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

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**FORM 10-Q**

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(Mark One)

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

For the quarterly period ended June 30, 2016

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

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**CYTORI THERAPEUTICS, INC.**

(Exact name of Registrant as Specified in Its Charter)

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**DELAWARE**  
(State or other jurisdiction  
of incorporation or organization)

**3020 CALLAN ROAD, SAN DIEGO, CALIFORNIA**  
(Address of principal executive offices)

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

**92121**  
(Zip Code)

**Registrant's telephone number, including area code: (858) 458-0900**

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

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

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

Large Accelerated Filer  Accelerated Filer   
Non-Accelerated Filer  (Do not check if a smaller reporting company) Smaller reporting company

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 July 31, 2016, there were 20,492,643 shares of the registrant's common stock outstanding.

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CYTORI THERAPEUTICS, INC.

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**PART I. FINANCIAL INFORMATION**

**Item 1. Financial Statements**

**CYTORI THERAPEUTICS, INC.  
CONSOLIDATED CONDENSED BALANCE SHEETS  
(UNAUDITED)**

	As of June 30, 2016	As of December 31, 2015
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 20,042,000	\$ 14,338,000
Accounts receivable, net of reserves of \$785,000 and \$797,000 in 2016 and 2015, respectively	911,000	1,052,000
Inventories, net	4,534,000	4,298,000
Other current assets	1,263,000	1,555,000
Total current assets	26,750,000	21,243,000
Property and equipment, net	1,380,000	1,631,000
Restricted cash and cash equivalents	350,000	350,000
Other assets	1,449,000	1,521,000
Intangibles, net	8,829,000	9,031,000
Goodwill	3,922,000	3,922,000
Total assets	\$ 42,680,000	\$ 37,698,000
<b>Liabilities and Stockholders' Equity</b>		
Current liabilities:		
Accounts payable and accrued expenses	\$ 6,585,000	\$ 6,687,000
Current portion of long-term obligations, net of discount	3,494,000	—
Joint venture purchase obligation	—	1,750,000
Total current liabilities	10,079,000	8,437,000
Deferred revenues	106,000	105,000
Long-term deferred rent and other	111,000	269,000
Long-term obligations, net of discount, less current portion	13,663,000	16,681,000
Total liabilities	23,959,000	25,492,000
Commitments and contingencies		
Stockholders' equity (deficit):		
Series A 3.6% convertible preferred stock, \$0.001 par value; 5,000,000 shares authorized; 13,500 shares issued; no shares outstanding in 2016 and 2015	—	—
Common stock, \$0.001 par value; 75,000,000 shares authorized; 20,492,601 and 13,003,893 shares issued and outstanding in 2016 and 2015, respectively	20,000	13,000
Additional paid-in capital	386,845,000	368,214,000
Accumulated other comprehensive income	617,000	996,000
Accumulated deficit	(368,761,000)	(357,017,000)
Total stockholders' equity	18,721,000	12,206,000
Total liabilities and stockholders' equity	\$ 42,680,000	\$ 37,698,000

SEE NOTES TO UNAUDITED CONSOLIDATED CONDENSED FINANCIAL STATEMENTS

**CYTORI THERAPEUTICS, INC.**  
**CONSOLIDATED CONDENSED STATEMENTS OF OPERATIONS AND COMPREHENSIVE (LOSS) INCOME**  
**(UNAUDITED)**

	For the Three Months Ended		For the Six Months Ended	
	June 30,		June 30,	
	2016	2015	2016	2015
Product revenues	\$ 1,126,000	\$ 1,614,000	\$ 2,459,000	\$ 2,516,000
Cost of product revenues	585,000	1,296,000	1,152,000	1,894,000
Gross profit	541,000	318,000	1,307,000	622,000
Development revenues:				
Government contracts and other	1,699,000	1,847,000	3,284,000	3,291,000
	1,699,000	1,847,000	3,284,000	3,291,000
Operating expenses:				
Research and development	5,247,000	6,048,000	9,374,000	10,012,000
Sales and marketing	889,000	654,000	1,924,000	1,493,000
General and administrative	2,328,000	2,793,000	4,614,000	5,292,000
Change in fair value of warrant liabilities	—	(13,122,000)	—	2,322,000
Total operating expenses	8,464,000	(3,627,000)	15,912,000	19,119,000
Operating (loss) income	(6,224,000)	5,792,000	(11,321,000)	(15,206,000)
Other income (expense):				
Income (loss) on asset disposal	—	(1,000)	2,000	8,000
Loss on debt extinguishment	—	(260,000)	—	(260,000)
Interest income	2,000	3,000	4,000	3,000
Interest expense	(645,000)	(936,000)	(1,302,000)	(2,007,000)
Other income (expense), net	462,000	(148,000)	874,000	(47,000)
Total other expense	(181,000)	(1,342,000)	(422,000)	(2,303,000)
Net (loss) income	\$ (6,405,000)	\$ 4,450,000	\$ (11,743,000)	\$ (17,509,000)
Beneficial conversion feature for convertible preferred stock	—	—	—	(661,000)
Net (loss) income allocable to common stockholders	\$ (6,405,000)	\$ 4,450,000	\$ (11,743,000)	\$ (18,170,000)
Net income (loss) per share allocable to common stockholders				
Basic	\$ (0.43)	\$ 0.48	\$ (0.84)	\$ (2.22)
Diluted	\$ (0.43)	\$ 0.45	\$ (0.84)	\$ (2.22)
Weighted average shares used in calculating net income (loss) per share allocable to common stockholders				
Basic	14,778,616	9,266,141	13,932,496	8,179,403
Diluted	14,778,616	9,824,538	13,932,496	8,179,403
Comprehensive (loss) income:				
Net (loss) income	\$ (6,405,000)	\$ 4,450,000	\$ (11,743,000)	\$ (17,509,000)
Other comprehensive (loss) income – foreign currency translation adjustments	(130,000)	215,000	(379,000)	251,000
Comprehensive (loss) income	\$ (6,535,000)	\$ 4,665,000	\$ (12,122,000)	\$ (17,258,000)

SEE NOTES TO UNAUDITED CONSOLIDATED CONDENSED FINANCIAL STATEMENTS

**CYTORI THERAPEUTICS, INC.**  
**CONSOLIDATED CONDENSED STATEMENTS OF CASH FLOWS**  
**(UNAUDITED)**

	For the Six Months Ended June 30,	
	2016	2015
<b>Cash flows from operating activities:</b>		
Net loss	\$ (11,743,000)	\$ (17,509,000)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	574,000	510,000
Amortization of deferred financing costs and debt discount	468,000	500,000
Joint Venture acquisition obligation accretion	24,000	307,000
Provision for expired inventory	26,000	—
Change in fair value of warrants	—	2,322,000
Stock-based compensation expense	645,000	1,146,000
Loss on asset disposal	2,000	—
Loss on debt extinguishment	—	260,000
Increases (decreases) in cash caused by changes in operating assets and liabilities:		
Accounts receivable	66,000	544,000
Inventories	(380,000)	730,000
Other current assets	137,000	(106,000)
Other assets	34,000	407,000
Accounts payable and accrued expenses	(431,000)	1,089,000
Deferred revenues	1,000	151,000
Long-term deferred rent	(158,000)	(139,000)
Net cash used in operating activities	(10,735,000)	(9,788,000)
<b>Cash flows from investing activities:</b>		
Purchases of property and equipment	(105,000)	(497,000)
Expenditures for intellectual property	—	(13,000)
Net cash used in investing activities	(105,000)	(510,000)
<b>Cash flows from financing activities:</b>		
Principal payments on long-term obligations	—	(25,032,000)
Proceeds from long-term obligations	—	17,700,000
Debt issuance costs and loan fees	—	(1,854,000)
Joint Venture purchase payments	(1,774,000)	(1,123,000)
Proceeds from exercise of employee stock options and warrants	—	4,986,000
Proceeds from sale of common stock, net	18,179,000	24,930,000
Dividends paid on preferred stock	—	(75,000)
Net cash provided by financing activities	16,405,000	19,532,000
Effect of exchange rate changes on cash and cash equivalents	139,000	(14,000)
Net increase in cash and cash equivalents	5,704,000	9,220,000
Cash and cash equivalents at beginning of period	14,338,000	14,622,000
Cash and cash equivalents at end of period	\$ 20,042,000	\$ 23,842,000
<b>Supplemental disclosure of cash flows information:</b>		
Cash paid during period for:		
Interest	\$ 805,000	\$ 1,202,000
<b>Supplemental schedule of non-cash investing and financing activities:</b>		
Conversion of preferred stock into common stock	—	10,000
Declared dividend related to preferred stock	—	3,000

SEE NOTES TO UNAUDITED CONSOLIDATED CONDENSED FINANCIAL STATEMENTS

**CYTORI THERAPEUTICS, INC.**  
**NOTES TO CONSOLIDATED CONDENSED FINANCIAL STATEMENTS**  
**June 30, 2015**  
**(UNAUDITED)**

**1. Basis of Presentation**

Our accompanying unaudited consolidated condensed financial statements as of June 30, 2016 and for the three and six months ended June 30, 2016 and 2015 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, 2015 has been derived from the audited financial statements at December 31, 2015, 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 Cytori Therapeutics, Inc., and our subsidiaries (the Company) have been included. Operating results for the three and six months ended June 30, 2016 are not necessarily indicative of the results that may be expected for the year ending December 31, 2016. 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, 2015, filed with the Securities and Exchange Commission on March 11, 2016.

On May 10, 2016, following stockholder and Board approval, an amendment (the “Amendment”) to the Company’s amended and restated certificate of incorporation, as amended was filed and declared effective, which Amendment effectuated a one-for-fifteen (1:15) reverse stock split of the Company’s (i) outstanding common stock, and (ii) common stock reserved for issuance upon exercise of outstanding warrants and options (the “1:15 Reverse Stock Split”). Upon effectiveness of the 1:15 Reverse Stock Split, the number of shares of the Company’s common stock (x) issued and outstanding decreased from approximately 200 million shares (as of May 10, 2016) to approximately 13.3 million shares; (y) reserved for issuance upon exercise of outstanding warrants and options decreased from approximately 16 million shares to approximately 1.1 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 6.5 million common shares to approximately 0.4 million common shares. In connection with the 1:15 Reverse Stock Split, the Company also decreased the total number of its authorized shares of common stock from 290 million to 75 million. The number of authorized shares of preferred stock remained unchanged. Following the 1:15 Reverse Stock Split, certain reclassifications have been made to the prior periods’ financial statements to conform to the current period’s presentation. The Company adjusted shareholders’ equity to reflect the 1:15 Reverse Stock Split by reclassifying an amount equal to the par value of the additional shares arising from the split from common stock to the Additional Paid-in Capital during the first quarter of fiscal 2016, resulting in no net impact to shareholders’ equity on our consolidated balance sheets. The Company’s shares of common stock commenced trading on a split-adjusted basis on May 12, 2016. 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.

The following table provides a brief description of recent accounting pronouncements that had and/or could have a material impact on the Company’s consolidated condensed financial statements. The Company is currently evaluating the impact of adopting the following standards on its consolidated financial statements.

**New Accounting Standards Issued But Not Yet Effective**

ASU Number and Name	Description	Date of Adoption
2016-09, Compensation — Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting	The standard simplifies the following aspects of accounting for share-based payments awards: accounting for income taxes, classification of excess tax benefits on the statement of cash flows, forfeitures, statutory tax withholding requirements, classification of awards as either equity or liabilities and classification of employee taxes paid on statement of cash flows when an employer withholds shares for tax-withholding purposes. Transition method: Various.	January 1, 2017. Early adoption is permitted.
2016-02, Leases (Topic 842)	The standard creates Topic 842, Leases which supersedes Topic 840, Leases, and introduces a lessee model that brings substantially all leases onto the balance sheet while retaining most of the principles of the existing lessor model in U.S. GAAP and aligning many of those principles with ASC 606, Revenue from Contracts with Customers. Transition method: modified retrospective approach with certain practical expedients.	January 1, 2019. Early adoption is permitted.

2015-11, Inventory (Topic 330): Simplifying the Measurement of Inventory	The standard replaces the current lower of cost or market test with a lower of cost or net realizable value test. Transition method: prospectively.	January 1, 2017. Early adoption is permitted.
2014-09, Revenue from Contracts with Customers (Topic 606)	The standard provides a single and comprehensive revenue recognition model for all contracts with customers to improve comparability. The revenue standard contains principles that an entity will apply to determine the measurement of revenue and timing of when it is recognized. The standard requires an entity to recognize revenue to depict the transfer of goods or services to customers at an amount that the entity expects to be entitled to in exchange for those goods or services. Transition method: a full retrospective or modified retrospective approach.	January 1, 2018 (as deferred by ASU No. 2015-14). Earlier application is permitted only as of January 1, 2017.
2016-08, Revenue from Contracts with Customers (Topic 606) — Principal versus Agent Considerations (Reporting Revenue Gross versus Net)	The standard clarifies how an entity should identify the unit of accounting for the principal versus agent evaluation and apply the control principle to certain types of arrangements. The amendments also re-frame the indicators to focus on evidence that an entity is acting as a principal rather than as an agent, revise existing examples and add new ones. Transition method: a full retrospective or modified retrospective approach.	January 1, 2018 (as deferred by ASU No. 2015-14). Earlier application is permitted only as of January 1, 2017.
2016-10, Revenue from Contracts with Customers (Topic 606): Identifying Performance Obligations and Licensing	This standard clarifies the following two aspects of Topic 606: identifying performance obligations and the licensing implementation guidance, while retaining the related principles for those areas. This standard reduces the cost and complexity of applying Topic 606 to the identification of promised goods or services, and it also includes implementation guidance on licensing. Transition method: a full retrospective or modified retrospective approach.	January 1, 2018 (as deferred by ASU No. 2015-14). Earlier application is permitted only as of January 1, 2017.
2016-12, Revenue from Contracts with Customers (Topic 606): Identifying Performance Obligations and Licensing	This standard addresses narrow-scope improvements to the guidance on collectability, noncash consideration, and completed contracts at transition as well as providing a practical expedient for contract modifications.	January 1, 2018 (as deferred by ASU No. 2015-14). Earlier application is permitted only as of January 1, 2017.
2014-15, Presentation of Financial Statements - Going Concern (Subtopic 205-40): Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern.	The amendments in this update will require management to assess, at each annual and interim reporting period, the entity's ability to continue as a going concern and, if management identifies conditions or events that raise substantial doubt about the entity's ability to continue as a going concern within one year after the date that the financial statements are issued, to disclose in the notes to the entity's financial statements the principal conditions or events that raised substantial doubt about the entity's ability to continue as a going concern, management's evaluation of their significance, and management's plans that alleviated or are intended to alleviate substantial doubt about the entity's ability to continue as a going concern.	January 1, 2017. Early adoption is permitted.

