

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

**FORM 10-Q**

(Mark One)

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

For the quarterly period ended September 30, 2019

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.**

(previously known as Cytori Therapeutics, Inc.)

(Exact name of Registrant as Specified in Its Charter)

**DELAWARE**

(State or other jurisdiction  
of incorporation or organization)

**4200 MARATHON BLVD., SUITE 200, AUSTIN, TX**

(Address of principal executive offices)

**33-0827593**

(I.R.S. Employer  
Identification No.)

**78756**

(Zip Code)

Registrant's telephone number, including area code: (737) 255-7194

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

Non-Accelerated Filer

Accelerated Filer

Smaller reporting company

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised 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 November 8, 2019, there were 3,770,588 shares of the registrant's common stock outstanding.

**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	PSTV	Nasdaq Capital Market
Series S Warrant	PSTVZ	Nasdaq Capital Market

**PLUS THERAPEUTICS, INC.**  
**(previously known as Cytori Therapeutics, Inc.)**

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**PART I. FINANCIAL INFORMATION**

**Item 1. Financial Statements**

**PLUS THERAPEUTICS, INC.**  
**(previously known as Cytori Therapeutics, Inc.)**  
**CONSOLIDATED CONDENSED BALANCE SHEETS**  
**(UNAUDITED)**  
**(in thousands, except share and par value data)**

	As of September 30, 2019	As of December 31, 2018
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 16,834	\$ 5,261
Accounts receivable	4,781	178
Restricted cash	40	40
Inventories, net	107	107
Other current assets	502	785
Current assets held for sale	—	3,277
Total current assets	<u>22,264</u>	<u>9,648</u>
Property and equipment, net	2,209	2,299
Operating lease right-of-use assets	818	—
Other assets	52	39
Noncurrent assets held for sale	—	11,633
Goodwill	372	372
Total assets	<u>\$ 25,715</u>	<u>\$ 23,991</u>
<b>Liabilities and Stockholders' Equity</b>		
Current liabilities:		
Accounts payable and accrued expenses	\$ 3,334	\$ 2,777
Operating lease liability	156	—
Term loan obligations, net of discount	10,937	14,202
Current liabilities held for sale	—	580
Total current liabilities	<u>14,427</u>	<u>17,559</u>
Other noncurrent liabilities	38	46
Noncurrent operating lease liability	684	—
Warrant liability	10,406	916
Noncurrent liabilities held for sale	—	245
Total liabilities	<u>25,555</u>	<u>18,766</u>
Commitments and contingencies (Notes 8 and 9)		
Stockholders' equity:		
Preferred stock, \$0.001 par value; 5,000,000 shares authorized; 1,959 and 4,606 shares issued and outstanding in 2019 and 2018, respectively	—	—
Common stock, \$0.001 par value; 100,000,000 shares authorized; 2,841,588 and 296,609 shares issued and outstanding in 2019 and 2018, respectively	3	—
Additional paid-in capital	426,311	418,390
Accumulated other comprehensive income	—	1,218
Accumulated deficit	(426,154)	(414,383)
Total stockholders' equity	<u>160</u>	<u>5,225</u>
Total liabilities and stockholders' equity	<u>\$ 25,715</u>	<u>\$ 23,991</u>

See Accompanying Notes to these Consolidated Condensed Financial Statements

**PLUS THERAPEUTICS, INC.**  
**(previously known as Cytori Therapeutics, Inc.)**  
**CONSOLIDATED CONDENSED STATEMENTS OF OPERATIONS AND COMPREHENSIVE INCOME (LOSS)**  
**(UNAUDITED)**  
**(in thousands, except share and per share data)**

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2019	2018	2019	2018
<b>Development revenues:</b>				
Government contracts and other	\$ 4,771	\$ 454	\$ 5,810	\$ 2,270
	<u>4,771</u>	<u>454</u>	<u>5,810</u>	<u>2,270</u>
<b>Operating expenses:</b>				
Research and development	921	1,226	3,636	3,887
Sales and marketing	94	118	305	596
General and administrative	1,076	1,337	3,313	4,639
Total operating expenses	2,091	2,681	7,254	9,122
Operating income (loss)	<u>2,680</u>	<u>(2,227)</u>	<u>(1,444)</u>	<u>(6,852)</u>
<b>Other income (expense):</b>				
Interest income	6	11	20	30
Interest expense	(366)	(513)	(1,477)	(1,379)
Change in fair value of warrants	(561)	1,676	(69)	1,676
Warrant issuance cost	(1,233)	(343)	(1,233)	(343)
Total other income (expense)	(2,154)	831	(2,759)	(16)
Income (loss) from continuing operations	\$ 526	\$ (1,396)	\$ (4,203)	\$ (6,868)
Loss from discontinued operations	—	(934)	(7,568)	(3,530)
Net Income (loss)	<u>\$ 526</u>	<u>\$ (2,330)</u>	<u>\$ (11,771)</u>	<u>\$ (10,398)</u>
Income (Loss) from continuing operations	\$ 526	\$ (1,396)	\$ (4,203)	\$ (6,868)
Beneficial conversion feature for convertible preferred stock	(554)	(2,487)	(554)	(2,487)
Net loss allocable to common stockholders - continuing operations	\$ (28)	\$ (3,883)	\$ (4,757)	\$ (9,355)
Net loss allocable to common stockholders - discontinued operations	\$ —	\$ (934)	\$ (7,568)	\$ (3,530)
Basic and diluted net loss per share attributable to common stockholders from continuing operations	\$ (0.03)	\$ (22.27)	\$ (8.78)	\$ (67.09)
Basic and diluted net loss per share attributable to common stockholders from discontinued operations	\$ —	\$ (5.36)	\$ (13.97)	\$ (25.31)
Net loss per share, basic and diluted	\$ (0.03)	\$ (27.63)	\$ (22.75)	\$ (92.40)
Basic and diluted weighted average shares used in calculating net loss per share attributable to common stockholders	826,548	174,324	541,777	139,452
<b>Comprehensive income (loss):</b>				
Net income (loss)	\$ 526	\$ (2,330)	\$ (11,771)	\$ (10,398)
Other comprehensive loss – foreign currency translation adjustments	—	(55)	—	(205)
Comprehensive income (loss)	<u>\$ 526</u>	<u>\$ (2,385)</u>	<u>\$ (11,771)</u>	<u>\$ (10,603)</u>

See Accompanying Notes to these Consolidated Condensed Financial Statements

**PLUS THERAPEUTICS, INC.**  
**(previously known as Cytori Therapeutics, Inc.)**  
**CONSOLIDATED CONDENSED STATEMENTS OF STOCKHOLDERS' EQUITY (DEFICIT)**  
**(UNAUDITED)**  
**(in thousands, except share and par value data)**

	Convertible preferred stock		Common stock		Additional paid-in capital	Accumulated other comprehensive income (loss)	Accumulated deficit	Total stockholders' equity (deficit)
	Shares	Amount	Shares	Amount				
Balance at December 31, 2017	2,431	\$ —	115,652	\$ —	\$ 413,362	\$ 1,387	\$ (401,749)	\$ 13,000
Share-based compensation	—	—	—	—	143	—	—	143
Sale of common stock, net	—	—	202	—	27	—	—	27
Conversion of Series B Convertible Preferred Stock into common stock	(1,228)	—	7,375	—	—	—	—	—
Foreign currency translation adjustment and accumulated other comprehensive income	—	—	—	—	—	(281)	—	(281)
Net loss	—	—	—	—	—	—	(4,409)	(4,409)
Balance at March 31, 2018	<u>1,203</u>	<u>\$ —</u>	<u>123,229</u>	<u>\$ —</u>	<u>\$ 413,532</u>	<u>\$ 1,106</u>	<u>\$ (406,158)</u>	<u>\$ 8,480</u>
Share-based compensation	—	—	—	—	96	—	—	96
Sale of common stock, net	—	—	192	—	(297)	—	—	(297)
Conversion of Series B Convertible Preferred Stock into common stock	(17)	—	103	—	—	—	—	—
Foreign currency translation adjustment and accumulated other comprehensive income	—	—	—	—	—	131	—	131
Net loss	—	—	—	—	—	—	(3,659)	(3,659)
Balance at June 30, 2018	<u>1,186</u>	<u>\$ —</u>	<u>123,524</u>	<u>\$ —</u>	<u>\$ 413,331</u>	<u>\$ 1,237</u>	<u>\$ (409,817)</u>	<u>\$ 4,751</u>
Share-based compensation	—	—	—	—	86	—	—	86
Sale of common stock, net	6,723	—	29,407	—	3,686	—	—	3,686
Conversion of Series B and Series C Convertible Preferred Stock into common stock	(3,285)	—	80,895	—	—	—	—	—
Foreign currency translation adjustment and accumulated other comprehensive income	—	—	—	—	—	(55)	—	(55)
Beneficial conversion feature related to Series C Convertible	—	—	—	—	2,487	—	—	2,487
Accretion of beneficial conversion feature related to Series C Convertible Preferred Stock	—	—	—	—	(2,487)	—	—	(2,487)
Net loss	—	—	—	—	—	—	(2,330)	(2,330)
Balance at September 30, 2018	<u>4,624</u>	<u>\$ —</u>	<u>233,826</u>	<u>\$ —</u>	<u>\$ 417,103</u>	<u>\$ 1,182</u>	<u>\$ (412,147)</u>	<u>\$ 6,138</u>
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 C 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 loss	—	—	—	—	—	—	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>

See Accompanying Notes to these Consolidated Condensed Financial Statements

**PLUS THERAPEUTICS, INC.**  
**(previously known as Cytori Therapeutics, Inc.)**  
**CONSOLIDATED CONDENSED STATEMENTS OF CASH FLOWS**  
**(UNAUDITED)**  
**(in thousands)**

