UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended June 30, 2017

OR

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

For the transition period from

Commission file number 001-34375

to

CYTORI THERAPEUTICS, INC.

(Exact name of Registrant as Specified in Its Charter)

DELAWARE (State or other jurisdiction

(State or other jurisdiction of incorporation or organization)

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

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

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 \boxtimes No \square

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 Non-Accelerated Filer

(Do not check if a smaller reporting company)

Accelerated Filer□Smaller reporting company⊠Emerging growth company□

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

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

As of August 1, 2017, there were 34,716,318 shares of the registrant's common stock outstanding.

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

92121 (Zip Code)

CYTORI THERAPEUTICS, INC.

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

	As	of June 30, 2017	As o	f December 31, 2016
Assets				
Current assets:				
Cash and cash equivalents	\$	9,028	\$	12,560
Accounts receivable, net of reserves of \$167 in both 2017 and 2016,				
respectively		807		1,242
Restricted cash		429		350
Inventories, net		4,243		3,725
Other current assets		1,116		870
Total current assets		15,623		18,747
Property and equipment, net		3,387		1,157
Other assets		1,712		2,336
Intangibles, net		7,832		8,447
Goodwill		3,922		3,922
Total assets	\$	32,476	\$	34,609
Liabilities and Stockholders' Equity				
Current liabilities:				
Accounts payable and accrued expenses	\$	6,485	\$	5,872
Current portion of long-term obligations, net of discount		6,744		6,629
Total current liabilities		13,229		12,501
Deferred revenues		110		97
Long-term deferred rent and other		136		17
Long-term obligations, net of discount, less current portion		7,771		11,008
Total liabilities		21,246		23,623
		21,240		23,023
Commitments and contingencies (Note 9)				
Stockholders' equity:				
Series A 3.6% convertible preferred stock, \$0.001 par value; 5,000,000 shares authorized; 13,500 shares issued; no shares outstanding in 2017 and 2016		_		_
Common stock, \$0.001 par value; 75,000,000 shares authorized; 33,328,401 and				
21,707,890 shares issued and outstanding in 2017 and 2016, respectively		33		22
Additional paid-in capital		402,670		388,769
Accumulated other comprehensive income		1,183		1,258
Accumulated deficit		(392,656)		(379,063)
Total stockholders' equity		11,230		10,986
Total liabilities and stockholders' equity	\$	32,476	\$	34,609

SEE NOTES TO UNAUDITED CONSOLIDATED CONDENSED FINANCIAL STATEMENTS

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

	For the Three Months Ended June 30,				For the Six Month			
		2017		2016		2017		2016
Product revenues	\$	969	\$	1,126	\$	1,560	\$	2,459
Cost of product revenues		401		503		811		971
Amortization of intangible assets		306		82		612		181
Gross profit		262		541		137		1,307
Development revenues:								
Government contracts and other		531		1,699		1,549		3,284
		531		1,699	-	1,549		3,284
Operating expenses:				<u> </u>		<u> </u>		
Research and development		2,992		5,247		6,281		9,374
Sales and marketing		1,263		889		2,202		1,924
General and administrative		2,119		2,328		4,227		4,614
In process research and development acquired from Azaya Therapeutics		<u> </u>				1,686		
Total operating expenses		6,374		8,464		14,396		15,912
Operating loss		(5,581)		(6,224)	_	(12,710)		(11,321)
Other income (expense):								
Interest income		7		2		18		4
Interest expense		(538)		(645)		(1,129)		(1,302)
Other income, net		63		462		228		876
Total other expense		(468)		(181)		(883)		(422)
Net loss	\$	(6,049)	\$	(6,405)	\$	(13,593)	\$	(11,743)
Basic and diluted net loss per share	\$	(0.19)	\$	(0.43)	\$	(0.50)	\$	(0.84)
Basic and diluted weighted average shares used in calculating net loss per share	Ť	31,250,872	Ť	14,778,616	-	26,993,619	Ť	13,932,496
Comprehensive loss:								
Net loss	\$	(6,049)	\$	(6,405)	\$	(13,593)	\$	(11,743)
Other comprehensive loss – foreign currency translation		(, -)				(, -)		
adjustments		(15)		(130)		(75)		(379)
Comprehensive loss	\$	(6,064)	\$	(6,535)	\$	(13,668)	\$	(12,122)

