as amended. All statements other than statements of historical facts included in this Quarterly Report on Form 10-Q are forward-looking statements. The words "hopes," "believes," "anticipates," "plans," "seeks," "estimates," "projects," "expects," "intends," "may," "could," "should," "would," "will," "continue," and similar expressions are intended to identify forward-looking statements. The following uncertainties and factors, among others, could affect future performance and cause actual results to differ materially from those matters expressed in or implied by forward-looking statements:

- our ability to raise sufficient funds by mid-2021 in order for us to start the Phase 3 portion of our Validive Phase 2b/3 clinical trial and thereafter in order to complete the trial, support further development of camsirubicin in and beyond the Phase 2 trial, support further development of potential radio-immuno-therapeutics to treat severe COVID-19 (patients with SARS-CoV-2 infection) and generally to support our current and any future product candidates through completion of clinical trials, approval processes and, if applicable, commercialization;
- our ability to find a suitable pharmaceutical partner to further our development efforts, if we are unable to raise sufficient additional financing;
- risks and uncertainties associated with our research and development activities, including our clinical trials;
- estimated timeframes for our clinical trials and regulatory reviews for approval to market products;
- plans to research, develop and commercialize our current and future product candidates;
- the rate and degree of market acceptance and competitive clinical efficacy and safety of any products for which we receive marketing approval;
- the difficulties of commercialization, marketing and manufacturing capabilities and strategy;
- uncertainties of intellectual property position and strategy;
- challenging future financial performance;
- the risks inherent in our estimates regarding expenses, capital requirements and need for additional financing;
- the uncertain impact of government laws and regulations;
- our ability to attract and retain key personnel;
- the impact of the COVID-19 pandemic on our ability to advance our clinical programs and raise additional financing; and
- uncertainty of financial and operational projections.

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

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.

PART I

FINANCIAL INFORMATION

Item 1. Financial Statements

Monopar Therapeutics Inc.

Condensed Consolidated
Balance Sheets
(Unaudited)

	June 30, 2020	December 31, 2019*
Assets		
Current assets:		
Cash and cash equivalents	$ 12,546,189	$ 13,213,929
Other current assets	183,416	15,711
Total current assets	12,729,605	13,229,640
Other non-current assets	73,050	122,381
Total assets	$ 12,802,655	$ 13,352,021
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable, accrued expenses and other current liabilities	$ 525,748	$ 724,165
Current portion of bank loan	47,379	—
Total current liabilities	573,127	724,165
Long-term liabilities:		
Non-current portion of bank loan	75,021	—
Total long-term liabilities	75,021	—
Total liabilities	648,148	724,165
Commitments and contingencies (Note 6)		
Stockholders' equity:		
Common stock, par value of $0.001 per share, 40,000,000 authorized, 10,735,973 and 10,587,632 shares issued and outstanding at June 30, 2020 and December 31, 2019, respectively	10,736	10,587
Additional paid-in capital	40,572,598	38,508,825
Accumulated other comprehensive loss	(11,554)	(10,970)
Accumulated deficit	(28,417,273)	(25,880,586)
Total stockholders' equity	12,154,507	12,627,856
Total liabilities and stockholders' equity	$ 12,802,655	$ 13,352,021

* 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 June 30,		Six Months Ended June 30,	
	2020	**2019**	**2020**	**2019**
Operating expenses:				
Research and development	$ 832,503	$ 329,294	$ 1,176,910	$ 1,164,894
General and administrative	631,629	602,815	1,423,236	1,174,524
Total operating expenses	1,464,132	932,109	2,600,146	2,339,418
Loss from operations	(1,464,132)	(932,109)	(2,600,146)	(2,339,418)
Other income:				
Interest income, net	18,322	26,409	63,459	57,483
Net loss	(1,445,810)	(905,700)	(2,536,687)	(2,281,935)
Other comprehensive income:				
Foreign currency translation gain (loss)	3,457	1,067	(584)	(1,060)
Comprehensive loss	$ (1,442,353)	$ (904,633)	$ (2,537,271)	$ (2,282,995)
Net loss per share:				
Basic and diluted	$ (0.14)	$ (0.10)	$ (0.24)	$ (0.25)
Weighted average shares outstanding:				
Basic and diluted	10,648,285	9,291,421	10,628,635	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		Additional Paid-in Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balance at January 1, 2019	9,291,421	$ 9,291	$ 28,567,221	$ (2,396)	$ (21,655,712)	$ 6,918,404
Stock-based compensation (non-cash)	—	—	233,776	—	—	233,776
Net loss	—	—	—	—	(1,376,235)	(1,376,235)
Accumulated other comprehensive loss	—	—	—	(2,127)	—	(2,127)
Balance at March 31, 2019	9,291,421	9,291	28,800,997	(4,523)	(23,031,947)	5,773,818
Stock-based compensation (non-cash)	—	—	257,633	—	—	257,633
Net loss	—	—	—	—	(905,700)	(905,700)
Accumulated other comprehensive gain	—	—	—	1,067	—	1,067
Balance at June 30, 2019	9,291,421	$ 9,291	$ 29,058,630	$ (3,456)	$ (23,937,647)	$ 5,126,818

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balance at January 1, 2020	10,587,632	$ 10,587	$ 38,508,825	$ (10,970)	$ (25,880,586)	$ 12,627,856
Issuance of common stock under a Capital on Demand™ Sales Agreement with JonesTrading Institutional Services LLC, net of commissions and fees of $16,284	33,903	34	526,109	—	—	526,143
Issuance of common stock to non-employee directors pursuant to vested restricted stock units	1,288	1	(1)	—	—	—
Stock-based compensation (non-cash)	—	—	338,497	—	—	338,497
Offering costs	—	—	(2,161)	—	—	(2,161)
Net loss	—	—	—	—	(1,090,877)	(1,090,877)
Accumulated other comprehensive loss	—	—	—	(4,041)	—	(4,041)
Balance at March 31, 2020	10,622,823	10,622	39,371,269	(15,011)	(26,971,463)	12,395,417
Issuance of common stock under a Capital on Demand™ Sales Agreement with JonesTrading Institutional Services LLC, net of commissions and fees of $29,425	111,858	113	950,577	—	—	950,690
Issuance of common stock to non-employee directors pursuant to vested restricted stock units	1,292	1	(1)		—	—
Stock-based compensation (non-cash)	—	—	367,358	—	—	367,358
Offering costs	—	—	(116,605)			(116,605)
Net loss	—	—	—	—	(1,445,810)	(1,445,810)
Accumulated other comprehensive gain	—	—	—	3,457	—	3,457
Balance at June 30, 2020	10,735,973	$ 10,736	$ 40,572,598	$ (11,554)	$ (28,417,273)	$ 12,154,507

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

Monopar Therapeutics Inc.