	<u>For the Nine Months Ended September 30,</u>	
	<u>2019</u>	<u>2018</u>
<b>Cash flows from operating activities:</b>		
Net loss	\$ (11,771)	\$ (10,398)
Adjustments to reconcile net loss to net cash used in operating activities:		
Noncash lease expense	22	—
Depreciation and amortization	778	1,465
Amortization of deferred financing costs and debt discount	354	383
Provision for excess inventory	—	433
Change in fair value of warrants	69	(1,676)
Allocation of issuance costs associated with warrants	1,233	343
Share-based compensation expense	106	325
Loss on asset disposal	—	23
Loss on sale of business	6,306	—
Increases (decreases) in cash caused by changes in operating assets and liabilities:		
Accounts receivable	(4,851)	(316)
Inventories	274	615
Other current assets	252	514
Other assets	298	7
Accounts payable and accrued expenses	(95)	(1,274)
Deferred revenues	29	93
Other long-term liabilities	54	(24)
Net cash used in operating activities	<u>(6,942)</u>	<u>(9,487)</u>
<b>Cash flows from investing activities:</b>		
Purchases of property and equipment	(8)	(128)
Proceeds from sale of business, net	2,789	—
Net cash provided by (used in) investing activities	<u>2,781</u>	<u>(128)</u>
<b>Cash flows from financing activities:</b>		
Principal payment of long-term obligations	(642)	—
Payment of financing lease liability	(75)	—
Proceeds from exercise of warrants	491	—
Proceeds from sale of common stock, net of offering cost	15,964	6,246
Net cash provided by financing activities	<u>15,738</u>	<u>6,246</u>
Effect of exchange rate changes on cash and cash equivalents	(4)	(10)
Net increase (decrease) in cash and cash equivalents	11,573	(3,379)
Cash, cash equivalents, and restricted cash at beginning of period	5,301	10,225
Cash, cash equivalents, and restricted cash at end of period	<u>\$ 16,874</u>	<u>\$ 6,846</u>
<b>Supplemental disclosure of cash flows information:</b>		
Cash paid during period for:		
Interest	\$ 1,071	\$ 990
<b>Supplemental schedule of non-cash investing and financing activities:</b>		
Proceeds from sales of business, net, paid directly to lender for principal payment of long-term obligations	\$ 3,050	\$ —
Offering cost paid in warrants	\$ 213	\$ —
Unpaid offering costs	\$ 403	\$ —
Reclass of warrants upon exercise from liability to equity	\$ 794	\$ —

See Accompanying Notes to these Consolidated Condensed Financial Statements

**PLUS THERAPEUTICS, INC.**  
**(previously known as Cytori Therapeutics, Inc.)**  
**NOTES TO CONSOLIDATED CONDENSED FINANCIAL STATEMENTS**  
**September 30, 2019**  
**(UNAUDITED)**

**1. Basis of Presentation and New Accounting Standards**

Our accompanying unaudited consolidated condensed financial statements as of September 30, 2019 and for the three and nine months ended September 30, 2019 and 2018 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. Our consolidated condensed balance sheet at December 31, 2018 has been derived from the audited financial statements at December 31, 2018, 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 our subsidiaries (collectively, the “Company” or “Plus Therapeutics”) have been included. Operating results for the three and nine months ended September 30, 2019 are not necessarily indicative of the results that may be expected for the year ending December 31, 2018. These financial statements should be read in conjunction with the consolidated financial statements and notes therein included in our Annual Report on Form 10-K for the year ended December 31, 2018, filed with the Securities and Exchange Commission on March 29, 2019.

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”), 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 (defined in Note 4).

**Amendments to Certificate of Incorporation and Reverse Stock Splits**

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”. Additionally, the Company changed its trading symbol for its Series S warrants to “PSTVZ”.

On May 23, 2018, following stockholder and Board approval, the Company filed a Certificate of Amendment to its Amended and Restated Certificate of Incorporation, as amended (the “Amendment”), with the Secretary of State of the State of Delaware to (i) effectuate a one-for-ten (1:10) reverse stock split (the “Reverse Stock Split”) of its common stock, par value \$0.001 per share, without any change to its par value, and (ii) increase the number of authorized shares of the Company’s common stock from 75 million to 100 million shares (which amount is not otherwise affected by the Reverse Stock Split). The Amendment became effective on the filing date. Upon effectiveness of the Reverse Stock Split, the number of shares of the Company’s common stock (x) issued and outstanding decreased from approximately 61.6 million shares (as of May 23, 2018) to approximately 6.2 million shares; (y) reserved for issuance upon exercise of outstanding warrants and options decreased from approximately 23.4 million shares to approximately 2.3 million shares, and (z) reserved but unallocated under our current equity incentive plans (including the stockholder-approved share increase to the Company’s 2014 Equity Incentive Plan) decreased from approximately 9.1 million common shares to approximately 0.9 million common shares. No fractional shares were issued in connection with the Reverse Stock Split. Proportional adjustments for the reverse stock split were made to the Company’s outstanding stock options, warrants and equity incentive plans for all periods presented.

On August 5, 2019, following stockholder and Board approval, the Company filed a Certificate of Amendment (the “August 2019 Amendment”) to its Amended and Restated Certificate of Incorporation (the Amendment), as amended, with the Secretary of State of the State of Delaware to effectuate a one-for-fifty (1:50) reverse stock split (the “August 2019 Reverse Stock Split”) of its common stock, par value \$0.001 per share, without any change to its par value. The August 2019 Amendment became effective on the filing date. The August 2019 Reverse Stock Split became effective for trading purposes as of the commencement of trading on the Nasdaq Capital Market on August 6, 2019. There was no change in the Company’s Nasdaq ticker symbol, “PSTV,” as a result of the August 2019 Reverse Stock Split. Upon effectiveness, each 50 shares of issued and outstanding common stock were converted into one newly issued and outstanding share of common stock. The Company’s 5,000,000 shares of authorized Preferred Stock were not affected by the August 2019 Reverse Stock Split. No fractional shares were issued in connection with the August 2019 Reverse Stock Split. Any fractional shares of common Stock that would have otherwise resulted from the August 2019 Reverse Stock Split were rounded up to the nearest whole share. Outstanding equity awards and the shares available for future grant under the Company’s Amended and Restated 2004 Equity Incentive Plan, 2011 Employee Stock Purchase Plan, 2014 Amended and Restated Equity Incentive Plan and 2015 New Employee Incentive Plan were proportionately reduced (rounded down to the nearest whole share), and the exercise prices of outstanding equity awards were proportionately increased (rounded up to the nearest whole cent) to give effect to the August 2019 Reverse Stock Split.

## **Recently Issued and Recently Adopted Accounting Pronouncements**

### **Recently Issued Accounting Pronouncements**

In February 2017, the Financial Accounting Standards Board (the “FASB”) issued ASU 2017-04, *Simplifying the Test for Goodwill Impairment*, to simplify how all entities assess goodwill for impairment by eliminating Step 2 from the goodwill impairment test. As amended, the goodwill impairment test will consist of one step comparing the fair value of a reporting unit with its carrying amount. An entity should recognize a goodwill impairment charge for the amount by which the reporting unit’s carrying amount exceeds its fair value. This update is effective for annual periods beginning after December 15, 2019, and interim periods within those periods. Early adoption is permitted for interim or annual goodwill impairment tests performed on testing dates after January 1, 2017. We are currently evaluating the impact that this standard will have on our consolidated financial statements.

### **Recently Adopted Accounting Pronouncements**

In February 2016, the FASB issued Accounting Standards Update (“ASU”) 2016-02, *Leases*. Under this new guidance, at the commencement date, lessees will be required to recognize (i) a lease liability, which is a lessee’s obligation to make lease payments arising from a lease, measured on a discounted basis and (ii) a right-of-use asset, which is an asset that represents the lessee’s right to use, or control the use of, a specified asset for the lease term. This guidance is not applicable for leases with a term of 12 months or less. The Company adopted ASC 842 as of January 1, 2019, electing the optional transition method that allows for a cumulative-effect adjustment in the period of adoption and did not restate prior periods. The Company elected the package of practical expedients permitted under the transition guidance. As a result of the adoption, the Company recorded right-of-use assets and liabilities. As of September 30, 2019, the Company’s right-of-use assets and liabilities were \$0.8 million associated with its operating leases. See Note 8 for further discussion on leases.

## **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. Our 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**

We generated income from continuing operations of \$526,000 for the three months ended September 30, 2019, primarily due to recognition of \$4.6 million of revenue from the BARDA contract due to the finalization of the indirect cost rates under the contract, which is a onetime event. We incurred losses from continuing operations of \$4.2 million for the nine months ended September 30, 2019. We have an accumulated deficit of \$426.2 million as of September 30, 2019. These factors raise substantial doubt about our ability to continue as a going concern.



To date, the operating losses have been funded primarily from outside sources of invested capital including the September 2019 Offering (defined below), 2018 Rights Offering (defined below), our Lincoln Park Purchase Agreement (defined in Note 11) with Lincoln Park Capital Fund, LLC (“Lincoln Park”), the Loan and Security Agreement, proceeds from sale of our Cell Therapy business (Note 6), and gross profits. However, 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. There can be no assurance that we will be able to continue to raise additional capital in the future. Our inability to raise additional cash would have a material and adverse impact on operations and would cause us to default on the Loan and Security Agreement with Oxford.

In September 2019, the Company finalized the indirect cost rate under the BARDA Agreement (Note 5) for indirect costs incurred during the years 2012 through 2019, which resulted in approximately \$4.6 million of revenue recognized during the three months ended September 30, 2019. The \$4.6 million was received in cash in October 2019.

In September 2019, the Company entered into an underwriting agreement with H.C. Wainwright & Co., LLC (the “Representative”), as representative of the underwriters (the “Underwriters”), pursuant to which the Company sold in an underwritten public offering an aggregate of (i) 289,000 Class A Units, each consisting of one share of common stock, par value \$0.001 per share, of the Company 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, the Company granted the Underwriters a 45-day option to purchase up to an additional 450,000 shares of the Company’s 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. The Company 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”).

The Company received net proceeds of approximate \$13.2 million from the September 2019 Offering, which it intends to use for working capital, payment of interest on its debt and general corporate purposes, which may include research and development of its oncology product pipeline, preclinical and clinical trials and studies, regulatory submissions, expansion of its sales and marketing organizations and efforts, intellectual property protection and enforcement and capital expenditures.

On April 24, 2019 the Company received \$3.4 million of net cash proceeds related to the sale of the UK Subsidiary and the Company’s Cell Therapy assets (excluding such assets used in Japan or relating to the Company’s 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 the Company received \$2.5 million of net cash proceeds related to the sale of the Japanese Subsidiary, and substantially all of the Company’s 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.

On June 1, 2018, we entered into a Sales Agreement with B. Riley FBR, Inc. (“B. Riley FBR”) to sell shares of our common stock having an aggregate offering price of up to \$6.5 million from time to time, through an “at the market” equity offering program (the “ATM Program”) under which B. Riley FBR will act as sales agent. The ATM Program financing facility has been exhausted and there is no availability remaining under this financing facility.

On July 25, 2018, we closed a rights offering originally filed under a Form S-1 registration statement in April 2018 (“2018 Rights Offering”). Pursuant to the 2018 Rights Offering, the Company sold an aggregate of 6,723 units consisting of a total of 6,723 shares of Series C Convertible Preferred Stock, immediately convertible into approximately 0.2 million shares of common stock and 7,059,150 warrants, exercisable for an aggregate of 141,183 shares of common stock at an exercise price of \$39.93 per share of common stock, resulting in total net proceeds to the Company of approximately \$5.7 million.