## 2. Use of Estimates

The preparation of Consolidated Condensed 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 goodwill and intangible assets for impairment, valuing warrants, determining the assumptions used in measuring share-based compensation expense, measuring accretion expense related to our acquisition of the joint venture, and valuing allowances for doubtful accounts and inventories.

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 Condensed Financial Statements in the periods they are determined to be necessary.

## 3. Liquidity

We incurred net losses of \$6.4 million and \$11.7 million for the three and six months ended June 30, 2016, respectively, and incurred net income of \$4.5 million and net losses of \$17.5 million for the three and six months ended June 30, 2015,

respectively. We have an accumulated deficit of \$ 369 million as of June 30, 2016 . Additionally, we have used net cash of \$ 10.7 million and \$ 9.8 million to fund our operating activities for the six months ended June 30, 2016 and 2015 , respectively .

To date, these operating losses have been funded primarily from outside sources of invested capital including our recently completed Rights Offering (discussed below), our At the Market equity facility, 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.

On June 15, 2016, the Company closed a Rights Offering originally filed under Form S-1 registration statement in April 2016. Pursuant to the Rights Offering, the Company sold an aggregate of 6,704,852 units consisting of a total of 6,704,852 shares of common stock and 3,352,306 warrants, with each warrant exercisable for one share of common stock at an exercise price of \$3.06 per share, resulting in total gross proceeds to Cytori of \$17.1 million. See Note 12 for further discussion on the June 2016 Rights Offering.

The Company continues to seek additional capital through product revenues, strategic transactions, including extension opportunities under the awarded U.S. Department of Health and Human Service's Biomedical Advanced Research and Development Authority ("BARDA") contract, and from other financing alternatives.

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

#### **4. Transactions with Olympus Corporation**

Under our Joint Venture Termination Agreement ("Termination Agreement"), dated May 8, 2013, with Olympus Corporation ("Olympus"), we were required to pay Olympus a total purchase price of \$6 million within two years of the date of the Termination Agreement. Pursuant to amendments to the Joint Venture Termination Agreement, dated April 30, 2015 and January 8, 2016, the Company's repayment obligations were extended through May 8, 2016. We made payments under the Termination Agreement totaling approximately \$4.2 million through December 31, 2015, as well as separate payments of \$0.5 million each in January 2016 and April 2016, and paid the remaining balance of \$0.8 million before the May 8, 2016 due date. There were no outstanding obligations to Olympus as of June 30, 2016.

#### **5. Long-term Debt**

On May 29, 2015, we entered into the Loan Agreement with Oxford Finance LLC, pursuant to which it funded an aggregate principal amount of \$17.7 million ("Term Loan"), subject to the terms and conditions set forth in the Loan 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 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 Agreement, the period for which the Company is 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 is 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, the Company is required to make a final payment fee in an aggregate amount equal to approximately \$1.1 million. In connection with the Term Loan, on May 29, 2015, we issued to the Lender warrants to purchase an aggregate of 94,441 shares of our common stock at an exercise price of \$10.35 per share. These warrants are exercisable on or after November 30, 2015 and will expire on May 29, 2025 and, following the authoritative accounting guidance, are equity classified.

In connection with the Loan Agreement, we prepaid all outstanding amounts under our prior loan agreement with Oxford and Silicon Valley Bank, at which time the Company's obligations under the prior loan agreement immediately terminated. The Company paid to the prior agent and the prior lenders (Oxford and Silicon Valley Bank) approximately \$25.4 million, consisting of the then outstanding principal balance due of approximately \$23.4 million, accrued but unpaid interest of approximately \$0.2 million, final payment and other agency fees of approximately \$1.8 million and other customary lender fees and expenses.

For Oxford, we accounted for this Term Loan as a debt modification. The Company retired \$3.1 million of the principal of the previous loan and the corresponding unamortized fees were expensed. The remaining fees of \$0.8 million were recorded as debt discount, and along with the new loan fees, will be amortized as an adjustment of interest expense using the effective interest method. For Silicon Valley Bank, which did not participate in the Term Loan, the payoff of the loan was accounted for as debt extinguishment. Accordingly, a total loss on debt extinguishment of \$0.3 million was recorded in the second quarter of 2015, which includes the unamortized fees and discounts along with final payment fees.

We allocated the aggregate proceeds of the Term Loan between the warrants and the debt obligations based on their relative fair values. The fair value of the warrants issued to the Lender was calculated utilizing the Black-Scholes option pricing model. The Black-Scholes option-pricing model incorporates various and highly sensitive assumptions including expected volatility,



expected term and risk-free interest rates. The expected volatility is based on the historical volatility of the Company's common stock over the most recent period. The risk-free interest rate for period within the contractual life of the warrant is based on the U.S. Treasury yield in effect at the time of grant. We will amortize the relative fair value of the warrants at the issuance date as a discount of \$ 0.8 million over the term of the loan using the effective interest method, with an effective interest rate of 14.95%. The Term Loan is collateralized by a security interest in substantially all of the Company's existing and after-acquired assets, subject to certain exceptions set forth in the Loan Agreement and excluding its intellectual property assets, which are subject to a negative pledge.

## 6. Revenue Recognition

### *Concentration of Significant Customers*

Two distributors and two direct customers comprised 76% of our revenue recognized for the six months ended June 30, 2016. Two distributors and one direct customer accounted for 75% of total outstanding accounts receivable (excluding receivables from U.S. Department and Human Service's Biomedical Advanced Research and Development Authority (BARDA)) as of June 30, 2016.

Two distributors and three direct customers comprised 68% of our revenue recognized for the six months ended June 30, 2015. Two direct customers accounted for 73% of total outstanding accounts receivable as of June 30, 2015.

Product revenues, classified by geographic location, are as follows:

	Three months ended				Six months ended			
	June 30, 2016		June 30, 2015		June 30, 2016		June 30, 2015	
	Product Revenues	% of Total	Product Revenues	% of Total	Product Revenues	% of Total	Product Revenues	% of Total
Americas	\$ 356,000	31%	\$ 272,000	17%	\$ 591,000	24%	\$ 477,000	19%
Japan	690,000	61%	352,000	22%	1,657,000	67%	957,000	38%
EMEA	74,000	7%	328,000	20%	205,000	8%	416,000	17%
Asia Pacific	6,000	1%	662,000	41%	6,000	1%	666,000	26%
Total product revenues	<u>\$ 1,126,000</u>	<u>100%</u>	<u>\$ 1,614,000</u>	<u>100%</u>	<u>\$ 2,459,000</u>	<u>100%</u>	<u>\$ 2,516,000</u>	<u>100%</u>

### *Research and Development*

We earn revenue for performing tasks under research and development agreements with governmental agencies like the Biomedical Advanced Research and Development Authority ("BARDA"). Revenues derived from reimbursement of direct out-of-pocket expenses for research costs associated with government contracts are recorded as government contract 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 \$1.7 million and \$3.3 million in BARDA revenue for the three and six months ended June 30, 2016, respectively, as compared to \$1.8 million and \$3.3 million for the three and six months ended June 30, 2015, respectively.

## 7. Inventories

Inventories are carried at the lower of cost or market, determined on the first-in, first-out (FIFO) method.

Inventories consisted of the following:

	June 30, 2016	December 31, 2015
Raw materials	\$ 972,000	\$ 1,009,000
Work in process	1,205,000	816,000
Finished goods	2,357,000	2,473,000
	<u>\$ 4,534,000</u>	<u>\$ 4,298,000</u>

## 8. Earnings per Share

Basic per share data is computed by dividing net income or loss applicable to common stockholders by the weighted average number of common shares outstanding during the period. Diluted per share data is computed by dividing net income or loss applicable to common stockholders by the weighted average number of common shares outstanding during the period increased to include, if dilutive, the number of additional common shares that would have been outstanding as calculated using the

treasury stock method. Potential common shares were related entirely to outstanding but unexercised options and warrants for all periods presented.

We have excluded all potentially dilutive securities, including unvested performance-based restricted stock, from the calculation of diluted loss per share attributable to common stockholders for the three and six month periods ended June 30, 2016 and six month period ended June 30, 2015, as their inclusion would be antidilutive. We have included 0.6 million dilutive securities for the purposes of calculating earnings per share for the three months ended June 30, 2015. Potentially dilutive common shares excluded from the calculations of diluted loss per share were 4.4 million for the six month periods ended June 30, 2016 and 3.7 million for the six month period ended June 30, 2015, respectively.

The following securities that could potentially decrease net loss per share in the future are not included in the determination of diluted loss per share as they are anti-dilutive:

	For the three months ended June 30,		For the six months ended June 30,	
	2016	2015	2016	2015
Outstanding stock options	803,507	528,429	803,507	570,214
Outstanding warrants	3,571,765	2,542,255	3,571,765	3,058,868
Restricted stock	17,960	41,677	17,960	41,677

## 9. Commitments and Contingencies

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 June 30, 2016, we have clinical research study obligations of \$4.8 million (\$3.8 million of which are expected to be complete within a year). Should the timing of the clinical trials change, the timing of the payment of these obligations would also change.

We lease facilities for our headquarters office location as well as international office locations. As of June 30, 2016, we have remaining lease obligations of \$ 3.1 million (\$ 2.3 million of which are expected to be completed within a year).

We are party to an agreement with Roche Diagnostics Corporation which requires us to make certain product purchase minimums. Pursuant to the agreement, as of June 30, 2016, we have a minimum purchase obligation of \$5.9 million, \$1.3 million of which is expected to be completed within a year.

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. Management believes that any liability to us that may arise as a result of currently pending legal proceedings will not have a material adverse effect on our financial condition, liquidity, or results of operations as a whole.

See Note 4 for a discussion of our commitments and contingencies related to our transactions with Olympus.

## 10. Fair Value Measurements

Fair value measurements are market-based measurements, not entity-specific measurements. Therefore, fair value measurements are determined based on the assumptions that market participants would use in pricing the asset or liability. 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.

As of June 30, 2016 and as of December 31, 2015, the Company did not have any assets or liabilities measured at fair value presented on the Company's balance sheets.

Warrants with exercise price reset features (down-round protection) were accounted for as liabilities, with changes in the fair value included in net loss for the respective periods. Because some of the inputs to our valuation model were either not observable or were not derived principally from or corroborated by observable market data by correlation or other means, the warrant liability was classified as Level 3 in the fair value hierarchy. All of these warrants were cashless exercised on or before December 31, 2015.

## 11. Fair Value

### 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 June 30, 2016 and December 31, 2015, 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, inventories, other current assets, accounts payable, accrued expenses and other liabilities approximate fair value due to the short-term nature of these instruments.

We utilize quoted market prices to estimate the fair value of our fixed rate debt, when available. If quoted market prices are not available, we calculate the fair value of our fixed rate debt based on a currently available market rate assuming the loans are outstanding through maturity and considering the collateral. In determining the current market rate for fixed rate debt, a market spread is added to the quoted yields on federal government treasury securities with similar terms to the debt.

At June 30, 2016 and December 31, 2015, the aggregate fair value and the carrying value of the Company's long-term debt were as follows:

	<u>June 30, 2016</u>		<u>December 31, 2015</u>	
	<u>Fair Value</u>	<u>Carrying Value</u>	<u>Fair Value</u>	<u>Carrying Value</u>
Long-term debt	\$ 17,187,000	\$ 17,157,000	\$ 16,844,000	\$ 16,681,000

Carrying value is net of debt discount of \$1.6 million and \$2.1 million as of June 30, 2016 and December 31, 2015, respectively.

The fair value of debt is classified as Level 3 in the fair value hierarchy as some of the inputs to our valuation model are either not observable quoted prices or are not derived principally from or corroborated by observable market data by correlation or other means.

## 12. Stockholders' Equity

### Preferred Stock

We have authorized 5 million shares of \$0.001 par value preferred stock. Our 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 13,500 shares of Series A 3.6% Convertible Preferred Stock that had been issued at June 30, 2016 and December 31, 2015, none of which were outstanding as of either date.

All outstanding shares of the Series A 3.6% Convertible Preferred Stock were converted into common stock during the fourth quarter of 2014 and the first quarter of 2015 at the option of the holders. The fair value of the common stock into which the Series A 3.6% Convertible 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 dividend to the preferred stockholders and, accordingly, an adjustment to net loss to arrive at net loss allocable to common stockholders. Certain shares of Series A 3.6% Convertible Preferred Stock were not convertible until stockholder approval, which occurred in January 2015. As a result, a dividend for the beneficial conversion feature of \$0.7 million was recorded during the quarter ended March 31, 2015.

In connection with the 3.6% Convertible Preferred Stock outstanding at December 31, 2014, we declared a cash dividend of \$0.08 million. The cash dividend was paid in January and April 2015.

### Common Stock

In May 2015, the Company entered into a Securities Purchase Agreement with certain institutional investors pursuant to which the Company agreed to sell up to \$25 million of units, with each unit consisting of one share of its common stock and one warrant to purchase one share of its common stock, in a registered direct offering. The purchase and sale of the units took place

in two separate closings. At the initial closing, which took place on May 8, 2015, the Company received approximately \$17.4 million in net proceeds from the sale of units. The second closing of the purchase and sale of the units occurred on August 27, 2015 upon satisfaction of certain conditions, including, without limitation, stockholder vote, and the Company received approximately \$2.1 million in net proceeds from the sale of 500,000 units of the 1,000,000 units available for sale at the second closing.