Condensed Consolidated
Statements of Cash Flows
(Unaudited)

	Six Months Ended June 30,	
	2020	**2019**
Cash flows from operating activities:		
Net loss	$ (2,536,687)	$ (2,281,935)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense (non-cash)	705,855	491,409
Changes in operating assets and liabilities, net		
Other current assets	(122,258)	(13,902)
Accounts payable, accrued expenses and other current liabilities	(167,954)	68,721
Net cash used in operating activities	(2,121,044)	(1,735,707)
Cash flows from financing activities:		
Cash proceeds from the sales of common stock under a Capital on Demand™ Sales Agreement with JonesTrading Institutional Services LLC, net of cash commissions and fees of $43,999	1,421,569	—
Offering costs	(89,521)	(26,177)
PPP forgivable bank loan	122,400	—
Net cash provided by (used in) financing activities	1,454,448	(26,177)
Effect of exchange rates	(1,144)	(1,060)
Net decrease in cash and cash equivalents	(667,740)	(1,762,944)
Cash and cash equivalents at beginning of period	13,213,929	6,892,772
Cash and cash equivalents at end of period	$ 12,546,189	$ 5,129,828

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

MONOPAR THERAPEUTICS INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

June 30, 2020

Note 1 - Nature of Business and Liquidity

Nature of Business

Monopar Therapeutics Inc. ("Monopar" or the "Company") is a clinical-stage biopharmaceutical company focused on developing proprietary therapeutics designed to extend life or improve quality of life for cancer patients. Monopar currently has three compounds in development: Validive® (clonidine mucobuccal tablet; clonidine MBT), a Phase 2b/3-ready, first-in-class mucoadhesive buccal 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 selective analog of doxorubicin engineered specifically to retain anticancer activity while minimizing toxic effects on the heart; and a preclinical stage uPAR targeted antibody, MNPR-101, for advanced cancers and severe COVID-19.

Liquidity

The Company has incurred an accumulated deficit of approximately $28.4 million as of June 30, 2020. To date, the Company has primarily funded its operations with the net proceeds from the Company's initial public offering of its common stock on Nasdaq, private placements of convertible preferred stock and of common stock, from the cash provided in the camsirubicin asset purchase transaction, from sales of its common stock in the public market under a Capital on Demand™ Sales Agreement and from a forgivable bank loan. Management believes that currently available resources will provide sufficient funds to enable the Company to meet its planned obligations past September 2021. 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 collaborative research agreements. There can be no certainty that future financing or collaborative research agreements will occur.

In December 2019, a novel strain of coronavirus ("COVID-19") surfaced in China and by March 2020 COVID-19 was designated a global pandemic, resulting in government-mandated travel restrictions and temporary shut-downs of non-essential businesses in many states in the United States. The Company is able to remain open but has allowed their employees to work from home, if required by local authorities. Due to the volatility of the stock markets resulting from travel restrictions and indeterminate but temporary business shut-downs, the Company faces challenges in raising substantial cash in the near-term. In response to the current COVID-19 pandemic and its effects on clinical trials, Monopar has modified the original adaptive design Phase 3 clinical trial for its lead product candidate, Validive, to be a Phase 2b/3 clinical trial to better fit the types of trials which can enroll patients in the current environment. This modification will allow the Company to initiate the clinical trial without requiring near-term financing. The decision to proceed to the Phase 3 portion of the clinical trial without a delay will largely be dependent on the Company's cash position closer to that time, anticipated to be in the second half of 2021. To initiate and complete the Phase 3 portion of the clinical trial, Monopar will require additional funding in the millions or tens of millions of dollars (depending on if the Company has consummated a collaboration or partnership or neither for Validive), which it is planning to pursue in the next 12 months. Due to many uncertainties, the Company is unable to estimate the pandemic's financial impact or duration at this time, or its potential impact on the Company's planned clinical trials.

Note 2 - Significant Accounting Policies

Basis of Presentation

These condensed consolidated financial statements include the financial results of Monopar Therapeutics Inc., 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.

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 June 30, 2020 and as of December 31, 2019, the Company's condensed consolidated results of operations and comprehensive loss for the three and six months ended June 30, 2020 and 2019, and the Company's condensed consolidated cash flows for the six months ended June 30, 2020 and 2019. 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 2020 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, 2019, included in the Company's Annual Report on Form 10-K filed with the United States Securities and Exchange Commission (the "SEC") on March 27, 2020.

Functional Currency

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

Comprehensive Loss

Comprehensive loss represents net loss plus any gains or losses not reported in the statements of operations and comprehensive loss, such as foreign currency translations gains and losses that are typically reflected on the 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 applies Accounting Standards Codification 205-40 ("ASC 205-40"), *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. ASC 205-40 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 July 2020, the Company analyzed its cash requirements through September 2021 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 a maturity of 90 days or less on the date of purchase to be cash equivalents. Cash equivalents as of June 30, 2020 and 2019 consisted of one money market account.

Deferred Offering Costs

Deferred offering costs represent legal, auditing, travel and filing fees 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 payments to development collaborators in excess of actual expenses incurred by the collaborator, measured at the end of each reporting period. Prepayments also include insurance premiums and software costs of $10,000 or more that are expensed monthly over the life of the contract. Prepaid expenses are reflected on the Company's balance sheets as other current assets.

Bank Loans

In May 2020, the Company applied for and received a bank loan pursuant to the Paycheck Protection Program ("PPP") established pursuant to the Coronavirus Aid, Relief, and Economic Security Act, as administered by the U.S. Small Business Administration ("SBA").

The SBA will forgive the bank loan pursuant to the PPP, if certain conditions are met, namely the bank loan must be used primarily for payroll during the 24-week period following receipt of the loan, without significant staffing reductions during that period. The Company believes it is eligible and intends to apply for loan forgiveness in August 2020 when the bank is able to process SBA loan forgiveness application. Should the bank loan not be forgiven, the Company would be required to pay 1% annual interest on the loan with principal and interest payments beginning approximately seven months after receipt of the loan with payments over 18 months. The Company has recorded the PPP loan on the balance sheet as of June 30, 2020 as current (due within 12 months) and non-current portions of bank loan.