SEE NOTES TO UNAUDITED CONSOLIDATED CONDENSED FINANCIAL STATEMENTS

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

		For the Six Month	s Ended	l June 30,
		2017		2016
Cash flows from operating activities:				
Net loss	\$	(13,593)	\$	(11,743)
Adjustments to reconcile net loss to net cash used in operating activities:				
Depreciation and amortization		1,052		574
Amortization of deferred financing costs and debt discount		418		468
In process research and development acquired from Azaya Therapeutics		1,686		_
Joint Venture acquisition obligation accretion		—		24
Provision for expired inventory		340		26
Stock-based compensation expense		410		645
Loss on asset disposal		19		2
Increases (decreases) in cash caused by changes in operating assets and liabilities:				
Accounts receivable		409		66
Inventories		159		(380)
Other current assets		(736)		137
Other assets		43		34
Accounts payable and accrued expenses		(194)		(431)
Deferred revenues		13		1
Long-term deferred rent		119		(158)
Net cash used in operating activities		(9,855)		(10,735)
Cash flows from investing activities:				
Purchases of property and equipment		(95)		(105)
Purchase of long-lived assets part of Azaya Therapeutics' acquisition		(1,201)		_
Change in restricted cash		(79)		_
Net cash used in investing activities		(1,375)		(105)
Cash flows from financing activities:				i
Principal payments on long-term obligations		(3,540)		
Joint Venture purchase payments		_		(1,774)
Proceeds from sale of common stock, net		11,225		18,179
Net cash provided by financing activities		7,685		16,405
Effect of exchange rate changes on cash and cash equivalents		13		139
Net (decrease) increase in cash and cash equivalents		(3,532)		5,704
Cash and cash equivalents at beginning of period		12,560		14,338
Cash and cash equivalents at end of period	\$	9,028	\$	20,042
Supplemental disclosure of cash flows information:	÷	5,020	Ψ	20,012
Cash paid during period for: Interest	\$	740	\$	805
Supplemental schedule of non-cash investing and financing activities:	¢	/40	Þ	805
	\$	2 211	\$	
Common stock issued in payment for the assets acquired from Azaya Therapeutics	Ф	2,311	Э	-

SEE NOTES TO UNAUDITED CONSOLIDATED CONDENSED FINANCIAL STATEMENTS

CYTORI THERAPEUTICS, INC. NOTES TO CONSOLIDATED CONDENSED FINANCIAL STATEMENTS June 30, 2017 (UNAUDITED)

1. Basis of Presentation and New Accounting Standards

Our accompanying unaudited consolidated condensed financial statements as of June 30, 2017 and for the three and six months ended June 30, 2017 and 2016 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, 2016 has been derived from the audited financial statements at December 31, 2016, 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 (collectively, the "Company") have been included. Operating results for the three and six months ended June 30, 2017 are not necessarily indicative of the results that may be expected for the year ending December 31, 2017. 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, 2016, filed with the Securities and Exchange Commission on March 24, 2017.

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 stockholders' equity to reflect the 1:15 Reverse Stock Split by reclassifying an amount equal to the par value of the shares eliminated by the split from common stock to the Additional Paid-in Capital during the first quarter of fiscal 2016, resulting in no net impact to stockholders' 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 C

Reclassifications

Certain immaterial reclassifications have been made to certain of the prior years' consolidated financial statements to conform to the current year presentation.

Recently Issued and Recently Adopted Accounting Pronouncements

Recently Issued Accounting Pronouncements

In May 2016, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) No. 2016-12, *Revenue from Contracts with Customers*, the amendment of which addressed 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. In April 2016, March 2016 and December 2016 the FASB issued ASU No. 2016-10, ASU No. 2016-08 and ASU No. 2016-20, respectively, the amendments of which further clarified aspects of Topic 606: identifying performance obligations and the licensing and implementation guidance, improvements to the operability and understandability of the implementation guidance on principal versus agent considerations and contract cost clarifications. The FASB issued the initial release of Topic 606 in ASU No. 2014-09, which requires entities to recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. Entities may use a full retrospective approach or report the cumulative effect as of the date of adoption. On July 9, 2015, the FASB voted to defer the effective date by one year to December 15, 2017 for interim and annual reporting periods beginning after that date. Early adoption of ASU 2016-10 is permitted but not before the original effective date (annual periods beginning after December 15, 2017). We performed a preliminary assessment of the impact of ASU 2014-09 and related



amendments on the consolidated financial statements, and considered all items outlined in the standard. In assessing the impact, we have outlined all revenue generating activities, mapped those activities to deliverables and traced those deliverables to the standard. We are currently assessing what impact the change in standard will have on those deliverables. We will continue to evaluate the future impact and method of adoption of ASU 2014-09 and related amendments on the consolidated financial statements and related disclosures throughout 2017. We will adopt the new standard beginning January 2018.

In February 2016, the FASB issued ASU 2016-02, *Leases*. Under this new guidance, at the commencement date, lessees will be required to recognize (i) a lease liability, which is a lessee's obligation to make lease payments arising from a lease, measured on a discounted basis and (ii) a right-of-use asset, which is an asset that represents the lessee's right to use, or control the use of, a specified asset for the lease term. This guidance is not applicable for leases with a term of 12 months or less. The new standard is effective for annual reporting periods, and interim periods within those periods, beginning after December 15, 2018, with early adoption permitted. We are currently evaluating the impact that this standard will have on our consolidated financial statements.

