

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

FORM 10-Q

(Mark One)

QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the quarterly period ended September 30, 2020

OR

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 001-34375

PLUS THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

DELAWARE
(State or other jurisdiction
of incorporation or organization)

33-0827593
(I.R.S. Employer
Identification No.)

4200 MARATHON BLVD., SUITE 200, AUSTIN, TX
(Address of principal executive offices)

78756
(Zip Code)

(737) 255-7194

(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, par value \$0.001 per share	PSTV	Nasdaq Capital Market

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 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	<input type="checkbox"/>	Accelerated Filer	<input type="checkbox"/>
Non-Accelerated Filer	<input checked="" type="checkbox"/>	Smaller reporting company	<input checked="" type="checkbox"/>
		Emerging growth company	<input type="checkbox"/>

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 financing 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 Exchange Act). Yes No

As of October 14, 2020, there were 4,779,584 shares of the registrant's common stock outstanding.

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CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING STATEMENTS

This report contains statements that may be deemed “forward-looking statements” within the meaning of U.S. securities laws. All statements in this report, other than statements of historical fact, are forward-looking statements. These forward-looking statements may be identified by terms such as “intend,” “expect,” “believe,” “anticipate,” “will,” “should,” “would,” “could,” “may,” “designed,” “potential,” and similar expressions, or the negative of such expressions. Such statements are based upon certain assumptions and assessments made by our management in light of their experience and their perception of historical trends, current conditions, expected future developments and other factors they believe to be appropriate.

These statements include, without limitation, statements regarding: our anticipated expenditures, including research and development, sales and marketing, and general and administrative expenses; our ability to benefit from the NIH/NCI award for continued clinical development of RNL™ for recurrent glioblastoma; the ability of RNL™ to safely and effectively deliver radiation directly to the tumor at large doses; the duration of any therapies employing RNL™; our ability to expand testing of RNL™ to additional sites; the potential size of the market for our products; future development and/or expansion of our products and therapies in our markets; our ability to generate product or development revenues and the sources of such revenue; the amounts that we will be obligated to pay under license agreements; our ability to effectively manage our gross profit margins; our ability to obtain and maintain regulatory approvals; expectations as to our future performance; portions of the “Liquidity and Capital Resources” section of this report; our need for additional financing and the availability thereof; our ability to sell shares of common stock to Lincoln Park Capital Fund, LLC pursuant to the terms of the purchase agreement that we have entered into with them and our ability to register and maintain the registration of the shares issued and issuable thereunder; our anticipated use of the net proceeds from the potential sale of shares of our common stock to Lincoln Park Capital Fund, LLC; any changes to our interest expenses; our ability to continue as a going concern; our ability to remain listed on the Nasdaq Capital Market; our ability to repay or refinance some or all of our outstanding indebtedness and our ability to raise capital in the future; our expectations as to the impact of recently issued or adopted accounting standards; our expectations as to the impact of the COVID-19 pandemic on our business and operating results; our beliefs as to the impact of any liability that may arise as a result of any legal proceedings; and the potential enhancement of our cash position through development, marketing, and licensing arrangements. Our actual results will likely differ, perhaps materially, from those anticipated in these forward-looking statements as a result of various factors, including, but not limited to: the early stage of our product candidates and therapies, the results of our research and development activities, including uncertainties relating to the clinical trials of our product candidates and therapies; our need and ability to raise additional cash, the outcome of our partnering/licensing efforts, risks associated with laws or regulatory requirements applicable to us, market conditions, product performance, potential litigation, competition within the regenerative medicine field, and the COVID-19 pandemic. The forward-looking statements included in this report are also subject to a number of additional material risks and uncertainties, including but not limited to the risks described under “Part I - Item 1A - Risk Factors” in our Annual Report on Form 10-K for the year ended December 31, 2019, and under “Part II, Item 1A - Risk Factors” in this Quarterly Report on Form 10-Q. These risks and uncertainties that could cause actual results to differ materially from expectations or those expressed in these forward-looking statements. We encourage you to read these risks carefully. We caution you not to place undue reliance on the forward-looking statements contained in this report. These statements, like all statements in this report, speak only as of the date of this report (unless an earlier date is indicated) and we undertake no obligation to update or revise the statements except as required by law.

PLUS THERAPEUTICS, INC.
CONSOLIDATED CONDENSED BALANCE SHEETS
(UNAUDITED)
(in thousands, except share and par value data)

	<u>As of September 30,</u> <u>2020</u>	<u>As of December 31,</u> <u>2019</u>
Assets		
Current assets:		
Cash and cash equivalents	\$ 7,626	\$ 17,552
Accounts receivable	—	1,169
Restricted cash	—	40
Inventories, net	107	107
Other current assets	916	957
Total current assets	<u>8,649</u>	<u>19,825</u>
Property and equipment, net	1,943	2,179
Operating lease right-of-use assets	671	781
Other assets	18	72
Goodwill	372	372
Total assets	<u>\$ 11,653</u>	<u>\$ 23,229</u>
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable and accrued expenses	\$ 2,083	\$ 3,279
Operating lease liability	140	147
Term loan obligations, net of discount	6,181	11,060
Total current liabilities	<u>8,404</u>	<u>14,486</u>
Noncurrent operating lease liability	545	646
Warrant liability	83	6,929
Other noncurrent liabilities	—	8
Total liabilities	<u>9,032</u>	<u>22,069</u>
Commitments and contingencies (Note 9)		
Stockholders' equity:		
Preferred stock, \$0.001 par value; 5,000,000 shares authorized; 1,954 and 1,959 shares issued and outstanding at September 30, 2020 and December 31, 2019, respectively	—	—
Common stock, \$0.001 par value; 100,000,000 shares authorized; 4,591,415 and 3,880,588 shares issued and outstanding at September 30, 2020 and December 31, 2019, respectively	5	4
Additional paid-in capital	432,540	426,426
Accumulated deficit	(429,924)	(425,270)
Total stockholders' equity	<u>2,621</u>	<u>1,160</u>
Total liabilities and stockholders' equity	<u>\$ 11,653</u>	<u>\$ 23,229</u>

See Accompanying Notes to these Consolidated Condensed Financial Statements

PLUS THERAPEUTICS, INC.
CONSOLIDATED CONDENSED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(UNAUDITED)
(in thousands, except share and per share data)

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2020	2019	2020	2019
Development revenues:				
Government contracts and other	\$ —	\$ 4,771	\$ 303	\$ 5,810
Operating expenses:				
Research and development	336	921	1,604	3,636
In process research and development acquired from NanoTx	—	—	781	—
Sales and marketing	104	94	319	305
General and administrative	956	1,076	3,788	3,313
Total operating expenses	1,396	2,091	6,492	7,254
Operating income (loss)	(1,396)	2,680	(6,189)	(1,444)
Other income (expense):				
Interest income	2	6	47	20
Interest expense	(253)	(366)	(854)	(1,477)
Change in fair value of warrants	(81)	(561)	2,342	(69)
Warrant issuance cost	—	(1,233)	—	(1,233)
Total other income (expense)	(332)	(2,154)	1,535	(2,759)
Income (Loss) from continuing operations	(1,728)	526	(4,654)	(4,203)
Loss from discontinued operations	—	—	—	(7,568)
Net income (loss)	\$ (1,728)	\$ 526	\$ (4,654)	\$ (11,771)
Income (Loss) from continuing operations	\$ (1,728)	\$ 526	\$ (4,654)	\$ (4,203)
Beneficial conversion feature for convertible preferred stock	—	(554)	—	\$ (554)
Net loss allocable to common stockholders - continuing operations	\$ (1,728)	\$ (28)	\$ (4,654)	\$ (4,757)
Net loss allocable to common stockholders - discontinued operations	\$ —	\$ —	\$ —	\$ (7,568)
Basic and diluted net loss per share attributable to common stockholders - continuing operations	\$ (0.39)	\$ (0.03)	\$ (1.13)	\$ (8.78)
Basic and diluted net loss per share attributable to common stockholders - discontinued operations	\$ —	\$ —	\$ —	\$ (13.97)
Net loss per share, basic and diluted	\$ (0.39)	\$ (0.03)	\$ (1.13)	\$ (22.75)
Basic and diluted weighted average shares used in calculating net loss per share attributable to common stockholders	4,402,221	826,548	4,113,928	541,777

See Accompanying Notes to these Consolidated Condensed Financial Statements

PLUS THERAPEUTICS, INC.
CONSOLIDATED CONDENSED STATEMENTS OF STOCKHOLDERS' EQUITY
(UNAUDITED)
(in thousands)

	Convertible preferred stock		Common stock		Additional paid-in capital	Accumulated other comprehensive income	Accumulated deficit	Total stockholders' equity
	Shares	Amount	Shares	Amount				
Balance at December 31, 2018	4,606	\$ —	296,609	\$ —	\$ 418,390	\$ 1,218	\$ (414,383)	\$ 5,225
Share-based compensation	—	—	—	—	49	—	—	49
Sale of common stock, net	—	—	139,855	—	1,873	—	—	1,873
Conversion of Series B Convertible Preferred Stock into common stock	(66)	—	1,653	—	—	—	—	—
Foreign currency translation adjustment and accumulated other comprehensive income	—	—	—	—	—	(140)	—	(140)
Net loss	—	—	—	—	—	—	(3,150)	(3,150)
Balance at March 31, 2019	<u>4,540</u>	<u>\$ —</u>	<u>438,117</u>	<u>\$ —</u>	<u>\$ 420,312</u>	<u>\$ 1,078</u>	<u>\$ (417,533)</u>	<u>\$ 3,857</u>
Share-based compensation	—	—	—	—	28	—	—	28
Sale of common stock, net	—	—	5,000	—	64	—	—	64
Foreign currency translation adjustment and accumulated other comprehensive income	—	—	—	—	—	(1,078)	—	(1,078)
Net loss	—	—	—	—	—	—	(9,147)	(9,147)
Balance at June 30, 2019	<u>4,540</u>	<u>\$ —</u>	<u>443,117</u>	<u>\$ —</u>	<u>\$ 420,404</u>	<u>\$ —</u>	<u>\$ (426,680)</u>	<u>\$ (6,276)</u>
Share-based compensation	—	—	—	—	29	—	—	29
Sale of common stock, pre-funded warrants and warrants for common stock, net of offering costs of \$0.6 million	—	—	2,000,510	3	4,594	—	—	4,597
Conversion of Series B and Series C convertible preferred stock into common stock	(2,581)	—	332,546	—	—	—	—	—
Exercise of warrants	—	—	65,415	—	490	—	—	490
Warrant derivative liability reclassified to equity due to exercise of warrants	—	—	—	—	794	—	—	794
Beneficial conversion feature related to Series C Convertible Preferred Stock	—	—	—	—	554	—	—	554
Accretion of beneficial conversion feature related to Series C Convertible Preferred Stock	—	—	—	—	(554)	—	—	(554)
Net income	—	—	—	—	—	—	526	526
Balance at September 30, 2019	<u>1,959</u>	<u>\$ —</u>	<u>2,841,588</u>	<u>\$ 3</u>	<u>\$ 426,311</u>	<u>\$ —</u>	<u>\$ (426,154)</u>	<u>\$ 160</u>
Balance at December 31, 2019	1,959	\$ —	3,880,588	\$ 4	\$ 426,426	\$ —	\$ (425,270)	\$ 1,160
Share-based compensation	—	—	—	—	12	—	—	12
Net loss	—	—	—	—	—	—	(1,087)	(1,087)
Balance at March 31, 2020	<u>1,959</u>	<u>\$ —</u>	<u>3,880,588</u>	<u>\$ 4</u>	<u>\$ 426,438</u>	<u>\$ —</u>	<u>\$ (426,357)</u>	<u>\$ 85</u>
Issuance of common stock for exercise of warrants	—	—	162,500	—	366	—	—	366
Reclassification of warrant liabilities	—	—	—	—	4,264	—	—	4,264
Issuance of common stock for in process research and development acquired from NanoTx Therapeutics	—	—	230,769	—	381	—	—	381
Share-based compensation	—	—	—	—	43	—	—	43
Net loss	—	—	—	—	—	—	(1,839)	(1,839)
Balance at June 30, 2020	<u>1,959</u>	<u>\$ —</u>	<u>4,273,857</u>	<u>\$ 4</u>	<u>\$ 431,492</u>	<u>\$ —</u>	<u>\$ (428,196)</u>	<u>\$ 3,300</u>
Issuance of common stock for exercise of warrants	—	—	317,521	1	714	—	—	715
Reclassification of warrant liabilities	—	—	—	—	240	—	—	240
Conversion of Series B convertible preferred stock into common stock	(5)	—	37	—	—	—	—	—
Share-based compensation	—	—	—	—	94	—	—	94
Net loss	—	—	—	—	—	—	(1,728)	(1,728)
Balance at September 30, 2020	<u>1,954</u>	<u>\$ —</u>	<u>4,591,415</u>	<u>\$ 5</u>	<u>\$ 432,540</u>	<u>\$ —</u>	<u>\$ (429,924)</u>	<u>\$ 2,621</u>

See Accompanying Notes to these Consolidated Condensed Financial Statements

PLUS THERAPEUTICS, INC.
CONSOLIDATED CONDENSED STATEMENTS OF CASH FLOWS
(UNAUDITED)
(in thousands)