Concentration of Credit Risk

Financial instruments that potentially subject the Company to concentration of credit risk consist of cash and cash equivalents. The Company maintains cash and cash equivalents at two reputable financial institutions. As of June 30, 2020, the balance at one financial institution was in excess of the $250,000 Federal Deposit Insurance Corporation ("FDIC") insurable limit. The Company has not experienced any losses on its deposits since inception and management believes the Company is not exposed to significant risks with respect to these financial institutions.

Fair Value of Financial Instruments

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

ASC 820, *Fair Value Measurements and Disclosures*, as amended, addresses 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.

The standard establishes a hierarchy for inputs used in measuring fair value that maximizes the use of observable inputs and minimizes the use of unobservable inputs by requiring that the most observable inputs be used when available. Observable inputs reflect assumptions market participants would use in pricing an asset or liability based on market data obtained from independent sources. Unobservable inputs reflect a reporting entity's pricing an asset or liability developed based on the best information available 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 six months ended June 30, 2020 and the year ended December 31, 2019. The following table presents the assets and liabilities 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 at June 30, 2020 and December 31, 2019.

Assets and Liabilities Measured at Fair Value on a Recurring Basis

June 30, 2020	Level 1	Total
Assets		
Cash equivalents[1]	$ 12,397,916	$ 12,397,916
Total	$ 12,397,916	$ 12,397,916

December 31, 2019	Level 1	Total
Assets		
Cash equivalents[1]	$ 13,083,536	$ 13,083,536
Total	$ 13,083,536	$ 13,083,536

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

Net Loss per Share

Net loss per share for the three and six months ended June 30, 2020 and 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 six months ended June 30, 2020 and 2019 is calculated by dividing net loss by the weighted-average shares of the sum of a) weighted average common stock outstanding (10,648,285 and 10,628,635 shares for the three and six months ended June 30, 2020, respectively; 9,291,421 shares for the three and six months ended June 30, 2019) and b) potentially dilutive shares of common stock (such as stock options and restricted stock units) outstanding during the period. As of June 30, 2020 and 2019, potentially dilutive securities included

stock-based awards to purchase up to 1,296,573 and 1,105,896 shares of the Company's common stock, respectively. For the three and six months ended June 30, 2020 and 2019, 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, service providers, 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 six months ended June 30, 2020 and 2019, the Company had no clinical trials in progress.

Collaborative Agreements

The Company and its collaborative partners are 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 six months ended June 30, 2020 and 2019, 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 six months ended June 30, 2020 and 2019, 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.

Income Taxes

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 carryforwards. Deferred income tax assets and liabilities are measured using the currently enacted tax rates that apply to taxable income in effect for the years in which those tax assets and liabilities are expected to be realized or settled.

The Company regularly assesses the likelihood that its deferred income tax assets will be realized from recoverable income taxes or recovered from future taxable income. To the extent that the Company believes any amounts are more likely 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 determines deferred income tax assets that were previously determined to be unrealizable are now realizable, the respective valuation allowance would be reversed, resulting in an adjustment to earnings in the period such determination is made.

Internal Revenue Code Section 382 ("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. To date, the Company has not conducted a Section 382 study, however, because the Company will continue to raise significant amounts of equity in the coming years, the Company expects that Section 382 will limit the Company's usage of NOLs in the future.

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. As a result, the Company recorded a full valuation allowance as of June 30, 2020 and December 31, 2019. 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 six months ended June 30, 2020 and 2019, 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. In addition, the Company is subject to local tax laws of France and Australia. 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, 2019, 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 June 30, 2020. 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 and restricted stock unit ("RSU") 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 or the closing stock price on the date of grant in the case of RSUs.

Stock-based compensation costs for awards granted to employees and non-employee directors are based on the fair value of the underlying instrument calculated using the Black-Scholes option-pricing model on the date of grant for stock options and using the closing stock price on the date of grant for RSUs 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 vested and was recognized as an expense over the period in which services were rendered. 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 Accounting Standards Updates ("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. The Company adopted this ASU and has determined that it had no material effect on its condensed consolidated financial statements and footnote disclosures for the three and six months ended June 30, 2020.

Note 3 - Capital Stock

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 each director nominated to the board and one vote per share 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.

Sales of Common Stock

On December 23, 2019, the Company closed the initial public offering of its common stock. The Company sold 1,277,778 shares of its common stock at a public offering price of $8.00 per share pursuant to an underwriting agreement with JonesTrading Institutional Services, LLC ("JonesTrading"). The Company paid JonesTrading a customary commission and reimbursement of a portion of their legal fees incurred in connection with the offering, which in aggregate totaled approximately $0.7 million. Net proceeds on a cash basis were approximately $9.4 million, after deducting underwriting discounts and accrued, unpaid offering expenses. The Company had incurred and paid prior to the initial public offering approximately $0.6 million of fundraising expenses which were capitalized on the Company's balance sheet as deferred offering costs and were reclassified as offering expenses (a contra-equity balance sheet account) upon the closing of the Company's initial public offering. After deducting previously paid offering expenses of approximately $0.6 million, the accrual basis net proceeds were $8.8 million as reported on the Company's consolidated statement of stockholders' equity as of December 31, 2019 included in the Company's Annual Report on Form 10-K filed with the SEC on March 27, 2020. The Company's common stock began trading on the Nasdaq Capital Market on December 19, 2019.

On January 13, 2020, the Company entered into a Capital on Demand™ Sales Agreement with JonesTrading, as sales agent, pursuant to which Monopar may offer and sell (at its discretion), from time to time, through or to JonesTrading shares of Monopar's common stock, having an aggregate offering price of up to $19.7 million. Pursuant to this agreement, as of June 30, 2020, the Company sold 145,761 shares of its common stock at an average gross price per share of $10.45 for net proceeds of $1,476,833, after commissions and fees of $45,709.

As of June 30, 2020, the Company had 10,735,973 shares of common stock issued and outstanding.

Note 4 - Stock Incentive Plan

In April 2016, the Company's Board of Directors and stockholders representing a majority of the Company's outstanding stock at that time, approved the 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-based awards in the form of stock options, restricted stock units, stock appreciation rights and other stock-based awards to employees, non-employee directors and consultants. In October 2017, the Company's Board of Directors voted to increase the stock award pool to 1,600,000 shares of common stock, which subsequently was approved by the Company's stockholders. In April 2020, the Company's Board of Directors voted to increase the stock award pool to 3,100,000 (and increase of 1,500,000 shares of common stock), which was approved by the Company's stockholders in June 2020.