In August 2016, the FASB issued ASU 2016-15, *Statement of Cash Flows (Topic 230): Classification of certain cash receipts and cash payments*, which addresses the following eight specific cash flow issues: debt prepayment or debt extinguishment costs; settlement of zero-coupon debt instruments or other debt instruments with coupon interest rates that are insignificant in relation to the effective interest rate of the borrowing; contingent consideration payments made after a business combination; proceeds from the settlement of insurance claims; proceeds from the settlement of corporate-owned life insurance policies (including bank-owned life insurance policies); distributions received from equity method investees; beneficial interests in securitization transactions; and separately identifiable cash flows and application of the predominance principle. The new standard is effective for annual reporting periods, and interim periods within those periods, beginning after December 15, 2017, with early adoption permitted. We do not anticipate that the adoption of ASU 2016-15 will have a material impact on our consolidated financial statements.

In November 2016, the FASB issued Accounting Standards Update No. 2016-18, *Restricted Cash*, which requires entities to show the changes in the total of cash, cash equivalents, restricted cash and restricted cash equivalents in the statement of cash flows. As a result, entities will no longer present transfers between cash and cash equivalents and restricted cash and restricted cash equivalents in the statement of cash flows. The amendments in this update should be applied using a retrospective transition method to each period presented. This update is effective for annual periods beginning after December 15, 2017, and interim periods within those fiscal years with early adoption permitted, including adoption in an interim period. The adoption of this standard will change the presentation of our statement of cash flows to include our restricted cash balance with the non-restricted cash balances. We do not anticipate that the adoption of ASU 2016-18 will have a material impact on our consolidated financial statements.

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

In May 2017, the FASB issued ASU 2017-09, *Compensation-Stock Compensation*, to provide clarity and reduce both 1) diversity in practice and 2) cost and complexity when applying the guidance in Topic 718 to a change in the terms or conditions of a share-based payment award. ASU 2017-09 provides guidance about which changes to the terms or conditions of a share-based payment award require an entity to apply modification accounting under Topic 718. The amendments in ASU 2017-09 are effective for fiscal years, and interim periods within those years, beginning after December 15, 2017. Early adoption is permitted, including adoption in any interim period. The amendments in ASU 2017-09 should be applied prospectively to an award modified on or after the adoption date. We do not anticipate that the adoption of ASU 2016-18 will have a material impact on our consolidated financial statements.

Recently Adopted Accounting Pronouncements

In July 2015, FASB issued ASU 2015-11, *Simplifying the Measurement of Inventory*. This update applies to companies that measure inventory on a first in, first out, or FIFO, or average cost basis. Under this update, companies are to measure their inventory at the lower of cost and net realizable value. Net realizable value is the estimated selling prices in the ordinary course of business, less reasonably predictable costs of completion. The amendments in this update are effective for annual reporting periods, and interim periods within those periods, beginning after December 15, 2016 with earlier application permitted as of the beginning of an interim or annual reporting period. The adoption, effective January 1, 2017, did not have a material impact on our consolidated financial statements.

In March 2016, the FASB issued ASU 2016-09, *Improvements to Employee Share-Based Payment Accounting*, which involves several aspects of the accounting for stock-based payment transactions, including the income tax consequences, classification of



awards as either equity or liabilities, and classification on the statement of cash flows. This new guidance will require all income tax effects of awards to be recognized as income tax expense or benefit in the income statement when the awards vest or are settled, as opposed to additional paid-in-capital where it is currently recorded. It also will allow an employer to repurchase more of an employee's shares than it can today for tax withholding purposes without triggering liability accounting. All tax-related cash flows resulting from stock-based payments are to be reported as operating activities on the statement of cash flows. The guidance also allows a Company to make a policy election to either estimate the number of awards that are expected to vest or account for forfeitures as they occur. This new standard is effective for annual reporting periods, and interim periods within those periods, beginning after December 15, 2016, with early adoption permitted. We have elected to keep our policy consistent for the application of a forfeiture rate and, as such, the adoption of this standard did not have a material impact on our consolidated financial statements.

In January 2017, the FASB issued Accounting Standards Update No. 2017-01, *Clarifying the Definition of a Business*, which clarifies and provides a more robust framework to use in determining when a set of assets and activities is a business. The amendments in this update should be applied prospectively on or after the effective date. This update is effective for annual periods beginning after December 15, 2017, and interim periods within those periods. Early adoption is permitted for acquisition or deconsolidation transactions occurring before the issuance date or effective date and only when the transactions have not been reported in issued or made available for issuance financial statements. We elected to early adopt the new guidance effective January 1, 2017 and this guidance was used in our assessment of the Azaya Therapeutics asset purchase agreement entered into in February 2017.