On December 17, 2015, the Company and the holders of October 2014 warrants agreed to amend the October 2014 Warrants pursuant to an Amendment to Common Stock Purchase Warrant (the "2014 Amendment"). Also on December 17, 2015, the Company and the holders of the May 2015 Warrants and the August 2015 Warrants (collectively the "2015 Warrants") agreed to amend the 2015 Warrants pursuant to an Amendment to Series A-1 Warrant to Purchase Common Stock and Amendment to Series A-2 Warrant to Purchase Common Stock, respectively (the "2015 Amendment" and, together with the 2014 Amendment, the "Warrant Amendments"). The Warrant Amendments provide that the holders may exercise their warrants on a "cashless exercise" basis in whole on or prior to December 31, 2015, whereby each exercising holder of the amended 2015 Warrants would receive 0.75 shares for each warrants share exercised and each exercising holder of the amended 2014 Warrants would receive 0.69 shares for each warrant share exercised. In addition, the Warrant Amendments removed certain provisions which provided that the exercise price of the Warrants would be reset in the event of certain equity issuances by the Company for a price below the exercise price of the Warrants as of the time of such issuance. All 2014 Warrants and all 2015 Warrants were cashless exercised on or before December 31, 2015.

From January 1, 2016 and through June 30, 2016, we sold 766,382 shares of our common stock under an at-the-market offering program ("ATM"), receiving total net proceeds of approximately \$2.7 million.

Pursuant to a registration statement on Form S-1, originally filed on April 6, 2016, as amended (the "Registration Statement"), and declared effective by the U.S. Securities and Exchange Commission ("SEC") on May 26, 2016, and related prospectus (as supplemented), the Company registered, offered and sold to its participating stockholders of record as of the announced May 20, 2016 record date, one non-transferable subscription right for each share of common stock held by each stockholder as of the record date (the "Rights Offering"). Each right entitled the holder thereof to purchase one unit at the subscription price of \$2.55 per unit, composed of one share of common stock and 0.5 of a warrant, with each whole warrant exercisable to purchase one share of common stock at an exercise price of \$3.06 per share for 30 months from the date of issuance. Pursuant to the Rights Offering, which closed on June 15, 2016, the Company sold an aggregate of 6,704,852 units, resulting in total net proceeds to the Company of \$15.3 million, respectively. The warrants issued pursuant to the Rights Offering are currently listed on NASDAQ under the symbol "CTYXW." 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 \$7.65 per share for 10 consecutive trading days.

## 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 (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, 2015.

### **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 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 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 and actual results will likely differ, perhaps materially, from those suggested by such forward-looking statements.*

*This Quarterly report on Form 10-Q refers to trademarks such as Cytori Cell Therapy, Celution and StemSource. Solely for convenience, our trademarks and tradenames referred to in this Form 10-Q may appear without the ® or ™ symbols, but such references are not intended to indicate in any way that we will not assert, to the fullest extent under applicable law, our rights to these trademarks and tradenames.*

### **General**

We develop cellular therapeutics uniquely formulated and optimized for specific diseases and medical conditions and related products. Our lead therapeutics are currently targeted for impaired hand function in scleroderma, osteoarthritis of the knee, stress urinary incontinence, and deep thermal burns including those complicated by radiation exposure.

Our cellular therapeutics are collectively known by the trademarked name, Cytori Cell Therapy, and consist of a mixed population of specialized cells including stem cells that are involved in response to injury, repair and healing. These cellular therapeutics are extracted from an adult patient's own adipose (fat) tissue using our fully automated Celution System, which includes a device, proprietary enzymes, and sterile consumable sets utilized at the point-of-therapeutic application or potentially at an off-site processing center. Cytori Cell Therapy can either be administered to the patient the same day or cryopreserved for future use. An independent published study has reported that our proprietary technology process resulted in higher nucleated cell viability, less residual enzyme activity, less processing time, and improved economics in terms of cell progenitor output compared to the three other semi-automated and automated processes that were reviewed.

Our primary near-term goal is for Cytori Cell Therapy to be the first cell therapy to market for the treatment of impaired hand function in scleroderma, through Cytori-sponsored and supported clinical development efforts. The STAR trial is a 48-week, randomized, double blind, placebo-controlled phase III pivotal clinical trial of 80 patients in the U.S. The trial evaluates the safety and efficacy of a single administration of Cytori Cell Therapy, or ECCS-50, in scleroderma patients affecting the hands and fingers. The first sites for the scleroderma study were initiated in July 2015 and completed enrollment of 88 patients in June 2016. We anticipate that we will receive 48-week follow-up data on this phase III pivotal clinical trial in mid-2017.

With respect to the remainder of our clinical pipeline, we received Investigational Device Exemption, or IDE, approval from the U.S. Food and Drug Administration, or the FDA, in late 2014 for our phase II ACT-OA osteoarthritis study and in early 2015 we initiated this study, and enrollment was completed in June 2015. The 48-week analysis was performed as planned and the top-line data are described in the "Osteoarthritis" section below. In July 2015, a Company-supported male stress urinary incontinence, or SUI, trial in Japan for male prostatectomy patients (after prostate surgery) received approval to begin enrollment from the Japanese Ministry of Health, Labor and Welfare, or MHLW. The goal of this investigator-initiated trial is to gain regulatory approval in Japan of Cytori Cell Therapy for this indication. We are also developing a treatment for thermal burns combined with radiation injury under a contract from the Biomedical Advanced Research Development Authority, or BARDA, a division of the U.S. Department of Health and Human Services. We are also exploring other development opportunities in a variety of other conditions.

In addition to our targeted therapeutic development, we have continued to commercialize our Cytori Cell Therapy technology under select medical device approvals, clearances and registrations to research and commercial customers in Europe, Japan and other regions. Many of these customers are research customers evaluating new therapeutic applications of Cytori Cell Therapy. The sale of systems, consumables and ancillary products contributes a margin that partially offsets our operating expenses and will continue to play a role in fostering familiarity within the medical community with our technology. These sales have also facilitated the discovery of new applications for Cytori Cell Therapy by customers conducting investigator-initiated and funded research.

#### ***Lead Indication: Scleroderma***

Scleroderma is a rare and chronic autoimmune disorder associated with fibrosis of the skin, and destructive changes in blood vessels and multiple organ systems as the result of a generalized overproduction of collagen. Scleroderma affects approximately 50,000 patients in the U.S. (women are affected four times more frequently than men) and is typically detected between the ages of 30 and 50. More than 90 percent of scleroderma patients have hand involvement that is typically progressive and can result in chronic pain, blood flow changes and severe dysfunction. The limited availability of treatments for scleroderma may provide some benefit but do little to modify disease progression or substantially improve symptoms. Treatment options are directed at protecting the hands from injury and detrimental environmental conditions as well as the use of vasodilators. When the disease is advanced, immunosuppressive and other medications may be used but are often accompanied by significant side effects.

In January 2015, the FDA granted unrestricted IDE approval for a pivotal clinical trial, named the "STAR" trial, to evaluate Cytori Cell Therapy as a potential treatment for impaired hand function in scleroderma. The STAR trial is a 48-week, randomized, double blind, placebo-controlled pivotal clinical trial of 80 patients in the U.S. The trial evaluates the safety and efficacy of a single administration of ECCS-50 in patients with scleroderma affecting the hands and fingers. The STAR trial uses the Cochin Hand Function Scale, or CHFS, a validated measure of hand function, as the primary endpoint measured at six months after a single administration of ECCS-50 or placebo. Patients in the placebo group will be eligible for crossover to the active arm of the trial after all patients have completed 48 weeks of follow up. In February 2015, the FDA approved our request to increase the number of investigational sites from 12 to up to 20. The increased number of sites served to broaden the geographic coverage of the trial and facilitate trial enrollment. The enrollment of this trial began in August 2015 and was completed at 88 patients in June 2016. We anticipate that we will receive 48-week follow-up data on this phase III pivotal clinical trial in mid-2017.

The STAR trial is predicated on a completed investigator-initiated pilot phase I/II trial performed in France termed SCLERADEC I. The SCLERADEC I trial received partial support from Cytori. The results were published in the *Annals of the Rheumatic Diseases* in May 2014 and demonstrated approximately a 50 percent improvement at six months across four important and validated endpoints used to assess the clinical status in patients with scleroderma with impaired hand function. Patients perceived their health status to be improved as shown by a 45.2% and 42.4% decrease of the Scleroderma Health Assessment Questionnaire, or

SHAQ, at month 2 (p=0.001) and at month 6 (p=0.001), respectively. A 47% and 56% decrease of the CHFS at month 2 and month 6 in comparison to baseline was observed (p<0.001 for both). Grip strength increased at month 6 with a mean improvement of +4.8±6.4 kg for the dominant hand (p=0.033) and +4.0±3.5 kg for the non-dominant hand (p=0.002). Similarly, an increase in pinch strength at month 6 was noted with a mean improvement of +1.0±1.1 kg for the dominant hand (p=0.009) and +0.8±1.2 kg for the non-dominant hand (p=0.050). Among subjects having at least one digital ulcer, or DU, at inclusion, total number of DU decreased, from 15 DUs at baseline, 10 at month 2 and 7 at month 6. The average reduction of the Raynaud's Condition Score from baseline was 53.7% at month 2 (p<0.001) and 67.5% at month 6 (p<0.001). Hand pain showed a significant decrease of 63.6% at month 2 (p=0.001) and 70% at month 6 (p<0.001). One year results were published in September 2015 in the journal *Rheumatology*. Relative to baseline, the CHFS and the SHAQ improved by 51.3% and 46.8% respectively (p<0.001 for both). The Raynaud's score improved by 63.2% from baseline (p<0.001). Other findings at one-year included a 30.5% improvement in grip strength (p=0.002) and a 34.5% improvement in hand pain (p=0.052). In February 2016, two-year follow up data in the SCLERADEC I trial was presented at the Systemic Sclerosis World Congress, which demonstrated sustained improvement in the following four key endpoints: Cochin Hand Function Score (CHFS), Scleroderma Health Assessment Questionnaire, Raynaud's Condition Score (which assesses severity of Raynaud's Phenomenon), and hand pain, as assessed by a standard visual analogue scale. The major findings at 24 months following a single administration of ECCS-50 were as follows:

- Hand dysfunction assessed by the CHFS, showed a 62% reduction in hand dysfunction at two years (p<0.001).
- Raynaud's Condition Score decreased by an average of 89% over baseline at two years (p<0.001).
- Hand pain, as measured by a 100 mm Visual Analogue Scale, and the Scleroderma Health Assessment Questionnaire (SHAQ) score at two years both showed improvement of 50% over baseline (p=0.01 and p<0.001 respectively).
- Improvement of 20% in grip strength and 330% in pinch strength at two years (p=0.05 and p=0.004 respectively).
- Continued reduction in the number of ulcers from 15 at baseline to 9 at one year and 6 at two years.

In 2014, Drs. Guy Magalon and Brigitte Granel, under the sponsorship of the Assistance Publique - Hôpitaux de Marseille, submitted a study for review for a follow-up phase III randomized, double-blind, placebo-controlled trial in France using Cytori Cell Therapy, to be supported by Cytori. The trial name is SCLERADEC II and was approved by the French government in April 2015. Enrollment of this trial commenced in October 2015. Patients will be followed for 6 months post-procedure.

In January 2016, we entered into an agreement with Idis Managed Access, part of Clinigen Group plc, or Idis, to establish a managed access program, or MAP, in select countries across Europe, the Middle East and Africa, or EMEA, for patients with impaired hand function due to scleroderma. We established this MAP, also known as an "early access" or "named patient" program, to make our ECCS-50 therapy available to patients in advance of obtaining regulatory clearance. We believe this MAP is justified and needed based on a number of factors, including scleroderma's status as a rare disease, the favorable risk-benefit profile reported by the 12-patient, open-label SCLERADEC I clinical study results, our two scleroderma phase III trials currently enrolling, and clear unmet scleroderma patient needs. We hope to offer our ECCS-50 therapy to patients who are unable to participate in our scleroderma clinical trials, generally due to a lack of geographic proximity to a site. Beyond the benefit of helping patients in need of new therapies for scleroderma, the MAP will increase awareness of and facilitate a positive experience with Cytori Cell Therapy among healthcare providers in advance of commercialization, will allow for tracking and collection of key program data and documentation which will provide valuable insight regarding the demand for and use of Cytori Cell Therapy, and will provide us with pricing insight for our ECCS-50 therapy.

In April 2016, the European Commission, acting on the positive recommendation from the European Medicines Agency Committee for Orphan Medicinal Products, issued orphan drug designation to a broad range of Cytori Cell Therapy formulations when used for the treatment of hand dysfunction and Raynaud's Phenomenon in patients with scleroderma under Community Register of Orphan Medicinal Products number EU/3/16/1643.

### ***Osteoarthritis***

Osteoarthritis is a disease of the entire joint involving the cartilage, joint lining, ligaments and underlying bone. The breakdown of tissue leads to pain, joint stiffness and reduced function. It is the most common form of arthritis and affects an estimated 13.9% of US adults over the age of 25, and 33.6% of U.S. adults over the age of 65. Current treatments include physical therapy, non-steroidal anti-inflammatory medications, viscosupplement injections, and total knee replacement. A substantial medical need exists as present medications have limited efficacy and joint replacement is a relatively definitive treatment for those with the most advanced disease.

In the later part of 2014, we received approval by the FDA to begin an exploratory U.S. IDE pilot (phase IIa/b) trial of Cytori Cell Therapy in patients with osteoarthritis of the knee. The trial, called ACT-OA, is a 94-patient, randomized, double-blind, placebo controlled study involving two doses of Cytori Cell Therapy, a low dose and a high dose, and was conducted over 48 weeks. The randomization is 1:1:1 between the control, low and high dose groups. Enrollment on this trial began in February 2015 and was

completed in June 2015. The goal of this proof-of-concept trial is to help determine: (1) safety and feasibility of the ECCO-50 therapeutic for osteoarthritis, (2) provide dosing guidance and (3) explore key trial endpoints useful for a phase III trial.

Top-line analysis of the final 48-week data has recently been completed. The primary objective of this prospective, randomized, placebo controlled study was to evaluate the safety and feasibility of intraarticular injection of Celution prepared adipose-derived regenerative cells injected into knees of patients with chronic knee pain due to osteoarthritis. A total of 94 patients were randomized (33 placebo, 30 low dose ECCS-50, 31 high dose ECCS-50). In general, a clear difference between low and high dose ECCS-50 was not observed and therefore the data for both groups have been combined. Numerous endpoints were evaluated that can be summarized as follows:

- Intraarticular application of a single dose of ECCO-50 is feasible in an outpatient day-surgery setting; no serious adverse events were reported related to the fat harvest, cell injection or to the cell therapy.
- Consistent trends observed in most secondary endpoints at 12, 24 and 48 weeks in the target knee of the treated group relative to placebo control group; 12 week primary endpoint of single pain on walking question did not achieve statistical significance.
- Consistent trends observed in all 6 pre-specified MRI Osteoarthritis Knee Score (MOAKS) classification scores suggesting decrease in target knee joint pathologic features at 48 weeks for the treated group relative to placebo control group.