On August 28, 2018, we received a written notice from Nasdaq staff indicating that, based upon the closing bid price of our common stock for the prior 30 consecutive business days, we no longer meet the requirement to maintain a minimum bid price of \$1.00 per share, as set forth in Nasdaq Listing Rule 5550(a)(2). In accordance with Nasdaq Listing Rule 5810(c)(3)(A), we were provided an initial period of 180 calendar days, or until February 25, 2019, in which to regain compliance. We were also granted an additional compliance period of 180 calendar days, or until August 26, 2019, in which to regain compliance after meeting the continued listing requirement for market value of publicly held shares and all other initial listing standards for the Nasdaq Capital Market, with the exception of the bid price requirement, and providing notice to Nasdaq staff of our intent to cure the deficiency during this second compliance period, by effecting a reverse stock split, if necessary. In order to regain compliance with the minimum bid price requirement, the closing bid price of our common stock must have been at least \$1.00 per share for a minimum of 10 consecutive business days during the 180-day period. In August 2019, we consummated a 1-for-50 reverse stock split pursuant to which the minimum bid price of our common stock rose above \$1.00. On August 29, 2019, The Company received written notice from Nasdaq staff that it has regained compliance with the Nasdaq Stock Market Listing Rule 5550(a)(2) concerning the minimum bid price per share of its common stock. On August 16, 2019, the Company received written notice from the Nasdaq indicating that the Company no longer meets the requirements for continued listing under Nasdaq Listing Rule 5550(a)(4) due to the Company’s failure to meet the minimum 500,000 publicly held shares requirement for continued listing. On September 11, 2019, the Company received written notice from Nasdaq staff that, based on having 786,807 publicly held share outstanding as of August 31, 2019, the Company had regained compliance with Nasdaq Listing Rule 5550(a)(4). However, on August 19, 2019, the Company received written notice from Nasdaq indicating that, based on the

Company's stockholders' deficit of \$6.3 million as of June 30, 2019, as reported in the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2019, it is no longer in compliance with the minimum stockholders' equity requirement for continued listing on the Nasdaq Capital Market under Nasdaq Listing Rule 5550(b)(1), which requires listed companies to maintain stockholders' equity of at least \$2.5 million. Based on our stockholders' equity of \$160,000 as of September 30, 2019, we do not meet the minimum stockholders' equity requirement for continued listing on the Nasdaq Capital Market under Nasdaq Listing Rule 5550(b)(1). The Company expects to receive written notice from Nasdaq staff to that effect following the filing of this Quarterly Report on Form 10-Q. In addition, as of September 30, 2019, we do not meet the alternative compliance standards relating to the market value of listed securities or net income from continuing operations. We intend to evaluate various courses of action to regain compliance with Nasdaq Listing Rule 5550(b)(1) within the compliance period specified by Nasdaq. However, there can be no assurance that we will be able to regain compliance within such compliance period.

On September 21, 2018, the Company entered into a purchase agreement and a registration rights agreement, with Lincoln Park, pursuant to which the Company has the right to sell to Lincoln Park and Lincoln Park is 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, subject to the satisfaction of certain conditions. Through December 31, 2018, the Company sold a total of 12,802 shares for proceeds of approximately \$0.3 million through the Lincoln Park Purchase Agreement and 32,170 shares for proceeds of approximately \$0.3 million were sold during the nine months ended September 30, 2019. The Company believes there is less than \$0.1 million remaining available under this financing facility. See Note 11 for further discussion on the Lincoln Park Agreement.

We continue to seek additional capital through strategic transactions and from 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.

Should we be unable to raise additional cash from outside sources, this would have a material adverse impact on our operations.

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. Term Loan Obligations**

On May 29, 2015, the Company entered into the Loan and Security Agreement, pursuant to which Oxford funded an aggregate principal amount of \$17.7 million ("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, we were previously required to make interest only payments through June 1, 2016 and thereafter we were required to make payments of principal and accrued interest in equal monthly installments sufficient to amortize the Term Loan through June 1, 2019, the maturity date. On February 23, 2016, we received an acknowledgement and agreement from Oxford related to the positive data on our U.S. ACT-OA clinical trial. As a result, pursuant to the Loan and Security Agreement, the period for which we are required to make interest-only payments was extended from July 1, 2016 to January 1, 2017. All unpaid principal and interest with respect to the Term Loan was scheduled to be due and payable in full on June 1, 2019. At maturity of the Term Loan, or earlier repayment in full following voluntary prepayment or upon acceleration, we are required to make a final payment in an aggregate amount equal to approximately \$1.1 million. In connection with the Term Loan, on May 29, 2015, we issued to Oxford warrants to purchase an aggregate of 189 shares of our 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.

On September 20, 2017, the Company entered into an amendment to the Term Loan, pursuant to which, among other things, Oxford agreed to reduce the minimum liquidity covenant level originally at \$5 million to \$1.5 million. The amendment also extended the interest-only period under the Loan and Security Agreement through August 1, 2018, as the Company successfully closed on a financing and received unrestricted net cash proceeds in excess of \$5 million on or before December 29, 2017.

On June 19, 2018, the Company entered into a second amendment (the "Second Amendment") to the Term Loan with Oxford. The Second Amendment extended the interest-only period under the Term Loan to December 1, 2018 if the Company receives unrestricted gross cash proceeds of at least \$15 million from the sale and issuance of the Company's equity securities on or before August 31, 2018. The Company agreed to pay Oxford an amendment fee of \$250,000 at the earlier of maturity or acceleration of the loan.

On August 31, 2018, the Company entered into a third amendment (the “Third Amendment”) to the Term Loan with Oxford. The Third Amendment extends the interest-only period under the Term Loan to December 31, 2018 and also requires that the Company pay to Oxford, in accordance with its pro rata share of the loans, 75% of all proceeds received (i) from the issuance and sale of unsecured subordinated convertible debt, (ii) in connection with a joint venture, collaboration or other partnering transaction, (iii) in connection with any licenses, (iv) from dividends (other than non-cash dividends from wholly owned subsidiaries) and (v) from the sale of any assets (such requirement, the “Prepayment Requirement”). The Prepayment Requirement does not apply to proceeds from the sale and issuance of the Company’s equity securities, other than convertible debt. The Prepayment Requirement shall apply until an aggregate principle amount of \$7.0 million has been paid pursuant to the Prepayment Requirement. However, if less than \$7.0 million has been paid pursuant to the Prepayment Requirement on December 31, 2018 then the Company is required to promptly make additional payments until an aggregate principal amount of \$7.0 million has been paid. The Company agreed to pay Oxford an amendment fee of \$50,000 at the earlier of maturity or acceleration of the loan.

On December 31, 2018, the Company entered into a fourth amendment (the “Fourth Amendment”) to the Term Loan with Oxford. Oxford agreed to extend the maturity date from June 1, 2019 to June 1, 2020. The Fourth Amendment increased the minimum liquidity covenant level from \$1.5 million to \$2.0 million and extended the interest-only period under the Loan and Security Agreement to March 1, 2019. The Fourth Amendment also required that the Company achieve one of the following by January 31, 2019: enter into an asset sale agreement with a minimum unrestricted net cash proceeds to the Company of \$4.0 million; enter into a binding agreement for the issuance and sale of its equity securities or unsecured convertible subordinated debt which would result in unrestricted gross cash proceeds of not less than \$7.5 million; or enter into a merger agreement pursuant to which the obligations under the Loan and Security Agreement would be paid down to a level satisfactory to Oxford. The Company agreed to pay Oxford an amendment fee of \$350,000 at the earlier of maturity or acceleration of the loan.

On February 13, 2019, the Company entered into a fifth amendment (the “Fifth Amendment”) to the Term Loan primarily to extend the January 31, 2019 obligations under the Fourth Amendment to February 28, 2019. On March 4, 2019, the Company entered into a sixth amendment to the Term Loan primarily to extend the Fifth Amendment principal payment obligations to March 29, 2019. On April 29, 2019, the Company entered into a seventh amendment (the “Seventh Amendment”) to the Term Loan, pursuant to which, among other things, Oxford agreed to interest only payments starting May 1, 2019, with amortization payments resuming on May 1, 2020. On July 15, 2019, the Company entered into an eighth amendment (the “Eighth Amendment”) to the Term Loan primarily to obtain the consent from Oxford for its name change to Plus Therapeutics, Inc.

The Term Loan, as amended, is collateralized by a security interest in substantially all of the Company’s existing and subsequently acquired assets, subject to certain exceptions set forth in the Loan and Security Agreement, as amended. The intellectual property assets collateral which was directly related to the sales of cell therapy assets was released in April 2019 after partial payment of the loan principal. As of September 30, 2019, we were in compliance with all of the debt covenants under the Loan and Security Agreement.

Interest expense for the three and nine months ended September 30, 2019 and 2018 was \$0.4 million and \$1.5 million and was \$0.5 million and \$1.4 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 \$0.4 million for the three and nine months ended September 30, 2019, respectively, and \$0.2 million and \$0.4 million for the three and nine months ended September 30, 2018, 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, our 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 our 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 us or a declaration of material adverse change by our lender, under the Term Loan, the lender would be entitled to exercise its remedies thereunder, including the right to accelerate the debt, upon which we may be required to repay all amounts then outstanding under the Term Loan, which could materially harm our financial condition. As of September 30, 2019, we were in compliance with all covenants under the Term Loan and have not received any notification or indication from Oxford to invoke the material adverse change clause. However, due to our negative cash flows from operations and the substantial doubt about our ability to continue as a going concern, the entire principal amount of the Term Loan is presented as short-term. We will continue to evaluate the debt classification on a quarterly basis and evaluate for reclassification in the future should our financial condition improve.

## **5. Revenue Recognition**

### *Development Revenue*

We earn revenue for performing tasks 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 our statements of operations. We recognized \$4.8 million and \$5.8 million in development revenue for the three and nine months ended September 30, 2019, respectively, as compared to \$0.5 million and \$2.3 million for the three and nine months ended September 30, 2018, respectively.

On July 21, 2019, the Company received an order from the U.S. Department of Health and Human Services / Office of the Assistant Secretary for Preparedness and Response / Biomedical Advanced Research and Development Authority (“HHS/ASPR/BARDA”) regarding Contract HHSO100201200008C dated September 27, 2012 (as amended, the “Agreement”) to suspend all work on the Agreement, including the RELIEF clinical trial, except for certain activities related to orderly close out of the trial and contract. This order was based on previous discussions between the Company and HHS/ASPR/BARDA concerning the best path forward for both parties in light of the difficulty of enrolling the RELIEF trial and the Company’s previously disclosed restructuring plan. Pursuant to the order, on or before January 17, 2020, the contract will be terminated by HHS/ASPR/BARDA.

In September 2019, the Company 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 reimbursement revenue recognized during the three months ended September 30, 2019. The \$4.6 million was received in cash in October 2019.

#### *Concentration of Significant Customers*

After the Company sold its cell therapy business, BARDA accounted for 100% of our revenue from continuing operations which are recognized for the nine months ended September 30, 2019 and accounted for 100% of total outstanding accounts receivable presented in the accompanying consolidated condensed financial statements.