	For the Nine Months Ended September 30,	
	2020	2019
Cash flows used in operating activities:		
Net loss	\$ (4,654)	\$ (11,771)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	273	778
Amortization of deferred financing costs and debt discount	428	354
In process research and development acquired from NanoTx Therapeutics	781	—
Noncash lease expenses	2	22
Change in fair value of warrants	(2,342)	69
Share-based compensation expense	149	106
Loss on sale of business	—	6,508
Allocation of issuance costs associated with warrants	—	1,233
Increases (decreases) in cash caused by changes in operating assets and liabilities:		
Accounts receivable	1,169	(4,851)
Inventories	—	274
Other current assets	516	252
Other assets	54	298
Accounts payable and accrued expenses	(1,586)	(297)
Deferred revenues	—	29
Other long-term liabilities	—	54
Net cash used in operating activities	<u>(5,210)</u>	<u>(6,942)</u>
Cash flows provided by (used in) investing activities:		
Purchases of property and equipment	(37)	(8)
In process research and development acquired from NanoTx Therapeutics	(400)	—
Proceeds from sale of business	—	5,637
Net cash provided by (used in) investing activities	<u>(437)</u>	<u>5,629</u>
Cash flows used in financing activities:		
Principal payments of long-term obligations	(5,307)	(3,490)
Payment of financing lease liability	(93)	(75)
Proceeds from exercise of warrants	1,081	491
Proceeds from sale of common stock, net	—	15,964
Net cash provided by (used in) financing activities	<u>(4,319)</u>	<u>12,890</u>
Effect of exchange rate changes on cash and cash equivalents	—	(4)
Net increase (decrease) in cash and cash equivalents	<u>(9,966)</u>	<u>11,573</u>
Cash, cash equivalents, and restricted cash at beginning of period	17,592	5,301
Cash, cash equivalents, and restricted cash at end of period	<u><u>7,626</u></u>	<u><u>16,874</u></u>
Supplemental disclosure of cash flows information:		
Cash paid during period for:		
Interest	\$ 470	\$ 1,071
Supplemental schedule of non-cash investing and financing activities:		
Issuance costs paid in common stock	\$ 463	\$ —
Common stock issued in payment for in process research and development	\$ 381	\$ —
Offering cost paid in warrants	\$ —	\$ 213
Unpaid offering costs	\$ 12	\$ 403

See Accompanying Notes to these Consolidated Condensed Financial Statements

PLUS THERAPEUTICS, INC.
NOTES TO CONSOLIDATED CONDENSED FINANCIAL STATEMENTS
September 30, 2020
(UNAUDITED)

1. Basis of Presentation and New Accounting Standards

The accompanying consolidated condensed financial statements as of September 30, 2020 and for the three and nine months ended September 30, 2020 and 2019 have been prepared in accordance with accounting principles generally accepted in the United States of America for interim financial information. Accordingly, they do not include all of the information and footnotes required by accounting principles generally accepted in the United States of America for annual financial statements. The consolidated condensed balance sheet at December 31, 2019 has been derived from the audited financial statements at December 31, 2019 but does not include all of the information and footnotes required by accounting principles generally accepted in the United States of America for complete financial statements. In the opinion of management, all adjustments (consisting of normal recurring adjustments) considered necessary for a fair presentation of the financial position and results of operations of Plus Therapeutics, Inc., and its subsidiaries (collectively, the “Company”) have been included. Operating results for the three and nine months ended September 30, 2020 are not necessarily indicative of the results that may be expected for the year ending December 31, 2020. These financial statements should be read in conjunction with the consolidated financial statements and notes therein included in the Company’s Annual Report on Form 10-K for the year ended December 31, 2019, filed with the Securities and Exchange Commission on March 30, 2020.

On March 30, 2019, the Company entered into an Asset and Share Sale and Purchase Agreement (the “Lorem Purchase Agreement”) with Lorem Vascular Pte. Ltd. (“Lorem”), pursuant to which, among other things, Lorem agreed to purchase the Company’s UK subsidiary, Cytori Ltd. (the “UK Subsidiary”), and the Company’s cell therapy assets, excluding such assets used in Japan or relating to the Company’s contract with the U.S. Department of Health and Human Service’s Biomedical Advanced Research and Development Authority (“BARDA”). Both the Company and Lorem made customary representations, warranties and covenants in the Lorem Purchase Agreement. The transaction was completed on April 24, 2019 and the Company received \$4.0 million of cash proceeds, of which \$1.7 million was used to pay down principal, interest and fees under the Loan and Security Agreement, dated May 29, 2015 (the “Loan and Security Agreement”) (Note 5), with Oxford Finance, LLC (“Oxford”).

On April 19, 2019, the Company entered into an Asset and Share Sale and Purchase Agreement (the “Shirahama Purchase Agreement”) with Seijirō Shirahama, pursuant to which, among other things, Mr. Shirahama agreed to purchase the Company’s Japanese subsidiary, Cytori Therapeutics, K.K. (the “Japanese Subsidiary”), and substantially all of the Company’s cell therapy assets used in Japan. Both the Company and Mr. Shirahama made customary representations, warranties and covenants in the Shirahama Purchase Agreement. The transaction was completed on April 25, 2019 and the Company received \$3.0 million of cash proceeds, of which \$1.4 million was used to pay down principal, interest and fees under the Loan and Security Agreement.

Amendments to Certificate of Incorporation

On July 29, 2019, the Company amended its Certificate of Incorporation with the State of Delaware to change its corporate name from Cytori Therapeutics, Inc. to Plus Therapeutics, Inc. The Company also changed its trading symbol for its common stock on the Nasdaq Capital Market to “PSTV”.

Recently Issued Accounting Pronouncements

In September 2016, the FASB issued ASU 2016-13, Financial Instruments - Credit Losses (Topic 326), Measurement of Credit Losses on Financial Instruments. The standard amends the impairment model by requiring entities to use a forward-looking approach based on expected losses to estimate credit losses for most financial assets and certain other instruments that aren’t measured at fair value through net income. For available-for-sale debt securities, entities will be required to recognize an allowance for credit losses rather than a reduction in carrying value of the asset. Entities will no longer be permitted to consider the length of time that fair value has been less than amortized cost when evaluating when credit losses should be recognized. This new guidance is effective in the first quarter of 2023 for calendar-year SEC filers that are smaller reporting companies as of the one-time determination date. Early adoption is permitted beginning in 2019. The Company plans to adopt the new guidance on January 1, 2023, and it does not expect that adoption of this standard will have a material impact on its consolidated financial statements and related disclosures.

In August 2020, the FASB issued ASU No. 2020-06, Debt - Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging - Contracts in Entity’s Own Equity (Subtopic 815-40) (“ASU 2020-06”). ASU 2020-06 eliminates the beneficial conversion and cash conversion accounting models for convertible instruments. It also amends the accounting for certain contracts in an entity’s own equity that are currently accounted for as derivatives because of specific settlement provisions. In addition, ASU 2020-06 modifies how particular convertible instruments and certain contracts that may be settled

in cash or shares impact the diluted EPS computation. The amendments in ASU 2020-06 are effective for smaller reporting companies as defined by the SEC for fiscal years beginning after December 15, 2023, including interim periods within those fiscal years. Early adoption is permitted, but no earlier than fiscal years beginning after December 15, 2020. The Company is currently evaluating the impact of ASU 2020-06 on its financial statements.

Recently Adopted Accounting Pronouncements

In August 2018, the FASB issued ASU No. 2018-13 (ASU 2018-13), *Changes to the Disclosure Requirements for Fair Value Measurement*. This ASU eliminates, adds and modifies certain disclosure requirements for fair value measurements as part of its disclosure framework project. The standard is effective for all entities for financial statements issued for fiscal years beginning after December 15, 2019, and interim periods within those fiscal years. The Company adopted ASU 2018-13 as of January 1, 2020, which did not have a material impact on the Company's financial statements.

2. Use of Estimates

The preparation of consolidated financial statements in conformity with U.S. generally accepted accounting principles requires management to make estimates and assumptions affecting the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements, and the reported amounts of revenue and expenses during the reporting period. The Company's most significant estimates and critical accounting policies involve recognizing revenue, reviewing assets for impairment, determining the assumptions used in measuring share-based compensation expense, valuing warrants, and valuing allowances for doubtful accounts.

Actual results could differ from these estimates. Management's estimates and assumptions are reviewed regularly, and the effects of revisions are reflected in the consolidated financial statements in the periods they are determined to be necessary.

3. Liquidity and Going Concern

The Company incurred net losses of \$1.7 million and \$4.7 million for the three and nine months ended September 30, 2020, respectively. The Company had an accumulated deficit of \$429.9 million as of September 30, 2020. Additionally, it used net cash of \$5.2 million to fund its operating activities for the nine months ended September 30, 2020. These factors raise substantial doubt about the Company's ability to continue as a going concern.

To date, these operating losses have been funded primarily from outside sources of invested capital, proceeds raised from the Loan and Security Agreement, and gross profits. The Company has had, and will continue to have, an ongoing need to raise additional cash from outside sources to fund its future clinical development programs and other operations. The Company anticipates using its new equity line facility entered into on September 30, 2020 with Lincoln Park Capital Fund, LLC ("Lincoln Park") (Note 11) to raise additional cash. The Company's inability to raise additional cash would have a material and adverse impact on its business and operations and would cause it to default on its loan.

The Company continues to seek additional capital through strategic transactions and from other financing alternatives. Without additional capital, the Company's current working capital will not provide adequate funding to make debt repayments or support its research, sales and marketing efforts and product development activities at their current levels. If sufficient additional capital is not raised, the Company will at a minimum need to significantly reduce or curtail its research and development and other operations, and this would negatively affect its ability to achieve corporate growth goals.

The accompanying consolidated condensed financial statements have been prepared assuming the Company will continue to operate as a going concern, which contemplates the realization of assets and settlement of liabilities in the normal course of business, and do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts and classifications of liabilities that may result from uncertainty related to its ability to continue as a going concern.

4. Fair Value Measurements

Fair value measurements are market-based measurements, not entity-specific measurements. Therefore, fair value measurements are determined based on the assumptions that market participants would use in pricing the asset or liability. The Company follows a three-level hierarchy to prioritize the inputs used in the valuation techniques to derive fair values. The basis for fair value measurements for each level within the hierarchy is described below:

- Level 1: Quoted prices in active markets for identical assets or liabilities.
- Level 2: Quoted prices for similar assets or liabilities in active markets; quoted prices for identical or similar instruments in markets that are not active; and model-derived valuations in which all significant inputs are observable in active markets.
- Level 3: Valuations derived from valuation techniques in which one or more significant inputs are unobservable in active markets.

Warrants issued by the Company in connection with a rights offering originally filed under a Form S-1 registration statement in April 2018 (“Series T Warrants”) and in an underwritten public offering in September 2019 (“Series U Warrants”) are classified as liability instruments initially upon issuance. Because some of the inputs to the Company’s valuation model are either not observable or are not derived principally from or corroborated by observable market data by correlation or other means, the warrant liability is classified as Level 3 in the fair value hierarchy.

The estimated fair value of the Series T Warrants as of September 30, 2020 and December 31, 2019 was determined by using an option pricing model with the following assumptions. The Series T Warrants will be marked to market as of each balance sheet date until they are exercised or upon expiration, with the changes in fair value recorded as non-operating income or loss in the statements of operations and comprehensive loss.

	As of September 30, 2020	As of December 31, 2019
Expected term	0.55 years	1.1 years
Common stock market price	\$ 2.56	\$ 2.40
Risk-free interest rate	0.11%	1.59%
Expected volatility	128%	168%
Resulting fair value (per warrant)	\$ 1.04	\$ 1.47

The Company estimated the fair value of the Series U Warrants with the Black Scholes model with the following assumptions. The Series U Warrants that have not been amended (Note 11) will be marked to market as of each balance sheet date until they are exercised or upon expiration, with the changes in fair value recorded as non-operating income or loss in the statements of operations and comprehensive loss.

	As of September 30, 2020	As of December 31, 2019
Expected term	4 years	4.75 years
Common stock market price	\$ 2.56	\$ 2.40
Risk-free interest rate	0.22%	1.68%
Expected volatility	146%	135%
Resulting fair value (per warrant)	\$ 2.21	\$ 1.94

The following table summarizes the change in Level 3 warrant liability value (in thousands):

Warrant liability	Three Months Ended		Nine Months Ended	
	September 30, 2020	September 30, 2019	September 30, 2020	September 30, 2019
Beginning balance	\$ 242	\$ 424	\$ 6,929	\$ 916
Issuance	—	10,215	—	10,215
Exercise/settlement	—	(794)	—	(794)
Change in fair value	81	561	(2,342)	69
Reclassification to equity	(240)	—	(4,504)	—
Ending balance	<u>\$ 83</u>	<u>\$ 10,406</u>	<u>\$ 83</u>	<u>\$ 10,406</u>

5. Term Loan Obligations

On May 29, 2015, the Company entered into the Loan and Security Agreement, pursuant to which it funded an aggregate principal amount of \$17.7 million (the "Term Loan"), subject to the terms and conditions set forth in the Loan and Security Agreement. The Term Loan accrues interest at a floating rate of at least 8.95% per annum, comprised of three-month LIBOR rate with a floor of 1.00% plus 7.95%. Pursuant to the Loan and Security Agreement, as amended, the Company is required to make interest only payments through May 1, 2021 and thereafter it is required to make payments of principal and accrued interest in equal monthly installments sufficient to amortize the Term Loan through September 1, 2024, the maturity date. At maturity of the Term Loan, or earlier repayment in full following voluntary prepayment or upon acceleration, the Company is required to make a final payment in an aggregate amount equal to approximately \$3.2 million. In connection with the Term Loan, on May 29, 2015, the Company issued to Oxford warrants to purchase an aggregate of 188 shares of the Company's common stock at an exercise price of \$5,175 per share. These warrants became exercisable as of November 30, 2015 and will expire on May 29, 2025 and, following the authoritative accounting guidance, are equity classified and its respective fair value was recorded as a discount to the debt.

From September 2017 to March 2019, the Company entered into a total of seven amendments to the Term Loan which, amongst other things, extended the interest only period, required repayment of \$3.1 million using the proceeds received from sale of the Company's former UK and Japan subsidiaries as described in Note 1, increased the final payment, increased the final payment fee upon maturity or early repayment of the Term Loan, and increased the minimum liquidity covenant level to \$2.0 million.