In summary, the ACT-OA phase II trial demonstrated feasibility of same day fat harvesting, cell processing and intraarticular administration of autologous ADRCs (ECCS-50) with a potential for a cell benefit effect. Additional analyses are ongoing. The accumulated data and experience gained will be critical in considering designs of further clinical trials in osteoarthritis and other potential indications. As well, the multicenter nature of the trial in the United States provides relevant information as to optimizing commercialization.

### ***Stress Urinary Incontinence***

Another therapeutic target under evaluation by Cytori in combination with the University of Nagoya and the Japanese MHLW is stress urinary incontinence in men following surgical removal of the prostate gland, which is based on positive data reported in a peer reviewed journal resulting from the use of adipose-derived regenerative cells processed by our Celution System. The ADRESU trial is a 45 patient, open-label, multi-center, and single arm trial that was approved by Japan's MHLW in July 2015 and is being led by both Momokazu Gotoh, MD, Ph.D., Professor and Chairman of the Department of Urology and Tokunori Yamamoto, MD, Ph.D., Associate Professor Department of Urology at University of Nagoya Graduate School of Medicine. The goal of this investigator-initiated trial will be to apply for product approval for Cytori Cell Therapy technology for this indication. This clinical trial is primarily sponsored and funded by the Japanese government. Enrollment of this trial began in September 2015.

### ***Cutaneous and Soft Tissue Thermal and Radiation Injuries***

Cytori Cell Therapy is also being developed for the treatment of thermal burns combined with radiation injury. In the third quarter of 2012, we were awarded a contract valued at up to \$106 million with BARDA to develop a medical countermeasure for thermal burns. The initial base period included \$4.7 million over two years and covered preclinical research and continued development of Cytori's Celution System to improve cell processing.

In 2014, an In-Process Review Meeting was held at which Cytori confirmed completion of the objectives of the initial phase of the contract. In August 2014, BARDA exercised contract option 1 in the amount of approximately \$12 million. In December 2014, this was supplemented with an additional \$2 million. This funded continuation of research, regulatory, clinical and other activities required for submission of an Investigational Device Exemption, or IDE, request to the FDA for a pilot clinical trial using Cytori Cell Therapy (DCCT-10) for the treatment of thermal burns. Upon receipt of IDE approval to execute this pilot clinical trial, we anticipate that BARDA will provide funding to cover costs associated with execution of the clinical trial and related activities, currently estimated at approximately \$8.3 million.

Our contract with BARDA contains two additional options to fund a pivotal clinical trial and additional preclinical work in thermal burn complicated by radiation exposure. These options are valued at up to \$45 million and \$23 million, respectively.

The total award under the BARDA contract is intended to support all clinical, preclinical, regulatory and technology development activities needed to complete the FDA approval process for use of Cytori Cell Therapy, or DCCT-10, in thermal burn injury under a device-based PMA regulatory pathway and to provide preclinical data in burn complicated by radiation exposure.



## Other Clinical Indications

Heart failure due to ischemic heart disease does not represent a current clinical target for us. Our ATHENA and ATHENA II trials related to that indication were truncated and we have minimized expenses related to initiatives in this area. While we may use the data from these trial programs for regulatory support for our other indications and also for publication in peer reviewed forums, we are not actively pursuing indications related to these trials. The 12 month results of the ATHENA Trials were presented by the investigators at the Society of Cardiac Angiography and Interventions Annual Scientific Meeting on May 5, 2016 and data has been published on the Catheterization and Cardiovascular Interventions journal in June 2016.

## Results of Operations

### Product revenues

Product revenues consisted of revenues primarily from the sale of Cytori Cell Therapy-related products.

The following table summarizes the components for the three and six months ended June 30, 2016 and 2015:

	For the three months ended June 30,		For the six months ended June 30,	
	2016	2015	2016	2015
Product revenues - third party	\$ 1,126,000	\$ 1,614,000	\$ 2,459,000	\$ 2,516,000

We experienced a decrease of \$0.5 million in product revenue during the three months ended June 30, 2016 as compared to the same period in 2015, due to decreased revenue in Asia Pacific of \$0.6 million, primarily due to the opening order from Lorem Vascular in the second quarter of 2015 and lack of ongoing orders, decreased revenue in EMEA of \$0.3 million, primarily due to non-recurring revenue generated from the sale of raw materials used to manufacture the divested Puregraft product in the second quarter of 2015, offset by increased revenues in Japan of \$0.3 million due to continued adoption of Cytori Cell Therapy primarily in the aesthetic business. We experienced a decrease of \$0.1 million in product revenue during the six months ended June 30, 2016 as compared to the same period in 2015, due to decreased revenues in Asia Pacific of \$0.6 million and EMEA of \$0.2 million, offset by increased revenues in Japan of \$0.7 million for the same matters outlined above.

*The future* : We expect to continue to generate a majority of product revenues from the sale of Cytori Cell Therapy-related products to researchers, clinicians, and distributors in EMEA, Japan, Asia Pacific, and the Americas. In Japan and EMEA, researchers will use our technology in ongoing and new investigator-initiated and funded studies focused on, but not limited to, hand scleroderma, Crohn's disease, peripheral artery disease, erectile dysfunction, and diabetic foot ulcers. ECCS-50 therapy for hand scleroderma will be accessible to patients and physicians through a managed access program, or MAP, that we initiated in EMEA in 2016. In the America's, Cytori's partner, Kerastem, is utilizing the Cytori Cell Therapy technology as part of its FDA-approved STYLE trial for patients with alopecia, or hair loss. Overall, we expect 2016 product revenues for the full year to grow modestly as compared to 2015.

### Cost of product revenues

Cost of product revenues relate primarily to Cytori Cell Therapy-related products and includes material, manufacturing labor, and overhead costs. The following table summarizes the components of our cost of revenues for the three and six months ended June 30, 2016 and 2015:

	For the three months ended June 30,		For the six months ended June 30,	
	2016	2015	2016	2015
Cost of product revenues	\$ 576,000	\$ 1,276,000	\$ 1,127,000	\$ 1,855,000
Share-based compensation	9,000	20,000	25,000	39,000
Total cost of product revenues	\$ 585,000	\$ 1,296,000	\$ 1,152,000	\$ 1,894,000
Total cost of product revenues as % of product revenues	52.0%	80.3%	46.8%	75.3%

Cost of product revenues as a percentage of product revenues was 52.0% and 46.8% for the three and six months ended June 30, 2016 and 80.3% and 75.3% for the three and six months ended June 30, 2015, respectively. Fluctuation in this percentage is due to the product mix, distributor and direct sales mix, geographic mix and allocation of overhead.

*The future*: We expect to continue to see variation in our gross profit margin as the product mix, distributor and direct sales mix and geographic mix comprising revenues fluctuate. In addition, in 2016, as part of our EMEA managed access program we anticipate

the ability to command a premium price for ECCS-50 for the treatment of hand impairment due to scleroderma, a rare (or orphan) disease, which may increase our gross profit margin.

#### Development revenues

Under our government contract with BARDA, we recognized a total of \$1.7 million and \$3.3 million in revenues for the three and six months ended June 30, 2016, respectively which included allowable fees as well as cost reimbursements. During the three and six months ended June 30, 2016, we incurred \$1.6 million and \$3.1 million in qualified expenditures, respectively. We recognized a total of \$1.9 million and \$3.3 million in revenues for the three and six months ended June 30, 2015, respectively which included allowable fees as well as cost reimbursements. During the three and six months ended June 30, 2015, we incurred \$1.7 million and \$3.1 million in qualified expenditures, respectively. The decrease in revenues for the three and six months ended June 30, 2016 as compared to the same periods in 2015 is primarily due to slight decreases in research and development activities related to BARDA.

*The future* : In August 2014, BARDA exercised Option 1 of our contract for us to perform research, regulatory, clinical and other tasks required for initiation of a pilot clinical trial of the Cytori Cell Therapy in thermal burn injury (DCCT-10). The contract was amended in December 2014 to reflect amendments to the Statement of Work, and reorganization of the contract options for a total fixed fee of up to \$14 million. We expect the work associated with Option 1, as amended, to be completed by the end of 2016 and overall contract revenues to remain materially consistent with 2015.

#### Research and development expenses

Research and development expenses relate to the development of a technology platform that involves using adipose tissue as a source of autologous regenerative cells for therapeutic applications as well as the continued development efforts related to our clinical trials.

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

The following table summarizes the components of our research and development expenses for the three and six months ended June 30, 2016 and 2015:

	For the three months ended June 30,		For the six months ended June 30,	
	2016	2015	2016	2015
General research and development	\$ 5,121,000	\$ 5,906,000	\$ 9,113,000	\$ 9,743,000
Share-based compensation	126,000	142,000	261,000	269,000
Total research and development expenses	<u>\$ 5,247,000</u>	<u>\$ 6,048,000</u>	<u>\$ 9,374,000</u>	<u>\$ 10,012,000</u>

The decrease in research and development expenses for the three and six months ended June 30, 2016 as compared to the same periods in 2015 is due to a decrease of approximately \$0.7 million in study related expenses as our ACT-OA phase II clinical trial fully enrolled during the second quarter 2015, offset by expenses related to our STAR phase III clinical trial that fully enrolled during the second quarter of 2016.

*The future* : We expect aggregate research and development expenditures to decrease in the second half of 2016 as we completed the U.S. ACT-OA clinical trial in 2016, and completed enrollment in the U.S. STAR clinical trial in June 2016.

#### 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 six months ended June 30, 2016 and 2015:

	For the three months ended June 30,		For the six months ended June 30,	
	2016	2015	2016	2015
Sales and marketing	\$ 846,000	\$ 627,000	\$ 1,832,000	\$ 1,437,000
Share-based compensation	43,000	27,000	92,000	56,000
Total sales and marketing expenses	<u>\$ 889,000</u>	<u>\$ 654,000</u>	<u>\$ 1,924,000</u>	<u>\$ 1,493,000</u>

The increase in sales and marketing expense during the three and six months ended June 30, 2016 as compared to the same periods in 2015 is mainly attributed to the increase in salary and related benefits expense (excluding share-based compensation) of \$0.2 million for both periods, as well as increase in professional services expense of \$0.2 million for both periods mostly due to investments in the EMEA managed access program and commercial planning activities for scleroderma in the U.S. These increases are offset by immaterial decreases in other activities during the three months ended June 30, 2016, compared to the same period in 2015.

*The future:* We expect sales and marketing expenditures to stabilize or slightly increase during the second half of 2016, associated with investments in our EMEA managed access program and commercial planning activities for hand scleroderma, knee osteoarthritis and stress urinary incontinence.

#### 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 six months ended June 30, 2016 and 2015:

	For the three months ended June 30,		For the six months ended June 30,	
	2016	2015	2016	2015
General and administrative	\$ 2,178,000	\$ 2,294,000	\$ 4,347,000	\$ 4,510,000
Share-based compensation	150,000	499,000	267,000	782,000
Total general and administrative expenses	<u>\$ 2,328,000</u>	<u>\$ 2,793,000</u>	<u>\$ 4,614,000</u>	<u>\$ 5,292,000</u>

The decrease in general and administrative expenses during the three and six months ended June 30, 2016 as compared to the same periods in 2015 is mainly attributed to a decrease in charges incurred for professional services of \$0.1 million and \$0.2 million, respectively, consistent with our ongoing cost curtailment efforts.

*The future:* We expect general and administrative expenditures to remain at current levels or slightly increase throughout 2016.

#### Share-based compensation expenses

Stock-based compensation expenses include charges related to options and restricted stock awards issued to employees, directors and non-employees along with charges related to the employee stock purchases under the Employee Stock Purchase Plan, or ESPP. We measure stock-based compensation expense based on the grant-date fair value of any awards granted to our employees. Such expense is recognized over the requisite service period.

The following table summarizes the components of our share-based compensation expenses for the three and six months ended June 30, 2016 and 2015:

	For the three months ended June 30,		For the six months ended June 30,	
	2016	2015	2016	2015
Cost of product revenues	\$ 9,000	\$ 20,000	\$ 25,000	\$ 39,000
Research and development-related	126,000	142,000	261,000	269,000
Sales and marketing-related	43,000	27,000	92,000	56,000
General and administrative-related	150,000	499,000	267,000	782,000
Total share-based compensation	<u>\$ 328,000</u>	<u>\$ 688,000</u>	<u>\$ 645,000</u>	<u>\$ 1,146,000</u>

The decrease in share-based compensation expenses for the three and six months ended June 30, 2016 as compared to the same periods in 2015 is primarily related to a lower annual grant caused by reductions in headcount and due to the decline in the stock price during 2016 as compared to the same periods in 2015, and its corresponding impact into the 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 June 30, 2016, the total compensation cost related to non-vested stock options and stock awards not yet recognized for all our plans is approximately \$1.7 million which is expected to be recognized as a result of vesting under service conditions over a weighted average period of 1.65 years.

### Change in fair value of warrant liability

The following is a table summarizing the change in fair value of our warrant liability for the three and six months ended June 30, 2016 and 2015:

	For the three months ended June 30,		For the six months ended June 30,	
	2016	2015	2016	2015
Change in fair value of warrant liability	\$ —	\$ (13,122,000)	\$ —	\$ 2,322,000

The change in fair value of our warrant liability for the three and six months ended June 30, 2016 as compared to the same period in 2015 is due to the fact that all warrants with price reset features accounted for as liabilities were cashless exercised on or before December 31, 2015.

*The future:* We do not expect any further changes in fair value of warrant liability, as all of our outstanding warrants with exercise price reset features were settled during December 2015.

### Financing items

The following table summarizes interest income, interest expense, and other income and expense for the three and six months ended June 30, 2016 and 2015:

	For the three months ended June 30,		For the six months ended June 30,	
	2016	2015	2016	2015
Income (loss) on asset disposal	\$ —	\$ (1,000)	\$ 2,000	\$ 8,000
Loss on debt extinguishment	—	(260,000)	—	(260,000)
Interest income	2,000	3,000	4,000	3,000
Interest expense	(645,000)	(936,000)	(1,302,000)	(2,007,000)
Other income (expense), net	462,000	(148,000)	874,000	(47,000)
Total	\$ (181,000)	\$ (1,342,000)	\$ (422,000)	\$ (2,303,000)

- In connection with the May 2015 Loan Agreement, a loss on debt extinguishment was recorded that relate to the payoff of the prior loan obligations.
- Interest expense decreased for the three and six months ended June 30, 2016 as compared to the same periods in 2015, due to pay down and refinancing of principal loan balance in May 2015.
- The changes in other income (expense) during the three and six months ended June 30, 2016 as compared to the same periods in 2015 resulted primarily from changes in exchange rates related to transactions in foreign currency.