## 6. 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. The following table summarizes the calculation of the loss on sale of the cell therapy business, which will be finalized during the fourth quarter of 2019 (in thousands):

Consideration received	\$	7,000
Transaction costs		(1,161)
Net cash proceeds		5,839
Less:		
Carrying value of business and assets sold		12,145
Net loss on sale of business	\$	6,306

There were no assets or liabilities related to discontinued operations as of September 30, 2019. Assets and liabilities related to discontinued operations or held for sale as of December 31, 2018 consisted of the following:

	<b>December 31, 2018</b>	
<b>Assets</b>		
Current assets held for sale:		
Accounts receivable, net	\$	108
Inventory, net		2,841
Other current assets		328
Long-term assets held for sale:		
Property and equipment, net		260
Other noncurrent assets		1,866
Goodwill		3,550
Intangible assets, net		5,957
Total assets	\$	14,910
<b>Liabilities</b>		
Current liabilities held for sale:		
Accounts payable and accrued liabilities	\$	580
Other noncurrent liabilities		78
Deferred revenues		167
Noncurrent liabilities	\$	825

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

	<u>Three months ended September 30,</u>		<u>Nine months ended September 30,</u>	
	2018	2019	2018	2018
Product revenue	\$ 858	\$ 901	\$ 2,249	
Costs of revenue	628	857	1,837	
Gross profit	230	44	412	
Operating expenses:				
Research and development	689	656	2,479	
Sales and marketing	337	411	1,060	
General and administrative	147	185	560	
Total operating expenses	1,173	1,252	4,099	
Operating loss	(943)	(1,208)	(3,687)	
Other income (expense)	9	140	157	
	(934)	\$ (1,068)	\$ (3,530)	

During the three and nine months ended September 30, 2019 and 2018, 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 revenues and costs of product revenues for these periods have been recorded in loss from discontinued operations in the consolidated condensed statements of operations.

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

	<u>For the nine months ended September 30,</u>	
	2019	2018
Depreciation and amortization	\$ 467	\$ 1,207
Provision for excess inventory	\$ —	\$ 433
Loss on asset disposal	\$ —	\$ 23

## 7. 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, without consideration for common stock equivalents. 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.

Net loss per share for the three and nine months ended September 30, 2019 included a deemed dividend of \$554,000 due to beneficial conversion feature recorded as a result of the adjustment of the conversion price of Series C Preferred Stock from \$39.93 to \$7.50 per share in August 2019. Net loss per share for the three and nine months ended September 30, 2018 included a deemed dividend of \$2.5 million to account for the beneficial conversion feature in connection with issuance of Series C Preferred Stock.

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

	<u>For the Nine Months Ended September 30,</u>	
	2019	2018
Outstanding stock options	254,000	177,000
Preferred stock	298,000	95,000
Outstanding warrants	3,637,000	185,000
Total	4,189,000	457,000

## 8. Commitments

### 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. In connection with certain operating leases, the Company has security deposits recorded and maintained as restricted cash totaling \$40 thousand as of September 30, 2019.

The Company leases office and storage facilities and equipment under various operating and financing lease agreements. The initial terms of these leases range from 2 to 11 years and 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 years and rates):

	<u>September 30, 2019</u>
<b>Assets</b>	
Operating	\$ 818
Financing	180
Total leased assets	\$ 998
<b>Liabilities</b>	
Current:	
Operating	\$ 156
Financing	144
Noncurrent:	
Operating	\$ 684
Financing	38
Total lease liabilities	\$ 1,022
Weighted-average remaining lease term (years) - operating leases	6.96
Weighted-average remaining lease term (years) - finance leases	1.32
Weighted-average discount rate - operating leases	7.97%
Weighted-average discount rate - finance leases	5.00%

The table below summarizes the Company's lease costs from its Unaudited Consolidated Statements of Operations, and cash payments from its Unaudited Consolidated Statements of Cash Flows during the three and nine months ended September 30, 2019 (in thousands):

	Three months ended September 30, 2019	Nine months ended September 30, 2019
Lease expense:		
Operating lease expense	\$ 56	\$ 169
Finance lease expense:		
Depreciation of right-of-use assets	32	85
Interest expense on lease liabilities	2	7
Total lease expense	\$ 90	\$ 261
Cash payment information:		
Operating cash used for operating leases	\$ 38	\$ 147
Financing cash used for financing leases	1	75
Total cash paid for amounts included in the measurement of lease liabilities	\$ 39	\$ 222

The Company's future minimum annual lease payments under operating and financing leases at September 30, 2019 are as follows (in thousands):

	Financing Leases	Operating Leases
Remaining 2019	\$ 59	\$ 75
2020	122	205
2021	7	183
2022	—	123
2023	—	100
Thereafter	—	448
Total minimum lease payments	\$ 188	\$ 1,134
Less: amount representing interest	(6)	(294)
Present value of obligations under leases	182	840
Less: current portion	(144)	(156)
Noncurrent lease obligations	\$ 38	\$ 684

#### *Other commitments*

We have 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, 2019, we have clinical research study obligations of \$2.4 million, \$1.9 million of which is expected to be paid within a year. Should the timing of the clinical trials change, the timing of the payment of these obligations would also change.

## **9. Contingencies**

We are 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.

On July 25, 2019, Tap Advisors LLC ("Tap") filed suit against the Company in the Supreme Court of the State of New York, County of New York, alleging the Company breached an agreement made in 2017, whereby Tap would provide certain financial advisory services to the Company. Tap seeks to recover fees of approximately \$3.7 million (plus attorneys' fees) that allegedly have not been paid by the Company related to the sale of its cell therapy business in April 2019. The Company believes the complaint is without merit and plans to vigorously defend itself in this matter. At September 30, 2019, the probable outcome of this litigation cannot be determined.

## 10. Financial Instruments

We disclose fair value information about all financial instruments, whether or not recognized in the balance sheet, for which it is practicable to estimate fair value. The disclosures of estimated fair value of financial instruments at September 30, 2019, and as of December 31, 2018, were determined using available market information and appropriate valuation methods. Considerable judgment is necessary to interpret market data and develop estimated fair value. The use of different market assumptions or estimation methods may have a material effect on the estimated fair value amounts.

The carrying amounts for cash and cash equivalents, accounts receivable, other current assets, accounts payable, accrued expenses and other liabilities approximate fair value due to the short-term nature of these instruments. Further, based on the borrowing rates currently available for loans with similar terms, we believe the fair value of long-term debt approximates its carrying value.

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. We follow 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.

The changes in the fair value of liability classified warrants are included in net income (loss) for the respective periods. Because some of the inputs to our 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.

## 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 we issue without further action by the common stockholders. There were no shares of Series A 3.6% Convertible Preferred Stock outstanding as of September 30, 2019 or December 31, 2018. There were 1,021 and 1,112 shares of Series B Convertible Preferred Stock issued and outstanding as of September 30, 2019 and December 31, 2018, respectively. There were 938 and 3,494 shares of Series C Preferred Stock issued and outstanding as of September 30, 2019 and December 31, 2018, respectively.

On July 25, 2018, the Company filed a Certificate of Designation of Preferences, Rights and Limitations of Series C Convertible Preferred Stock (the "Certificate of Designation") with the Delaware Secretary of State creating a new series of its authorized preferred stock, par value \$0.001 per share, designated as the Series C Convertible Preferred Stock (the "Series C Preferred Stock"). The number of shares initially constituting the Series C Preferred Stock was set at 7,000 shares. Pursuant to a registration statement on Form S-1 originally filed on April 27, 2018, as amended, and 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 each consisting of one share of Series C Preferred Stock and 1,050 warrants for \$1,000 per unit. 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. On August 2, 2019, in connection with a sale of common stock, the Company notified holders of the Company's Series C Preferred Stock that the conversion price of such stock was reduced from \$39.93 to \$7.50. The reduction of the effective conversion price of the Series C Preferred Stock resulted in a beneficial conversion feature recorded as a deemed dividend to the Series C Preferred Stock holders in the amount of \$554,000. The deemed dividend is recorded as a reduction to loss available for common stockholder for basic and diluted loss per share calculation (Note 7). In addition, on August 2, 2019, the Company notified holders of the Company's Series T Warrants that the exercise price of such warrants was reduced from \$0.7986 to \$0.15, so that every 50 Series T warrants can be exercised into one share of common stock at \$7.50. On September 25, 2019, in connection with the September 2019 Offering, 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 \$3.2132, and the conversion price of the Series C Preferred Stock was reduced from \$7.50 to \$3.2132.

As of September 30, 2019, there were 3,788,400 outstanding Series T Warrants which can be exercised into in aggregate 75,768 shares of common stock. In addition, there were 938 shares of Series C Preferred Stock that can be exercised into 291,920 shares of common stock.



The fair value of the common stock into which the Series C Preferred Stock was convertible on the date of issuance exceeded the proceeds allocated to the preferred stock, resulting in the beneficial conversion feature that we recognized as a deemed dividend to the preferred stockholders and, accordingly, an adjustment to net loss to arrive at net loss allocable to common stockholders. We recorded a deemed dividend within additional paid-in capital of \$2.5 million for the quarter ended December 31, 2018, related to a beneficial conversion feature included in the issuance of our Series C Convertible Preferred Stock.

Based on the relevant authoritative accounting guidance, the warrants were liability classified at the issuance date. The warrants may be redeemed by the Company at \$0.01 per warrant prior to their expiration if the Company's common stock closes above \$181.50 per share, subject to adjustment, for 20 consecutive trading days. The initial fair value of the liability associated with these warrants was \$3.1 million, and the fair value decreased to \$0.2 million as of September 30, 2019. The main driver for the change in the fair value of warrants at September 30, 2019, was related to exercise of 3.2 million of the warrants during the three months ended September 30, 2019, and the change in our stock price. All future changes in the fair value of the warrants will be recognized in the Company's consolidated statements of operations until they are either exercised or expire. The warrants are not traded in an active securities market, and as such the estimated the fair value as of September 30, 2019 was determined by using an option pricing model with the following assumptions:

	As of September 30, 2019	As of December 31, 2018
Expected term	1.6 years	2.1 years
Common stock market price	\$ 3.42	\$ 14.50
Risk-free interest rate	1.70%	2.48%
Expected volatility	176%	125%
Resulting fair value (per 50 warrants as of September 30, 2019)	\$ 2.53	\$ 0.13

Expected volatility was computed using daily pricing observations of traded shares of the Company for recent periods that correspond to the expected term of the warrants. We believe this method produces an estimate that is representative of our expectations of future volatility over the expected term of these warrants. We currently have no reason to believe future volatility over the expected remaining life of these warrants is likely to differ materially from historical volatility. The expected life is based on the remaining contractual term of the warrants. The risk-free interest rate is the U.S. Treasury bond rate as of the valuation date.