In January 2020, the Company's Plan Administrator Committee granted two new hire stock option grants and a consultant stock option grant to the Company's acting chief medical office, in aggregate, for the purchase of 15,125 shares of the Company's common stock with exercise prices ranging from $16.80 to $17.75. The stock options have a 10-year term and vest over 1 to 4 years.

In February 2020, the Company's Plan Administrator Committee (with regards to non-officer employees) and the Company's Compensation Committee, as ratified by the Board of Directors (in the case of officers and non-employee directors) granted an aggregate of 189,985 stock options with exercise prices ranging from $12.93 to $14.35 as annual equity grants to executive officers, non-employee directors and staff. All stock options have a 10-year term and vest over 1 to 4 years. The annual equity grants also included an aggregate 45,722 restricted stock units to executive officers, non-employee directors and staff which vest over 1 to 4 years.

In May 2020, the Company's Plan Administrator Committee granted stock option grants to a new hire and an employee, in aggregate, for the purchase of 4,000 shares of the Company's common stock with exercise prices ranging from $7.61 to $7.66. All stock options have a 10-year term and vest over 4 years.

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, recent private financings or the Company's closing prices on Nasdaq since the Company's listing on December 19, 2019. Stock options generally expire after 10 years.

Stock option activity under the Plan was as follows:

	Options Outstanding	
	Number of Options	Weighted-Average Exercise Price
		$
Balances at January 1, 2019	**1,105,896**	**2.99**
Granted	—	—
Forfeited	—	—
Exercised	(18,433)	5.97
Balances at December 31, 2019	**1,087,463**	**2.94**
Granted[(1)]	209,110	14.42
Forfeited	—	—
Exercised	—	—
Balances at June 30, 2020	**1,296,573**	4.79

(1) 209,110 options vest as follows: options to purchase up to 180,401 shares of the Company's common stock vest 6/48ths on the six-month anniversary of grant date and 1/48th per month thereafter; options to purchase up to 22,584 shares of the Company's common stock vest quarterly over one year; and options to purchase up to 6,125 shares of the Company's common stock vest monthly over one year. The exercise prices per share of the 209,110 options are as follows: for 186,985 options $14.35; for 9,000 options $17.75; for 6,125 options $16.80; for 3,000 options $12.93; for 2,000 options $7.66 and for 2,000 options $7.61.

A summary of options outstanding as of June 30, 2020 is shown below:

Exercise Prices	Number of Shares Subject to Options Outstanding	Weighted-Average Remaining Contractual Term in Years	Number of Shares Subject to Options Fully Vested and Exercisable	Weighted-Average Remaining Contractual Term in Years
$ 0.00-$5.00	555,420	6.21 years	509,500	6.17 years
$ 5.01-$10.00	536,043	8.02 years	328,154	7.97 years
$ 10.01-$15.00	189,985	9.59 years	32,218	9.59 years
$ 15.01-$20.00	15,125	9.55 years	3,063	9.59 years
	1,296,573	7.49 years	872,935	6.99 years

Restricted stock unit activity under the Plan was as follows:

	Restricted Stock Units	Weighted-Average Grant Date Fair Value per Unit
Unvested balance at January 1, 2020	—	$ —
Granted	45,722	12.93
Vested	(2,580)	12.93
Forfeited	—	—
Unvested Balance at June 30, 2020	**43,142**	**12.93**

During the three months ended June 30, 2020 and 2019, the Company recognized $248,889 and $164,600, respectively, of employee and non-employee director stock-based compensation expense as general and administrative expenses and $100,898 and $72,324, respectively, as research and development expenses. During the six months ended June 30, 2020 and 2019, the Company recognized $469,655 and $315,326, respectively, of employee and non-employee director stock-based compensation expense as general and administrative expenses and $201,069 and $134,665, respectively, as research and development expenses. The stock-based compensation expense is allocated on a departmental basis, based on the classification of the 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 months ended June 30, 2020 and 2019 was $17,571 and $20,708, and for the six months ended June 30, 2020 and 2019 $35,131 and $41,418, respectively.

The fair value of options granted from inception to June 30, 2020 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, 0.4% 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 4,000 and 209,110 stock option grants during the three and six months ended June 30, 2020, respectively. For the three and six months ended June 30, 2020 the weighted average grant date fair value was $5.43 per share and $9.22 per share, respectively. There were no stock option grants during the three and six months ended June 30, 2019. For the three months ended June 30, 2020 and 2019, the fair value of shares vested was $0.4 million and $0.3 million, respectively. For the six months ended June 30, 2020 and 2019, the fair value of shares vested was $0.6 million and $0.5 million, respectively. At June 30, 2020, the aggregate intrinsic value of outstanding stock options was approximately $4.9 million of which approximately $4.3 million was vested and approximately $0.6 million is expected to vest (representing options to purchase up to 423,638 shares of the Company's common stock), and the weighted-average exercise price in aggregate was $4.79 which includes $2.84 for fully vested stock options and $8.79 for stock options expected to vest. At June 30, 2020, the unamortized unvested balance of stock-based compensation was approximately $3.0 million to be amortized over 2.93 years.

Note 5 - Related Party Transactions

In December 2019, Tactic Pharma, LLC ("Tactic Pharma"), purchased 125,000 shares of Monopar's common stock in Monopar's initial public offering at $8 per share for an aggregate $1 million, at which time its beneficial ownership in Monopar was 41.6%. As of June 30, 2020, Tactic Pharma beneficially owned 41.0% of Monopar's common stock.

During the three and six months ended June 30, 2020 and 2019, the Company was governed by six members of its Board of Directors ("Related Parties"). The Related Parties are also current common stockholders (owning approximately an aggregate 3% of the common stock outstanding as of June 30, 2020). None of the Related Parties received compensation other than market-rate salary, market-rate stock-based compensation and benefits and performance-based bonus or in the case of non-employee directors, market-rate Board fees and market-rate stock-based compensation. Three of the Board members are also Managing Members of Tactic Pharma as of June 30, 2020. Chandler D. Robinson is the Company's Co-Founder, Chief Executive Officer, common stockholder, Managing Member of Tactic Pharma, former Manager of the predecessor LLC, Manager of CDR Pharma, LLC and Board member of Monopar as a C Corporation. Andrew P. Mazar is the Company's Co-Founder, Executive Vice President of Research and Development, Chief Scientific Officer, common stockholder, Managing Member of Tactic Pharma, former Manager of the predecessor LLC and Board member of Monopar as a C Corporation. Michael Brown is a Managing Member of Tactic Pharma (as of February 1, 2019 with no voting power as it relates to the Company), a previous managing member of Monopar as an LLC, common stockholder and Board member of Monopar as a C Corporation. Christopher M. Starr is the Company's Co-Founder, Executive Chairman of the Board of Directors, common stockholder, former Manager of the predecessor LLC and Board member of Monopar as a C Corporation.