*The future:* We expect interest expense in 2016 to decrease as we refinanced and decreased the principal of our outstanding Term Loan with Oxford Finance, LLC in 2015.

## **Liquidity and Capital Resources**

### Short-term and long-term liquidity

The following is a summary of our key liquidity measures at June 30, 2016 and December 31, 2015:

	As of June 30, 2016	As of December 31, 2015
Cash and cash equivalents	\$ 20,042,000	\$ 14,338,000
Current assets	\$ 26,750,000	\$ 21,243,000
Current liabilities	10,079,000	8,437,000
Working capital	\$ 16,671,000	\$ 12,806,000

We incurred net losses of \$6.4 million and \$11.7 million for the three and six months ended June 30, 2016, respectively and incurred net income of \$4.5 million and net loss of \$17.5 million for the three and six months ended June 30, 2015, respectively. We have an accumulated deficit of \$368.8 million as of June 30, 2016. Additionally, we have used net cash of \$10.7 million and \$9.8 million to fund our operating activities for the six months ended June 30, 2016 and 2015, respectively.

To date, these operating losses have been funded primarily from outside sources of invested capital including our recently completed Rights Offering, our At the Market equity facility, 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.

On June 15, 2016, the Company closed a Rights Offering originally filed under Form S-1 registration statement in April 2016. Pursuant to the Rights Offering, the Company sold an aggregate of 6,704,852 units consisting of a total of 6,704,852 shares of common stock and 3,352,306 warrants, with each warrant exercisable for one share of common stock at an exercise price of \$3.06 per share, resulting in total gross proceeds to Cytori of \$17.1 million.

The Company continues to seek additional capital through product revenues, strategic transactions, including extension opportunities under the awarded U.S. Department of Health and Human Service’s Biomedical Advanced Research and Development Authority (“BARDA”) contract, and from other financing alternatives.

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

As of June 30, 2016, 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, 2015.

Cash (used in) provided by operating, investing, and financing activities for the six months ended June 30, 2016 and 2015 is summarized as follows:

	<u>For the six months ended June 30,</u>	
	<u>2016</u>	<u>2015</u>
Net cash used in operating activities	\$ (10,735,000)	\$ (9,788,000)
Net cash used in investing activities	(105,000)	(510,000)
Net cash provided by financing activities	16,405,000	19,532,000
Effect of exchange rate changes on cash and cash equivalents	139,000	(14,000)
Net increase in cash and cash equivalents	<u>\$ 5,704,000</u>	<u>\$ 9,220,000</u>

#### Operating activities

Net cash used in operating activities for the six months ended June 30, 2016 was \$10.7 million. Overall, our operational cash use increased during the six months ended June 30, 2016 as compared to the same period in 2015, due primarily to a decrease in losses from operations (when adjusted for non-cash items) of \$2.4 million offset by \$3.4 million in changes in working capital.

#### Investing activities

Net cash used in investing activities for the six months ended June 30, 2016 resulted from cash outflows for payment for purchases of property and equipment of \$0.1 million. The cash outflow was \$0.4 million lower than the same period in 2015 due to expense reduction efforts implemented throughout 2016.

#### Financing Activities

The net cash provided by financing activities for the six months ended June 30, 2016 related primarily to a sale of common stock through our Rights Offering and ATM offering program. The cash inflow from financing activities was approximately \$3.1 million lower than the same period in 2015, primarily due to the fact that there was \$11.7 million less in capital raised during the six months ended June 30, 2016 as compared to the same period in 2015, an increase of \$0.6 million in Joint Venture purchase payments to Olympus, and \$9.2 million decrease in principal payment on long-term obligations and loan fees.

#### **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 remain consistent with those reported in our Annual Report on Form 10-K for the fiscal year ended December 31, 2015 .

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

We are exposed to market risk related to fluctuations in interest rates and in foreign currency exchange rates. There have been no material changes in our market risks during the quarter ended June 30, 2016.

#### **Interest Rate Exposure**

We are not subject to market risk due to fluctuations in interest rates on our long-term obligations as they bear a fixed rate of interest. We might be exposed to increase in interest rates related to future financing activities to support our operations.

#### **Foreign Currency Exchange Rate Exposure**

Our exposure to market risk due to fluctuations in foreign currency exchange rates relates primarily to our activities in Europe and Japan. Transaction gains or losses resulting from cash balances and revenues have not been significant in the past and we are not currently engaged in any hedging activity in the Euro, the Yen or other currencies. Based on our cash balances and revenues derived from markets other than the United States for the three months ended June 30, 2016, a hypothetical 10% adverse change in the Euro or Yen against the U.S. dollar would not result in a material foreign currency exchange loss. Consequently, we do not expect that reductions in the value of such sales denominated in foreign currencies resulting from even a sudden or significant fluctuation in foreign exchange rates would have a direct material impact on our financial position, results of operations or cash flows.

Notwithstanding the foregoing, the indirect effect of fluctuations in interest rates and foreign currency exchange rates could have a material adverse effect on our business, financial condition and results of operations. For example, foreign currency exchange rate fluctuations may affect international demand for our products. In addition, interest rate fluctuations may affect our customers' buying patterns. Furthermore, interest rate and currency exchange rate fluctuations may broadly influence the United States and foreign economies resulting in a material adverse effect on our business, financial condition and results of operations.

### **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 Chief Executive Officer and Chief 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 Chief Executive Officer and Chief 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 Chief Executive Officer and Chief 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 June 30, 2016 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

## **PART II. OTHER INFORMATION**

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

From time to time, we have been involved in routine litigation incidental to the conduct of our business. As of June 30, 2016, we were not a party to any 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, 2015, 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. If any of the risks described in our Annual Report on Form 10-K, our Quarterly Reports, or 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.

***If you hold warrants issued pursuant to our recently completed rights offering, you may be limited in your ability to engage in certain hedging transactions that could provide you with financial benefits.***

On June 15, 2016, we closed our rights offering to subscribe for units at a subscription price of \$2.55 per unit, or the Rights Offering. Pursuant to the Rights Offering, we sold to our stockholders of record (as of May 20, 2016) an aggregate of 6,704,852 units consisting of 6,704,852 shares of common stock and 3,352,306 warrants, or Warrants, with each Warrant exercisable for one share of common stock at an exercise price of \$3.06 per share.

Holder of Warrants were required to represent to us that they will not enter into any short sale or similar transaction with respect to our common stock for so long as they continue to hold Warrants. These requirements prevent our Warrant holders from pursuing certain investment strategies that could provide them greater financial benefits than they might have realized had they not been required to make this representation.

***Absence of a public trading market for the Warrants may limit the ability to resell the Warrants.***

The Warrants are listed for trading on NASDAQ under the symbol “CYTXW,” but there can be no assurance that a robust market will exist for the Warrants. Even if a market for the Warrants does develop, the price of the Warrants may fluctuate and liquidity may be limited. If the Warrants cease to be eligible for continued listing on NASDAQ, or if the market for the Warrants does not fully develop (or subsequently weakens), then purchasers of the Warrants may be unable to resell the Warrants or sell them only at an unfavorable price for an extended period of time, if at all. Future trading prices of the 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 Warrants and the common stock issuable upon exercise of the Warrants;
- the interest of securities dealers in making and maintaining a market; and
- the market for similar securities.

***The market price of our common stock may never exceed the exercise price of the Warrants issued in connection with the Rights Offering.***

The Warrants issued pursuant to the Rights Offering became exercisable upon issuance and will expire 30 months from the date of issuance. The market price of our common stock may never exceed the exercise price of the Warrants prior to their date of expiration. Any Warrants not exercised by their date of expiration will expire worthless and we will be under no further obligation to the Warrant holder.

***The Warrants contain features that may reduce Warrant holders’ economic benefit from owning them.***

The Warrants contain features that allow us to redeem the Warrants and that prohibit Warrant holders from engaging in certain investment strategies. We may redeem the Warrants for \$0.01 per Warrant once the closing price of our common stock has equaled or exceeded \$7.65 per share, subject to adjustment, for ten consecutive trading days, provided that we may not do so prior to the first anniversary of closing of the Rights Offering, and only upon not less than 30 days’ prior written notice of redemption. If we give notice of redemption, Warrant holders will be forced to sell or exercise their Warrants or accept the redemption price. The notice of redemption could come at a time when it is not advisable or possible for Warrant holders to exercise the Warrants. As a result, Warrant holders may be unable to benefit from owning the Warrants being redeemed. In addition, for so long as Warrant holders continue to hold Warrants, they will not be permitted to enter into any short sale or similar transaction with respect to our common stock. This could prevent Warrant holders from pursuing investment strategies that could provide them greater financial benefits from owning the Warrants

***Since the Warrants are executory contracts, they may have no value in a bankruptcy or reorganization proceeding.***

In the event a bankruptcy or reorganization proceeding is commenced by or against us, a bankruptcy court may hold that any unexercised Warrants are executory contracts that are subject to rejection by us with the approval of the bankruptcy court. As a result, holders of the Warrants may, even if we have sufficient funds, not be entitled to receive any consideration for their Warrants or may receive an amount less than they would be entitled to if they had exercised their Warrants prior to the commencement of any such bankruptcy or reorganization proceeding.

***If we are unable to retain key personnel, we may not be able to sustain or grow our business.***

Our ability to operate successfully and manage our potential future growth depends significantly upon our ability to attract, retain, and motivate highly skilled and qualified research, technical, clinical, regulatory, sales, marketing, managerial and financial personnel. We compete for talent with numerous companies, as well as universities and non-profit research organizations. Our future success also depends on the personal efforts and abilities of the principal members of our senior management and scientific staff to provide strategic direction, manage our operations, and maintain a cohesive and stable environment. We have not entered into any employment agreements with our executive officers or key personnel, nor do we maintain key man life insurance on the lives of any of the members of our senior management. Although we have a stock option plan pursuant to which we provide our executive officers with various economic incentives to remain employed with us, these incentives may not be sufficient to retain them. The loss of key personnel for any reason or our inability to hire, retain, and motivate additional qualified personnel in the future could prevent us from sustaining or growing our business.

***The results of the United Kingdom's referendum on withdrawal from the European Union may have a negative effect on global economic conditions, financial markets and our business.***

In June 2016, a majority of voters in the United Kingdom elected to withdraw from the European Union in a national referendum. The referendum was advisory, and the terms of any withdrawal are subject to a negotiation period that could last at least two years after the government of the United Kingdom formally initiates a withdrawal process. Nevertheless, the referendum has created significant uncertainty about the future relationship between the United Kingdom and the European Union, including with respect to the laws and regulations that will apply as the United Kingdom determines which European Union laws to replace or replicate in the event of a withdrawal. The referendum has also given rise to calls for the governments of other European Union member states to consider withdrawal. These developments, or the perception that any of them could occur, have had and may continue to have a material adverse effect on global economic conditions and the stability of global financial markets, and may significantly reduce global market liquidity and restrict the ability of key market participants to operate in certain financial markets. Any of these factors could depress economic activity and restrict our access to capital, which could have a material adverse effect on our business, financial condition and results of operations and reduce the price of our 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**

Refer to the Exhibit Index immediately following the signature page, which is incorporated herein by reference.



**SIGNATURES**

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

**CYTORI THERAPEUTICS, INC.**

Dated: August 5, 2016

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

Dated: August 5, 2016

By: /s/ Tiago Girao  
Tiago Girao  
*VP of Finance and Chief Financial Officer*

## Exhibits Index

Exhibit No.	Description
1.1	Form of Dealer-Manager Agreement by and between Cytori Therapeutics, Inc., Maxim Group LLC (incorporated by reference to our Registration Statement on Form S-1/A, filed with the Commission on May 10, 2016)
1.2	Amendment No. 1 to Dealer-Manager Agreement, dated June 12, 2016, by and between Cytori Therapeutics, Inc., Maxim Group LLC (incorporated by reference to our Current Report on Form 8-K filed with the Commission on June 13, 2016)
3.1	Composite Certificate of Incorporation (incorporated by reference to our Annual Report on Form 10-K filed with the Commission on March 16, 2015)
3.2	Amended and Restated Bylaws of Cytori Therapeutics, Inc. (incorporated by reference to our Quarterly Report on Form 10-Q filed with the Commission on August 14, 2003)
3.3	Amendment to Amended and Restated Bylaws of Cytori Therapeutics, Inc. (incorporated by reference to our Current Report on Form 8-K filed with the Commission on May 6, 2014)
3.4	Certificate of Designation of Preferences, Rights and Limitations of Series A 3.6% Convertible Preferred Stock (incorporated by reference to our Current Report on Form 8-K filed with the Commission on October 8, 2014)
3.5	Certificate of Amendment to Amended and Restated Certificate of Incorporation, as amended (incorporated by reference to our Current Report on Form 8-K filed with the Commission on May 10, 2016)
4.1	Form of Non-Transferable Subscription Rights Certificate (incorporated by reference to our Registration Statement on Form S-1/A, filed with the Commission on May 10, 2016)
4.2	Form of Series R Warrant underlying the Units (incorporated by reference to our Registration Statement on Form S-1/A, filed with the Commission on May 10, 2016)
4.3	Form of Warrant Agreement by and between Cytori Therapeutics, Inc. and Broadridge Corporate Issuer Solutions, Inc. (incorporated by reference to our Registration Statement on Form S-1/A, filed with the Commission on May 10, 2016)
10.1**	Amendment of Solicitation/Amendment of Contract, effective April 1, 2016, by and between ASPR-BARDA and Cytori Therapeutics, Inc.
31.1	Certification of Principal Executive Officer Pursuant to Securities Exchange Act Rule 13a-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 (filed herewith).
31.2	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 (filed herewith).
32.1*	Certifications Pursuant to 18 U.S.C. Section 1350/ Securities Exchange Act Rule 13a-14(b), as adopted pursuant to Section 906 of the Sarbanes - Oxley Act of 2002 (filed herewith).
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

\* These certifications are being furnished solely to accompany this report pursuant to 18 U.S.C. 1350 and are not being filed for purposes of Section 18 of the Securities and Exchange Act of 1934 and are 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.