#### Common Stock

As mentioned in Note 3, the Company completed the September 2019 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. By September 30, 2019, 1,672,000 pre-funded warrants were exercised, with the remaining 1,039,000 exercised in October 2019. The Series U Warrants remained outstanding as of September 30, 2019 and have a term of five years from the issuance date. In addition, the Company issued warrants to the Representatives to purchase 75,000 shares of its common stock at \$6.25 per share with a term of 5.0 years from the issuance date, in the form of Series U Warrants.

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

The Company estimated the fair value of the Series U Warrants on the issuance date as well as at the quarter end of September 30, 2019 with the Black Scholes model. The Series U 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 statement of operations and comprehensive income (loss).

	As of September 25, 2019	As of September 30, 2019
Expected term	5 years	5 years
Common stock market price	\$ 3.42	\$ 3.42
Risk-free interest rate	1.60%	1.55%
Expected volatility	134.9%	134.9%
Resulting fair value (per warrant)	\$ 2.90	\$ 2.90

In accordance with authoritative guidance, the proceeds from the September 2019 Offering was allocated using the residual method, first to the Series U Warrants at the full fair value and the remainder to equity. The Series U Warrants and the Representative Warrants are revalued at each balance sheet date with change in fair value recorded as other income or loss in the statement of operations and comprehensive income (loss).

The following table summarizes the change in our Level 3 Series T and Series U warrants liabilities carrying value (in thousands):

<b>Warrant liability</b>	<b>September 30, 2019</b>		<b>December 31, 2018</b>	
Beginning balance	\$	916	\$	3,148
Issuance		10,215		—
Exercises/Settlement		(794)		—
Change in fair value		69		(2,233)
Ending balance	\$	<u>10,406</u>	\$	<u>916</u>

On June 1, 2018, the Company entered into a Sales Agreement with B. Riley FBR to sell shares of its common stock having an aggregate offering price of up to \$6.5 million through its ATM Program. Through September 30, 2019, the Company sold a total of 0.2 million shares for proceeds of approximately \$3.8 million through the ATM Program. The ATM Program financing facility has been exhausted and there is no availability remaining under this financing facility.

On September 21, 2018, the Company entered into a Purchase Agreement (the “Lincoln Park Purchase Agreement”) with Lincoln Park pursuant to which the Company has the right to sell to Lincoln Park and Lincoln Park is 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. The Company may direct Lincoln Park, at its sole discretion and subject to certain conditions, to purchase up to 5,000 shares of common stock on any business day but in no event will the amount of a single Regular Purchase (as defined in the Lincoln Park Purchase Agreement) exceed \$1.0 million. The purchase price of shares of common stock related to the Regular Purchases will be based on the prevailing market prices of such shares at the time of sales. The Company’s sales of shares of common stock to Lincoln Park under the Lincoln Park Purchase Agreement are limited to the number of shares that would result in the beneficial ownership by Lincoln Park and its affiliates, at any single point in time, of no more than 4.99% of the then outstanding shares of the common stock. 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 under an accelerated purchase will shares be sold to Lincoln Park on a day the closing price of the Company’s common stock is less than the floor price of \$12.50 per share as set forth in the Lincoln Park Purchase Agreement. Through December 31, 2018, the Company sold a total of 12,802 shares for proceeds of approximately \$0.3 million through the Lincoln Park Purchase Agreement and 32,170 shares for proceeds of approximately \$0.3 million were sold during the nine months ended September 30, 2019. The Company believes there is less than \$0.1 million remaining available under this financing facility.

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

Our Management’s Discussion and Analysis of Financial Condition and Results of Operations, or MD&A, includes the following sections:

- Overview that discusses our operating results and some of the trends that affect our business.
- Results of Operations that includes a more 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.

You should read this MD&A in conjunction with the financial statements and related notes in Item 1 and our Annual Report on Form 10-K for the fiscal year ended December 31, 2018, as revised in Form 8-K filed on September 10, 2019.

### **CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING STATEMENTS**

*This report contains certain statements that may be deemed “forward-looking statements” within the meaning of U.S. securities laws. All statements, other than statements of historical fact, that address activities, events or developments that we intend, expect, project, believe or anticipate and similar expressions or future conditional verbs such as will, should, would, could or may occur in the future are forward-looking statements. 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 about our anticipated expenditures, including research and development, sales and marketing, and general and administrative expenses; 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 revenues; 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, including our potential need for additional financing and the availability thereof; 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; 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: 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, and competition within the regenerative medicine field, to name a few. The forward-looking statements included in this report are subject to a number of additional material risks and uncertainties, including but not limited to the risks described under the “Risk Factors” in Item 1A of Part I below, which we encourage you to read carefully.*

*We encourage you to read the risks described under “Risk Factors” 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. Such forward-looking statements are not guarantees of future performance.*

### **Overview**

Plus Therapeutics, Inc. is a clinical-stage pharmaceutical company focused on the discovery, development, and manufacturing scale up 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 exploit 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.

## Recent Developments

In September 2019, the Company finalized the indirect cost rate under the BARDA Agreement (Note 5) for indirect costs incurred during the years 2012 through 2019, which resulted in approximately \$4.6 million reimbursement revenue recognized during the three months ended September 30, 2019. The \$4.6 million was received in cash in October 2019.

In September 2019, the Company entered into an underwriting agreement with H.C. Wainwright & Co., LLC (the “Representative”), as representative of the underwriters (the “Underwriters”), pursuant to which the Company sold the Underwriters in an underwritten public offering an aggregate of (i) 289,000 Class A Units, each consisting of one share of common stock, par value \$0.001 per share, of the Company 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. In addition, the Company granted the Underwriters Series U Warrants to purchase up to 450,000 shares of common stock. The Company 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.

The net proceeds to the Company from the offering was approximately \$13.2 million, after deducting underwriting discounts and commissions and other estimated offering expenses and excluding the exercise of any warrants and the Underwriters’ option to purchase additional securities. The Company intends to use the net proceeds from the offering for working capital, payment of interest on its debt and general corporate purposes, which may include research and development of its oncology product pipeline, preclinical and clinical trials and studies, regulatory submissions, expansion of its sales and marketing organizations and efforts, intellectual property protection and enforcement and capital expenditures.

The Series U Warrants are exercisable upon issuance and will expire on the five-year anniversary of the date of issuance. The exercise price of the Series U Warrants is \$5.00 per share of Common Stock. The Series V Warrants are exercisable upon issuance and will be exercisable until all of the Series V Warrants are exercised in full. The exercise price of the Series V Warrants is \$0.0001 per share of Common Stock. The Series U Warrants and the Series V Warrants may not be exercised by the holder to the extent that, after giving effect to an exercise, the holder, together with its affiliates and certain related parties, would beneficially own more than 4.99% (or, at the election of the purchaser prior to the date of issuance, 9.99%) of the Common Stock then outstanding (subject to the right of the holder to increase or decrease such beneficial ownership limitation upon notice to the Company, provided that such limitation cannot exceed 9.99%, and provided that any increase in the beneficial ownership limitation will not be effective until 61 days following notice of such increase from the holder to the Company). The Company does not intend to apply for listing of the Series U Warrants or the Series V Warrants on the Nasdaq Capital Market, any other securities exchange or any other trading system.

## Pipeline

We intend to build our pipeline by in-licensing and/or acquiring drugs for niche and orphan markets, initially in oncology, that address significant unmet or substantially underserved medical needs and that represent global revenue opportunities greater than \$250 million. We intend to focus our pipeline on products that maximize our in-house expertise in nanoparticle drug design and complex formulation and leverage accelerated regulatory pathways by the U.S. Food and Drug Administration (FDA).

Our lead product candidate, DocePLUS, is a protein-stabilized PEGylated liposomal formulation of docetaxel, for which the process of preparation is patented. The active pharmaceutical ingredient, docetaxel, was approved by the FDA in 1999 and commonly used for treating cancers of the breast, head, neck, stomach, prostate, and lung.

In nonclinical studies utilizing mouse tumor models (lung, prostate, pancreatic, and mesothelioma), DocePLUS exhibited anti-tumor activity and was well-tolerated.

A Phase 1 clinical trial was conducted under an approved FDA Investigational New Drug application to examine the safety, pharmacokinetics, and pharmacodynamics of DocePLUS in 29 patients with solid tumors. The completed and published trial demonstrated that DocePLUS has an acceptable tolerability, a favorable pharmacokinetic profile, as well as promising anti-tumor activity that we believe warrants further exploration in larger Phase 2 trials.

The development targets for DocePLUS are potentially broad, however our initial focus is to develop a new second-line treatment option for small cell lung cancer. Single-agent chemotherapy with IV topotecan is currently the only FDA approved drug for platinum-sensitive patients who relapse at least 60 days after initiation of first-line treatment. Intravenously administered topotecan demonstrates activity in this population, however, overall response rate (24%), response duration (3.3 months), time to progression (3.1 months), and overall survival (5.8 months) were not statistically improved over CAV (cyclophosphamide, doxorubicin, and vincristine) treatment in a randomized comparative trial of patients with recurrent or progressive small cell lung cancer. Patients receive 1.5 mg/m<sup>2</sup> IV infusion of topotecan over 30 minutes daily for 5 consecutive days, starting on Day 1 of a 21-day cycle. We believe there is a clinical need for more effective and convenient treatment options for patients with small cell lung cancer with platinum-sensitive disease who relapsed.

Besides potential safety and efficacy benefits of DocePLUS, the dosing regimen for DocePLUS in small cell lung cancer patients will be only a 60 minute infusion on a single day, starting on Day 1 of a 21-day cycle. This approach will reduce the patient's number of visits to an infusion center from 5 (IV topotecan) to 1 in a given 21-day cycle. Overall, DocePLUS is intended to provide an effective, safe, and convenient therapeutic option for small cell lung cancer patients, thereby improving the quality of life for this population.

Recent key events associated with DocePLUS development include:

- In September 2018, the FDA granted DocePLUS an orphan drug designation for the treatment of small cell lung cancer.
- In the first half of 2019, we collaborated with an experienced global market evaluation firm in mapping the current and anticipated landscape, performing primary market research with U.S. medical oncologists and payers, suggesting small cell lung cancer as well as several other oncology targets represent compelling future disease targets with significant patient-benefit and revenue potential.
- In July 2019, we announced receipt of FDA feedback including confirmation that a 505(b)(2) application appears to be an acceptable regulatory path with docetaxel injection as a potentially acceptable listed drug. Furthermore, the FDA agreed that the completed nonclinical studies are sufficient to support the initiation of a clinical trial of DocePLUS in patients with platinum-sensitive small cell lung cancer who have progressed at least 60 days after initiation of first-line therapy.