2. Use of Estimates

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

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

3. Liquidity

We incurred net losses of \$6.0 million and \$13.6 million for the three and six months ended June 30, 2017, and \$6.4 million and \$11.7 million for the three and six months ended June 30, 2016. We have an accumulated deficit of \$392.7 million as of June 30, 2017. Additionally, we have used net cash of \$9.9 million and \$10.7 million to fund our operating activities for the six months ended June 30, 2017 and 2016, respectively. These factors raise substantial doubt about the Company's ability to continue as a going concern.

Further, the Loan and Security Agreement, with Oxford Finance, LCC ("Oxford"), as further described in Note 5, requires us to maintain a minimum of \$5.0 million in unrestricted cash and cash equivalents on hand to avoid an event of default under the Loan and Security Agreement. Based on our cash and cash equivalents on hand of approximately \$9.0 million at June 30, 2017, and our obligation to make payments of principal of \$0.6 million plus accrued interest in monthly installments, we estimate that we must raise additional capital and/or obtain a waiver or restructure the Loan and Security Agreement in September 2017 to avoid defaulting under our \$5.0 million minimum cash/cash equivalents covenant.

To date, these operating losses have been funded primarily from outside sources of invested capital including our recently completed underwritten public offering, Lincoln Park Purchase Agreement with Lincoln Park Capital Fund, LLC ("Lincoln Park") and the Rights Offering (each defined below), our at-the-market ("ATM") equity facility, the Loan and Security Agreement and gross profits. We have had, and we will continue to have, an ongoing need to raise additional cash from outside sources to fund our future clinical development programs and other operations. Our inability to raise additional cash will have a material and adverse impact on operations and will cause us to default on our loan.

On April 11, 2017, we entered into an underwriting agreement (the "Underwriting Agreement") with Maxim Group LLC "Maxim") relating to the issuance and sale of 8.6 million shares of our common stock, par value \$0.001 per share. The price to the public in this offering was \$1.10 per share. Maxim agreed to purchase the shares from us pursuant to the Underwriting Agreement at a price of \$1.0395 per share. The net proceeds to us from the offering were approximately \$8.7 million, after deducting underwriting discounts and commissions and estimated offering expenses payable by us. The offering closed on April 17, 2017. In addition, under the terms of the Underwriting Agreement, we granted Maxim a 45-day option to purchase up to 944,000 additional shares of common stock. On May 31, 2017, Maxim exercised their overallotment option and purchased



849,000 shares at \$1.10 per share. The net proceeds to us were \$0.8 million, after deducting underwriting costs and offering expenses payable by us.

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.

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

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

4. 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 \$6.0 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, 2017 and December 31, 2016.

5. Long-term Debt

On May 29, 2015, we entered into the Loan and Security Agreement, dated May 29, 2015, with Oxford, 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 and Security Agreement. The Term Loan accrues interest at a floating rate of at least 8.95% per annum, comprised of three-month LIBOR rate with a floor of 1.00% plus 7.95%. Pursuant to the Loan and Security Agreement, we were previously required to make interest only payments through June 1, 2016 and thereafter we were required to make payments of principal and accrued interest in equal monthly installments sufficient to amortize the Term Loan through June 1, 2019, the maturity date. On February 23, 2016, we received an acknowledgement and agreement from Oxford related to the positive data on our U.S. ACT-OA clinical trial. As a result, pursuant to the Loan and Security Agreement, the period for which we are required to make interest-only payments was extended from July 1, 2016 to January 1, 2017. All unpaid principal and interest with respect to the Term Loan 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, we are required to make a final payment in an aggregate amount equal to approximately \$1.1 million. In connection with the Term Loan, on May 29, 2015, we issued to Oxford warrants to purchase an aggregate of 94,441 shares of our common stock at an exercise price of \$10.35 per share. These warrants became exercisable as of November 30, 2015 and will expire on May 29, 2025 and, following the authoritative accounting guidance, are equity classified and its respective fair value was recorded as a discount to the debt.

The Term Loan is collateralized by a security interest in substantially all of the Company's existing and subsequently acquired assets, subject to certain exceptions set forth in the Loan and Security Agreement and excluding its intellectual property assets, which are subject to a negative pledge. The minimum liquidity covenant is \$5.0 million. As of June 30, 2017, we were in compliance with all of the debt covenants under the Loan and Security Agreement.

Our interest expense for the three and six months ended June 30, 2017 was \$0.5 million and \$1.1 million and for the three and six months ended June 30, 2016 was \$0.6 million and \$1.3 million, respectively. Interest expense is calculated using the effective interest method, therefore it is inclusive of non-cash amortization in the amount of \$0.2 million and \$0.4 million for the three and six months ended June 30, 2017 and \$0.2 million and \$0.5 million for the three and six months ended June 30, 2016, related to the amortization of the debt discount, capitalized loan costs, and accretion of final payment.