\*\* Filed herewith.

<b>AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT</b>		<b>I. C O N T R A C T I D C O D E</b>	<b>P A G E O F P A G E S</b>	
			1	2
2. AMENDMENT/MODIFICATION NO. 0004	3. EFFECTIVE DATE See Block 16C	4. REQUISITION/PURCHASE REQ. NO.	5. PROJECT NO. (If applicable)	
6. ISSUED BY ASPR-BARDA 200 Independence Ave., S.W. Room 640-G Washington DC 20201	CODE ASPR-BARDA	7. ADMINISTERED BY (if other than Item 6) ASPR-BARDA 3 30 Independence Ave, SW, Rm G644 Washington DC 20201	CODE	ASPR-BARDA01
8. NAME AND ADDRESS OF CONTRACTOR (No., street, county, State and ZIP Code)  CYTORI THERAPEUTICS, INC 1386447 CYTORI THERAPEUTICS, INC. 3020 3020 CALLAN RD SAN DIEGO CA 921211109		(x)	9A. AMENDMENT OF SOLICITATION NO.	
CODE 1386447			9B. DATED (SEE ITEM 11)	
FACILITY CODE		X	10A. MODIFICATION OF CONTRACT/ORDER NO. HHS0100201200008C	
			10B. DATED (SEE ITEM 13) 09/28/2012	

**11. THIS ITEM ONLY APPLIES TO AMENDMENTS OF SOLICITATIONS**

The above numbered solicitation is amended as set forth in Item 14. The hour and date specified for receipt of Offers  is extended.  is not extended. Offers must acknowledge receipt of this amendment prior to the hour and date specified in the solicitation or as amended, by one of the following methods: (a) By completing Items 8 and 15, and returning \_\_\_\_\_ copies of the amendment; (b) By acknowledging receipt of this amendment on each copy of the offer submitted; or (c) By separate letter or telegram which includes a reference to the solicitation and amendment numbers. FAILURE OF YOUR ACKNOWLEDGEMENT TO BE RECEIVED AT THE PLACE DESIGNATED FOR THE RECEIPT OF OFFERS PRIOR TO THE HOUR AND DATE SPECIFIED MAY RESULT IN REJECTION OF YOUR OFFER. If by virtue of this amendment you desire to change an offer already submitted, such change may be made by telegram or letter, provided each telegram or letter makes reference to the solicitation and this amendment, and is received prior to the opening hour and date specified.

12. ACCOUNTING AND APPROPRIATION DATA (If required)  
See Schedule

**13. THIS ITEM ONLY APPLIES TO MODIFICATION OF CONTRACTS/ORDERS. IT MODIFIES THE CONTRACT/ORDER NO. AS DESCRIBED IN ITEM 14 .**

CHECK ONE	A. THIS CHANGE ORDER IS ISSUED PURSUANT TO: (Specify authority) THE CHANGES SET FORTH IN ITEM 14 ARE MADE IN THE CONTRACT ORDER NO. IN ITEM 10A.
	B. THE ABOVE NUMBERED CONTRACT/ORDER IS MODIFIED TO REFLECT THE ADMINISTRATIVE CHANGES (such as changes in paying office, appropriation date, etc.) SET FORTH IN ITEM 14, PURSUANT TO THE AUTHORITY OF FAR 43.103(b).
X	C. THIS SUPPLEMENTAL AGREEMENT IS ENTERED INTO PURSUANT TO AUTHORITY OF: FAR 52.243-2 Alternate 1 (APR 1987) Changes - cost-reimbursement and Mutual agreement of the parties
	D. OTHER (Specify type of modification and authority)

**E. IMPORTANT:** Contractor  Is not.  Is required to sign this document and return \_\_\_\_\_ copies to the issuing office.

**14. DESCRIPTION OF AMENDMENT/MODIFICATION (Organized by UCF section headings, including solicitation/contract subject matter where feasible.)**

Tax ID Number: 33-0827593

DUNS Number: 111029179

Proof of Concept for Use of the Celution System as a Medical Countermeasure for Thermal Burn

A. The purpose of this modification is to revise the SOW for Proof of Concept for Use of the Celution System as a Medical Countermeasure for Thermal Burn.

B. This is a bilateral, supplemental agreement no-cost modification. The total contract amount and all other terms and conditions remain the same.

Continued ...

Except as provided herein, all terms and conditions of the document referenced in Item 9A or 10A, as heretofore changed, remains unchanged and in full force and effect.

15A. NAME AND TITLE OF SIGNER (Type or print) TIAGO M.GIKAO CFO		16A. NAME AND TITLE OF CONTRACTING OFFICER (Type or print) WENDELL CONYERS	
15B. CONTRACTOR/OFFEROR  /s/ TIAGO M.GIKAO CFO (Signature of person authorized to sign)	15C. DATE SIGNED  3/30/16	16B. UNITED STATES OF AMERICA  /s/ WENDELL CONYERS (Signature of Contracting Officer)	16C. DATE SIGNED  4-1-2016

NSN 7540-01-152-8070  
Previous edition unusable

STANDARD FORM 30 (REV. 10-83)  
Prescribed by GSA  
FAR (48 CFR) 53.243

**NAME OF OFFEROR OR CONTRACTOR**  
CYTORI THERAPEUTICS, INC 1386447

ITEM NO. (A)	SUPPLIES/SERVICES (B)	QUANTITY (C)	UNIT (D)	UNIT PRICE (E)	AMOUNT (F)
	Period of Performance: 09/28/2012 to 09/27/2016				

Contract No. HHS0100201200008C Modification #04	Continuation Sheet Block 14	Page 3 of 15
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## **SUMMARY OF CHANGES**

### **Revised Statement of Work for Option 1**

#### **Preface**

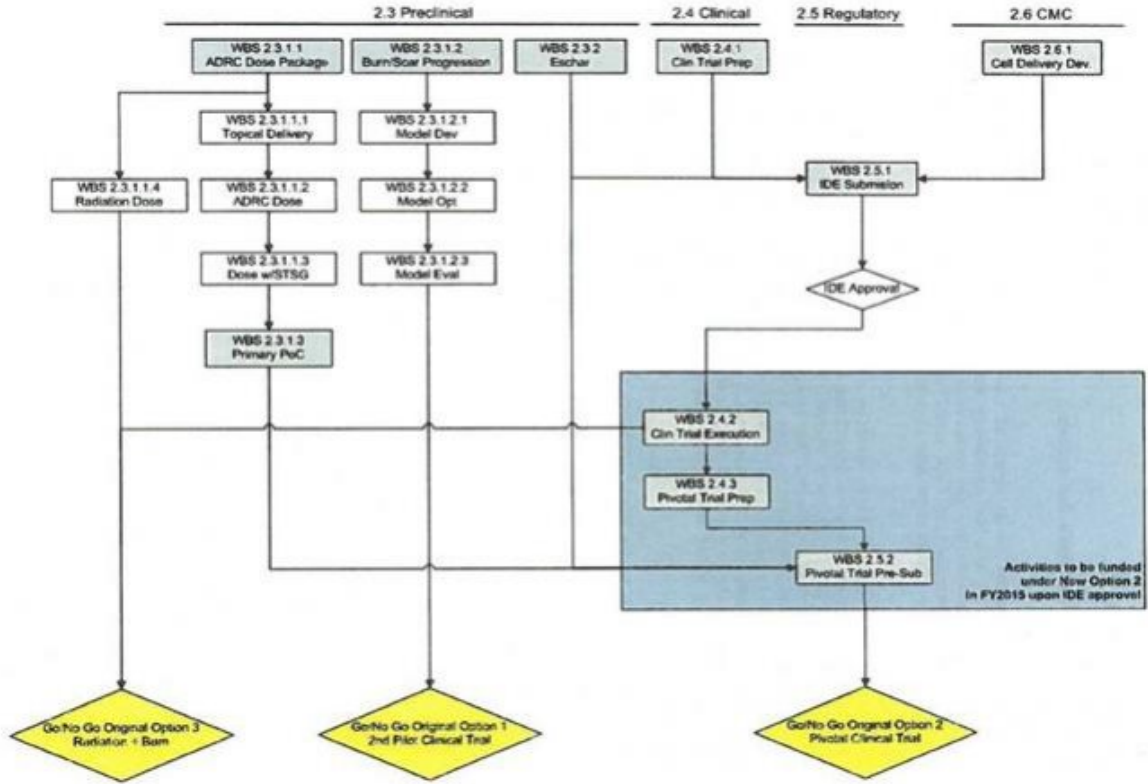
Independently and not as an agent of the Government, the Contractor shall be required to furnish all the necessary services, qualified personnel, material, equipment, and facilities, not otherwise provided by the Government, as needed to perform the Statement of Work submitted in response to Broad Agency Announcement (BAA) BARDA CBRN BAA 11-100-SOL-00009.

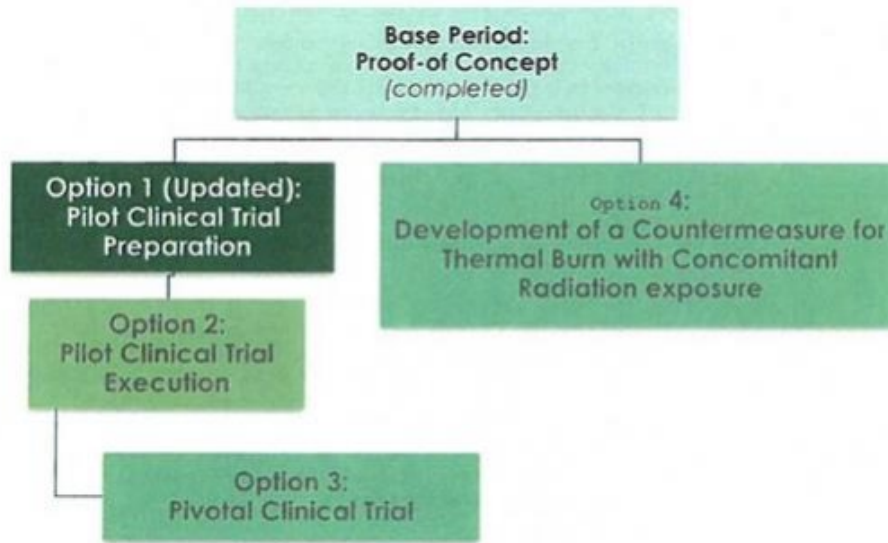
#### **Introduction**

The goal of this project is to develop a countermeasure for thermal burn injury that requires minimal to no stockpiling and that is effective in the treatment of both thermal burn injury and thermal burn injury that is complicated by concomitant radiation exposure. The issue of stockpiling will be addressed by development of a countermeasure that is effectively pre-deployed through regular commercially viable use. Ideally, this commercial use is in both thermal burn—thereby ensuring availability within the burn center of persons trained in operation and use of the countermeasure in burn—and outside of burn, thereby bolstering wider commercial viability.

## Timeline

A flowchart of the tasks within this CLIN is shown below.





- Option 1, as amended from the original Statement of Work, includes research and development, regulatory, clinical, and other tasks required for preparation for a Pilot Clinical Trial of the Celution System in thermal burn injury. Activities include those needed to obtain FDA approval to execute the trial. The Option also includes development of a system and process suitable for delivering ADRCs to thermal burn wounds within the clinical trial as well as preclinical activities dedicated to increasing understanding of the countermeasure in thermal burn.
- Option 2, is to be funded in FY16 or FY17 upon FDA approval to initiate the Pilot Clinical Trial. Option 2 (New) includes tasks needed to execute and complete the Pilot Clinical Trial, those needed to prepare trial data for submission to FDA within a Pre-Submission Meeting Package in support of a proposed Pivotal Trial, and, potentially, support for ongoing development of CT-X2.
  - Option 2 is to be triggered by FDA approval to execute the study
- Option 3 includes a Pivotal Clinical Trial leading to FDA licensure for use of the Celution System in thermal burn injury. Given the likely timing of the start of activities under Option 2 it is probable that this activity will be executed under a new contract rather than as an Option of the current contract.
  - Option 3 will be triggered by the FDA's response to the proposed Pivotal Study Design and Clinical and Preclinical Support Data submitted in a Pre-Submission Meeting Package. Specifically, the Option will be triggered if the FDA indicates adequacy of the study design and preclinical and clinical data set with regard to moving forward to the proposed clinical trial. Given the likely timing of the start of activities under Option 3 it is probable that this activity will be executed under a new contract rather than as an Option of the current contract.
- Option 4 includes studies to optimize the treatment for thermal burn injury with concomitant radiation exposure. Ideally these activities would lead to development of FDA Emergency Use Instructions
  - The triggers for Option 4 remain unchanged from the original submission. Specifically, it will be triggered if the following three parameters are met: (1) autologous ADRCs mediate improved healing of thermal burn injury in an irradiated animal; (2) the cell output of the CT-X2 is equivalent or superior to that of the Celution 800; and (3) ADRCs can be obtained from patients with thermal burn injury. Studies executed within WBS 2.3.1.1.5 may further inform this decision. Given the likely timing of the start of activities under Option 4 it is probable that this activity will be executed under a new contract rather than as an Option of the current contract.
- The current CLIN includes activities in WBS 2.3.1.2 (Burn Wound/Scar Progression). Demonstration of efficacy and practicability of ADRC treatment to reduce scar progression following burn wounds to a meaningful degree would trigger consideration of a further new component of support which would fund a Pilot Clinical Trial in Burn Wound Progression.
  - Specifically, such an Option would be triggered if the application of ADRCs led to a reduction of more than approximately 33% in the incidence or severity of scarring.

## **Base Period**

The Base Period obtained proof of concept data for use of the Celution System as a medical countermeasure for combined injury involving radiation exposure and thermal burn injury. Specifically, in the absence of radiation exposure, autologous ADRCs improved healing parameters including increased burn wound re-epithelialization. The same improved healing was also observed in animals subjected to total body irradiation sufficient to induce profound, transient myelosuppression. Viable, functional ADRCs were reliably and reproducibly obtained from patients with severe full thickness thermal burn injury. Finally, a prototype of Cytori's next generation Celution System (CT-X2) showed cell processing capabilities that were equivalent or superior to those of the current generation system, Celution 800.