Our next step is to conduct a Phase 2 clinical trial in small cell lung cancer under our existing, approved Investigation New Drug application. We expect the goal of this trial is to assess safety and investigate efficacy signals in patients with platinum-sensitive small cell lung cancer who have progressed. We expect the trial will also support the statistical powering or a pivotal trial for the same indication. We expect to receive FDA approval of the Phase 2 clinical trial protocol in the fourth quarter of 2019, enroll the first patient in the third quarter of 2020 and complete patient enrollment in the second half of 2021.

We have also completed significant development work on DoxoPLUS, a generic version of Janssen's DOXIL®/CAELYX®, a PEGylated liposomal encapsulated doxorubicin for the treatment of breast and ovarian cancer, multiple myeloma, and Kaposi's sarcoma. PEGylated liposomal encapsulated doxorubicin is a heavily relied upon chemotherapeutic used globally for treating many types of cancer. We believe that data from a 38-patient European study of DoxoPLUS has met the statistical criteria for bioequivalence to CAELYX®, the current reference listed drug in Europe. We believe that these bioequivalence data for DoxoPLUS can serve as a basis for a Marketing Authorization Application to be submitted to the European Medicines Agency, or EMA. The market size for PEGylated liposomal encapsulated doxorubicin in Europe is approximately \$120 million. Our plan is to partner DoxoPLUS and we are currently in discussions with third parties. We do not currently plan to expend any more of our own funds to advance DoxoPLUS.

While we are continually looking at other product development candidates, we do not currently have any active product candidates other than DocePLUS.

## **Results of Operations**

### Development revenues

Under our government contract with BARDA, we recognized a total of \$4.8 million and \$5.8 million in revenues for the three and nine months ended September 30, 2019, respectively, which included allowable fees as well as cost reimbursements. During the three and nine months ended September 30, 2019, we incurred \$0.2 million and \$1.2 million in qualified expenditures, respectively. During the three and nine months ended September 30, 2018, we recognized revenue of \$0.5 million and \$2.3 million, and incurred \$0.4 million and incurred \$2.1 million in qualified expenditures, respectively.

The increase in revenues for the three and nine months ended September 30, 2019 as compared to the same period in 2018 is primarily due to \$4.6 million of revenue recognized during the third quarter ended September 30, 2019 under the BARDA contract based on retrospective changes in indirect cost rates during fiscal years 2012 through 2019.

*The future:* On July 21, 2019, we received an order from BARDA to suspend all work related to the RELIEF clinical trial, except for certain activities related to orderly close out of the trial and contract. Pursuant to the order, on or before January 17, 2020, the contract will be terminated by BARDA.

### Research and development expenses

Research and development expenses include costs associated with the design, development, testing and enhancement of our product candidates, 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, 2019 and 2018 (in thousands):

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2019	2018	2019	2018
Research and development	\$ 911	\$ 1,202	\$ 3,604	\$ 3,817
Share-based compensation	10	24	32	70
Total research and development expenses	\$ 921	\$ 1,226	\$ 3,636	\$ 3,887

The decrease in research and development expenses for the nine months ended September 30, 2019 as compared to the same period in 2018 is due primarily to a decrease of \$0.7 million in professional services, and \$0.2 million in printing services and \$0.1 million in product sample, offset by increase of \$0.6 million in product studies. The decrease in research and development expenses for the three months ended September 30, 2019 as compared to the same period in 2018 is due primarily to a decrease of \$0.5 million in professional services.

*The future:* We expect aggregate research and development expenditures to remain at current levels for the balance of 2019, as we work on clinical activities on the RELIEF clinical trial and our ongoing development efforts of DocePLUS.

#### Sales and marketing expenses

Sales and marketing expenses include costs of sales and marketing personnel, events and tradeshows, customer and sales representative education and training, 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, 2019 and 2018 (in thousands):

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2019	2018	2019	2018
Sales and marketing	\$ 92	\$ 107	\$ 296	\$ 545
Share-based compensation	2	11	9	51
Total sales and marketing expenses	\$ 94	\$ 118	\$ 305	\$ 596

Sales and marketing expenses decreased by \$0.3 million during the nine months ended September 30, 2019 as compared to the same period in 2018 due primarily to decreases of \$0.2 million in salaries and benefits as well as of \$0.1 million in professional services because of the decreased efforts of our commercial activities. There is no material variance for the three months ended September 30, 2019 as compared to the same period in 2018.

*The future:* We expect sales and marketing expenditures to decrease during the balance of 2019 due to the sale of our Cell Therapy business in April 2019.

#### 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, 2019 and 2018 (in thousands):

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2019	2018	2019	2018
General and administrative	\$ 1,059	\$ 1,288	\$ 3,248	\$ 4,443
Share-based compensation	17	49	65	196
Total general and administrative expenses	\$ 1,076	\$ 1,337	\$ 3,313	\$ 4,639

General and administrative expenses decreased by \$0.3 million and \$1.3 million during the three and nine months ended September 30, 2019, respectively, as compared to the same periods in 2018. The variance for three months is primarily due to the decrease of \$0.2 million in salaries, benefits and professional services. The decrease for the nine months period is primarily driven by one-time expenses of \$0.6 million related to the termination of a Lease Agreement for office space for our corporate headquarters in San Diego, California. In addition, during 2019 there was a decrease of \$0.5 million in corporate and legal professional fees.

*The future:* We expect general and administrative expenditures to decrease during the balance of 2019 due to the sale of our Cell Therapy business in April 2019.

### 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 share-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, 2019 and 2018 (in thousands):

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2019	2018	2019	2018
Research and development-related	10	24	32	70
Sales and marketing-related	2	11	9	51
General and administrative-related	17	49	65	196
Total share-based compensation	<u>\$ 29</u>	<u>\$ 84</u>	<u>\$ 106</u>	<u>\$ 317</u>

The decrease in share-based compensation expense for the three and nine months ended September 30, 2019 as compared to the same periods in 2018 is primarily related to lower annual grant activity to remaining employees caused by reductions in headcount and due to the decline in the stock price during 2019 as compared to the same period in 2018, and its corresponding impact on share-based compensation.

*The future:* We expect to continue to grant options and stock awards (which will result in an expense) 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, 2019, the total compensation cost related to non-vested stock options and stock awards not yet recognized for all our plans is approximately \$0.1 million which is expected to be recognized as a result of vesting under service conditions over a weighted average period of 1.6 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, 2019 and 2018 (in thousands):

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2019	2018	2019	2018
Interest income	\$ 6	\$ 11	\$ 20	\$ 30
Interest expense	(366)	(513)	(1,477)	(1,379)
Change in fair value of warrants	(561)	1,676	(69)	1,676
Warrant issuance cost	(1,233)	(343)	(1,233)	(343)
Total	<u>\$ (2,154)</u>	<u>\$ 831</u>	<u>\$ (2,759)</u>	<u>\$ (16)</u>

Interest expense increased for the nine months ended September 30, 2019 as compared to the same period in 2018, due to the inclusion of amendment fees added to our debt.

Changes in fair value of our warrant liability are primarily due to fluctuations in the valuation inputs, as well as reduction in the number of warrants outstanding due to exercises of the 2018 Rights Offering warrants during the quarter ended September 30, 2019. See Note 11 to the consolidated financial statements included elsewhere herein for disclosure and discussion of our warrant liability.

Warrant issuance cost represents the financing issuance costs allocated to warrants issued in July 2018 and September 2019.

*The future:* We expect interest expense in 2019 to decrease slightly in the second half of this year. In addition, regarding to the changes in fair value of warrants, there could be material fluctuations in the value of warrants in future periods because our stock price can be volatile. Future changes in the fair value of the warrant liability will be recognized in earnings until such time as the warrants are exercised or expire.

## Liquidity and Capital Resources

### Short-term and long-term liquidity

The following is a summary of our key liquidity measures at September 30, 2019 and December 31, 2018 (in thousands):

	As of September 30, 2019	As of December 31, 2018
Cash and cash equivalents	\$ 16,834	\$ 5,261
Current assets	\$ 22,264	\$ 6,371
Current liabilities	14,427	16,979
Working capital (deficit)	\$ 7,837	\$ (10,608)

We generated income from continuing operations of \$526,000 and incurred net losses from continuing operations of \$4.2 million for the three and nine months ended September 30, 2019, respectively. We have an accumulated deficit of \$426.2 million as of September 30, 2019. Additionally, we used net cash of \$6.9 million to fund our operating activities for the nine months ended September 30, 2019. 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 including our recently completed September 2019 Offering, 2018 Rights Offering (defined below), our Lincoln Park Purchase Agreement (defined below) with Lincoln Park Capital Fund, LLC, or Lincoln Park, the Loan and Security Agreement and gross profits. We have had, and we will likely 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.

In September 2019, we finalized the indirect cost rate under the BARDA Agreement (Note 5) for indirect costs incurred during the years 2012 through 2019, which resulted in approximately \$4.6 million of revenue recognized during the three months ended September 30, 2019. The full amount of the cost reimbursement was received in cash in October 2019.

In September 2019, the Company entered into an underwriting agreement with the Representative, pursuant to which the Company sold in an underwritten public offering an aggregate of (i) 289,000 Class A Units, each consisting of one share of common stock, par value \$0.001 per share, of the Company (the "Common Stock") 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, the Company granted the Underwriters a 45-day option to purchase up to an additional 450,000 shares of the Company's Common Stock and/or Series U Warrants at the public offering price, less underwriting discounts and commissions. The Underwriters exercised their option for the additional 450,000 Series U Warrants. The Company 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.

We received net proceeds of approximate \$13.2 million from the September 2019 Offering, which it intends to use for working capital, payment of interest on its debt and general corporate purposes, which may include research and development of its oncology product pipeline, preclinical and clinical trials and studies, regulatory submissions, expansion of its sales and marketing organizations and efforts, intellectual property protection and enforcement and capital expenditures.

On April 24, 2019 we received \$3.4 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 the Company's 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 the Company received \$2.5 million of net cash proceeds related to the sale of the Japanese Subsidiary, 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.

On June 1, 2018, we entered into a Sales Agreement with B. Riley FBR, Inc. ("B. Riley FBR") to sell shares of our common stock having an aggregate offering price of up to \$6.5 million from time to time, through an "at the market" equity offering program (the "ATM Program") under which B. Riley FBR will act as sales agent. The ATM Program financing facility has been exhausted and there is no availability remaining under this financing facility.

On July 25, 2018, we closed a rights offering originally filed under a Form S-1 registration statement in April 2018, or the 2018 Rights Offering. Pursuant to the 2018 Rights Offering, the Company sold an aggregate of 6,723 units consisting of a total of 6,723 shares of Series C Convertible Preferred Stock, immediately convertible into approximately 0.2 million shares of common stock and 7,059,150 warrants, exercisable for an aggregate of 141,183 shares of common stock at an exercise price of \$39.93 per share of common stock, resulting in total net proceeds to the Company of approximately \$5.7 million.