During the three months ended March 31, 2019, the Company paid or accrued approximately $33,725 in 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. The family member personally billed a *de minimis* amount of time on the Company's legal engagement with the law firm in this period.

Note 6 – Commitments and Contingencies

License, 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 2b/3 clinical trial, 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 June 30, 2020, 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 $1 million one-time license fee.

Grupo Español de Investigación en Sarcomas ("GEIS")

In June 2019, the Company executed a clinical collaboration agreement 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 anticipated to begin in the second half 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 $2 million to $3 million per year. During the three and six months ended June 30, 2020, the Company incurred approximately $33,000 in GEIS clinical-related expenses. In addition, the Company incurred approximately $246,000 and $264,000 in clinical material manufacturing and database management expenses for the Phase 2 camsirubicin clinical trial for the three and six months ended June 30, 2020, respectively. 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, LLC ("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 June 30, 2020, 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 was January 1, 2018 through December 31, 2019, at which time the lease was on a month-to-month basis. In addition, effective February 2019, the Company leased additional office space in the same building on a month-to-month basis.

During the three months ended June 30, 2020 and 2019, the Company recognized operating lease expenses of $14,620 and $13,462, respectively. During the six months ended June 30, 2020 and 2019, the Company recognized operating lease expenses of $28,103 and $24,965, respectively.

Effective January 1, 2019, the Company adopted ASU 2016-02, as amended by ASU 2018-10, which requires the Company to record leases on its condensed consolidated balance sheet (a) a lease liability and (b) a right-of-use asset. Because the Company had no lease obligation (other than on a month-to-month basis) past December 31, 2019, the Company had no lease liability and right-of-use asset on its condensed consolidated balance sheet as of June 30, 2020 or December 31, 2019.

Legal Contingencies

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

Indemnification

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

Paycheck Protection Program ("PPP") Bank Loan

In May 2020, the Company applied for and received a $122,400 PPP bank loan established pursuant to the Coronavirus Aid, Relief, and Economic Security Act, as administered by the U.S. Small Business Administration ("SBA").

The SBA will forgive the bank loan pursuant to the PPP, if certain conditions are met, namely the bank loan must be used primarily for payroll during the 24-week period following receipt of the loan, without significant staffing reductions during that period. The Company believes it is eligible and intends to apply for loan forgiveness in August 2020 when the bank is able to process SBA loan forgiveness application. Should the bank loan not be forgiven, the Company would be required to pay 1% annual interest on the loan with principal and interest payments beginning approximately seven months after receipt of the loan with payments over 18 months. The Company has recorded the PPP loan on the balance sheet as of June 30, 2020 as current (due within 12 months) and non-current portions of bank loan, although the Company anticipates to reclassify the liability to a contra-expense account on the Company's statements of operations and comprehensive loss in the second half of 2020, if the Company's PPP bank loan is fully forgiven by the SBA.

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 extend life or improve quality of life for cancer patients. We are building a drug development pipeline through the licensing and acquisition of oncology therapeutics in late preclinical and clinical development stages. We leverage our scientific and clinical experience to help reduce the risk and accelerate the clinical development of our drug product candidates.

In December 2019, we closed our initial public offering. We sold 1,277,778 shares of our common stock at a public offering price of $8.00 per share. Net proceeds were approximately $9.4 million, after deducting underwriting discounts and accrued, unpaid offering expenses. Our common stock began trading on the Nasdaq Capital Market on December 19, 2019.

In January 2020, we entered into a Capital on Demand™ Sales Agreement with JonesTrading Institutional Services, LLC ("JonesTrading"), as sales agent, pursuant to which we may offer and sell (at our discretion), from time to time, through or to JonesTrading shares of our common stock, having an aggregate offering price of up to $19.7 million. Pursuant to this agreement, as of June 30, 2020, we have sold 145,761 shares of our common stock at an average gross price per share of $10.45 for net proceeds of $1,476,832, after commissions of $45,709.

In June 2020, we entered into a 50/50 collaboration development agreement with NorthStar Medical Radioisotopes, LLC ("NorthStar") to develop potential Radio-Immuno-Therapeutics ("RITs") to treat severe COVID-19 (patients with SARS-CoV-2 infection). NorthStar is a commercial producer and supplier of medical radioisotopes. This collaboration combines NorthStar's expertise in the innovative production, supply, and distribution of important medical radioisotopes with our expertise in therapeutic drug development and our pre-IND stage humanized urokinase plasminogen activator receptor ("uPAR") targeted monoclonal antibody known as MNPR-101, along with a proprietary portfolio of related monoclonal antibodies that target uPAR or its ligand uPA. uPAR seems to be selectively expressed on aberrantly activated immune cells. In response to coronavirus infection, these rogue immune cells produce pro-inflammatory cytokines that can cause runaway inflammation throughout the body, commonly referred to as a cytokine storm. It is this systemic hyper-inflammatory state that is thought to be largely responsible for the severe lung injury and multiple organ damage that contributes to poor outcomes and death in patients with severe COVID-19.

In this collaboration, NorthStar and we plan to couple MNPR-101 to a therapeutic radioisotope supplied by NorthStar in order to create a highly selective agent that has the potential to kill aberrantly activated cytokine-producing immune cells. By eradicating these cells with a targeted RIT, the goal is to spare healthy cells while quickly reducing the cytokine storm and its harmful systemic effects. Under the agreement, NorthStar and we will start out sharing development costs 50/50, and the initial financial commitment for each company is nominal. Additional financial contributions will be subject to mutual agreement of the parties.