The Term Loan Agreement contains customary indemnification obligations and customary events of default, including, among other things, our failure to fulfill certain obligations under the Term Loan and the occurrence of a material adverse change, which is defined as a material adverse change in our business, operations, or condition (financial or otherwise), a material impairment of the prospect of repayment of any portion of the loan. In the event of default by us under the Term Loan, the lender would be entitled to exercise its remedies thereunder, including the right to accelerate the debt, upon which we may be required to repay all amounts then outstanding under the Term Loan, which could harm our financial condition. Oxford has not invoked the material adverse change clause.



6. Revenue Recognition

Concentration of Significant Customers

Three direct customers comprised 63% of our revenue recognized for the six months ended June 30, 2017. Two direct customers accounted for 77% of total outstanding accounts receivable (excluding receivables from the Biomedical Advanced Research Development Authority, a division of the U.S. Department of Health and Human Services ("BARDA")) as of June 30, 2017.

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 as of June 30, 2016.

Product revenues, classified by geographic location, are as follows (in thousands):

		Three mont	ths ended		Six months ended							
	 June 30), 2017	June	30, 2016	June 3	80, 2017	June 3	0, 2016				
	roduct venues	% of Total	Product Revenues	% of Total	Product Revenues	% of Total	Product Revenues	% of Total				
Americas	\$ 55	6%	\$ 356	31%	5 \$ 203	13%	\$ 591	24%				
Japan	835	86%	690	61%	б 1,155	74%	1,657	67%				
EMEA	74	8%	74	7%	б 186	12%	205	8%				
Asia Pacific	5	0%	е	1%	б 16	1%	6	1%				
Total product revenues	\$ 969	100%	\$ 1,126	100%	\$ 1,560	100%	\$ 2,459	100%				

Research and Development

We earn revenue for performing tasks under research and development agreements with governmental agencies like BARDA. Revenues derived from reimbursement of direct out-of-pocket expenses for research costs associated with government contracts are recorded as government contracts and other within development revenues. Government contract revenue is recorded at the gross amount of the reimbursement. The costs associated with these reimbursements are reflected as a component of research and development expense in our statements of operations. We recognized \$0.5 million and \$1.5 million in BARDA revenue for the three and six months ended June 30, 2017, as compared to \$1.7 million and \$3.3 million for the three and six months ended June 30, 2016.

7. Inventories

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

Inventories consisted of the following (in thousands):

	June 30, 20	June 30, 2017					
Raw materials	\$ 1	,522	\$	885			
Work in process		996		1,021			
Finished goods	1	,725		1,819			
	\$ 4	243	\$	3 725			

8. Loss per Share

Basic per share data is computed by dividing net income or loss applicable to common stockholders by the weighted average number of common shares outstanding during the period. Diluted per share data is computed by dividing net income or loss applicable to common stockholders by the weighted average number of common shares outstanding during the period increased to include, if dilutive, the number of additional common shares that would have been outstanding as calculated using the treasury stock method. Potential common shares were related 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, 2017 and 2016, as their inclusion would be antidilutive. Potentially dilutive common shares excluded from the calculations of diluted loss per share were 4.9 million for both the three and six months ended June 30, 2017, which includes 3.6 million outstanding warrants and 1.3 million options and restricted stock awards. Potentially dilutive common shares excluded from the calculation of diluted loss per share were 4.2 million for the three and six months ended June 30, 2017.

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, 2017, we have clinical research study obligations of \$2.3 million, which is expected to be paid within a year. Should the timing of the clinical trials change, the timing of the payment of these obligations would also change.

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, 2017, we have a minimum purchase obligation of \$7.5 million, \$0.5 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.

On February 27, 2017, we entered into a Lease Agreement of office space for our corporate headquarters in San Diego, California (the "Lease"). The initial term of the Lease is 63 months and may be extended upon mutual agreement. We are scheduled to take possession of the premises on November 1, 2017, unless they are earlier occupied by us or the commencement date is delayed to allow for substantial completion of tenant improvements. In connection with the Lease, we issued a letter of credit, or Letter of Credit, in favor of the Landlord in the initial principal amount of approximately \$0.1 million, which Letter of Credit and corresponding restricted cash increased to \$0.3 million on June 1, 2017, and will increase to \$0.5 million on the commencement date. The Letter of Credit will remain in effect for the term of the Lease.

In addition to the base rent, we will also be obligated under the Lease to make certain payments for operating expenses, property taxes, insurance, insurance deductibles and other amounts.

On January 27, 2017, we entered into a Lease Agreement of office space for our office in Tokyo, Japan (the "Japan Lease"). The initial term of the Japan Lease is 61 months, and may be extended upon mutual agreement. The Lease commenced on April 15, 2017.

We lease facilities for our headquarters office location as well as international office locations. As of June 30, 2017, we have remaining lease obligations of \$7.5 million, \$1.7 million of which are expected to be completed within a year.

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, 2017, and as of December 31, 2016, the Company did not have any assets or liabilities measured at fair value presented on the Company's balance sheets.