On March 29, 2020, the Company entered into the Ninth Amendment of the Loan and Security Agreement ("Ninth Amendment"), pursuant to which Oxford agreed to defer the start date of principal repayment from May 1, 2020 to May 1, 2021 and extended the term of the Term loan from September 1, 2021 to September 1, 2024. In addition, pursuant to the Ninth Amendment, on April 1, 2020, the Company made a \$5.0 million paydown of principal upon execution of the Ninth Amendment and \$0.3 million of related final payment. After giving effect to this payment, there is \$4.3 million of principal outstanding under the Loan Agreement. In addition, an amendment fee of \$1.0 million will be payable in connection with the Amendment at the earlier of the maturity date, acceleration of the loans and the making of certain prepayments. All other major terms remained consistent.

Under authoritative guidance, the Ninth Amendment does not meet the criteria to be accounted for as a troubled debt restructuring. In addition, the Company performed a quantitative analysis and determined that the terms of the new debt and original debt instrument are not substantially different. Accordingly, the Ninth Amendment is accounted for as debt modification. A new effective interest rate that equates the revised cash flows to the carrying amount of the original debt is computed and applied prospectively.

The Term Loan, as amended, is collateralized by a security interest in substantially all of the Company's existing and subsequently acquired assets, including its intellectual property assets, subject to certain exceptions set forth in the Loan and Security Agreement, as amended. The intellectual property asset collateral will be released upon the Company achieving a certain liquidity level when the total principal outstanding under the Loan and Security Agreement is less than \$3 million. As of September 30, 2020, there was \$4.3 million principal amount outstanding under the Term Loan, and the Company was in compliance with all of the debt covenants under the Loan and Security Agreement.

The Company's interest expense for the three months ended September 30, 2020 and 2019 was \$0.3 million and \$0.4 million, respectively. The Company's interest expense for the nine months ended September 30, 2020 and 2019 was \$0.9 million and \$1.5 million, respectively. Interest expense is calculated using the effective interest method, therefore it is inclusive of non-cash amortization in the amount of \$0.1 million and \$0.1 million for the three months ended September 30, 2020 and 2019, and \$0.4 million and \$0.4 million for the nine months ended September 30, 2020 and 2019, respectively, related to the amortization of the debt discount, capitalized loan costs, and accretion of final payment.

The Loan and Security Agreement, as amended, contains customary indemnification obligations and customary events of default, including, among other things, the Company's failure to fulfill certain obligations under the Term Loan, as amended, and the occurrence of a material adverse change, which is defined as a material adverse change in the Company's business, operations, or condition (financial or otherwise), a material impairment of the prospect of repayment of any portion of the loan. In the event of default by the Company or a declaration of material adverse change by its lender, under the Term Loan, the lender would be entitled to exercise its remedies thereunder, including the right to accelerate the debt, upon which the Company may be required to repay all amounts then outstanding under the Term Loan, which could materially harm the Company's financial condition. As of September 30, 2020, the Company has not received any notification or indication from Oxford to invoke the material adverse change clause. However, due to the Company's current cash flow position and the substantial doubt about its ability to continue as a going concern, the entire principal amount of the Term Loan is presented as short-term. The Company will continue to evaluate the debt classification on a quarterly basis and evaluate for reclassification in the future should its financial condition improve.

6. Revenue Recognition

Development Revenue

The Company received revenue for tasks performed under research and development agreements with governmental agencies, like BARDA, which is outside of the scope of the new revenue recognition guidance. Revenues derived from reimbursement of direct out-of-pocket expenses for research costs associated with government contracts are recorded as government contracts and other within development revenues. Government contract revenue is recorded at the gross amount of the reimbursement. The costs associated with these reimbursements are reflected as a component of research and development expense in the Company's consolidated condensed statements of operations and comprehensive loss.

The BARDA contract was terminated by the U.S. Department of Health and Human Services effective in December 2019 and the contract close out process was completed during the three months ended September 30, 2020. During the three and nine months ended September 30, 2020, the Company recognized \$0 and \$0.3 million in development revenue and related costs related to unreimbursed costs prior to termination of the contract, respectively.

7. Discontinued Operations

As explained in Note 1, on April 24, 2019 and April 25, 2019, the Company completed the sale of its cell therapy business to Lorem and Mr. Shirahama, respectively. The following table summarizes the calculation of the loss on the sale of the cell therapy business, which was finalized during the fourth quarter of 2019 (in thousands):

Consideration received	\$	7,000
Transaction costs		(1,363)
Net cash proceeds		5,637
Less:		
Carrying value of business and assets sold		12,145
Net loss on sale of business	\$	(6,508)

There were no assets or liabilities related to discontinued operations as of September 30, 2020 or December 31, 2019.

The following table summarizes the results of discontinued operations for the nine months ended September 30, 2019 (in thousands). Discontinued operations did not have an impact on the Company's results of operations during the three months ended September 30, 2019, or the three and nine months ended September 30, 2020.

	<u>Nine Months Ended</u> <u>September 30, 2019</u>	
Product revenue	\$	901
Cost of revenue		857
Gross profit		44
Operating expenses:		
Research and development		656
Sales and marketing		411
General and administrative		185
Total operating expenses		1,252
Operating loss		(1,208)
Other income (expense)		140
Loss from discontinued operations	\$	(1,068)

During the nine months ended September 30, 2019, revenues from discontinued operations were related to the cell therapy business. Because of the sale of the cell therapy business to Lorem and Mr. Shirahama, all product revenue and costs of product revenues for these periods have been recorded in loss from discontinued operations in the consolidated condensed statements of operations and comprehensive loss.

Included in the statements of cash flows are the following non-cash adjustments related to the discontinued operations (in thousands):

	<u>Nine Months Ended September 30,</u>			
	<u>2020</u>	<u>2019</u>		
Depreciation and amortization	\$	—	\$	467

8. Loss per Share

Basic per share data is computed by dividing net income or loss applicable to common stockholders by the weighted average number of common shares outstanding during the period. Diluted per share data is computed by dividing net income or loss applicable to common stockholders by the weighted average number of common shares outstanding during the period increased to include, if dilutive, the number of additional common shares that would have been outstanding as calculated using the treasury stock method. Potential common shares were related to outstanding but unexercised options, multiple series of preferred stock, and warrants for all periods presented.

The following were excluded from the diluted loss per share calculation for the periods presented because their effect would be anti-dilutive:

	Nine Months Ended September 30,	
	2020	2019
Outstanding stock options	531,336	254,000
Outstanding warrants	3,121,125	3,637,000
Preferred stocks	422,985	298,000
Total	4,075,446	4,189,000

9. Commitments and Contingencies

Leases

At the inception of a contractual arrangement, the Company determines whether the contract contains a lease by assessing whether there is an identified asset and whether the contract conveys the right to control the use of the identified asset in exchange for consideration over a period of time. If both criteria are met, the Company calculates the associated lease liability and corresponding right-of-use asset upon lease commencement using a discount rate based on the rate implicit in the lease or an incremental borrowing rate commensurate with the term of the lease.

The Company records lease liabilities within current liabilities or long-term liabilities based upon the length of time associated with the lease payments. The Company records its operating lease right-of-use assets as long-term assets. Right-of-use assets for financing leases are recorded within property and equipment, net in the balance sheet. Leases with an initial term of 12 months or less are not recorded on the balance sheet. Instead, the Company recognizes lease expense for these leases on a straight-line basis over the lease term.

The Company leases laboratory, office and storage facilities in San Antonio, Texas, under operating lease agreements that expire in 2028. The Company also leases certain office space in Austin, Texas under a month-to-month operating lease agreement. In addition, the Company leases certain equipment under various operating and finance leases. The lease agreements generally provide for periodic rent increases, and renewal and termination options. The Company's lease agreements do not contain any material variable lease payments, residual value guarantees or material restrictive covenants.

Certain leases require the Company to pay taxes, insurance, and maintenance. Payments for the transfer of goods or services such as common area maintenance and utilities represent non-lease components. The Company elected the package of practical expedients and therefore does not separate non-lease components from lease components.

The table below summarizes the Company's lease liabilities and corresponding right-of-use assets (in thousands, except year and rates):

	As of September 30, 2020	
Assets		
Operating	\$	671
Financing		39
Total leased assets	\$	710
Liabilities		
Current:		
Operating	\$	140
Financing		39
Noncurrent:		
Operating		545
Financing		—
Total lease liabilities	\$	724
Weighted-average remaining lease term (years) - operating leases		6.53
Weighted-average remaining lease term (years) - finance leases		0.37
Weighted-average discount rate - operating leases		7.9%
Weighted-average discount rate - finance leases		5.0%

The table below summarizes the Company's lease costs from its consolidated condensed statement of operations and comprehensive loss, and cash payments from its consolidated condensed statement of cash flows during the three and nine months ended September 30, 2020 (in thousands):

	Three Months Ended		Nine Months Ended	
	September 30, 2020	September 30, 2019	September 30, 2020	September 30, 2019
Lease expense:				
Operating lease expense	\$ 52	\$ 56	\$ 160	\$ 169
Finance lease expense:				
Depreciation of right-of-use assets	32	32	95	85
Interest expense on lease liabilities	1	2	4	7
Total lease expense	\$ 85	\$ 90	\$ 259	\$ 261
Cash payment information:				
Operating cash used for operating leases	\$ 56	\$ 38	\$ 155	\$ 147
Financing cash used for financing leases	42	1	93	75
Total cash paid for amounts included in the measurement of lease liabilities	\$ 98	\$ 39	\$ 248	\$ 222

Total rent expense for the three and nine months ended September 30, 2020 was \$48,000 and \$177,000, respectively, which includes leases in the table above, month-to-month operating leases, and common area maintenance charges.

The Company's future minimum annual lease payments under operating and financing leases at September 30, 2020 are as follows in (thousands):

	Financing Leases	Operating Leases
Remaining 2020	\$ 32	\$ 49
2021	7	183
2022	—	123
2023	—	100
Thereafter	—	447
Total minimum lease payments	\$ 39	\$ 902
Less: amount representing interest	—	(217)
Present value of obligations under leases	39	685
Less: current portion	39	(140)
Noncurrent lease obligations	\$ —	\$ 545

Other commitments

The Company has entered into agreements with various research organizations for pre-clinical and clinical development studies, which have provisions for cancellation. Under the terms of these agreements, the vendors provide a variety of services including conducting research, recruiting and enrolling patients, monitoring studies and data analysis. Payments under these agreements typically include fees for services and reimbursement of expenses. The timing of payments due under these agreements is estimated based on current study progress. As of September 30, 2020, the Company did not have obligations related to its clinical research agreements.

The Company is subject to various claims and contingencies related to legal proceedings. Due to their nature, such legal proceedings involve inherent uncertainties including, but not limited to, court rulings, negotiations between affected parties and governmental actions. Management assesses the probability of loss for such contingencies and accrues a liability and/or discloses the relevant circumstances, as appropriate. Management believes that any liability to the Company that may arise as a result of currently pending legal proceedings will not have a material adverse effect on the Company's financial condition, liquidity, or results of operations as a whole.

10. NanoTx License Agreement

On March 29, 2020, the Company and NanoTx, Corp. ("NanoTx") entered into a Patent and Know-How License Agreement (the "NanoTx License Agreement"), pursuant to which NanoTx granted the Company an irrevocable, perpetual, exclusive, fully paid-up license, with the right to sublicense and to make, develop, commercialize and otherwise exploit certain patents, know-how and technology related to the development of radiolabeled nanoliposomes.

On May 7, 2020, all closing conditions under the NanoTx License Agreement were satisfied and the Company paid an upfront payment of \$400,000 in cash and issued 230,769 shares of its common stock to NanoTx. Cash and the fair value of common stock issued totaled \$781,000 and is recorded as in-process research and development expenses in the consolidated condensed statement of operations and comprehensive loss for the three and nine months ended September 30, 2020. Pursuant to the terms of the NanoTx License Agreement, the Company may be required to pay up to \$136.5 million in development and sales milestone payments and a tiered single-digit royalty on U.S. and European sales.

11. Stockholders' Equity

Preferred Stock

The Company has authorized 5,000,000 shares of preferred stock, par value \$0.001 per share. The Company's Board of Directors is authorized to designate the terms and conditions of any preferred stock the Company issues without further action by the common stockholders. There were no shares of Series A 3.6% Convertible Preferred Stock outstanding as of September 30, 2020 or December 31, 2019. There were 1,016 and 1,021 shares of Series B Convertible Preferred Stock outstanding as of each of September 30, 2020 and December 31, 2019, respectively. There were 938 shares of Series C Preferred Stock outstanding as of September 30, 2020 and December 31, 2019.

As of September 30, 2020, there were 938 outstanding shares of Series C Preferred Stock that can be converted into an aggregate of 416,889 shares of common stock, and 1,016 shares of Series B Convertible Preferred Stock that can be converted into an aggregate of 6,096 shares of common stock. In April 2020, in connection with the Warrant Amendments (defined below), the conversion price of the Series C Preferred Stock was reduced from \$3.2132 per share to \$2.25 per share.

Warrants

Pursuant to a registration statement on Form S-1 originally filed on April 27, 2018, as amended, which became effective on July 17, 2018, and related prospectus (as supplemented), the Company registered and distributed to holders of its common stock and Series B Convertible Preferred Stock, at no charge, non-transferable subscription rights to purchase up to an aggregate of 20,000 units for \$1,000 a unit. Each such unit consisted of one share of Series C Preferred Stock and 1,050 warrants ("Series T Warrants"). Pursuant to the 2018 Rights Offering, which closed on July 25, 2018, the Company sold an aggregate of 6,723 units, resulting in total net proceeds to the Company of approximately \$5.7 million. In April 2020, in connection with Warrant Amendments (defined below), the exercise price of the Series T Warrants was further adjusted such that every 50 warrants can be exercised into one share of common stock for \$2.25.

As of September 30, 2020, there were 3,787,350 outstanding Series T Warrants that can be exercised into an aggregate of 75,747 shares of common stock.