Given the COVID-19 pandemic and its effects on clinical trials and fundraising, we have adjusted our clinical development plan accordingly to fit what is feasible in the current environment. We are presently simplifying the adaptive design of the Phase 3 clinical trial for our lead product candidate, Validive (clonidine mucobuccal tablet; clonidine MBT), to a Phase 2b/3 that will allow us to minimize touch points with patients and sites. This design will allow us to advance to the Phase 3 portion of the trial if supported by the Phase 2b data. We are aiming to enroll the first patient in the Phase 2b portion of the trial in the second half of 2020. This modification will allow us to initiate the clinical trial without requiring near-term financing. The decision to proceed to the Phase 3 portion of the clinical trial without a delay will largely be dependent on our cash position closer to that time, anticipated to be in the second half of 2021. To initiate and complete the Phase 3 portion of the clinical trial, we will require additional funding in the millions or tens of millions of dollars (depending on if we have consummated a collaboration or partnership or neither for Validive), which we are planning to pursue in the next 12 months. We are continuing to devote a portion of the net proceeds from our initial public offering to fund our camsirubicin Phase 2 clinical trial for which we signed a collaboration agreement in June 2019 with Grupo Español de Investigación en Sarcomas ("GEIS"), discussed in further detail below. We believe we have funds sufficient to enable GEIS to commence its open label Phase 2 clinical trial in the second half of 2020 and to obtain results from the run-in portion of the trial.

Our Product Candidates

Validive

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

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

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 (alpha-2AR) on macrophages (white blood cells present in the immune tissues of the oropharynx) suppressing pro-inflammatory cytokine expression. Validive exerts its effects locally in the oral cavity and oropharynx over a prolonged period of time through its unique MBT formulation. Patients who develop SOM are also at increased risk of developing late onset toxicities, including trismus (jaw, neck, and throat spasms), dysphagia, and lung complications, which are often irreversible and lead to increased hospitalization and the need for further interventions sometimes years after completion of chemoradiotherapy. We believe that a reduction in the incidence and duration of SOM by Validive will have the potential to reduce treatment discontinuation and/or treatment delays potentially leading to improved survival outcomes, and reducing or eliminating these long-term morbidities resulting from CRT.

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 CRT-induced SOM in patients with OPC since CRT is the standard of care treatment, and we do not anticipate this changing for years to come.

A pre-Phase 3 meeting with the FDA was held and based on the meeting discussion, a Phase 3 clinical protocol and accompanying statistical analysis plan ("SAP") was submitted to the FDA for review and comments. We have also received protocol assistance and advice on our Phase 3 protocol and SAP from the European Medicines Agency Committee on Human Medicinal Products (EMA/CHMP/SAWP). Based on comments and guidance provided by FDA and EMA, and our analysis of the current COVID-19 pandemic and its effects on clinical trials, we have modified our original adaptive design Phase 3 clinical trial to be a sequential Phase 2b/3 clinical trial to better fit the current clinical research environment. The primary endpoint, absolute incidence of SOM, remains the same, but the overall design of the trial has been simplified and the touch points with the healthcare system have been minimized. The Validive program will now consist of a randomized Phase 2b/3 clinical trial in patients with OPC. Our aim is to commence the Phase 2b/3 clinical trial in the second half of 2020. Proceeding to the Phase 3 portion of the trial will be subject to the Phase 2b interim results and our ability to raise additional funding or find a suitable pharmaceutical partner.

Camsirubicin

Our second product candidate, camsirubicin, is a novel analog of doxorubicin which has been designed to reduce the cardiotoxic side effects generated by doxorubicin while retaining anti-cancer activity. Camsirubicin is not metabolized to the derivatives that are believed to be responsible for doxorubicin's cardiotoxic effects. A Phase 2 clinical trial for camsirubicin has been completed in patients with advanced (e.g. unresectable or metastatic) soft tissue sarcoma ("ASTS"). Average life expectancy for these patients is 12-15 months. In this study, 52.6% of patients evaluable for tumor progression demonstrated clinical benefit (partial response or stable disease), which was proportional to dose and consistently observed at higher cumulative doses of camsirubicin (>1000 mg/m2). Camsirubicin was very well tolerated in this study and underscored the ability to potentially administer camsirubicin without restriction of cumulative dose in patients with ASTS. Doxorubicin is limited to a lifetime cumulative dose maximum of 450 mg/m2. Even if a patient is responding, they are pulled off of doxorubicin treatment once this cumulative dose has been reached.

Based on encouraging clinical results to date, we plan to continue the development of camsirubicin as 1st-line treatment in patients with ASTS, where the current first line treatment is doxorubicin. The aim is to administer camsirubicin without restricting cumulative dose, thereby potentially improving efficacy by keeping patients who are responding on treatment. In June 2019, we entered into a clinical collaboration with GEIS. GEIS will lead a multi-country, randomized, open-label Phase 2 clinical trial evaluating camsirubicin head-to-head against doxorubicin in patients with ASTS. GEIS is an internationally renowned non-profit organization focused on the research, development and management of clinical trials for sarcoma, that has worked with many of the leading biotech and global pharmaceutical companies. Enrollment of the trial is currently anticipated to begin in the second half of 2020, and to include approximately 170 ASTS patients, an interim analysis, and take around two years to enroll. The primary endpoint of the trial will be progression-free survival, with secondary endpoints including overall survival and incidence of treatment-emergent adverse events. In November 2019, the European Commission granted orphan drug designation for camsirubicin for the treatment of soft tissue sarcoma in the EU.

MNPR-101

Our third program, MNPR-101, is a novel first-in-class humanized monoclonal antibody to the urokinase plasminogen activator receptor ("uPAR") for the treatment of advanced cancers and severe COVID-19. We have entered into a collaboration development agreement with NorthStar to develop potential RITs to treat severe COVID-19. This collaboration combines NorthStar's expertise in the innovative production, supply, and distribution of important medical radioisotopes with our expertise in therapeutic drug development. NorthStar and we plan to couple MNPR-101 along with a proprietary portfolio of related monoclonal antibodies that target uPAR or its ligand uPA with a therapeutic radioisotope. uPAR seems to be selectively expressed on aberrantly activated immune cells. In response to coronavirus infection, these rogue immune cells produce pro-inflammatory cytokines that can cause runaway inflammation throughout the body, commonly referred to as a cytokine storm. It is this systemic hyper-inflammatory state that is thought to be largely responsible for the severe lung injury and further multiple organ damage that contributes to poor outcomes and death in patients with severe COVID-19.