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, 2017 and December 31, 2016, 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 equivalents, accounts receivable, other current assets, accounts payable, accrued expenses and other liabilities approximate fair value due to the short-term nature of these instruments. Further, based on the borrowing rates currently available for loans with similar terms, we believe the fair value of long-term debt approximates its carrying value.

11. Asset Purchase Agreement with Azaya Therapeutics

On February 15, 2017 (the "Closing Date"), we completed the acquisition from Azaya Therapeutics, Inc. ("Azaya") of certain tangible assets which consisted of a research lab, equipment and leasehold improvements and the assumption of certain of liabilities of Azaya, pursuant to an Asset Purchase Agreement (the "Agreement"). The book value of the tangible assets acquired was approximately \$3.0 million at the acquisition date. The assets acquired are located in a facility rented in San Antonio, TX, by Cytori. In addition, pursuant to the Agreement, we acquired intangible assets comprised of two drug candidates in process research and development (IPR&D) stage (i) ATI-0918, a generic bioequivalent formulation of DOXIL/CAELYX, a chemotherapy drug that is a liposomal formulation of doxorubicin (ATI-0918); and (ii) ATI-1123, a liposomal formulation of docetaxel (ATI-1123).

At the closing of the acquisition, we (i) issued 1,173,241 of shares of our common stock in Azaya's name, (A) 879,931 of which were delivered to Azaya promptly after the Closing, and (B) 293,310 of which were deposited into a 15-month escrow pursuant to a standard escrow agreement; and (ii) assumed the obligation to pay approximately \$1.8 million of Azaya's existing payables, all of which were paid on or prior to June 30, 2017. At the Closing Date, Azaya had no employees and therefore no Azaya employees were transitioned to us.

In addition, as of the Closing Date, the Company committed to certain contingent considerations to: (i) pay Azaya fixed commercialization milestone payments based upon achievement of certain net sales milestones for ATI-0918; (ii) make certain earn-out payments to Azaya equal to a mid-single-digit percentage of net sales of ATI-0918; and (iii) make certain earn-out payments to Azaya equal to a low single-digit percentage of net sales of any product (each a "Patented Product"), including ATI-1123, that practices a claim in the related patent assigned by Azaya to the Company (the "ATI-1123 Patent"). Our aggregate earn-out payment obligations to Azaya from global net sales of both ATI-0918 and any Patented Product will not exceed \$100.0 million (the "Earn-Out Cap").

Further, the Agreement provides that if we enter into certain assignments, licenses or other transfers of rights to a Patented Product or the ATI-1123 Patent, we will pay Azaya a percentage in the low to mid-teens of the consideration received by us, provided, that our aggregate payment obligation to Azaya for any such assignment, license or other transfer of rights will not exceed \$50.0 million.

If the Company or its successors, sublicenses or transferees sells a competing product to ATI-0918 at any time prior to satisfaction of the Earn-Out Cap, other than because ATI-0918 fails to receive marketing authorization from the European Medicines Agency within a certain period of time or fails to generate a minimum threshold of net sales within a pre-determined amount of time, then 50% of the net sales of such competing product would be deemed to be net sales of ATI-0918 under the Agreement for purposes of calculating commercialization milestone payments and earn-out payments.

We accounted for the acquisition as an asset acquisition because the acquired set of assets did not meet the definition of a business. The total consideration of \$4.3 million, which consists of \$2.3 million related to the fair value of the common stock issued to Azaya at the acquisition date, \$1.8 million in assumed liabilities and \$0.2 million in acquisition costs, was allocated to the assets acquired based on their relative fair values at the time of acquisition. All other future payments were deemed contingent consideration which will be accounted for when the contingency is resolved and the consideration is paid or becomes payable.

When determining the fair value of tangible assets acquired, the Company estimated the cost to replace the tangible asset with a new asset, taking into consideration such factors as age, condition and the economic useful life of the asset. When determining the fair value of intangible assets acquired, the Company used a discounted cash flow model with key inputs being the applicable discount rate, market growth rates and the timing and amount of future cash flows. The acquired IPR&D is in the early stage of development. Additional research, pre-clinical studies, and regulatory approvals must be successfully completed prior to selling any product. Because there is no current alternative use for the IPR&D, following the authoritative accounting guidance, the Company has expensed it in full on the Closing Date. The Company measured the fair value of the shares issued as consideration in the acquisition of the assets based on the stock price at the acquisition date. Transaction costs directly related to the acquisition of the assets have been capitalized. The total consideration was allocated on a relative fair value basis to the assets acquired, as follows (in thousands):

	Februa	ry 15, 2017
Tangible assets	\$	2,586
Intangible assets		1,686
Total assets	\$	4,272
Accounts payable	\$	1,796
Fair value of the common stock issued		2,311
Transaction costs		165
Total consideration	\$	4,272

12. Stockholders' Equity

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. The warrants issued pursuant to the Rights Offering are currently listed on NASDAQ under the symbol "CYTXW." Based on the relevant authoritative accounting guidance, the warrants were equity classified at the issuance date. The warrants may be redeemed by the Company at \$0.01 per warrant prior to their expiration if the Company's common stock closes above \$7.65 per share for 10 consecutive trading days.