On September 25, 2019, the Company completed an underwritten public offering. The Company issued 289,000 shares of its common stock, along with pre-funded warrants to purchase 2,711,000 shares of its common stock and Series U Warrants to purchase 3,450,000 shares of its common stock at \$5.00 per share. The Series U Warrants have a term of five years from the issuance date. In addition, the Company issued warrants to H.C. Wainwright & Co., LLC, as representatives of the underwriters, to purchase 75,000 shares of its common stock at \$6.25 per share with a term of 5 years from the issuance date, in the form of Series U Warrants (the "Representative Warrants").

In accordance with authoritative guidance, the pre-funded warrants are classified as equity. The Series U Warrants and the Representative Warrants are classified at issuance as liabilities due to a contingent obligation for the Company to settle the Series U Warrants with cash upon certain change in control events.

Between April and September 2020, the Company entered into revised warrant agreements with the holders of 3,447,500 Series U Warrants ("Warrant Amendments"). In return for reducing the strike price of the warrants to \$2.25 per share, the warrant holders agreed to amend the settlement provisions upon a fundamental transaction such that the warrants would meet the requirements to be classified within stockholders' equity. In September 2020, the Company entered into revised warrant agreements for the Representative Warrants that reduced the strike price of the warrants to \$2.81 per share, and the warrant holders agreed to amend the settlement provisions upon a fundamental transaction such that the Representative Warrants would meet the requirements to be classified within stockholders' equity. Accordingly, approximately \$4.5 million of warrant liability was reclassified to the stockholders' equity section of the balance sheet on the respective effective date of the Warrant Amendment. In addition, approximately \$0.7 million of other income representing change in the fair value of amended warrants from April 1, 2020 to the respective effective date of the Warrant Amendments is recorded in the consolidated condensed statement of operations and comprehensive loss for the nine months ended September 30, 2020.

As of September 30, 2020, there were 3,045,000 outstanding Series U Warrants which can be exercised into an aggregate of 3,045,000 shares of common stock.

Common Stock

On September 21, 2018, the Company entered into a purchase agreement (the "2018 Purchase Agreement") with Lincoln Park pursuant to which the Company had the right to sell to Lincoln Park and Lincoln Park was obligated to purchase up to \$5.0 million of shares of the Company's common stock over the 24-month period following October 15, 2018. Through December 31, 2018, the Company sold a total of 12,802 shares for proceeds of approximately \$0.3 million through the 2018 Purchase Agreement. During the year ended December 31, 2019, the Company sold a total of 32,170 shares for proceeds of approximately \$0.3 million. The Company believes there is no amount remaining available under this financing facility as of September 30, 2020.

On September 30, 2020, the Company entered into a new purchase agreement (the "2020 Purchase Agreement") and registration rights agreement pursuant to which Lincoln Park has committed to purchase up to \$25.0 million of the Company's common stock. Under the terms and subject to the conditions of the 2020 Purchase Agreement, the Company has the right, but not the obligation, to sell to Lincoln Park, and Lincoln Park is obligated to purchase up to \$25.0 million of the Company's common stock. Such sales of common stock by the Company, if any, will be subject to certain limitations, and may occur from time to time, at the Company's sole discretion, over the 36-month period commencing on the date that the registration statement covering the resale of shares of common stock that have been and may be issued under the 2020 Purchase Agreement, is declared effective by the SEC and a final prospectus in connection therewith is filed. As of September 30, 2020, the Company has not sold any shares of common stock under the 2020 Purchase Agreement.

The 2020 Purchase Agreement provides that the number of shares the Company may sell to Lincoln Park on any single business day in a regular purchase is 50,000, but that amount may be increased up to 100,000 shares, depending upon the market price of the Company's common stock at the time of sale and subject to a maximum limit of \$500,000 per regular purchase. The purchase price per share for each such regular purchase will be based on prevailing market prices of the Company's common stock immediately preceding the time of sale as computed under the 2020 Purchase Agreement. In addition to regular purchases, the Company may also direct Lincoln Park to purchase other amounts as accelerated purchases or as additional accelerated purchases if the closing sale price of the common stock exceeds certain threshold prices as set forth in the 2020 Purchase Agreement. There are no trading volume requirements or restrictions under the Lincoln Park Purchase Agreement. There is no upper limit on the price per share that Lincoln Park must pay for common stock under a regular purchase or an accelerated purchase and in no event will shares be sold to Lincoln Park on a day when the Company's common stock closing sale price is less than \$0.25 per share.

On June 16, 2020, the Company received stockholder approval pursuant to Nasdaq Listing Rules 5635(a), 5635(b) and 5635(d) to permit issuances of the Company's common stock (including the issuance of more than 19.99% of the Company's common stock) to Lincoln Park pursuant to the 2020 Purchase Agreement. Based on the closing price of the Company's common stock of \$1.05 per share on March 16, 2020 (the Company's lowest closing sale price since January 1, 2020 as reported on Nasdaq.com) the maximum number of shares the Company could issue and sell under the 2020 Purchase Agreement is approximately 23.8 million shares. Accordingly, the Company requested and received stockholder approval for the issuance of up to 23.8 million shares of the Company's common stock under the 2020 Purchase Agreement. The Company would seek additional stockholder approval before issuing more than 23.8 million shares.

Lincoln Park has no right to require the Company to sell any shares of common stock to Lincoln Park, but Lincoln Park is obligated to make purchases as the Company directs, subject to certain conditions.

Actual sales of shares of common stock to Lincoln Park under the 2020 Purchase Agreement will depend on a variety of factors to be determined by the Company from time to time, including, among others, market conditions, the trading price of the common stock and determinations by the Company as to the appropriate sources of funding for the Company and its operations.

The net proceeds under the 2020 Purchase Agreement to the Company will depend on the frequency and prices at which the Company sells shares of its stock to Lincoln Park. On October 2, 2020, the Company issued 180,701 shares of common stock to Lincoln Park as a commitment fee in connection with entering into the 2020 Purchase Agreement. The \$0.5 million fair value of the commitment fee shares was recorded as other current assets as of September 30, 2020, and the Company expects to sell its common stock pursuant to the 2020 Purchase Agreement during the three months ending December 31, 2020.

12. Stock-based Compensation

On February 6, 2020, the Company amended the Company's 2015 New Employee Incentive Plan (the "2015 Plan") to increase the total number of shares of common stock reserved for issuance under the plan by 250,000 shares. Awards may only be granted under the 2015 Plan to employees who were not previously an employee or director of the Company, or following a bona fide period of non-employment, as a material inducement to entering into employment with the Company. As of September 30, 2020 there were 210,389 shares of common stock remaining and available for future issuances under the 2015 Plan.

On June 16, 2020, the stockholders of the Company approved the Company's 2020 Stock Incentive Plan ("2020 Plan"), which replaced the Company's 2014 Equity Incentive Plan. The 2020 Plan provides for the award or sale of shares of common stock (including restricted stock), the award of stock units and stock appreciation rights, and the grant of both incentive stock options to purchase common stock. The 2020 Plan provides for the issuance of up to 550,000 shares of common stock, and the number of shares available for issuance will be increased to the extent that awards granted under the 2020 Plan and the Company's 2014 Equity Incentive Plan are forfeited or expire (except as otherwise provided in the 2020 Plan). As of September 30, 2020, there were 159,939 shares of common stock remaining and available for future issuances under the 2020 Plan.

A summary of activity for the nine months ended September 30, 2020 is as follows:

	Options	Weighted Average Exercise Price	Aggregate Intrinsic Value
Outstanding as of December 31, 2019	1,865	\$ 2,968.22	
Granted	530,000	\$ 2.12	
Cancelled/forfeited	(529)	\$ 2,486.82	
Outstanding as of September 30, 2020	531,336	\$ 10.01	\$ 233,000
Vested as of September 30, 2020	39,114	\$ 106.86	\$ 17,500
Vested and expected to be vested as of September 30, 2020	482,121	\$ 10.66	\$ 211,500

As of September 30, 2020, the total compensation cost related to non-vested stock options not yet recognized for the Company's plans is approximately \$786,000, which is expected to be recognized as a result of vesting under service conditions over a weighted average period of 2.99 years.

13. COVID-19 Pandemic and CARES Act

A novel strain of coronavirus (COVID-19) was declared a global pandemic by the World Health Organization in March 2020. COVID-19 has presented substantial public health and economic challenges and is affecting economies, financial markets and business operations around the world. International and U.S. governmental authorities in impacted regions have taken action in an effort to slow the spread of COVID-19, including issuing varying forms of "stay-at-home" orders, and restricting business functions outside of one's home. In response, the Company put restrictions on employee travel and working from its executive offices with many employees continuing their work remotely. While the Company has implemented additional health and safety precautions and protocols in response to the pandemic and government guidelines, the Company has not yet experienced a significant impact on its business and operations. However, the Company may experience disruptions that could adversely impact its business operations as well as its preclinical studies and clinical trials. The Company is currently continuing the clinical trials it has underway in sites across the U.S., and, although there has been no significant impact to date, the Company expects that COVID-19 precautions may directly or indirectly impact the timeline for some of its clinical trials. Some of the Company's clinical trial sites, including those located in areas severely impacted by the pandemic, have placed new patient enrollment into clinical trials on hold or, for patients traveling from out-of-state, have implemented a 14-day self-quarantine before appointments. In addition, some clinical trial sites have imposed limited accessibility to conduct clinical monitoring and training on-site. The Company considered the impacts of COVID-19 on the assumptions and estimates used to prepare its consolidated condensed financial statements and determined that there were no material adverse impacts on the Company's results of operations and financial position at September 30, 2020. The full extent to which the COVID-19 pandemic will directly or indirectly impact its business, results of operations and financial condition, will depend on future developments that are highly uncertain, including as a result of new information that may emerge concerning COVID-19 and the actions taken to contain or treat it, as well as the economic impact on local, regional, national and international markets.

In response to the COVID-19 pandemic, the Coronavirus Aid, Relief and Economic Security Act ("CARES Act") was signed into law on March 27, 2020. The CARES Act, among other things, includes tax provisions relating to refundable payroll tax credits, deferment of employer's social security payments, net operating loss utilization and carryback periods, modifications to the net interest deduction limitations and technical corrections to tax depreciation methods for qualified improvement property (QIP). The CARES Act had no material impact on the Company's income tax provision for the three and nine months ended September 30, 2020. The Company continues to evaluate the impact of the CARES Act on its financial position, results of operations and cash flows.

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

The following discussion and analysis should be read in conjunction with the unaudited consolidated condensed financial information and the notes thereto included herein, as well as the "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our audited financial statements and notes thereto contained in our Annual Report on Form 10-K for the year ended December 31, 2019, as filed on March 30, 2020. This discussion contains forward-looking statements that involve risks and uncertainties. Our actual results and the timing of events could differ materially from those anticipated in these forward-looking statements as a result of several factors, including those set forth under the caption "Cautionary Note Regarding Forward-Looking Statements" in this report, as well as under "Part I – Item 1A - Risk Factors" in our Annual Report on Form 10-K for the year ended December 31, 2019, in other subsequent filings with the SEC, and elsewhere in this Quarterly Report on Form 10-Q. These statements, like all statements in this report, speak only as of the date of this Quarterly Report on Form 10-Q (unless another date is indicated), and we undertake no obligation to update or revise these statements in light of future developments.

Our Management's Discussion and Analysis of Financial Condition and Results of Operations includes the following sections:

- Overview that discusses our business and some of the relevant trends.
- Results of Operations that includes a detailed discussion of our revenue and expenses.
- Liquidity and Capital Resources which discusses key aspects of our statements of cash flows, changes in our financial position and our financial commitments.
- Significant changes since our most recent Annual Report on Form 10-K in the Critical Accounting Policies and Significant Estimates that we believe are important to understanding the assumptions and judgments underlying our financial statements.

Overview

Plus Therapeutics, Inc. is a clinical-stage pharmaceutical company focused on the development, manufacture and commercialization of complex and innovative treatments for patients battling cancer and other life-threatening diseases.

Our proprietary nanotechnology platform is currently centered around the enhanced delivery of a variety of drugs using novel liposomal encapsulation technology. Liposomal encapsulation has been extensively explored and undergone significant technical and commercial advances since it was first developed. Our platform is designed to facilitate new delivery approaches and/or formulations of safe and effective, injectable drugs, potentially enhancing the safety, efficacy and convenience for patients and healthcare providers.

We plan to leverage our nanotechnology platform and expertise using a simple multi-step model that enables us to address unmet needs or underserved conditions while managing risks and minimizing development costs through: (1) mapping of the current and anticipated market landscape to clearly understand the clinical and commercial opportunities and defining nanotechnology options, (2) redesign of known, safe and effective active pharmaceutical ingredients with new nanotechnology, (3) manufacture-to-scale of the reformulated drug along with critical non-clinical (i.e. bench, animal) analyses, (4) evaluation of early-stage clinical utility with a focus on proving safety and defining efficacy over the current standard of care, and (5) partnering the innovative treatment for late-stage clinical trials, regulatory approval, and commercial launch.

Plus' current pipeline includes three clinical stage drugs:

- Rhenium NanoLiposomes (RNL™), a novel liposomal radiotherapeutic, the lead indication is recurrent glioblastoma (rGBM) that is currently being evaluated in the U.S. NIH/NCI-supported, multi-center ReSPECT™ Phase 1 dose finding clinical trial;
- DocePLUS™, a novel liposomal chemotherapeutic, which has completed a U.S. Phase 1 clinical trial; and
- DoxoPLUS™, a novel liposomal chemotherapeutic, clinical bioequivalence demonstrated to Janssen's CAELYX® in ovarian cancer patients.