On August 28, 2018, we received a written notice from Nasdaq staff indicating that, based upon the closing bid price of our common stock for the prior 30 consecutive business days, we no longer meet the requirement to maintain a minimum bid price of \$1.00 per share, as set forth in Nasdaq Listing Rule 5550(a)(2). In accordance with Nasdaq Listing Rule 5810(c)(3)(A), we were provided an initial period of 180 calendar days, or until February 25, 2019, in which to regain compliance. We were also granted an additional compliance period of 180 calendar days, or until August 26, 2019, in which to regain compliance after meeting the continued listing requirement for market value of publicly held shares and all other initial listing standards for the Nasdaq Capital Market, with the exception of the bid price requirement, and providing notice to Nasdaq staff of our intent to cure the deficiency during this second compliance period, by effecting a reverse stock split, if necessary. In order to regain compliance with the minimum bid price requirement, the closing bid price of our common stock must have been at least \$1.00 per share for a minimum of 10 consecutive business days during the 180-day period. In August 2019, we consummated a 1-for-50 reverse stock split pursuant to which the minimum bid price of our common stock rose above \$1.00. On August 29, 2019, we received written notice from Nasdaq staff that we had regained compliance with the Nasdaq Stock Market Listing Rule 5550(a)(2) concerning our minimum bid price per share of our common stock.

On August 16, 2019, the Company received written notice from the Nasdaq indicating that the Company no longer meets the requirements for continued listing under Nasdaq Listing Rule 5550(a)(4) due to the Company's failure to meet the minimum 500,000 publicly held shares requirement for continued listing. On September 11, 2019, we received written notice from Nasdaq staff that, based on having 786,807 publicly held shares outstanding as of August 31, 2019, we had regained compliance with Nasdaq Listing Rule 5550(a)(4).

In addition, on August 19, 2019, the Company received written notice from Nasdaq indicating that, based on the Company's stockholders' deficit of \$6.3 million as of June 30, 2019, as reported in the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2019, it is no longer in compliance with the minimum stockholders' equity requirement for continued listing on the Nasdaq Capital Market under Nasdaq Listing Rule 5550(b)(1), which requires listed companies to maintain stockholders' equity of at least \$2.5 million. Based on our stockholders' equity of \$160,000 as of September 30, 2019, we do not meet the minimum stockholders' equity requirement for continued listing on the Nasdaq Capital Market under Nasdaq Listing Rule 5550(b)(1). We expect to receive written notice from Nasdaq staff to that effect following the filing of this Quarterly Report on Form 10-Q. In addition, as of September 30, 2019, we do not meet the alternative compliance standards relating to the market value of listed securities or net income from continuing operations. We intend to evaluate various courses of action to regain compliance with Nasdaq Listing Rule 5550(b)(1) within the compliance period specified by Nasdaq. However, there can be no assurance that we will be able to regain compliance within such compliance period.

On September 21, 2018, the Company entered into a purchase agreement and a registration rights agreement, with Lincoln Park, pursuant to which the Company has the right to sell to Lincoln Park and Lincoln Park is 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, subject to the satisfaction of certain conditions. Through December 31, 2018, the Company sold a total of 12,802 shares for proceeds of approximately \$0.3 million through the Lincoln Park Purchase Agreement and 32,170 shares for proceeds of approximately \$0.3 million were sold during the nine months ended September 30, 2019. The Company believes there is less than \$0.1 million remaining available under this financing facility.

We continue to seek additional capital through strategic transactions and from 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.

Should we be unable to raise additional cash from outside sources, this would have a material adverse impact on our operations.

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.

As of September 30, 2019, there have been no material changes outside the ordinary course of our business to the contractual obligations we reported in our Annual Report on Form 10-K for the fiscal year ended December 31, 2018, except for the amendments to the Loan and Security Agreement.

On April 24, 2019 the Company received \$3.4 million of net cash proceeds related to the sale of the Company's UK subsidiary, Cytori Ltd., and the Company's Cell Therapy assets, 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 the Company received \$2.5 million of net cash proceeds related to the sale of the Company's Japanese subsidiary, Cytori Therapeutics, K.K., and substantially all of the Company's Cell Therapy assets used in Japan, of which \$1.4 million was used to pay down principal, interest and fees on the Loan and Security Agreement.

Cash (used in) provided by operating, investing, and financing activities for the three and nine months ended September 30, 2019 and 2018 is summarized as follows (in thousands):

	For the Nine Months Ended September 30,	
	2019	2018
Net cash used in operating activities	\$ (6,942)	\$ (9,487)
Net cash provided by (used in) investing activities	2,781	(128)
Net cash provided by financing activities	15,738	6,246
Effect of exchange rate changes on cash and cash equivalents	(4)	(10)
Net increase (decrease) in cash and cash equivalents	\$ 11,573	\$ (3,379)

#### Operating activities

Net cash used in operating activities for the nine months ended September 30, 2019 was \$6.9 million compared to \$9.5 million in the same period of 2018. Overall, our operational cash use decreased during the nine months ended September 30, 2019 as compared to the same period in 2018, due primarily to a decrease in losses from operations (when adjusted for non-cash items).

#### Investing activities

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 net proceeds of \$2.8 million. Net cash used in investing activities for the nine months ended September 30, 2018 is related to the purchase of fixed assets.

#### Financing Activities

Net cash provided by 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, offset by the principal payment of long-term obligations of \$0.6 million. Net cash provided by financing activities for the nine months ended September 30, 2018 is primarily related to sales of common and preferred stocks of \$6.2 million, net of costs from sale primarily through our 2018 Rights Offering and ATM program.

#### **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.

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, 2018, as revised in the Form 8-K filed on September 10, 2019. There have been no material changes, other than the adoption of Accounting Standards Codification 842, *Leases*, during the nine months ended September 30, 2019.

#### **Item 3. Quantitative and Qualitative Disclosures about Market Risk**

As of September 30, 2019, there have been no material changes in our market risks from those described in Item 7A “Quantitative and Qualitative Disclosures About Market Risk” in our Annual Report on Form 10-K for the fiscal year ended December 31, 2018, except that the Company no longer has ongoing operations outside of the United States following the sale of our cell therapy.

#### **Item 4. Controls and Procedures**

##### *Evaluation of Disclosure Controls and Procedures*

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in our reports filed or furnished 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 principal executive officer and principal financial 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 principal executive officer and principal financial officer, of the effectiveness of our disclosure controls and procedures, as such term is defined under Rule 13a-15(e) promulgated under the Securities Exchange Act of 1934, as amended, as of the end of the period covered by this Quarterly Report on Form 10-Q. Based on the foregoing, our principal executive officer and principal financial officer concluded that our disclosure controls and procedures were effective 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, 2019 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

## **PART II. OTHER INFORMATION**

### **Item 1. Legal Proceedings**

From time to time, we have been involved in routine litigation incidental to the conduct of our business.

On July 25, 2019, Tap Advisors LLC (“Tap”) filed suit against the Company in the Supreme Court of the State of New York, County of New York, alleging the Company breached an agreement made in 2017, whereby Tap would provide certain financial advisory services to the Company. Tap seeks to recover fees of approximately \$3.7 million (plus attorneys’ fees) that allegedly have not been paid by the Company related to the sale of its cell therapy business in April 2019. The Company believes the complaint is without merit and plans to vigorously defend itself in this matter. At September 30, 2019, the probable outcome of this litigation cannot be determined.

We are not currently a party to any other material legal proceeding.

### **Item 1A. Risk Factors**

Our business is subject to various risks, including those described in Item 1A “Risk Factors” of our Annual Report on Form 10-K for the fiscal year ended December 31, 2018 filed with the U.S. Securities and Exchange Commission on March 29, 2019 and our subsequent Quarterly Reports on Form 10-Q, which we strongly encourage you to review with all other information contained or incorporated by reference in this report before you decide to invest in our common stock. In addition to those risk factors, we identified the following new risks or substantive changes from the risks described in our Annual Report on Form 10-K, as updated by our subsequent Quarterly Reports on Form 10-Q. If any of the risks described in our Annual Report on Form 10-K or our subsequent Quarterly Reports on Form 10-Q discussed below actually occurs, our business, financial condition, results of operations and our future growth prospects could be materially and adversely affected. Under these circumstances, the trading price of our common stock could decline, and you may lose all or part of your investment.

#### **Risks Related to our Financial Position and Capital Requirements**

***We will need substantial additional funding to develop our product candidates and for our future operations. If we are unable to obtain the funds necessary to do so, we will be required to delay, scale back or eliminate our product development activities or may be unable to continue our business.***

We have had, and we will continue to have, an ongoing need to raise additional cash from outside sources to continue funding our operations, including our continuing substantial research and development expenses. We do not currently believe that our cash balance will be sufficient to fund the development and marketing efforts required to reach profitability without raising additional capital from accessible sources of financing in the near future. Our future capital requirements will depend on many factors, including:

- our ability to raise capital to fund our operations on terms acceptable to us, or at all;
- our perceived capital needs with respect to our development programs, and any delays in, adverse events of, and excessive costs of such programs beyond what we currently anticipate;
- our ability to establish and maintain collaborative and other arrangements with third parties to assist in bringing our products to market and the cost of such arrangements at the time;
- costs associated with the operations at our San Antonio, Texas facility;
- the cost of manufacturing our product candidates, including compliance with good manufacturing practices applicable to our product candidates;
- expenses related to the establishment of sales and marketing capabilities for product candidates awaiting approval or products that have been approved;

- the level of our sales and marketing expenses;
- competing technological and market developments; and
- our ability to introduce and sell new products.

We have secured capital historically from grant revenues, collaboration proceeds, and debt and equity offerings. We will need to secure substantial additional capital to fund our future operations. We cannot be certain that additional capital will be available on terms acceptable to us, 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), surrendering of our rights to some technologies or product opportunities, delaying of our clinical trials or regulatory and reimbursement efforts, or curtailing of or even ceasing operations.

Our financing plans include pursuing additional cash through use of offering programs, strategic corporate partnerships, licensing and sales of assets and equity. In July 2018, we completed a public offering in which we distributed to holders of our 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 each consisting of one share of Series C Preferred Stock and 1,050 warrants to purchase one share of our common stock at a subscription price of \$1,000 per unit, or the 2018 Rights Offering. Each share of Series C Preferred Stock is convertible into 25 shares of our common stock subject to adjustment. We sold an aggregate of 6,723 units as part of the 2018 Rights Offering.