On December 22, 2016, we entered into a Purchase Agreement (the "Lincoln Park Purchase Agreement") with Lincoln Park Capital, LLC ("Lincoln Park") pursuant to which we have the right to sell to Lincoln Park and Lincoln Park is obligated to purchase up to \$20.0 million in amounts of shares, of our common stock, over the 30-month period commencing on the date that a registration statement, which we filed with the SEC in December 2016. We may direct Lincoln Park, at its sole discretion and subject to certain conditions, to purchase up to 100,000 shares of common stock on any business day but in no event will the amount of a single Regular Purchase (as defined in the Lincoln Park Purchase Agreement) exceed \$1.0 million. The purchase price of shares of common stock related to the Regular Purchases will be based on the prevailing market prices of such shares at the time of sales. Our sales of shares of common stock to Lincoln Park under the Lincoln Park Purchase Agreement are limited to no more than the number of shares that would result in the beneficial ownership by Lincoln Park and its affiliates, at any single point in time, of more than 9.99% of the then outstanding shares of the common stock. There are no trading volume requirements or restrictions under the Lincoln Park Purchase Agreement. There is no upper limit on the price per share that Lincoln Park must pay for common stock under a Regular Purchase or an accelerated purchase and in no event will shares be sold to Lincoln Park on a day our closing price is less than the floor price of \$0.50 per share as set forth in the Purchase Agreement. On December 22, 2016, we issued to Lincoln Park 127,419 shares of common stock with a market value on the date of issuance of approximately \$0.2 million as commitment shares in consideration for entering into the Lincoln Park Purchase Agreement. We will issue up to an additional 382,258 shares of common stock on a pro rata basis to Lincoln Park only as and when shares are sold under the Lincoln Park Purchase Agreement to Lincoln Park. Through June 30, 2017, we sold a total of 103,000 shares under the Lincoln Park Purchase Agreement, for proceeds of approximately \$0.2 million.

During the six months ended June 30, 2017, we sold 894,050 shares of our common stock under an ATM program, receiving total net proceeds of approximately \$1.5 million. During 2016, we sold 1,840,982 shares of our common stock under an ATM program, receiving total net proceeds of approximately \$4.4 million.



On April 11, 2017, we entered into an underwriting agreement with Maxim relating to the issuance and sale of 8.6 million shares of our common stock, par value \$0.001 per share. The price to the public in this offering is \$1.10 per share. Maxim agreed to purchase the shares from us pursuant to the Underwriting Agreement at a price of \$1.0395 per share. The net proceeds to us from the offering were approximately \$8.7 million, after deducting underwriting discounts and commissions and estimated offering expenses payable by us. The offering closed on April 17, 2017. In addition, under the terms of the underwriting agreement, we granted Maxim a 45-day overallotment option to purchase up to 944,000 additional shares of common stock. On May 31, 2017, Maxim exercised their overallotment option and purchased 849,000 shares at \$1.10 per share. The net proceeds to us were \$0.8 million, after deducting underwriting costs and offering expenses payable by us.

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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, 2016.

CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING STATEMENTS

This report contains certain statements that may be deemed "forward-looking statements" within the meaning of U.S. securities laws. All statements, other than statements of historical fact, that address activities, events or developments that we intend, expect, project, believe or anticipate and similar expressions or future conditional verbs such as will, should, would, could or may occur in the future are forward-looking statements. Such statements are based upon certain assumptions and assessments made by our management in light of their experience and their perception of historical trends, current conditions, expected future developments and other factors they believe to be appropriate.

These statements include, without limitation, statements about our anticipated expenditures, including research and development, sales and marketing, and general and administrative expenses; the potential size of the market for our products; future development and/or expansion of our products and therapies in our markets, our ability to generate product or development revenues and the sources of such revenues; our ability to effectively manage our gross profit margins; our ability to obtain and maintain regulatory approvals; expectations as to our future performance; portions of the "Liquidity and Capital Resources" section of this report, including our potential need for additional financing and the availability thereof; our ability to continue as a going concern; our ability to remain listed on the NASDAQ Capital Market; our ability to repay or refinance some or all of our outstanding indebtedness and our ability to raise capital in the future; and the potential enhancement of our cash position through development, marketing, and licensing arrangements. Our actual results will likely differ, perhaps materially, from those anticipated in these forward-looking statements as a result of various factors, including: the early stage of our product candidates and therapies; 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, Habeo Cell Therapy, Celution StemSource and Cytori Nanomedicine. Solely for convenience, our trademarks and tradenames referred to in this Form 10-Q may appear without the \mathbb{B} or \mathbb{T} 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.