BMEDA-Chelated Rhenium NanoLiposomes (RNL™), is our lead drug asset and is initially being developed for recurrent glioblastoma. RNL™ was part of the licensed radiotherapeutic portfolio that we acquired from NanoTx, Corp. ("NanoTx") on May 7, 2020. The licensed radiolabeled nanoliposome platform includes nanoliposome-encapsulated radionuclides for several cancer targets and was developed by a multi-institutional consortium based in Texas at the Mays Cancer Center / UT Health San Antonio MD Anderson Cancer Center led by Dr. Andrew Brenner, MD, PhD, who is the Koltz Chair in Neuro-Oncology Research and Co-Leader of the Experimental and Developmental Therapeutics Program. The licensed technology was previously funded by both the National Institutes of Health/National Cancer Institute (NIH/NCI) and the Cancer Prevention and Research Institute of Texas (CPRIT). Dr. Brenner's RNL research program has an active \$3M award from NIH/NCI which will financially support the continued clinical development of RNL for recurrent glioblastoma.

In treating recurrent glioblastoma, RNL™ is infused directly into the brain tumor via precision brain mapping and convection enhanced delivery technology that allows delivery of very high doses of radiation in patients whose cancer has recurred following initial surgical resection and treatment with chemo radiation. RNL™ is intended to safely and effectively deliver a dose of radiation directly to the tumor that is up to 15-20 times greater than that currently being given to patients using external beam radiation therapy.

Furthermore, unlike standard external beam radiation therapy (EBRT) that is delivered day after day for weeks in order to achieve a tolerated cumulative dose, RNL™ is administered to the patient in a single procedure during a 4-day hospital stay. RNL™ has a number of technical features that give it advantages over other approaches to treating glioblastoma and potentially other tumors. First, very high doses of Rhenium beta radiation, perhaps up to 15-20 times greater than EBRT, are delivered. Second, the Rhenium-186 isotope is a dual energy emitter. It's made in a nuclear reactor and delivers both a beta particle, or high energy free electron to kill rapidly dividing cancer cells, but it also emits a gamma particle for imaging person purposes, so doctors know with precision where the radiation is at any time during and after treatment. Third, it has a long half-life, or time on tumor, of approximately 90 hours. Fourth, RNL™ is delivered beyond the blood-brain barrier directly to the tumor with novel delivery and imaging technologies. Fifth, it has tumor micro fields that increase each Rhenium's atom another 2 to 4 millimeters to help reach a residual non-enhancing tumor. Sixth, it's metabolized safely by the kidneys without collateral damage to local structures and radio sensitive organs such as bone marrow, very similar to I-131 for thyroid cancer.

Recurrent glioblastoma is a cancer that affects about 12,000 people per year in the U.S. and for which there are currently few approved treatments that in aggregate provide only a marginal survival benefit. And notably, essentially all primary tumors recur after initial treatment. Even today, EBRT is the most effective component of the standard multimodal therapeutic regime used to treat glioblastoma. Multiple randomized studies show five-month improvement in survival with EBRT compared to an additional 2.5 months with the addition of chemotherapy and 3 months for tumor treating fields.

By infusing the RNL™ drug directly into the tumor, bypassing the blood-brain barrier, normal brain and external tissues are spared from radiation damage. In the case of these drugs the mechanism of action is unambiguous. We believe that radiation in the form of high energy electrons is effective against glioblastoma if an adequate dose can be effectively delivered. For comparison, current EBRT protocols for recurrent glioblastoma typically recommend a total max dose of about 35 Gy. In contrast to most recent patient dosed with RNL™ in our clinical trial received over 500 Gy without significant adverse effect to date.

In terms of the current clinical trial status, we are currently in a U.S. FDA approved Phase 1 dose finding study at two sites in Texas at UT Health San Antonio and UT Southwestern Medical Center in Dallas, with plans underway to expand to one additional sites in Texas, MD Anderson in Houston. Thus far, we have completed the fifth dosing escalation cohort. The radiation dose in the current cohort is now at approximately 15 times the dose that is typically delivered by EBRT.

Current activities related to both DocePLUS and DoxoPLUS are restricted to the identification of potential partners for these two drugs.

Recent Developments

Lincoln Park Purchase Agreement

On September 30, 2020, we entered into a purchase agreement (the "2020 Purchase Agreement") and registration rights agreement pursuant to which Lincoln Park Capital Fund, LLC ("Lincoln Park") has committed to purchase up to \$25.0 million of our common stock. Under the terms and subject to the conditions of the 2020 Purchase Agreement, we have the right, but not the obligation, to sell to Lincoln Park, and Lincoln Park is obligated to purchase up to \$25.0 million of our common stock. Such sales of common stock by us, if any, will be subject to certain limitations, and may occur from time to time, at our sole discretion, over the 36-month period commencing on the date that the registration statement covering the resale of shares of common stock that have been and may be issued under the 2020 Purchase Agreement, is declared effective by the SEC and a final prospectus in connection therewith is filed. The number of shares we may sell to Lincoln Park on any single business day in a regular purchase is 50,000, but that amount may be increased up to 100,000 shares, depending upon the market price of our common stock at the time of sale and subject to a maximum limit of \$500,000 per regular purchase. The purchase price per share for each such regular purchase will be based on prevailing market prices of our common stock immediately preceding the time of sale as computed under the 2020 Purchase Agreement. In addition to regular purchases, we may also direct Lincoln Park to purchase other amounts as accelerated purchases or as additional accelerated purchases if the closing sale price of the common stock exceeds certain threshold prices as set forth in the 2020 Purchase Agreement. We agreed to issue 180,701 shares of common stock to Lincoln Park as a commitment fee in connection with entering into the 2020 Purchase Agreement.

Fast Track Designation

On September 4, 2020, we were granted Fast Track designation from the U.S. Food and Drug Administration (FDA) for our lead investigational drug, Rhenium NanoLiposomes (RNL™), for the treatment of patients with recurrent glioblastoma. As previously reported, we also received orphan drug designation from the FDA for RNL for the treatment of patients with glioblastoma.

Fast Track designation confers several benefits to the drug development program including 1) more frequent meetings with the FDA to discuss the drug's development plan, 2) more frequent written communication from the FDA about such things as the design of the

proposed clinical trials and use of biomarkers, 3) eligibility for Accelerated Approval and Priority Review, if relevant criteria are met, and 4) Rolling Review, which means that a drug company can submit completed sections of its New Drug Application (NDA) for review by the FDA, rather than waiting until every section of the NDA is completed before the entire application can be reviewed. NDA review usually does not begin until the drug company has submitted the entire application to the FDA.

COVID-19 Impact

A novel strain of coronavirus (COVID-19) was declared a global pandemic by the World Health Organization in March 2020. COVID-19 has presented substantial public health and economic challenges and is affecting economies, financial markets and business operations around the world. International and U.S. governmental authorities in impacted regions have taken action in an effort to slow the spread of COVID-19, including issuing varying forms of “stay-at-home” orders, and restricting business functions outside of one’s home. In response, we have put restrictions on employee travel and working from our executive offices with many employees continuing their work remotely. While we have implemented additional health and safety precautions and protocols in response to the pandemic and government guidelines, we have not yet experienced a significant impact on our business and operations. However, we may experience disruptions that could adversely impact our business operations as well as our preclinical studies and clinical trials. We are currently continuing the clinical trials we have underway in sites across the U.S., and we expect that COVID-19 precautions may directly or indirectly impact the timeline for some of our clinical trials. Some of our clinical trial sites, including those located in areas severely impacted by the pandemic, have placed new patient enrollment into clinical trials on hold or, for patients traveling from out-of-state, have implemented a 14-day self-quarantine before appointments. In addition, some clinical trial sites have imposed limited accessibility to conduct clinical monitoring and training on-site. We considered the impacts of COVID-19 on the assumptions and estimates used to prepare our financial statements and determined that there were no material adverse impacts on our results of operations and financial position at September 30, 2020.

The full impact of the COVID-19 outbreak continues to evolve as of the date of this report. For example, as certain states and regions across the United States have relaxed various restrictions on businesses and other activities, it is uncertain whether and to what extent federal, state, or local governments may reinstate additional restrictions and safety protocols in response to any increases in COVID-19 cases. As such, it is uncertain as to the full magnitude that the pandemic will have on our operations, including our preclinical studies and clinical trials, financial condition, liquidity, and future results of operations. Management is actively monitoring the global situation and its impact on our clinical program and timeline, financial condition, liquidity, operations, suppliers, industry, and workforce. We continue to evaluate the extent to which delays as a result of COVID-19 will impact our ability to manufacture our product candidates for our clinical trials and conduct other research and development operations and maintain applicable timelines. Given the daily evolution of the COVID-19 outbreak and the global responses to curb its spread, we are not able to estimate the effects of the COVID-19 outbreak on our results of operations, financial condition, or liquidity for fiscal year 2020.

In response to the COVID-19 pandemic, the Coronavirus Aid, Relief and Economic Security Act (“CARES Act”) was signed into law on March 27, 2020. The CARES Act, among other things, includes tax provisions relating to refundable payroll tax credits, deferment of employer’s social security payments, net operating loss utilization and carryback periods, modifications to the net interest deduction limitations and technical corrections to tax depreciation methods for qualified improvement property (QIP). The CARES Act had no material impact on our income tax provision for the three and nine months ended September 30, 2020. We continue to evaluate the impact of the CARES Act on our financial position, results of operations and cash flows.

Results of Operations

Development revenues

Under our government contract with BARDA, we recognized a total of \$0 and \$0.3 million in revenues for the three and nine months ended September 30, 2020, and \$0 and \$0.3 million in qualified expenditures for those periods. The BARDA contract was terminated in December 2019 and the contract close out process was completed during the three months ended September 30, 2020.

Development revenue for the nine months ended September 30, 2019 included \$4.6 million of revenue recognized under the BARDA contract based on retrospective changes in indirect cost rates during fiscal years 2012 through 2019.

Research and development expenses

Research and development expenses include costs associated with the design, development, testing and enhancement of our products, payment of regulatory fees, laboratory supplies, pre-clinical studies and clinical studies.

The following table summarizes the components of our research and development expenses for the three and nine months ended September 30, 2020 and 2019 (in thousands):

	<u>Three Months Ended September 30,</u>		<u>Nine Months Ended September 30,</u>	
	<u>2020</u>	<u>2019</u>	<u>2020</u>	<u>2019</u>
Research and development	\$ 325	\$ 911	\$ 1,585	\$ 3,604
Share-based compensation	11	10	19	32
Total research and development expenses	\$ 336	\$ 921	\$ 1,604	\$ 3,636

The decrease in research and development expenses for the three and nine months ended September 30, 2020 as compared to the same period in 2019 is due primarily to decreased professional services as a result of discontinuing manufacturing subsequent to sale of our former cell therapy business, as well as reduction in research and development expenses related to Doceplus and Doxoplus.

We expect aggregate research and development expenditures to increase during the remainder of 2020 due to the expected costs of development of the RNL™ therapy acquired from NanoTx.

In process research and development acquired from NanoTx

In process research and development acquired from NanoTx in the amount of \$781,000 represents the upfront cash payment and fair value of 230,769 shares of common stock, with fair value of \$1.65 per share, issued to NanoTx in accordance with the terms of the License Agreement.

Sales and marketing expenses

Sales and marketing expenses include costs of marketing personnel, events and tradeshows, primary and secondary market research, and product and service promotion. The following table summarizes the components of our sales and marketing expenses for the three and nine months ended September 30, 2020 and 2019 (in thousands):

	<u>Three Months Ended September 30,</u>		<u>Nine Months Ended September 30,</u>	
	<u>2020</u>	<u>2019</u>	<u>2020</u>	<u>2019</u>
Sales and marketing	\$ 100	\$ 92	\$ 313	\$ 296
Share-based compensation	4	2	6	9
Total sales and marketing expenses	\$ 104	\$ 94	\$ 319	\$ 305

Sales and marketing expenses remained generally consistent for the three and nine months ended September 30, 2020 compared with the same period of 2019.

We expect sales and marketing expenditures to remain generally consistent on a quarterly basis for the remainder of 2020 as compared with the quarter ended September 30, 2020.

General and administrative expenses

General and administrative expenses include costs for administrative personnel, legal and other professional expenses, and general corporate expenses. The following table summarizes the general and administrative expenses for the three and nine months ended September 30, 2020 and 2019 (in thousands):

	<u>Three Months Ended September 30,</u>		<u>Nine Months Ended September 30,</u>	
	<u>2020</u>	<u>2019</u>	<u>2020</u>	<u>2019</u>
General and administrative	\$ 877	\$ 1,059	\$ 3,664	\$ 3,248
Share-based compensation	79	17	124	65
Total general and administrative expenses	\$ 956	\$ 1,076	\$ 3,788	\$ 3,313

General and administrative expenses decreased by \$0.1 million during the three months ended September 30, 2020, as compared to the same period in 2019 due to reduction of \$0.1 million of legal and professional fees in the three months ended September 30, 2020. General and administrative expenses increased by \$0.5 million during the nine months ended September 30, 2020, as compared to the same period in 2019 due to increase of \$0.5 million of legal and professional fees in the nine months ended September 30, 2020.

We expect general and administrative expenditures to remain generally consistent on a quarterly basis for the remainder of 2020 as compared with the quarter ended September 30, 2020.

Share-based compensation expense

Share-based compensation expense includes charges related to options and restricted stock awards issued to employees, directors and non-employees. We measure stock-based compensation expense based on the grant-date fair value of any awards granted to our employees. Such expense is recognized over the requisite service period.

The following table summarizes the components of our share-based compensation expenses for the three and nine months ended September 30, 2020 and 2019 (in thousands):

	<u>Three Months Ended September 30,</u>		<u>Nine Months Ended September 30,</u>	
	<u>2020</u>	<u>2019</u>	<u>2020</u>	<u>2019</u>
Research and development	\$ 11	10	\$ 19	32
Sales and marketing	4	2	6	9
General and administrative	79	17	124	65
Total share-based compensation	<u>\$ 94</u>	<u>\$ 29</u>	<u>\$ 149</u>	<u>\$ 106</u>

On June 16, 2020, our stockholders approved the 2020 Stock Incentive Plan (the "2020 Plan"). The 2020 Plan replaced our 2014 Equity Incentive Plan. Pursuant to the 2020 Plan, we reserved for issuance 550,000 shares of our common stock for future awards, and granted 444,000 options to our employees, directors, and, as appropriate, to non-employee service providers. In addition, previously-granted options will continue to vest in accordance with their original terms. As of September 30, 2020, the total compensation cost related to non-vested stock options and stock awards not yet recognized for all our plans is approximately \$786,000 which is expected to be recognized as a result of vesting under service conditions over a weighted average period of 2.99 years.