## **Option 1: Pilot Clinical Trial Preparation**

### **Specific Objectives and Scope**

As proposed herein, the Contractor intends to design, execute, and complete robust preclinical and to design a clinical study that meet two objectives: (1) obtain FDA approval to execute a pilot clinical trial of the countermeasure in thermal burn injury wherein said trial will inform and support development of a pivotal clinical trial to be funded by a future CLIN/contract option; and (2) execute preclinical studies that will expand understanding of the countermeasure with respect to cell dose, route of administration, and efficacy in arresting or slowing progression of indeterminate thickness thermal burn injury or in addressing scarring following thermal burn.

**Start Date: Q4, FY14**

### **WBS 2.1 Technical and Project Management: *Original and Supplement***

#### **Project-wide Activities**

##### ***Purpose***

Execution of activities throughout this project will require that meetings, site visits, In-Process Reviews, and related activities are properly coordinated and that the outcome of said activities be communicated to BARDA and other stakeholders in an efficient, timely manner. The purpose of these project-wide activities is to facilitate this coordination and communication.

##### ***Description***

Examples of activities performed to facilitate meetings, site visits, In-Process Reviews and similar activities include: scheduling meetings, timely distribution of an agenda in advance of the meeting, and timely distribution of meeting minutes, action items, and other deliverables after the meeting.

- Deliverable:** a. Ensure proper coordination of all meetings, site visits, In-Process Reviews  
b. Disposition of meeting minutes and action items and all deliverables under this Statement of Work to BARDA

**Success Criterion:** CO and PO deem meeting communications are managed satisfactorily

**Timing:** Full duration of project (including all options)

#### **2.1.1.1 Kick-off Meeting: *Unchanged from Original***

Following a kickoff meeting with BARDA, Cytori will update the project schedule and provide an updated Task and Deliverables list to the Contract Officer.

**Deliverable:** Updated Task and Deliverables Document

**Success Criterion:** Includes updates of tasks and deliverables as discussed with CO and PO during kickoff meeting

**Timing:** Q2, FY15

#### **2.1.1.2 Complete new hiring needed for execution of contract activities *Unchanged from Previous***

Execute hiring of new staff needed for execution of CLIN activities

**Deliverable:** Report showing that key positions have been filled and added to contract provided within bi-weekly meetings

**Success Criteria:** Positions identified during negotiations have been filled by qualified persons

**Timing:** Q3, FY15



### **2.1.2 Maintain Subcontractor Management Plan: *Unchanged from Previous***

Maintain Subcontractor Management Plan

**Deliverable:** Updated Subcontractor Management Plan

**Success Criteria:** Identifies key interactions between prime contractor and subcontractor with regard to progress updates and risk management

**Timing:** Semi-annually starting six months after award of CLIN

### **2.1.3 Maintain Risk Management Plan: *Unchanged from Previous***

Maintain Risk Management Plan

**Deliverable:** Updated Risk Management Plan

**Success Criteria:** Identifies key risks, assesses mitigations, contingencies, and impact as well as update process

**Timing:** Semi-annually starting six months after award of CLIN

### **2.1.4 EVMS Systems Report: *Unchanged from Previous***

EVMS Systems Report

**Deliverable:** EVMS Systems Report

**Success Criteria:** Acceptance by BARDA Contract Officer that the accounting and related systems are EVMS-compliant

**Timing:** Q2, FY15

## **2.2 Non-Clinical Toxicology**

Not applicable

## **2.3 Preclinical**

### **2.3.1 Porcine Studies:**

#### **2.3.1.1 ADRC Dose Package**

**Objective:** To determine the minimally effective dose of ADRCs in thermal burn injury

**Rationale:** In the Base Period Cytori has evaluated a narrow range of ADRC doses range limited at the upper end by the amount of adipose tissue easily obtainable from an individual mini-pig. The effectiveness of lower doses has not been assessed. The total dose of cells available for treatment is largely dependent on the volume of adipose tissue processed. Larger volumes require more collection and processing time and can increase risk. In order to appropriately balance risk and benefit it is important to determine the optimal cell dose so that the amount of tissue collected is adequate, but not excessive, for the size of the injury. This will be assessed by local delivery into the wound.

#### **2.3.1.1.1 ADRC Dose: Additional Evaluation of Previously Collected Biopsies: *Unchanged from Original, Studies Completed***

**Objective:** To evaluate value of additional evaluations

**Rationale:** Studies in WBS 1.3.1 executed within the Base Period collected biopsies that were subjected to a number of histologic and immunohistologic stains (for example; Masson's trichrome and immunostaining for Ki67 and CD31). Data from these stains was informative. As is often the case in research, the information obtained raised new questions that can be addressed by application of additional histologic approaches. However, there was insufficient time and insufficient funds to apply these approaches during the Base Period. These approaches have the capacity to be informative in the studies to be executed under Option 1. The activities to be executed under this WBS element will develop and validate selected additional markers on biopsies collected during the Base Period in anticipation of applying said stains in ADRC dose studies to be conducted under WBS 2.3.1.1 (Dose Package) and other activities in WBS 2.3.1.

**Approach:** Biopsies and sections have already been prepared and several core analyses have been performed. Additional digital imaging and analysis including immunohistochemical and molecular assessment of parameters associated with both normal healing and with scarring, particularly hypertrophic scarring, will be performed.

**Description:**

For each group multiple wound healing parameters will be assessed. Candidate stains include: Movat's stain (a pentachrome stain that is recommended by UTMB Galveston for analysis of hypertrophic scarring), alpha smooth muscle actin (for contraction-inducing myofibroblasts), decorin (reduced in hypertrophic scarring), and type III collagen. Similarly, commercially available molecular arrays targeted for wound healing may be used to interrogate existing biopsy samples. All stained slides will be digitally scanned prior analysis. Using software such as the ImageScope software, each slide can be annotated to identify superficial and mid/deep regions within the wound tissue. The percent of positive staining can be quantified using the Deconvolution analysis algorithm (Aperio). This software algorithm makes use of a deconvolution method to separate the red and blue stain of the Masson's Trichrome. Epithelial thickness can be determined by histomorphometric analysis on digital slides using the Image Scope software. 3-6 measurements throughout the wound site (at edges and the center) can be performed to determine the thickness of the stratified and cornified layer of the neo-epidermis.

**Deliverable:** Interim and Final Study Reports

**Success Criteria:** Acceptance of reports by BARDA Program

**Timing:** Q2, FY15

**2.3.1.1.2ADRC Dose: Topical Delivery : Unchanged from Original, Study Completed**

**Objective:** To determine the efficacy of topical delivery of ADRCs in thermal burn injury

**Rationale:** In the Base Period Cytori has demonstrated that delivery of ADRCs by direct injection into the base of the wound leads to increased epithelialization. Cytori's Burn Science Advisory Board has recommended that we evaluate mechanisms that might be easier and potentially faster to perform, in particular, topical delivery such as a spray, drip, or paint approach. A brief series of *in vitro* and *in vivo* studies similar to those executed in the base Period for other delivery routes is indicated in order to evaluate this approach.

**Approach:** These studies will use an approach selected during *in vitro* testing to apply viable ADRCs to burn wound following escharectomy.

**Description:**

Animals will receive thermal burn injury induced according to parameters optimized during the Base Period. Autologous ADRCs will be delivered on the same day as escharectomy. Different groups of animals will receive topical delivery of ADRCs with contralateral wounds used as matched control (treated with vehicle only). Healing will be evaluated by planimetry and histology at appropriate time points selected on the basis of results obtained in the Base Period. Each group will comprise a sufficient number of animals (for example, 4 or 6) .

**Deliverable:** Interim and Final Study Reports

**Success Criteria:** Achieves success parameter defined in study protocol agreed to by BARDA and the Contractor prior to initiation of studies

**Timing:** Q2, FY15

**2.3.1.1.3ADRC Dose: Dose Finding: Unchanged from Original, Study In Progress**

**Objective:** To determine the minimally effective dose of ADRCs in thermal burn injury

**Rationale:** In the Base Period Cytori has evaluated a narrow range of ADRC doses range limited at the upper end by the amount of adipose tissue easily obtainable from an individual mini-pig. In order to maximize the likelihood of seeing a difference between treated and control wounds the first arm will apply dosing in wounds that are not treated with a split thickness skin graft (STSG) where data obtained in the Base Period demonstrate a robust signal to noise ratio for ADRC-induced increased epithelial migration. Once a dose has been determined in this model it will be applied in follow-up studies that include STSG (WBS 2.3.1.1.4 below).

**Approach:** These studies will use the approach applied in the Base Period to assess effectiveness of ADRCs when delivered at different doses by either local (that is, injection or topical as assessed by WBS 2.3.1.1.2) or intravenous delivery. For the local injection arm of the study, each animal may act as its own control using a paired wound model in which wounds on one side of the animal will receive vehicle alone (control) while the matching wounds on the other side receive ADRC treatment. Given the clinical relevance of hypertrophic scarring and the relative resistance of Gottingen minipigs and Yorkshire farm swine to this phenomenon these studies may be extended to include the Red Duroc strain of pigs (in place of or in addition to other strains) which is known to have a native susceptibility to hypertrophic scarring that is more similar to that of humans.

**Description:**

Animals will receive thermal burn injury induced according to parameters optimized during the Base Period. Autologous ADRCs will be delivered on the same day as escharectomy. Different groups of animals will receive local injection of ADRCs. A suitable number (for example, four) of different ADRC doses will be evaluated. Doses selected will cover a wide range (for example, 250,000 ADRCs/cm<sup>2</sup>; 125,000 ADRCs/cm<sup>2</sup>; 50,000 ADRCs/cm<sup>2</sup>; and Control = no ADRCs). Healing will be evaluated by planimetry, histologic, and molecular analysis at appropriate time points selected on the basis of results obtained in the Base Period. Each group will comprise a sufficient number of animals (for example, 4 or 6).

**Deliverable:** Interim and Final Study Reports

**Success Criteria:** Achieves success parameter defined in study protocol agreed to by BARDA and the Contractor prior to initiation of studies

**Timing:** Q1, FY16

**2.3.1.1.4ADRC Dose: Confirmation with STSG: Deleted****2.3.1.1.5ADRC Dose: Confirmation with Higher Radiation Dose: Deleted****2.3.1. 2Burn/Scar Progression**

**Objective:** To obtain preclinical data that will allow assessment of feasibility of use of the Celution System as a treatment for burn wound progression or scarring.

**Rationale:** Burn wound progression is the pathophysiologic process by which a partial thickness thermal burn evolves over the first few days after injury to become a full thickness injury requiring a skin graft. This process occurs through vascular damage leading to ischemia: reperfusion injury and to the inflammatory response<sup>1</sup>. The same mechanisms that are proposed to be behind the efficacy of ADRCs observed in the Base Period (angiogenesis, modulation of inflammation, etc.) have the potential to mitigate burn progression. Similarly, the healing process following thermal burn injury can lead to scarring that is both disfiguring and that limits function, for example, limits range of motion of a joint. Interventions that impact progression of scar development and maturation have the potential to significantly improve burn care.

**Approach:**

The overall approach selected is taken from that applied in the Base Period for full thickness injury in which a porcine model of vertical burn wound progression or scarring taken from the published literature<sup>2,3</sup> is adapted, optimized, and validated and then used to assess efficacy of autologous ADRC treatment.

**2.3.1.2.1 Model Development: Unchanged from Original, Study Completed**

**Objective:** To develop an animal model that will allow assessment of the effects of treatment with autologous ADRCs to treat burn wound progression.

**Rationale:** While a suitable animal model has been described in the literature<sup>2</sup>, it has not previously been executed by this team. Pilot activities are needed to establish the basic model.

**Approach:** Porcine models widely used for evaluation of thermal burn injury and have also been used for evaluation of burn and scar progression. The approach to be applied is essentially identical to that used in the Base Period for creation of a full thickness burn wound with the exception that the progression model must create a wound that is only partial thickness at the time of application but which progresses to deep/full thickness over a period of 3-4 days after injury whereas a model of hypertrophic scarring will require longer follow-up after injury.

<sup>1</sup> Shupp, J.W., et al., *A review of the local pathophysiologic bases of burn wound progression. J Burn Care Res, 2010. 31(6): p. 849-73*

<sup>2</sup> Singer, A.J., et al., *Validation of a vertical progression porcine burn model. J Burn Care Res, 2011. 32(6): p. 638-46*

<sup>3</sup> Harunari, N., et al., *Histology of the thick scar on the female, red Duroc pig: Final similarities to human hypertrophic scar. Burns, 2006. 32(6): p669-677*

**Description:**

Each experimental animal will be subjected to thermal burn injury using the device developed for this purpose during the Base Period. These activities demonstrated that application of the device at a temperature of 200°C and contact pressure of 0.4kg/cm<sup>2</sup>, for 60 seconds created a reproducible full thickness injury. A published study<sup>2</sup> has shown that application of a similar device at a temperature of 80°C and contact pressure of 0.32kg/cm<sup>2</sup> for 20-30 seconds creates a partial thickness burn that progresses to full thickness. In these studies parameters of time, temperature, and contact pressure will be managed to determine the precise combination that generates a wound that reproducibly progresses from partial to full thickness over ~3-4 days after injury. The same approach may be used to generate a burn that develops to hypertrophic scarring in an appropriate pig strain.

Thermal burn wounds will be created in a suitable number of animals as described above and assessed by histology of biopsies performed at the time of injury and at suitable intervals (for example, 6 hours, 24 hours, 48 hours, 72 hours and 96 hours) after injury to assess burn depth and progression over the ~96 hour timeframe with the different burn induction parameters. For evaluation of scarring a similar approach will be applied using the Red Duroc strain that develops hypertrophic scarring that is similar to that of humans.

**Deliverable:** Interim and Final Study Reports

**Success Criteria:** Achieves success parameter defined in study protocol agreed to by BARDA and the Contractor prior to initiation of studies

**Timing:** Q1, FY15

**2.3.1.2.2 Model Optimization: Study in Progress**

**Objective:** To optimize an animal model that will allow assessment of the effects of treatment with autologous ADRCs to treat burn wound/scar progression.

**Rationale:** Assesses reproducibility of the model established in WBS 2.3.1.2.1 above.

**Approach:** The parameters defined to provide the intended model in WBS 2.3.1.2.1 will be assessed for reproducibility.