In addition, in September 2018, we entered into a purchase agreement, or the Lincoln Park Purchase Agreement, with Lincoln Park Capital Fund, LLC, or Lincoln Park, pursuant to which we may direct Lincoln Park to purchase up to \$5.0 million in shares of our common stock from time to time over the 24-month period following October 15, 2018, subject to the satisfaction of certain conditions. There is no guarantee that adequate funds will be available when needed from additional debt or equity financing, development and commercialization partnerships or from other sources or on terms acceptable to us. Through December 31, 2018, the Company sold a total of 12,802 shares for proceeds of approximately \$0.3 million through the Lincoln Park Purchase Agreement and 32,170 shares for proceeds of approximately \$0.3 million were sold during the nine months ended September 30, 2019. The Company believes there is less than \$0.1 million remaining available under this financing facility.

In addition to the funding sources previously mentioned, we continue to seek additional capital through state and federal development programs.

### **Risks Relating to the Securities Markets and an Investment in Our Stock**

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

Following notice from Nasdaq staff in June 2015 and December 2015, we had a hearing in January 2016 relating to our noncompliance with the \$1.00 minimum bid price per share requirement. The Nasdaq Hearing Panel granted us until May 31, 2016 to come into compliance with the minimum bid price requirement, including requirements relating to obtaining stockholders approval of a reverse stock split that would bring our stock price above \$1.00 per share for a minimum of 10 consecutive trading days. We transferred the listing of our common stock from the Nasdaq Global Market to the Nasdaq Capital Market in February 2016. In May 2016, we consummated a 1-for-15 reverse stock split pursuant to which the minimum bid price per share of our common stock rose above \$1.00. Pursuant to a letter dated May 26, 2016, the Nasdaq staff delivered notice to us that we had regained compliance with Nasdaq's minimum bid price rule.

On September 5, 2017, we received a written notice from Nasdaq staff indicating that, based upon the closing bid price of our common stock for the prior 30 consecutive business days, we no longer met the requirement to maintain a minimum bid price of \$1.00 per share, as set forth in Nasdaq Listing Rule 5550(a)(2). In accordance with Nasdaq Listing Rule 5810(c)(3)(A), we were provided a period of 180 calendar days, or until March 5, 2018, in which to regain compliance. We were granted an additional compliance period of 180 calendar days, or until September 4, 2018, in which to regain compliance after meeting the continued listing requirement for market value of publicly held shares and all other initial listing standards for the Nasdaq Capital Market, with the exception of the bid price requirement, and providing notice to Nasdaq staff of our intent to cure the deficiency during this second compliance period, by effecting a reverse stock split, if necessary. In May 2018, we consummated a 1-for-10 reverse stock split pursuant to which the minimum bid price of our common stock rose above \$1.00. On June 8, 2018, we received written notice from Nasdaq that we had regained compliance with the Nasdaq Stock Market Listing Rule 5500(a)(2) concerning our minimum bid price per share of our common stock.

On August 28, 2018, we received a written notice from Nasdaq staff indicating that, based upon the closing bid price of our common stock for the prior 30 consecutive business days, we no longer meet the requirement to maintain a minimum bid price of \$1.00 per share, as set forth in Nasdaq Listing Rule 5550(a)(2). In accordance with Nasdaq Listing Rule 5810(c)(3)(A), we were provided an initial period of 180 calendar days, or until February 25, 2019, in which to regain compliance. We were also granted an additional compliance period of 180 calendar days, or until August 26, 2019, in which to regain compliance after meeting the continued listing requirement for market value of publicly held shares and all other initial listing standards for the Nasdaq Capital Market, with the exception of the bid price requirement, and providing notice to Nasdaq staff of our intent to cure the deficiency during this second compliance period, by effecting a reverse stock split, if necessary. In order to regain compliance with the minimum bid price requirement, the closing bid price of our common stock must have been at least \$1.00 per share for a minimum of 10 consecutive business days during the 180-day period. In August 2019, we consummated a 1-for-50 reverse stock split pursuant to which the minimum bid price of our common stock rose above \$1.00. On August 29, 2019, we received written notice from Nasdaq staff that we

had regained compliance with the Nasdaq Stock Market Listing Rule 5550(a)(2) concerning our minimum bid price per share of our common stock.

On August 16, 2019, we received a written notice from Nasdaq staff indicating that we no longer meet the minimum publicly held shares requirement for continued listing on the Nasdaq Capital Market under Nasdaq Listing Rule 5550(a)(4), which requires listed companies to maintain at least 500,000 publicly held shares. On September 11, 2019, we received written notice from Nasdaq staff that, based on having 786,807 publicly held shares outstanding as of August 31, 2019, we had regained compliance with Nasdaq Listing Rule 5550(a)(4).

However, 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 meet 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), which requires listed companies to maintain stockholders' equity of at least \$2.5 million. In addition, as of September 30, 2019, we do not meet the alternative compliance standards relating to the market value of listed securities or net income from continuing operations. We intend to evaluate various courses of action to regain compliance with Nasdaq Listing Rule 5550(b)(1) within the compliance period specified by Nasdaq. However, there can be no assurance that we will be able to regain compliance within such compliance period.

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 OTC Bulletin Board or the "pink sheets."
- Shares of our common stock could be less liquid and marketable, thereby reducing the ability of stockholders to purchase or sell our shares as quickly and as inexpensively as they have done historically. If our stock is traded as a "penny stock," transactions in our stock would be more difficult and cumbersome.
- 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 decline.

***Absence of a public trading market for our Series U Warrants or Series V Warrants may limit the ability to resell the Series U Warrants or Series V Warrants.***

There is no established trading market for our Series U Warrants or Series V Warrants (together the "September 2019 Warrants") issued pursuant to the September 2019 Offering, and the September 2019 Warrants may not be widely distributed. We do not plan to apply to list the September 2019 Warrants for trading on any public market. Even if a market for the September 2019 Warrants does develop, the price of the September 2019 Warrants may fluctuate and liquidity may be limited. If a market for the September 2019 Warrants does not develop, then holders of the September 2019 Warrants may be unable to resell the September 2019 Warrants or sell them only at an unfavorable price for an extended period of time, if at all. Future trading prices of the September 2019 Warrants will depend on many factors, including:

- our operating performance and financial condition;
- our ability to continue the effectiveness of the registration statement covering the September 2019 Warrants and the common stock issuable upon exercise of the September 2019 Warrants;
- the interest of securities dealers in making and maintaining a market; and
- the market for similar securities.

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

None

**Item 3. Defaults Upon Senior Securities**

None

**Item 4. Mine Safety Disclosures**

Not applicable

**Item 5. Other Information**

None

Item 6. Exhibits

EXHIBIT INDEX

PLUS THERAPEUTICS, INC.  
(previously known as Cytori Therapeutics, Inc.)

Exhibit Number	Exhibit Title	Filed with this Form 10-Q	Incorporated by Reference		
			Form	File No.	Date Filed
3.1	<a href="#">Composite Certificate of Incorporation.</a>		10-K	001-34375 Exhibit 3.1	03/11/2016
3.2	<a href="#">Certificate of Amendment to Amended and Restated Certificate of Incorporation, as amended.</a>		8-K	001-34375 Exhibit 3.1	05/10/2016
3.3	<a href="#">Certificate of Amendment to Amended and Restated Certificate of Incorporation, as amended.</a>		8-K	001-34375 Exhibit 3.1	05/23/2018
3.4	<a href="#">Certificate of Amendment to Amended and Restated Certificate of Incorporation, as amended.</a>		8-K	001-34375 Exhibit 3.1	07/29/2019
3.5	<a href="#">Certificate of Amendment to Amended and Restated Certificate of Incorporation, as amended.</a>		8-K	001-34375 Exhibit 3.1	08/06/2019
3.6	<a href="#">Amended and Restated Bylaws of Plus Therapeutics, Inc.</a>		8-K	001-34375 Exhibit 3.2	07/29/2019
3.7	<a href="#">Certificate of Designation of Preferences, Rights and Limitations of Series A 3.6% Convertible Preferred Stock</a>		8-K	001-34375 Exhibit 3.1	10/08/2014
3.8	<a href="#">Certificate of Designation of Preferences, Rights and Limitations of Series B Convertible Preferred Stock</a>		8-K	001-34375 Exhibit 3.1	11/28/2017
3.9	<a href="#">Certificate of Designation of Preferences, Rights and Limitations of Series C Convertible Preferred Stock</a>		8-K	001-34375 Exhibit 3.1	07/25/2018
4.1	<a href="#">Form of Series U Warrants</a>		S-1/A	333-229485 Exhibit 4.37	09/16/2019
4.2	<a href="#">Form of Series V Warrants</a>		S-1/A	333-229485 Exhibit 4.38	09/16/2019
31.1	<a href="#">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</a>	X			
31.2	<a href="#">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</a>	X			
32.1*	<a href="#">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</a>	X			
101.INS	XBRL Instance Document				
101.SCH	XBRL Schema Document				
101.CAL	XBRL Calculation Linkbase Document				
101.DEF	XBRL Definition Linkbase Document				
101.LAB	XBRL Label Linkbase Document				
101.PRE	XBRL Presentation Linkbase Document				

\* This certification is being furnished solely to accompany this report pursuant to 18 U.S.C. 1350 and is not being filed for purposes of Section 18 of the Securities and Exchange Act of 1934 and is not to be incorporated by reference into any filing of the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

**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: November 14, 2019

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

Dated: November 14, 2019

By: /s/ Desiree Smith  
Desiree Smith  
*Principal Financial and 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. I am 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 my supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to me 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 my 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 my 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. I have disclosed, based on my most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - (a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize, and report financial information; and
  - (b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 14, 2019

/s/ Marc H. Hedrick

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Marc H. Hedrick,  
President & Chief Executive Officer



**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**

I, Desiree Smith, 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. I am 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 my supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to me 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 my 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 my 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. I have disclosed, based on my most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - (a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize, and report financial information; and
  - (b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 14, 2019

/s/ Desiree Smith

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Desiree Smith,  
Principal Financial and Accounting 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, 2019 as filed with the Securities and Exchange Commission on the date hereof, Marc H. Hedrick, as President & Chief Executive Officer of Plus Therapeutics, Inc. hereby certifies that:

1. The Form 10-Q report of Plus Therapeutics, Inc. that this certification accompanies fully complies with the requirements of Section 13(a) or 15(d), as applicable, of the Securities Exchange Act of 1934, as amended.
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: November 14, 2019

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

In connection with the Quarterly Report on Form 10-Q of Plus Therapeutics, Inc. for the quarterly period ended September 30, 2019 as filed with the Securities and Exchange Commission on the date hereof, Desiree Smith, as Principal Financial and Accounting Officer of Plus Therapeutics, Inc. hereby certifies that:

1. The Form 10-Q report of Plus Therapeutics, Inc. that this certification accompanies fully complies with the requirements of Section 13(a) or 15(d), as applicable, of the Securities Exchange Act of 1934, as amended.
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: November 14, 2019

By: /s/ Desiree Smith  
Desiree Smith  
Principal Financial and Accounting Officer