Financing items

The following table summarizes interest income, interest expense, and other income and expense for the three and nine months ended September 30, 2020 and 2019 (in thousands):

	<u>Three Months Ended September 30,</u>		<u>Nine Months Ended September 30,</u>	
	<u>2020</u>	<u>2019</u>	<u>2020</u>	<u>2019</u>
Interest income	\$ 2	\$ 6	\$ 47	\$ 20
Interest expense	(253)	(366)	(854)	(1,477)
Change in fair value of warrants	(81)	(561)	2,342	(69)
Warrant issuance cost	—	(1,233)	—	(1,233)
Total	<u>\$ (332)</u>	<u>\$ (2,154)</u>	<u>\$ 1,535</u>	<u>\$ (2,759)</u>

The decrease in interest expense for the three and nine months ended September 30, 2020 as compared to the same period in 2019 was primarily due to the repayments of debt principal of \$3.1 million in April 2019 and \$5.0 million in April 2020. The changes in fair value of our warrant liabilities are primarily due to fluctuations in the valuation inputs for the warrants. See Note 4 to the consolidated condensed financial statements included elsewhere herein for disclosure and discussion of our warrant liabilities.

We expect interest expense in 2020 to decrease as compared with 2019 due to principal repayment of \$5.0 million on April 1, 2020. In April, June, July and September 2020, we entered into revised warrant agreements with the holders of 3,447,500 Series U warrants and in September 2020, we entered into revised warrant agreements for 75,000 of Representative Warrants. In return for reducing the strike price of the warrants, the warrant holders agreed to amend the settlement provisions upon fundamental transactions. The amended Series U warrants meet the requirements for equity classification under authoritative accounting guidance and are no longer subject to mark to market accounting post amendment.

Liquidity and Capital Resources

Short-term and long-term liquidity

The following is a summary of our key liquidity measures at September 30, 2020 and December 31, 2019 (in thousands):

	<u>As of September 30,</u>	<u>As of December 31,</u>
	<u>2020</u>	<u>2019</u>
Cash and cash equivalents	\$ 7,626	\$ 17,552
Current assets	\$ 8,649	\$ 19,825
Current liabilities	8,404	14,486
Working capital	<u>\$ 245</u>	<u>\$ 5,339</u>

We incurred net losses of \$4.7 million for the nine months ended September 30, 2020. We have an accumulated deficit of \$429.9 million as of September 30, 2020. Additionally, we used net cash of \$5.2 million to fund our operating activities for the nine months ended September 30, 2020. These factors raise substantial doubt about our ability to continue as a going concern.

To date, these operating losses have been funded primarily from outside sources of invested capital in our common stock, proceeds raised from the Loan and Security Agreement, and gross profits. We have had, and we will continue to have, an ongoing need to raise additional cash from outside sources to fund our future clinical development programs and other operations. Our inability to raise additional cash would have a material and adverse impact on operations and would cause us to default on our loan.

On September 30, 2020, we entered into the 2020 Purchase Agreement and a registration rights agreement pursuant to which Lincoln Park committed to purchase up to \$25.0 million of our common stock. Under the terms and subject to the conditions of the 2020 Purchase Agreement, we have the right, but not the obligation, to sell to Lincoln Park, and Lincoln Park is obligated to purchase up to \$25.0 million of our common stock. Such sales of common stock by us, if any, will be subject to certain limitations, and may occur from time to time, at our sole discretion, over the 36-month period commencing on the date that the registration statement covering the resale of shares of common stock that have been and may be issued under the 2020 Purchase Agreement, is declared effective by the SEC and a final prospectus in connection therewith is filed. The net proceeds under the 2020 Purchase Agreement will depend on the frequency and prices at which we sell shares of our common stock to Lincoln Park. We expect that any proceeds received from such sales to Lincoln Park will be used for working capital and general corporate purposes.

On March 29, 2020, we entered into the Ninth Amendment, pursuant to which, among other things, Oxford agreed to defer the start date of principal repayment from May 1, 2020 to May 1, 2021. In addition, on April 1, 2020, we made a \$5.0 million paydown of principal upon execution of the Ninth Amendment. As a result of this Ninth Amendment, the term of the Term Loan has been extended from September 1, 2021 to September 1, 2024, with all other major terms remained consistent.

In September 2019, we finalized the indirect cost rate under the BARDA Agreement for indirect costs incurred during the years 2012 through 2019, which resulted in approximately \$4.6 million of revenue recognized during the year ended December 31, 2019. The BARDA contract was terminated in December 2019 and the contract close out process was completed during the three months ended September 30, 2020.

In September 2019, we entered into an underwriting agreement with H.C. Wainwright & Co., LLC (the "Representative"), as representative of the underwriters (the "Underwriters"), pursuant to which we sold in an underwritten public offering an aggregate of (i) 289,000 Class A Units, each consisting of one share of our common stock, par value \$0.001 per share, and one Series U warrant to purchase one share of common stock, and (ii) 2,711,000 Class B Units, each consisting of one pre-funded Series V warrant to purchase one share of common stock and one Series U warrant to purchase one share of common stock at a public offering price of \$5.00 per Class A Unit and \$4.9999 per Class B Unit ("September 2019 Offering"). In addition, we granted the Underwriters a 45-day option to purchase up to an additional 450,000 shares of our common stock and/or Series U warrants at the public offering price, less the underwriting discounts and commissions. The Underwriters exercised their option to purchase an additional 450,000 Series U warrants. We also issued to the Representative warrants (in the form of the Series U warrants) to purchase 75,000 shares of common stock with an exercise price of \$6.25 per share of common stock ("Representative Warrants"). In September 2020, we entered into revised warrant agreements for the Representative Warrants that reduced the strike price of the warrants to \$2.82 per share.

On April 24, 2019, we received \$3.3 million of net cash proceeds related to the sale of the UK subsidiary and our cell therapy assets (excluding such assets used in Japan or relating to our contract with BARDA), of which \$1.7 million was used to pay down principal, interest and fees on the Loan and Security Agreement, and on April 25, 2019, we received \$2.4 million of net cash proceeds related to the sale of our Japanese subsidiary, Cytori Therapeutics, K.K., and substantially all of our cell therapy assets used in Japan, of which \$1.4 million was used to pay down principal, interests and fees on the Loan and Security Agreement.

We continue to seek additional capital through strategic transactions and other financing alternatives. Without additional capital, current working capital and cash generated from sales will not provide adequate funding for research, sales and marketing efforts and product development activities at their current levels. If sufficient capital is not raised, we will at a minimum need to significantly reduce or curtail our research and development and other operations, and this would negatively affect our ability to achieve corporate growth goals. Although the stock markets and our stock price have recovered to some extent in recent weeks, there may likely be continued market volatility due to the pandemic or other events, which could cause our stock price to decline. This in turn will likely negatively impact our ability to raise funds through equity-related financings. Further, a continued global economic downturn may impair our ability to obtain additional financing through other means, such as strategic transactions or debt financing. The overall deterioration of the credit and financial markets due to the COVID-19 pandemic will likely generally reduce our ability to obtain additional financing to fund our operations.

Should we be unable to raise additional cash from outside sources or if we are unable to do so in a timely manner or on commercially reasonable terms, it would have a material adverse impact on our operations.

Cash provided by (used in) operating, investing, and financing activities for the nine months ended September 30, 2020 and 2019 is summarized as follows (in thousands):

	<u>For the Nine Months Ended September 30,</u>	
	<u>2020</u>	<u>2019</u>
Net cash used in operating activities	\$ (5,210)	\$ (6,942)
Net cash provided by (used in) investing activities	(437)	5,629
Net cash provided by (used in) financing activities	(4,319)	12,890
Effect of exchange rate changes on cash and cash equivalents	—	(4)
Net increase (decrease) in cash and cash equivalents	<u>\$ (9,966)</u>	<u>\$ 11,573</u>

Operating activities

Net cash used in operating activities for the nine months ended September 30, 2020 was \$5.2 million compared to \$6.9 million in the same period of 2019. Overall, our operational cash use decreased during the nine months ended September 30, 2020 as compared to the same period in 2019, due primarily to timing of cash payments made for operating assets and liabilities.

Investing activities

Net cash used in investing activities for the nine months ended September 30, 2020 was primarily related to cash payments made for in process research and development assets from NanoTx, and purchases of fixed assets. Net cash provided by investing activities for the nine months ended September 30, 2019 were related to the sale of the cell therapy business for gross proceeds of \$5.6 million.

Financing Activities

Net cash used for financing activities for the nine months ended September 30, 2020 was related to repayment of \$5.0 million of the Term Loan in April 2020, and cash payments for our finance leases, offset by cash proceeds received from warrant exercises of \$1.1 million. Net cash used in financing activities for the nine months ended September 30, 2019 was primarily related to net proceeds received in the September 2019 Offering and sale of common stock under the Lincoln Park Purchase Agreement of \$16.0 million, proceeds from exercise of warrants of \$0.5 million, offset by the principal payment of long-term obligations of \$3.5 million.

Critical Accounting Policies and Significant Estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the United States requires us to make estimates and assumptions that affect the reported amounts of our assets, liabilities, revenues and expenses, and that affect our recognition and disclosure of contingent assets and liabilities.

While our estimates are based on assumptions, we consider reasonable at the time they were made, our actual results may differ from our estimates, perhaps significantly. If results differ materially from our estimates, we will make adjustments to our financial statements prospectively as we become aware of the necessity for an adjustment.

Goodwill is reviewed for impairment annually or more frequently if indicators of impairment exist. We perform our impairment test annually during the fourth quarter. We operate in a single operating segment and reporting unit. We monitor the fluctuations in our share price and have experienced significant volatility during the year.

We estimate the fair value of liability classified warrants using an option pricing model. Following the authoritative accounting guidance, warrants with variable exercise price features or with potential cash settlement outside control of the Company are accounted for as liabilities, with changes in the fair value included in operating expenses.

We believe it is important for you to understand our most critical accounting policies. Our critical accounting policies and estimates are discussed in our Annual Report on Form 10-K for the fiscal year ended December 31, 2019 and there have been no material changes during the nine months ended September 30, 2020.

Item 3. Quantitative and Qualitative Disclosures about Market Risk

Not applicable.

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

We maintain “disclosure controls and procedures,” as such term is defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, that are designed to ensure that information required to be disclosed in our reports that we file or furnish pursuant to the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission’s rules and forms, and that such information is accumulated and communicated to our management, including our Chief Executive Officer

(our principal executive officer) and Chief Financial Officer (our principal financial officer and principal accounting officer), as appropriate, to allow for timely decisions regarding required disclosure. In designing and evaluating the disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives, and management necessarily is required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

As required by Rule 13a-15(b) under the Exchange Act, we carried out an evaluation, under the supervision and with the participation of our management, including our Chief Executive Officer (our principal executive officer) and Chief Financial Officer (our principal financial officer and principal accounting officer), of the effectiveness of our disclosure controls and procedures, as such term is defined under Rule 13a-15(e) and 15d-15(e) promulgated under the Exchange Act, as of the end of the period covered by this Quarterly Report on Form 10-Q. Based on the foregoing, our Chief Executive Officer (our principal executive officer) and Chief Financial Officer (our principal financial officer and principal accounting officer) concluded that our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) were effective at the reasonable assurance level as of the end of the period covered by this Quarterly Report.

Changes in Internal Control over Financial Reporting

There have been no changes in our internal control over financial reporting during the quarter ended September 30, 2020 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

Item 1. Legal Proceedings

From time to time, we have been involved in routine litigation incidental to the conduct of our business. As of September 30, 2020, we were not a party to any material legal proceedings.

Item 1A. Risk Factors

For a discussion of certain factors that could materially affect our business, financial condition, and operating results or that could cause actual results to differ materially from the results described in or implied by the forward-looking statements in this Quarterly Report on Form 10-Q, in addition to the information in the section entitled “Cautionary Statement Regarding Forward-Looking Statements,” you should carefully review and consider the information under “Part I, Item 1A- Risk Factors” in our Annual Report on Form 10-K for the year ended December 31, 2019, as well as the risk factors set forth below. The risk factors below are in addition to and supplement (and with respect to certain matters, update) the risk factors discussed in our Annual Report on Form 10-K. Other than as set forth below, there have been no material changes to the risk factors included in our Annual Report on Form 10-K for the year ended December 31, 2019.

Risks Related to our Business and Industry

We may require additional financing to sustain our operations, without which we may not be able to continue operations, and the terms of subsequent financings may adversely impact our stockholders.

We may direct Lincoln Park to purchase up to \$25.0 million worth of shares of our common stock under the 2020 Purchase Agreement over a 36-month period generally in amounts up to 50,000 shares of our common stock, which may be increased to up to 100,000 shares of our common stock depending on the market price of our common stock at the time of sale, provided that Lincoln Park’s committed obligation under such single Regular Purchase shall not exceed \$500,000.

The extent we rely on Lincoln Park as a source of funding will depend on a number of factors including the prevailing market price of our common stock and the extent to which we are able to secure working capital from other sources. If obtaining sufficient funding from Lincoln Park were to prove unavailable or prohibitively dilutive, we will need to secure another source of funding in order to satisfy our working capital needs. Even if we sell all \$25.0 million of shares of our common stock under the 2020 Purchase Agreement to Lincoln Park, we may still need additional capital to finance our future production plans and working capital needs, and we may have to raise funds through the issuance of equity or debt securities. Depending on the type and the terms of any financing we pursue, stockholders’ rights and the value of their investment in our common stock could be reduced. A financing could involve one or more types of securities including common stock, convertible debt or warrants to acquire common stock. These securities could be issued at or below the then prevailing market price for our common stock. In addition, if we issue secured debt securities, the holders of the debt would have a claim to our assets that would be prior to the rights of stockholders until the debt is paid. Interest on these debt securities would increase costs and negatively impact operating results. If the issuance of new securities results in diminished rights to holders of our common stock, the market price of our common stock could be negatively impacted.