We and NorthStar have filed a provisional patent application entitled "Precision Radioimmunotherapeutic Targeting of the Urokinase Plasminogen Activator Receptor (uPAR) for Treatment of Severe COVID-19 Disease" with the U.S. Patent and Trademark Office ("USPTO"). This application covers novel compositions and uses of cytotoxic radioisotopes attached to antibodies that bind to uPAR, thereby creating precision targeted radiotherapeutics, also known as uPRITs, for the treatment of severe COVID-19 and other respiratory diseases. Advanced COVID-19 patients frequently develop severe, life-threatening, pulmonary inflammation as a result of a viral induced cytokine storm. The development of this cytokine storm is associated with a high rate of mortality in severe COVID-19 patients, even with oxygen support and mechanical ventilation. uPRITs have been designed with the goal of selectively destroying the aberrantly activated immune cells responsible for causing the cytokine storm. By eradicating these cells with a targeted RIT, the goal is to spare healthy cells while quickly reducing the cytokine storm and its harmful systemic effects. The co-inventors of the provisional patent application are James Harvey, Chief Scientific Officer of NorthStar, and Andrew P. Mazar, our Chief Scientific Officer.

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".

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.

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 and RSUs. 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 or the closing stock price on date of grant in the case of RSUs.

Stock-based compensation costs for stock awards granted to our employees and non-employee directors are based on the fair value of the underlying instruments calculated using the Black-Scholes option-pricing model on the date of grant for stock options and using the closing stock price on the date of grant for RSUsand 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 six months ended June 30, 2020 and 2019 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.

Results of Operations

Comparison of the Three Months and Six Months Ended June 30, 2020 and June 30, 2019

The following tables summarize the results of our operations for the three and six months ended June 30, 2020 and 2019:

	Three Months Ended June 30,			Six Months Ended June 30,		
	(Unaudited)			*(Unaudited)*		
(in thousands)	**2020**	**2019**	**Variance**	**2020**	**2019**	**Variance**
Research and development expenses	$ 832	$ 329	$ 503	$ 1,177	$ 1,165	$ 12
General and administrative expenses	632	603	29	1,423	1,174	249
Total operating expenses	1,464	932	532	2,600	2,339	261
Operating loss	(1,464)	(932)	(532)	(2,600)	(2,339)	(261)
Interest income, net	18	26	(8)	63	57	6
Net loss	$ (1,446)	$ (906)	$ (540)	$ (2,537)	$ (2,282)	$ (255)

Research and Development Expenses

Research and Development ("R&D") expenses for the three months ended June 30, 2020 were approximately $832,000, compared to approximately $329,000, for the three months ended June 30, 2019. This represents an increase of approximately $503,000 primarily attributed to increases in expenses for the planning of the camsirubicin Phase 2 clinical trial including manufacturing of $213,000, increases in personnel costs for three new R&D employees, annual R&D personnel salary increases and annual (non-cash) equity grants of approximately $113,000, increases in Validive clinical trial planning and manufacturing costs of approximately $89,000, an increase in the allocation of the CEO's salary to R&D expenses of $79,000 and an increase in other R&D expenses of $9,000.

R&D expenses for the six months ended June 30, 2020 were approximately $1,177,000, compared to approximately $1,165,000, for the six months ended June 30, 2019. This represents an increase of approximately $12,000 primarily attributed to increases in expenses for the planning of the camsirubicin Phase 2 clinical trial including manufacturing of $202,000, increases in personnel costs for three new R&D employees, annual R&D personnel salary increases and annual (non-cash) equity grants of approximately $189,000, an increase to the allocation of the CEO's salary to R&D expenses of $82,000 and an increase in other R&D expenses of $33,000, partially offset by a decrease in Validive clinical trial planning and manufacturing costs of approximately $494,000.

General and Administrative Expenses

General and Administrative ("G&A") expenses for the three months ended June 30, 2020 were approximately $632,000, compared to approximately $603,000, for the three months ended June 30, 2019. This represents an increase of approximately $29,000 primarily attributed to: net increases in stock-based compensation for annual (non-cash) equity grants and annual G&A personnel salary increases of $110,000; external fees related to public company compliance of $28,000, net increases in general costs of operations of $23,000 offset by decreases in the CEO's compensation allocated to G&A expenses of $79,000, decreases in legal, patent and audit fees of $28,000; and decreases in stock-based compensation for non-employee directors (non-cash) of $25,000.

G&A expenses for the six months ended June 30, 2020 were approximately $1,423,000, compared to approximately $1,174,000, for the six months ended June 30, 2019. This represents an increase of approximately $249,000 primarily attributed to: net increases in stock-based compensation for annual (non-cash) equity grants and annual G&A personnel salary increases of $242,000; increases in legal, patent and audit fees of $39,000; external fees related to public company compliance of $62,000, and net increases in general costs of operations of $38,000, partially offset by decreases in the CEO's compensation allocated to G&A expenses of $82,000, and decreases in stock-based compensation for non-employee directors (non-cash) of $50,000.

Interest Income

Interest income for the three months ended June 30, 2020 compared to the three months ended June 30, 2019 decreased by approximately $8,000, due to the decrease in bank interest rates.

Interest income for the six months ended June 30, 2020 compared to the six months ended June 30, 2019 increased by approximately $6,000, due to the increase in bank balances resulting from our initial public offering in December 2019, partially offset by the decrease in bank interest rates.

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 $28.4 million as of June 30, 2020. 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 future operations. We will seek to obtain needed capital through a combination of equity offerings, debt financings, strategic collaborations and grant funding. To date, we have funded our operations through private placements of our preferred and common stock, the net receipt of funds related to the acquisition of camsirubicin, net proceeds from the initial public offering of our common stock and net proceeds from sales under our Capital on Demand™ Sales Agreement. We anticipate that the currently available funds as of July 31, 2020, will fund our operations through September 2021.

We invest our cash equivalents in a money market account.

Cash Flows

The following table provides information regarding our cash flows for the six months ended June 30, 2020 and 2019.

	Six Months Ended June 30,		Six Months Ended June 30, 2020 Versus Six Months Ended June 30, 2019
(in thousands)	**2020**	**2019**	**Variance**
Net cash used in operating activities	$ (2,121)	$ (1,736)	$ (385)
Net cash provided by (used in) financing activities	1,454	(26)	1,480
Effect of exchange rates	(1)	(1)	—
Net decrease in cash and cash equivalents	$ (668)	$ (1,763)	$ 1,095

Cash Flow Used in Operating Activities

The increase of approximately $385,000 in cash flow used in operating activities during the six months ended June 30, 2020, compared to the six months ended June 30, 2019, was primarily a result of increased R&D and G&A cash operating expenses.

Cash Flow Used in Investing Activities

There was no cash flow used in investing activities for the six months ended June 30, 2020 and 2019.