**Description:**

A series of wounds will be induced in a cohort of animals (for example, six animals per arm) using the approach determined in Model Development above (WBS 2.3.1.2.1). Animals will also undergo lipectomy for ADRC isolation for treatment of wounds assigned for treatment. Wounds will receive treatment with ADRCs or with vehicle control. The study will assess ability of ADRCs to modify the development of scarring and to treat a scar that has already developed or has started to develop (for example, six months after injury). Progression of scarring will be assessed by histologic and molecular analysis of biopsies taken at suitable intervals (for example, 6 hours, 24 hours, 48 hours, 72 hours and 96 hours) after injury or later times (for example, two weeks, two months, six months) to assess scarring.

**Deliverable:** Interim and Final Study Reports

**Success Criteria:** Achieves success parameter defined in study protocol agreed to by BARDA and the Contractor prior to initiation of studies

**Timing:** Q3, FY16

### 2.3.1.2.3 Model Evaluation: *Deleted*

### 2.3.1.3 Primary Proof of Concept: *Modified*

**Objective:** To demonstrate proof of concept for use of ADRCs in enhancing healing of thermal burn injury

**Rationale:**

These activities will obtain safety, efficacy, and mechanism of action data that can be included in the investigational Device Exemption application to be submitted to FDA under WBS 2.5.1

**Approach:** Conditions defined in the studies described above will be applied to evaluate healing when ADRCs are delivered following thermal burn injury.

**Description**

Animals will receive thermal burn injury induced according to parameters optimized in the studies described above. Wounds will be treated with either control or ADRCs. ADRCs applied at the time of the initial treatment will be applied locally (for example directly into or onto the wound) and/or by systemic administration (for example, by intravenous injection). Each group will comprise a sufficient number of animals (for example, 4 or 5). Healing will be evaluated at time points selected on the basis of results obtained in the studies described above (for example, at the time of application of the STSG and two weeks after application of STSG). Assessment of fibrosis and hypertrophic scarring at the treatment site may be performed a suitable time after injury (for example, six months). These *in vivo* activities may be supplemented by *in vitro* studies that examine mechanisms underlying *in vivo* observations, for example, prior studies have shown an effect of ADRCs on inflammatory cell infiltration and blood vessel density. These phenomena can be assessed by *in vitro* activities assessing endothelial cells and leukocytes.

**Deliverable:** Interim and Final Study Reports

**Success Criteria:** Achieves success parameter defined in study protocol agreed to by BARDA and the Contractor prior to initiation of studies

**Timing:** Q4, FY16

### 2.3.2 Human Thermal Burn ADRC Characterization: Eschar: *Complete: No further activity needed*

**Objective:** To characterize the ADRC population obtained from patients with thermal burn injury

**Rationale:** As currently proposed, the pilot clinical trial includes use of adipose tissue obtained by excision of adipose tissue exposed during tangential or fascial excision of eschar. Studies performed in the Base Period have provided evidence that the yield, viability, function, and composition of ADRCs obtained from material obtained from fascial excision escharectomy are all within the range seen when processing adipose tissue obtained by liposuction from healthy donors. The current studies are needed to expand on this preliminary data by collecting and evaluating additional specimens and by extending the study to include tissue obtained by tangential excision. In addition, optimal enzymatic digestion of the adipose tissue requires that the excised tissue be morselized into fragments creating a surface area-to-volume ratio that allows efficient extraction of ADRCs.

**Approach:** Adipose tissue from patients with thermal burn injury will be obtained following informed consent and processed to prepare ADRCs. The number and function of these cells will be assessed using approaches such as cell viability and cell characterization methods that are used routinely by Cytori for evaluation of cells from conventional sources (liposuction) as applied in the Base Period. This will include development of a rapid, efficient, and validated method by which the excised tissue is morselized.

### **Description**

Human adipose tissue will be obtained following informed consent from a sufficient number of patients (for example, 20) undergoing treatment for thermal burn injury. Research subjects will be drawn from burn programs located in geographic proximity to the Contractor's research facility (for example, at the University of California at San Diego Burns Center located approximately five miles from the Cytori laboratories) and the University of California at Irvine Burn Center (located approximately 80 miles from Cytori laboratories). The tissue will be processed to prepare morselized adipose tissue that will then be digested to prepare ADRCs. Cell yield and viability will be determined using a Nuclecounter™ device in accordance with standard practices at Cytori. Other examples of tools for characterization include multicolor flow cytometry to evaluate cell ADRC cellular composition, and molecular probes to evaluate the population as a whole.

**Deliverable:** Monthly Updates (during bi-weekly calls); Report for IDE Submission, and written Interim and Final Study Reports

**Success Criteria:** Achieves success parameter defined in study protocol agreed to by BARDA and the Contractor prior to initiation of studies

**Timing:** Monthly updates for enrollment reporting; Q1, FY15 for IDE Submission; Monthly reports to Q4 FY16; Q4, FY16 for interim and final reports.

## **2.4 Clinical Tasks : Unchanged from Original**

### **2.4.1 . 1Pilot Clinical Trial Preparation: Unchanged from Original**

**Objective:** To perform the groundwork necessary for FDA approval of a Pilot clinical trial of the use of the Celution System in thermal burn injury and for expedited start of enrollment in the trial following FDA approval.

**Rationale:** The Celution System is regulated as a device within the Center for Biologics Evaluation and Research (CBER). CBER has approved the use of the Celution System in three prior IDE clinical trials. In the course of discussions with the FDA regarding these studies the Agency communicated to Cytori that they strongly preferred the study design to include evaluation of cell dose. The proposed study will obtain the safety and feasibility of a pilot study with additional information of cell dose and assessment of secondary outcomes associated with efficacy. These data may allow determination of sample size in any Pivotal Trial to follow (as described in Option 2). Prior to filing the IDE package for this Pilot Trial, the clinical team must develop a detailed clinical protocol and Investigator's Brochure (IB). These and related activities associated with assessment and selection of potential clinical trial sites and CROs will be executed under WBS 2.4.1.4.

Additional tasks must be performed in order to minimize the delay between FDA approval and start of the trial itself. These include selection of a qualified Clinical research Organization and of clinical sites that have the capability to enroll patients and execute the study with the level of quality required to achieve study goals.

**Approach:** With the assistance of a Scientific Advisory Board, the team will develop the protocol and IB as for past Cytori IDE filings. The team will also execute clinical site evaluation, CRO evaluation, and an preliminary assessment of contractual matters to ensure that the budget for proposed Option 2 is accurate.

### **Purpose**

To provide the Regulatory team with the documentation needed to obtain FDA approval to initiate the specified clinical trial.

### **Description**

Activities to be conducted include: development of the clinical trial protocol; assessment and selection of Clinical Contract Research Organization (CRO); and assessment, selection, and qualification of clinical trial sites. These activities will be executed with input from Cytori's Thermal Burn Scientific Advisory Board.

**Deliverables:** Monthly Updates (during bi-weekly calls) Clinical Trial Protocol and Investigator's Brochure for IDE Submission Q1 FY16 Site Initiation Readiness Report Q4 FY16

**Success Criteria:** FDA approval of trial

**Timing:** Clinical Trial Protocol and Investigator's Brochure for IDE Submission Q4 FY16 Site Initiation Readiness Report Q6 FY16

## 2.5 Regulatory Tasks

### 2.5.1 Pilot Clinical Trial IDE Approval

#### Purpose

The FDA must grant approval before clinical use of an Investigational Device can be initiated. In the case of the Celution System in Thermal Burn Injury this will require approval under the Investigational Device Exemption mechanism.

#### Description

Cytori's regulatory team will prepare and submit a package of documents. Contents will be based upon the clinical trial protocol, data obtained in studies described above, and feedback received from the Agency in a Pre-IDE Meeting.

The content of the IDE package will largely mirror that used in prior submissions of this kind to the Agency. Contents will include relevant study reports from activities executed during the Base Period and Option 1. In the event that the FDA has additional questions to be answered following review of the initial package, the Regulatory team will develop, collate, and submit responses to said questions.

### 2.5.1 Pre-Submission Meeting

**Deliverable:** Presubmission Package and Meeting Minutes

**Success Criteria:** Clarity on path to successful IDE submission

**Timing:** Q3, FY16

### 2.5.2 IDE Approval

**Deliverable:** IDE Package and Responses (as required) to FDA Questions

**Success Criteria:** IDE Approval Granted by FDA

**Timing:** Q4, FY16

## 2.6 CMC

### 2.6.1 ADRC Delivery System

**Objective:** To develop a system capable of preparing adipose tissue obtained by excision rather than by liposuction for processing within the CT-X2 System and subsequent rapid, reproducible delivery to a thermal burn injury.

#### 2.6.1.1 Tissue Pre-Processing: *Unchanged*

**Objective:** To develop a system capable of preparing adipose tissue obtained by excision rather than by liposuction for processing.

**Rationale:** Cytori methods have been optimized for preparing ADRCs from tissue collected by liposuction. During this process the suction force combined with the geometry of the liposuction cannula cuts the adipose tissue into small fragments. The conditions for enzymatic digestion of this material are based upon the standard surface area to volume ratio of tissue prepared by liposuction. Tissue prepared by excision will have a different surface area to volume ratio and, hence, will not be processed optimally without pre-processing. Activities within WBS 2.6.1.1 are designed to develop a standard, reproducible, and clinically acceptable pre-processing method that will prepare excisional samples for optimal processing. Cytori has developed approaches for pre-processing the tissue that are acceptable for the laboratory, but not for the clinic. The activities to be performed in WBS 2.6.1.1 are intended to address this deficiency.

**Approach:** Human adipose tissue will be pre-processed by two methods; (1) Cytori's standard laboratory approach and (2) using tools and supplies commonly available in the operating room. Tissue will then be processed. The yield, viability, and composition of the ADRCs derived will be evaluated using methods described above (WBS 2.3.2).

**Description:** Human adipose tissue (see WBS 2.3.2) will be obtained following escharectomy. Adipose tissue will be excised from the sample and then sliced into fragments that approximate the size of fragments obtained by liposuction. Tissue slicing will be performed by two methods; (1) Cytori's standard laboratory approach and (2) using tools and supplies commonly available in the operating room. Tissue will then be processed. The yield, viability, and composition of the ADRCs derived will be evaluated using methods described above (WBS 2.3.2). Once the optimal approach using Operating Room materials has been developed, the approach will then be validated.

**Deliverable:** Validated Standard Operating Procedure with Validation Data

**Success Criteria:** Protocol accepted by FDA in IDE Submission

**Timing:** Q4, FY16

#### **2.6.1.2 Cell Delivery Mechanism: *Unchanged***

**Objective:** To develop a system capable of reproducibly and conveniently delivery ADRCs to a thermal wound following escharectomy.

**Rationale:** The current clinical protocol, based on preclinical data, specifies delivery ADRCs into the wound bed a single injection indicated for each 10cm<sup>2</sup> of treatment area. There is currently no off-the-shelf approach available that achieves this delivery without unnecessarily prolonging surgical time.

**Approach:** Injection of ADRCs into the wound could, for example, take the form of a powered dosing syringe delivering a specified volume of material (ADRCs) into the wound bed at each touch of the button. This markedly reduces strain in the Surgeon's hand for large wounds requiring many injections. Examples of this approach were presented to the FDA at the Pre-Submission meeting where they met with general approval with the natural proviso that full review in the IDE Submission would be required. For example, FDA indicated that they would require data showing that the output of the injection system was consistent over time. Another possible approach is a topical spray similar to that already used in burn care for application of fibrin glue used to help secure skin grafts. The activities performed herein will continue development of a suitable approach in order to complete the information needed for the IDE submission. Additional technical support will be required in the early phase of the clinical trial for matters such as set-up and training.

**Description:** Cytori engineers have already identified candidate powered syringe and spray systems that may be suitable for this purpose. These devices will be brought in-house. The convenience, time, and reproducibility of injection may be assessed by, for example, injecting ADRCs into surrogate materials, for example, porcine skin, human skin obtained from patients undergoing elective cosmetic procedures (eg: "tummy tuck") and/or into sample collection vials.

**Deliverable:** Interim and Final Reports

**Success Criteria:** Protocol accepted by FDA in IDE Submission

**Timing:** Q4, FY16

#### **2.6.1.3 ADRC Delivery System and Process: *Unchanged but renamed "WBS 2.6.2 Verification and Validation"***

**Objective:** To obtain data and reports that will allow FDA to assess the safety and suitability of the ADRC Delivery System and Process for use in the proposed clinical trial.

**Rationale:** Robust testing, verification, and validation of the system and process used for ADRC preparation and delivery is a necessary component of the package to be submitted for FDA review as part of obtaining approval to execute the proposed clinical trial.

**Approach:** FDA requirements and guidance documents specify a range of testing that must be performed on systems such as that proposed herein before said systems can be used in a clinical trial. Small companies like Cytori invariably find it more efficient to outsource much of this specialized testing to vendors with specific expertise. For this reason, certain aspects of the work proposed for WBS 2.6.1.3 will be executed by subcontractors.

#### ***Description***

CMC testing on hardware, consumable, and software elements of the Cell Delivery System and Process.



**Deliverables:**

1. Consumable component mold verification report
2. CMC Test Report of Cell Delivery System and Process circuit board element
3. Electromagnetic compatibility testing report
4. Consumables for use in testing to be executed by Cytori in WBS 2.3.1, WBS 2.3.2, WBS 2.4.1, WBS 2.5.1, and WBS 2.6.1
5. Software Verification and Validation report

**Success Criterion:** Reports accepted by FDA in IDE Submission

**Timing:** Q4 2016

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

Date: August 5, 2016

/s/ Marc H. Hedrick

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Marc H. Hedrick,

President & Chief Executive Officer

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

I, Tiago Girao, certify that:

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

Date: August 5, 2016

/s/ Tiago Girao

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Tiago Girao

*VP of Finance and Chief Financial Officer*

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

In connection with the Quarterly Report on Form 10-Q of Cytori Therapeutics, Inc. for the quarterly period ended June 30, 2016 as filed with the Securities and Exchange Commission on the date hereof, Marc H. Hedrick, as President & Chief Executive Officer of Cytori Therapeutics, Inc., and Tiago Girao, as VP of Finance and Chief Financial Officer of Cytori Therapeutics, Inc., each hereby certifies, respectively, that:

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

Dated: August 5, 2016

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

Dated: August 5, 2016

By: /s/ Tiago Girao  
Tiago Girao  
*VP of Finance and Chief Financial Officer*