Should the financing we require to sustain our working capital needs be unavailable or prohibitively expensive when we require it, the

consequences could be a material adverse effect on our business, operating results, financial condition and prospects.

The COVID-19 pandemic could adversely affect our business, results of operations, and financial condition.

The effects of the COVID-19 pandemic on our business continue to evolve and are difficult to predict. To date, the COVID-19 pandemic has significantly and negatively impacted the global economy, and the magnitude, severity, and duration of this impact is unclear and difficult to assess. To combat the spread of COVID-19, the United States and other locations in which we operate have imposed measures such as quarantines and “shelter-in-place” orders that are restricting business operations and travel and requiring individuals to work from home (“WFH”), which has impacted all aspects of our business as well as those of the third-parties with which we collaborate or upon which we rely for certain supplies and services. While certain states and regions across the United States have subsequently relaxed various restrictions on businesses and other activities, some of these areas, including Texas where our headquarters are located, have subsequently experienced an increase in COVID-19 cases. It is uncertain whether and to what extent federal, state, or local governments may reinstate additional restrictions and safety protocols in response to any increases in COVID-19 cases. The continuation of WFH and other restrictions for an extended period of time may negatively impact our productivity, research and development, operations, preclinical studies, clinical trials, business and financial results. Among other things, the COVID-19 pandemic may result in:

- a global economic recession or depression that could significantly and negatively impact our business or those of third parties upon which we rely for services and supplies;
- constraints on our ability to conduct our operations and our preclinical studies and clinical trials;
- constraints on our ability to partner with other companies to commercialize our product candidates;
- constraints on our business strategy to aggressively develop our Nanomedicine platforms;
- reduced productivity in our business operations, research and development, marketing, and other activities;
- disruptions to our third-party manufacturers and suppliers;
- increased costs resulting from WFH or from our efforts to mitigate the impact of COVID-19; and
- reduced access to financing to fund our operations due to a deterioration of credit and financial markets.

The continued disruption of the COVID-19 pandemic may negatively and materially impact our operating and financial operating results, including our cash flows. The resumption of normal business operations may be delayed and a resurgence of COVID-19 could occur, which would result in continued disruption to us or third parties with whom we do business. As a result, the effects of the COVID-19 pandemic could have a material adverse impact on our business, results of operations and financial condition for the remainder of 2020 and beyond.

A significant or prolonged downturn in the worldwide economy may harm our business.

The COVID-19 pandemic has caused a significant downturn in the worldwide economy, the severity, magnitude, and duration of which is uncertain. In addition, the deterioration in credit markets and financial markets could limit our ability to obtain external financing to fund our operations and capital expenditures. The downturn in the worldwide economy could have a material adverse effect on our business, results of operations, or financial condition.

We will need substantial additional funding to develop our products and conduct our future operations and to repay our outstanding debt obligations, and the impact of the COVID-19 pandemic on the financial markets will likely negatively impact our ability to raise additional financing. If we are unable to obtain the funds necessary to do so, we may be required to delay, scale back or eliminate our product development activities or may be unable to continue our business operations.

We do not currently believe that our cash resources will be sufficient to fund the development and marketing efforts required to reach profitability without raising additional capital in the near future. We will also continue to require substantial additional capital to continue our clinical development and potential commercialization activities and to pay our debt obligations. As a result, we have had, and we will continue to have, an ongoing need to raise additional capital from outside sources to continue funding our operations, including our continuing substantial research and development expenses. The amount and timing of our future funding requirements will depend on many factors, including the pace and results of our clinical development efforts.

We have secured capital historically from grant revenues, collaboration proceeds, and debt and equity offerings. To obtain additional capital, we may pursue debt and/or equity financing arrangements, strategic corporate partnerships, state and federal development programs, licensing arrangements, and sales of assets or debt or equity securities. On September 30, 2020, we entered into a new equity line facility with Lincoln Park to provide additional capital. We cannot be certain that additional capital will be available on terms acceptable to us, in a timely manner, or at all. If we are unsuccessful in our efforts to raise any such additional capital, we may be required to take actions that could materially and adversely harm our business, including a possible significant reduction in our research, development and administrative operations (including reduction of our employee base), the surrender of our rights to some technologies or product opportunities, delay of our clinical trials or regulatory and reimbursement efforts, or curtailment or cessation of operations. Further, if we are unable to raise additional capital, we may be unable to satisfy the covenants or meet our repayment obligations under our existing loan agreement.

Our stock price has been negatively impacted in part by the significant volatility and downturn in the financial markets due to the COVID-19 pandemic. This in turn will likely negatively impact our ability to raise funds through equity-related financing. Further, the global economic downturn and deterioration of the credit and financial markets may impair our ability to obtain additional financing through other means, such as strategic agreements or debt financing. Further any debt financing may contain restrictive covenants which limit our operating flexibility and any equity financing will likely result in additional and possibly significant dilution to existing stockholders. Failure to raise sufficient capital, as and when needed, would have a significant and negative impact on our financial condition and our ability to develop our product candidates.

The disruption and volatility in the global capital markets may impact our ability to obtain additional debt financings and may limit our ability to modify our existing debt facilities and increase the risk of non-compliance with covenants under our existing loan agreement.

Under the Loan and Security Agreement, Oxford made a term loan to us in an aggregate principal amount of \$17.7 million (the “Term Loan”) subject to the terms and conditions set forth therein. As of September 30, 2020, the outstanding principal balance of the Term Loan was \$4.3 million subsequent to a repayment of \$5.0 million on April 1, 2020 pursuant to the Ninth Amendment to the Loan and Security Agreement.

The Term Loan accrues interest at a floating rate equal to the three-month LIBOR rate (with a floor of 1.00%) plus 7.95% per annum. On March 29, 2020, we and Oxford amended the Loan and Security Agreement to extend the interest-only period. Beginning May 1, 2021, we will be required to make payments of principal and accrued interest in equal monthly installments to amortize the Term Loan through September 1, 2024, the new maturity date.

As security for our obligations under the Loan and Security Agreement, we granted a security interest in substantially all of our existing and after-acquired assets, excluding our intellectual property assets, subject to certain exceptions set forth in the Loan and Security Agreement. If we are unable to discharge these obligations, Oxford could foreclose on these assets, which would, at a minimum, have a severe material adverse effect on our ability to operate our business.

Our indebtedness to Oxford could adversely affect our operations and liquidity, by, among other things:

- causing us to use a larger portion of our cash flow to fund interest and principal payments, reducing the availability of cash to fund working capital and capital expenditures and other business activities;
- making it more difficult for us to take advantage of significant business opportunities, such as acquisition opportunities, and to react to changes in market or industry conditions; and
- limiting our ability to borrow additional monies in the future to fund working capital and capital expenditures and for other general corporate purposes.

The Loan and Security Agreement, as amended, requires us to maintain at least \$2.0 million in unrestricted cash and/or cash equivalents and includes certain reporting and other covenants, that, among other things, restrict our ability to (i) dispose of assets, (ii) change the business we conduct, (iii) make acquisitions, (iv) engage in mergers or consolidations, (v) incur additional indebtedness, (vi) create liens on assets, (vii) maintain any collateral account, (viii) pay dividends, (ix) make investments, loans or advances, (x) engage in certain transactions with affiliates, and (xi) prepay certain other indebtedness or amend other financing arrangements. If we fail to comply with any of these covenants or restrictions, such failure may result in an event of default, which if not cured or waived, could result in Oxford causing the outstanding loan amount to become immediately due and payable. If the maturity of our indebtedness is accelerated, we may not have, or be able to timely procure, sufficient cash resources to satisfy our debt obligations, and such acceleration would adversely affect our business and financial condition.

The COVID-19 pandemic has severely impacted the global economic activity and caused significant volatility and negative pressure in the financial markets. This volatility and downturn may affect our business, liquidity position, and financial results. This in turn may negatively impact our ability to remain in compliance with the financial and operating covenants under the Loan and Security Agreement and may restrict our ability to obtain covenant waivers, restructure or amend the terms of our existing debt, or obtain additional debt financing. If the maturity of our indebtedness is accelerated or if we are unable to amend the terms or obtain any necessary waivers under our debt facilities or obtain additional debt or other financing, it would materially and adversely affect our liquidity position and ability to fund our operations. This in turn would materially harm our business and financial conditions.

Our operating results have been and will likely continue to be volatile.

Our prospects must be evaluated in light of the risks and difficulties frequently encountered by emerging companies and particularly by such companies in rapidly evolving and technologically advanced biotech, pharmaceutical and medical device fields. Our visibility as to our future operating results and our clinical development timeline may be further limited by the impact of the ongoing COVID-19 pandemic. From time to time, we have tried to update our investors’ expectations as to our operating results. If we revise any timelines we may give with respect to our clinical trials, it could materially harm our reputation and the market’s perception of us and could cause our stock price to decline.

We rely on third parties to conduct our clinical trials, manufacture our product candidates, and perform other services. If these parties are not able to successfully perform due to the impact of the COVID-19 pandemic or otherwise, we may not be able to successfully complete clinical development, obtain regulatory approval or commercialize our product candidates and our business could be substantially harmed.

We rely on third parties in the performance of many of the clinical trial functions, including contract research organizations, that help execute our clinical trials, the hospitals and clinics at which our trials are conducted, the clinical investigators at the trial sites, and other third-party service providers. Failure of any third-party service provider to adhere to applicable trial protocols, laws and regulations in the conduct of one of our clinical trials could adversely affect the conduct and results of such trial (including possible data integrity issues), which could seriously harm our business. The COVID-19 pandemic has placed a strain on hospitals and clinics, contract research organizations, and other providers of clinical and medical supplies and equipment. This in turn could impact the ability of third parties such as hospitals to support our clinical trials or perform other services in support of our clinical programs. In addition, third parties may not prioritize our clinical trials relative to those of other customers due to resource or other constraints as a result of the COVID-19 pandemic. We may experience enrollment at a slower pace at certain of our clinical trial sites than initially anticipated. Further, our clinical trial sites may be required to suspend enrollment due to travel restrictions, workplace safety concerns, quarantine, facility closures, and other governmental restrictions. Some of our clinical trial sites have imposed limited accessibility to conduct clinical monitoring and training on-site. As a result, results from our clinical trials may be delayed, which in turn would have a material adverse impact on our clinical trial plans and timelines and impair our ability to successfully complete clinical development, obtain regulatory approval, or commercialize our product candidates. This in turn would substantially harm our business and operations.

We rely on third-party suppliers for certain components and raw materials and our development and commercialization of any of our product candidates could be stopped, delayed or made less profitable if those third parties are unable to provide us with sufficient quantities of such components or raw materials or are unable to do so at acceptable quality levels or prices due to the COVID-19 pandemic or otherwise.

We acquire some of our components and other raw materials from sole source suppliers. If there is an interruption in supply of our raw materials from a sole source supplier, there can be no assurance that we will be able to obtain adequate quantities of the raw materials within a reasonable time or at commercially reasonable prices. Interruptions in supplies due to pricing, timing, availability, the COVID-19 pandemic, or other issues with our sole source suppliers could have a negative impact on our ability to manufacture products and product candidates, which in turn could adversely affect the development and commercialization of our Nanomedicine product candidates and cause us to potentially breach our supply or other obligations under our agreements with certain other counterparties.

The COVID-19 pandemic has placed a significant strain on the pharmaceutical and medical industries, manufacturers of clinical supplies, and healthcare-related supplies and resources in general. For instance, we have experienced increased difficulties in obtaining certain materials for manufacturing that are also components of COVID vaccine candidates. The impact of the COVID-19 pandemic has exacerbated the risks to which we are subject due to our reliance on third-party (and in some cases, sole source) suppliers. Additionally, our suppliers may experience operational difficulties and resource constraints due to the impact of the COVID-19 pandemic. If our third-party suppliers were to encounter any of these difficulties, or otherwise fail to comply with their contractual obligations, our ability to provide our product candidates to patients in clinical trials would be jeopardized. Any delay or interruption in the procurement of clinical trial supplies could delay the completion of clinical trials, increase the costs associated with maintaining clinical trial programs and, depending upon the period of delay, require us to commence new clinical trials at additional expense or terminate clinical trials completely.

Due to our limited number of employees, our operations could be significantly and disproportionately impacted if any of our personnel were to test positive for COVID-19.

We maintain a very small executive team and have a limited number of employees. The manufacturing of our oncology drug assets is a highly complex process that requires significant experience and know-how. We also depend on the personal efforts and abilities of the principal members of our senior management and scientific staff to provide strategic direction, manage our operations, and maintain a cohesive and stable environment. In particular, we are highly dependent on our executive officers, especially Marc Hedrick, M.D., our Chief Executive Officer. If any of our personnel were to test positive for COVID-19, it would likely significantly impair our operations. The loss of services of any of our personnel, including Dr. Hedrick, particularly for an extended period due to COVID-19 or otherwise, would likely result in product development delays or the failure of our collaborations with current and future collaborators, which, in turn, may impede or delay our ability to develop and commercialize products and generate revenues. In addition, it could also result in difficulty to obtain additional funding for our development of products and our future operations.

We may face business disruption and related risks resulting from the COVID-19 pandemic and President Trump's invocation of the Defense Production Act, either of which could have a material adverse effect on our business.