Cash Flow Provided by (Used in) Financing Activities

The increase of approximately $1,480,000 in cash flow provided by financing activities for the six months ended June 30, 2020 compared to the six months ended June 30, 2019, was a result of sales of our common stock under our Capital on Demand™ Sales Agreement with JonesTrading and the receipt of a forgivable PPP bankloan.

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 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 and execute the regulatory strategy for camsirubicin;
- continue the preclinical activities and potentially enter clinical development of MNPR-101 for severe COVID-19;
- 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/quality 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 July 31, 2020, will fund our planned operations through September 2021. 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 including through our collaboration with NorthStar;
- 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.

Funding Requirements Second Half of 2020 Onward

Expenditures are expected to increase in the second half of 2020 onward for:

- contract research services and clinical site fees for the Validive Phase 2b/3 clinical trial;
- process development, manufacturing costs and clinical database management of camsirubicin in connection with the GEIS Phase 2 clinical trial;
- supporting the NorthStar collaboration;
- GEIS collaboration milestone fees; and
- employee compensation and consulting fees to support the planning and initiation of our Validive Phase 2b/3 clinical trial.

We are aiming to enroll the first patient in a Phase 2b/3 clinical trial for Validive in the second half of 2020. We will proceed to the Phase 3 portion of the clinical trial based on an interim analysis of the Phase 2b portion, pending our ability to raise sufficient funds. To commence the Phase 3 portion of the trial, we will require additional funding in the millions or tens of millions of dollars (depending on if we have consummated a collaboration or partnership or neither for Validive), or find a suitable pharmaceutical partner, both of which we are planning to pursue in the next 12 months. 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 second half 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 higher contract manufacturing costs, contract research organization fees, other clinical development costs and insurance costs that are not currently projected. The anticipated operating cost increases in the second half of 2020 onward are expected to be primarily driven by the funding of our planned Validive Phase 2b/3 clinical trial and in support of the GEIS Phase 2 clinical trial of camsirubicin. Beyond our need to raise additional funding in the next 12 months to start the Validive Phase 3 portion of the trial, we will also need significant additional funding thereafter in order to complete the clinical trial, support further development of camsirubicin in and beyond the Phase 2 trial to support our collaboration with NorthStar , if successful, and generally to support our current and any future product candidates through completion of trials, approval processes and, if applicable, commercialization.

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

License, 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 July 31, 2020, 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 anticipated to begin in the second half of 2020 and will include approximately 170 ASTS patients. We will provide study drug and supplemental financial support for the clinical trial averaging approximately $2 million to $3 million per year. Cumulatively through June 30, 2020, we incurred approximately $33,000 in GEIS clinical-related expenses. In addition, we incurred approximately $344,000 in clinical material manufacturing and database management expenses for the Phase 2 camsirubicin clinical trial. 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 July 31, 2020, 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 and development, 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 $2,520 per month for 24 months. This office space houses our current headquarters. On December 31, 2019, the office lease expired and we continued to lease on a month-to-month basis. 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 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 June 30, 2020, 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 three and six months ended June 30, 2020 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

Item 1A. Risk Factors

Except for the updated risk factor set forth below, 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 March 27, 2020.

Our operations and financial results could be adversely impacted by the global outbreak of the 2019 Novel Coronavirus (COVID-19), which has negatively impacted our stock price and our ability to raise substantial funds in the near-term, and may negatively impact our ability to manufacture our product candidates for our clinical trials, and our ability to accrue and conduct our planned clinical trials. Any such impact will negatively impact our financial condition and could require us to delay our clinical development programs.

In December 2019, a novel strain of coronavirus ("COVID-19") was reported to have surfaced in Wuhan, China, resulting in significant disruptions to Chinese manufacturing and supply chain, as well as travel restrictions in many countries. In March 2020, COVID-19 was designated a global pandemic and many countries, including the United States, have declared national emergencies and have implemented preventive measures by limiting large public gatherings (social distancing) and shelter-in-place mandates. Many employers are restricting non-essential work travel and are requiring that employees work from their homes to limit personal interaction. Many businesses are closed or are operating in a substantially reduced fashion and many employees have been laid off. While the extent of the impact of the COVID-19 pandemic on our business and financial results is uncertain, a continued and prolonged public health crisis such as the COVID-19 pandemic would have a negative impact on our business, financial condition and operating results. The COVID-19 pandemic has resulted in significant volatility and substantial declines in the stock markets, which has negatively impacted our stock price and negatively impacted our ability to raise significant funds in the near-term. It is unknown the potential impact in the long-term in the event of a prolonged disruption or recession. In addition, the COVID-19 pandemic could impact the conduct of clinical trials as a result of quarantines, site closures, travel limitations, delays in the manufacturing of our product candidates for our clinical trials due to supply chain disruptions, and delays in the initiation and enrollment of patients in our planned clinical trials, or other considerations if site personnel or trial subjects become infected with COVID-19, which would negatively impact our financial condition and could require us to delay our clinical development programs. Given the dynamic nature of these circumstances, the duration of any business disruption or potential impact of the COVID-19 pandemic to our business is difficult to predict. In response to the current COVID-19 pandemic and its effects on clinical trials, we have modified the original adaptive design Phase 3 clinical trial for our lead product candidate, Validive, to be a Phase 2b/3 clinical trial to better fit the types of trials which can enroll patients in the current environment. We are aiming to enroll the first patient in a Phase 2b/3 clinical trial for Validive in the second half of 2020. The Phase 3 portion of the clinical trial is anticipated to start right after the Phase 2b portion, pending our ability to raise sufficient funds. To commence the Phase 3 portion of the trial, we will require additional funding in the millions or tens of millions of dollars (depending on if we have consummated a collaboration or partnership or neither for Validive), or find a suitable pharmaceutical partner, both of which we are planning to pursue in the next 12 months. There can be no assurance that any such events will occur.

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 D. Robinson, Chief Executive Officer	Filed herewith
31.2	Certification of Kim R. Tsuchimoto, Chief Financial Officer	Filed herewith
32.1	Certification of Chandler D. Robinson, Chief Executive Officer and Kim R. 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: August 6, 2020

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

Dated: August 6, 2020

By: /s/ Kim R. Tsuchimoto
Kim R. Tsuchimoto
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: August 6, 2020

/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: August 6, 2020

/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 six months ended June 30, 2020, 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

August 6, 2020

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

August 6, 2020

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.