Our development programs could be disrupted and materially adversely affected by the COVID-19 pandemic. As a result of measures imposed by the governments in affected regions, many commercial activities, businesses and schools have been suspended as part of quarantines and other measures intended to contain this outbreak. The spread of COVID-19 worldwide has resulted in the International Health Regulations Emergency Committee of the World Health Organization declaring the outbreak of COVID-19 as a “public health emergency of international concern,” and the World Health Organization characterizing COVID-19 as a pandemic. International stock markets have also been significantly impacted and their volatility reflect the uncertainty associated with the potential economic impact of the outbreak. The volatility in the Dow Industrial Average since the end of February 2020 has been largely attributed to the effects of the COVID-19 pandemic. In response to the COVID-19 pandemic, President Trump invoked the Defense Production Act, codified at 50 U.S.C. §§ 4501 et seq. (the “Defense Production Act”). Pursuant to the, Defense Production Act the federal government may, among other things, require domestic industries to provide essential goods and services needed for the national defense. While we have not experienced any significant impact on our business as a result of the COVID-19 pandemic, we continue to assess the potential impact COVID-19 and the invocation of the Defense Production Act may have on our ability to effectively conduct our commercialization efforts and development programs and otherwise conduct our business operations as planned. There can be no assurance that we will not be further impacted by the COVID-19 pandemic or by any action taken by the federal government under the Defense Production Act, including downturns in business sentiment generally or in our industry and business in particular.

Risks Related to our Common Stock

The market price of our common stock is volatile and may continue to fluctuate significantly, which could result in substantial losses for stockholders.

The market price of our common stock has been, and may continue to be, subject to significant fluctuations. Among the factors that may cause the market price of our common stock to fluctuate are the risks described in this “Risk Factors” section and other factors, including:

- fluctuations in our operating results or the operating results of our competitors;
- the outcome of clinical trials involving the use of our products, including our sponsored trials;
- changes in estimates of our financial results or recommendations by securities analysts;
- variance in our financial performance from the expectations of securities analysts;
- changes in the estimates of the future size and growth rate of our markets;
- changes in accounting principles or changes in interpretations of existing principles, which could affect our financial results;
- conditions and trends in the markets we currently serve or which we intend to target with our product candidates;
- changes in general economic, industry and market conditions;
- the impact of the COVID-19 impact, including the magnitude, severity, duration, and uncertainty of the downturn in the domestic and global economies and financial markets;
- success of competitive products and services;
- changes in market valuations or earnings of our competitors;
- announcements of significant new products, contracts, acquisitions or strategic alliances by us or our competitors;
- our continuing ability to list our securities on an established market or exchange;
- the timing and outcome of regulatory reviews and approvals of our products;
- the commencement or outcome of litigation involving our company, our general industry or both;
- changes in our capital structure, such as future issuances of securities or the incurrence of additional debt;
- actual or expected sales of our common stock by the holders of our common stock; and
- the trading volume of our common stock.

In addition, the financial markets may experience a loss of investor confidence or otherwise experience continued volatility and deterioration due to the COVID-19 pandemic. A loss of investor confidence may result in extreme price and volume fluctuations in our common stock that are unrelated or disproportionate to the operating performance of our business, our financial condition or results of operations, which may materially harm the market price of our common stock and result in substantial losses for stockholders.

The sale or issuance of our common stock to Lincoln Park may cause dilution and the sale of the shares of common stock acquired by Lincoln Park, or the perception that such sales may occur, could cause the price of our common stock to fall.

On September 30, 2020, we entered into the 2020 Purchase Agreement with Lincoln Park, pursuant to which Lincoln Park has committed to purchase up to \$25.0 million of our common stock, subject to certain limitations. Upon the execution of the 2020 Purchase Agreement, we issued 180,701 shares of common stock as commitment shares to Lincoln Park in consideration for its

commitment to purchase additional shares of our common stock under the Purchase Agreement. The remaining shares of our common stock that may be issued under the Purchase Agreement may be sold by us to Lincoln Park at our discretion from time to time over a 36-month period commencing after the satisfaction of certain conditions set forth in the 2020 Purchase Agreement, including that the SEC has declared effective the registration statement that includes this prospectus and that such registration statement remains effective. The purchase price for the shares that we may sell to Lincoln Park under the 2020 Purchase Agreement will fluctuate based on the price of our common stock. Depending on market liquidity at the time, sales of such shares may cause the trading price of our common stock to fall.

We generally have the right to control the timing and amount of any future sales of our shares to Lincoln Park. Additional sales of our common stock, if any, to Lincoln Park will depend upon market conditions and other factors to be determined by us. We may ultimately decide to sell to Lincoln Park all, some, or none of the additional shares of our common stock that may be available for us to sell pursuant to the 2020 Purchase Agreement. If and when we do sell shares to Lincoln Park, after Lincoln Park has acquired the shares, Lincoln Park may resell all or some of those shares at any time or from time to time in its discretion. Therefore, sales to Lincoln Park by us could result in substantial dilution to the interests of other holders of our common stock. Additionally, the sale of a substantial number of shares of our common stock to Lincoln Park, or the anticipation of such sales, could make it more difficult for us to sell equity or equity-related securities in the future at a time and at a price that we might otherwise wish to effect sales.

We could be delisted from Nasdaq, which would materially harm the liquidity of our stock and our ability to raise capital.

The Nasdaq Stock Market has experienced significant volatility due to the COVID-19 pandemic, which has also impacted our stock price. In addition, we have a limited public float and our stock price has experienced a significant decline since our corporate restructuring in 2019. Between January 1, 2020 and September 30, 2020, our closing stock price has fluctuated from a high of \$3.14 at September 16, 2020 to a low of \$1.05 at March 23, 2020. In addition, Nasdaq requires listing issuers to comply with certain standards in order to remain listed on its exchange.

On August 19, 2019, we received a written notice from Nasdaq staff indicating that, based on our stockholders' deficit of \$6.3 million as of June 30, 2019, we no longer met the alternative compliance standards of market value of listed securities or net income from continuing operations for continued listing on the Nasdaq Capital Market under Nasdaq Listing Rule 5550(b)(1) (the "Nasdaq Rule"), which requires listed companies to maintain stockholders' equity of at least \$2.5 million. On August 12, 2020, we received a written notice from Nasdaq staff indicating that based on our Form 10-Q for June 30, 2020, evidencing stockholder's equity of \$3.3 million, the Nasdaq staff determined that we comply with the Nasdaq Rule and that the matter is closed. Based on our stockholders' equity of \$2.6 million as of September 30, 2020, we continue to meet the minimum stockholders' equity requirement for continued listing on the Nasdaq Capital Market under the Nasdaq Rule. However, there is no guarantee that we will continue to meet the listing requirement under the Nasdaq Rule, and if we fail to meet such requirement in the future, there is a risk that our common stock may be delisted from Nasdaq, which would adversely impact liquidity of our common stock and potentially result in even lower bid prices for our common stock.

If, for any reason, Nasdaq were to delist our securities from trading on its exchange and we are unable to obtain listing on another reputable national securities exchange, a reduction in some or all of the following may occur, each of which could materially adversely affect our stockholders:

- the liquidity and marketability of our common stock;
- the market price of our common stock;
- our ability to obtain financing for the continuation of our operations;
- the number of institutional and general investors that will consider investing in our common stock;
- the number of market makers in our common stock;
- the availability of information concerning the trading prices and volume of our common stock; and
- the number of broker-dealers willing to execute trades in shares of our common stock.

In addition, if we cease to be eligible to trade on Nasdaq, we may have to pursue trading on a less recognized or accepted market, such as the over the counter markets, our stock may be traded as a "penny stock" which would make transactions in our stock would be more difficult and cumbersome, and we may be unable to access capital on favorable terms or at all, as companies trading on alternative markets may be viewed as less attractive investments with higher associated risks, such that existing or prospective institutional investors may be less interested in, or prohibited from, investing in our common stock. This may also cause the market price of our common stock to further decline.

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

None.

Item 5. Other Information

We have used, and intend to continue to use, our Investor Relations website and social media sites, which may include Facebook, Instagram, LinkedIn, StockTwits, Twitter, Yahoo, and YouTube pages, as means of disclosing material non-public information and

for complying with our disclosure obligations under Regulation FD. Therefore, we encourage investors, the media, and others interested in our company to review the information we post on such social media channels.

EXHIBIT INDEX

PLUS THERAPEUTICS, INC.

Exhibit Number	Exhibit Title	Filed with this Form 10-Q	Incorporated by Reference		
			Form	File No.	Date Filed
3.1	Composite Certificate of Incorporation.		10-K	001-34375 Exhibit 3.1	03/11/2016
3.2	Certificate of Amendment to Amended and Restated Certificate of Incorporation.		8-K	001-34375 Exhibit 3.1	05/10/2016
3.3	Certificate of Amendment to Amended and Restated Certificate of Incorporation.		8-K	001-34375 Exhibit 3.1	05/23/2018
3.4	Certificate of Amendment to Amended and Restated Certificate of Incorporation.		8-K	001-34375 Exhibit 3.1	07/29/2019
3.5	Certificate of Amendment to Amended and Restated Certificate of Incorporation.		8-K	001-34375 Exhibit 3.1	08/06/2019
3.6	Certificate of Designation of Preferences, Rights and Limitations of Series A 3.6% Convertible Preferred Stock.		8-K	001-34375 Exhibit 3.1	10/08/2014
3.7	Certificate of Designation of Preferences, Rights and Limitations of Series B Convertible Preferred Stock.		8-K	001-34375 Exhibit 3.1	11/28/2017
3.8	Certificate of Designation of Preferences, Rights and Limitations of Series C Convertible Preferred Stock.		8-K	001-34375 Exhibit 3.1	07/25/2018
3.9	Amended and Restated Bylaws of Plus Therapeutics, Inc.		8-K	001-34375 Exhibit 3.2	07/29/2019
4.1	Form of Common Stock Certificate.		10-K	001-34375 Exhibit 4.33	03/09/2018
4.2	Form of Series T Warrant.		POS AM	333-224502 Exhibit 4.28	07/09/2018
4.3	Form of Series T Warrant Agreement between Plus Therapeutics, Inc. and Broadridge Corporation Issuer Solutions, Inc.		POS AM	333-224502 Exhibit 4.36	07/09/2018
4.4	Form of Series U Warrant.		S-1/A	333-229485 Exhibit 4.37	09/16/2019
4.5	Form of Warrant Amendment Agreement		8-K	001-34375 Exhibit 4.1	04/23/2020
4.6	Form of Underwriters' Warrant Amendment Agreement		8-K	001-34375 Exhibit 4.1	10/5/2020
10.1	Purchase Agreement, dated September 30, 2020, by and between Plus Therapeutics, Inc. and Lincoln Park Capital Fund, LLC		8-K	001-34375 Exhibit 10.1	10/6/2020
10.2	Registration Rights Agreement, dated September 30, 2020, by and between Plus Therapeutics, Inc. and Lincoln Park Capital Fund, LLC		8-K	001-34375 Exhibit 10.2	10/6/2020
31.1	Certification of Principal Executive Officer Pursuant to Securities Exchange Act Rule 13a-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002	X			

31.2	<u>Certification of Principal Financial and Accounting Officer Pursuant to Securities Exchange Act Rule 13a-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002</u>	X
32.1*	<u>Certifications Pursuant to 18 U.S.C. Section 1350/ Securities Exchange Act Rule 13a-14(b), as adopted pursuant to Section 906 of the Sarbanes - Oxley Act of 2002</u>	X
101.INS	XBRL Instance Document	X
101.SCH	XBRL Schema Document	X
101.CAL	XBRL Calculation Linkbase Document	X
101.DEF	XBRL Definition Linkbase Document	X
101.LAB	XBRL Label Linkbase Document	X
101.PRE	XBRL Presentation Linkbase Document	X

* In accordance with Item 601(b)(32)(ii) of Regulation S-K and SEC Release No. 34-47986, the certifications furnished in Exhibit 32.1 hereto is deemed to accompany this Form 10-Q and will not be deemed “filed” for purposes of Section 18 of the Exchange Act or deemed to be incorporated by reference into any filing under the Exchange Act or the Securities Act of 1933 except to the extent that the Company specifically incorporates it by reference.

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.

PLUS THERAPEUTICS, INC.

Dated: October 22, 2020

By: /s/ Marc H. Hedrick
Marc H. Hedrick
President & Chief Executive Officer (Duly Authorized Officer and Principal Executive Officer)

Dated: October 22, 2020

By: /s/ Andrew Sims
Andrew Sims
Chief Financial Officer (Duly Authorized Officer and Principal Financial Officer and Principal Accounting Officer)

**Certification of Principal Executive Officer Pursuant to
Securities Exchange Act Rule 13a-14(a),
as Adopted Pursuant to
Section 302 of the Sarbanes-Oxley Act of 2002**

I, Marc H. Hedrick, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Plus 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 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 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: October 22, 2020

/s/ Marc H. Hedrick

Marc H. Hedrick,

President & Chief Executive Officer

**Certification of Principal Financial Officer Pursuant to
Securities Exchange Act Rule 13a-14(a),
as Adopted Pursuant to
Section 302 of the Sarbanes-Oxley Act of 2002**

I, Andrew Sims, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Plus 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 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 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: October 22, 2020

/s/ Andrew Sims

Andrew Sims

Chief Financial Officer

CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350/ SECURITIES EXCHANGE ACT RULE 13a-14(b), AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report on Form 10-Q of Plus Therapeutics, Inc. for the quarterly period ended September 30, 2020 as filed with the Securities and Exchange Commission on the date hereof, Marc H. Hedrick, as President & Chief Executive Officer of Plus Therapeutics, Inc., and Andrew Sims, as VP of Finance and Chief Financial Officer of Plus Therapeutics, Inc., each hereby certifies, respectively, that:

1. The Form 10-Q report of Plus Therapeutics, Inc. that this certification accompanies fully complies with the requirements of Section 13(a) of the Securities Exchange Act of 1934.
2. The information contained in the Form 10-Q report of Plus Therapeutics, Inc. that this certification accompanies fairly presents, in all material respects, the financial condition and results of operations of Plus Therapeutics, Inc.

Dated: October 22, 2020

By: /s/ Marc H. Hedrick
Marc H. Hedrick
President & Chief Executive Officer

Dated: October 22, 2020

By: /s/ Andrew Sims
Andrew Sims
Chief Financial Officer & VP of Finance