Overview

Our strategy is to build a profitable and growing specialty therapeutics company focused on rare and niche opportunities frequently overlooked by larger companies but requiring breadth of scope, expertise and focus often not possessed by or available to smaller companies. To meet this objective, we have, thus far, identified two therapeutic development platforms, discussed below, and candidate therapeutics in our pipeline that hold promise for many patients and significant market potential. Our current corporate activities fall substantially into one of two key areas related to our two therapeutic development platforms: Cytori Cell Therapy and

Cytori Nanomedicine.

Cytori Cell Therapy, or "CCT", is based on the scientific discovery that the human adipose or fat tissue compartment is a source of a unique mixed population of stem, progenitor and regenerative cells that may hold substantial promise in the treatment of numerous diseases and conditions. To bring this promise to health providers, we are developing novel therapies prepared and administered at the patient's bedside with proprietary technologies that include therapyspecific reusable, automated Celution devices and single-use procedure sets consisting of Celution consumables, Celase reagent, and Intravase reagent. Our lead product candidate, HabeoTM Cell TherapyTM, is being evaluated in a U.S. pivotal clinical trial for the treatment of impaired hand function in scleroderma. On July 24, 2017, we announced top-line, preliminary data from our Phase III pivotal STAR trial of Habeo in patients with scleroderma. The U.S. multi-center STAR trial enrolled and evaluated 88 patients with scleroderma, including 51 patients within the diffuse cutaneous subset and 37 with limited cutaneous scleroderma. While the primary and secondary endpoints did not reach statistical significance at 24 or 48 weeks, the trial data reported clinically meaningful improvement in the primary and secondary endpoints of both hand function and scleroderma-associated functional disability, for Habeo treated patients compared to placebo, in the pre-specified subgroup of patients with diffuse cutaneous scleroderma. Additional CCT treatments are in various stages of development in the areas of immunology, urology, wound healings, and orthopedics. Further, our CCT platform is the subject of investigatorinitiated trials conducted by our partners, licensees and other third parties, some of which are supported by us and/or funded by government agencies and other funding sources. Currently, we internally manufacture the CCT processing device and procedure sets in the United States. and the United Kingdom and source our Celase and Intravase reagents from a third-party supplier. We also have obtained regulatory approval to sell some of our CCT products, including our Celution devices and disposable components, in certain markets outside the United States. In those markets, we have been able to further develop and improve our core technologies, gain expanded clinical and product experience and data, and generate sales.

The Cytori Nanomedicine platform features a liposomal nanoparticle technology for drug encapsulation that has thus far provided the foundation to bring two promising drugs into early/late stage clinical trials. Nanoparticle encapsulation is promising because it can help improve the trafficking and metabolism of many drugs, thus potentially enhancing the therapeutic profile and patient benefits. Our lead drug candidate, ATI-0918 is a generic version of pegylated liposomal encapsulated doxorubicin is a heavily relied upon chemotherapeutic used in many cancer types on a global basis. We believe that data from a 60-patient European study of ATI-0918 has met the statistical criteria for bioequivalence to CAELYX®, the current reference listed drug in Europe. We intend that these bioequivalence data will serve as a basis for our planned regulatory submission to the European Medicines Agency, or EMA, for ATI-0918. We are currently evaluating our options to ATI-0918 in the U.S. market. Our second nanomedicine drug candidate is ATI-1123, a novel and new chemical entity which is a nanoparticle-encapsulated form of docetaxel, also a standard chemotherapeutic drug used for many cancers. A Phase I clinical trial of ATI-1123 has been completed, and we are investigating possible expansion of this trial to Phase II, potentially in conjunction with a development partner. In addition, we are early in the long-term research and development of encapsulated regenerative medicine drugs, focused first on the treatment of scleroderma and related connective disorders. Finally, in connection with our acquisition of the ATI-0918 and ATI-1123 drug candidates, we have acquired know-how (including proprietary processes and techniques) and a scalable nanoparticle manufacturing plant in San Antonio, Texas from which we intend to test, validate and eventually manufacture commercial quantities of our nanoparticle drugs.

Cytori Cell Therapy

The 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 Cytori-sponsored <u>S</u>cleroderma <u>T</u>reatment with Celution Processed <u>A</u>dipose Derived <u>R</u>egenerative Cells, or STAR clinical trial, is a randomized, double-blind, placebo-controlled, Phase III pivotal clinical trial in the U.S. The purpose of the STAR trial is to evaluate the safety and efficacy of a single administration of HabeoTM Cell Therapy (formerly named ECCS-50) in patients with scleroderma affecting the hands. The first sites for our STAR trial were initiated in July 2015 and final enrollment of 88 patients was completed in June 2016. As noted above, preliminary assessment of unblinded topline data show that while the primary and secondary endpoints did not reach statistical significance at 24 or 48 weeks, the trial data reported clinically meaningful improvement in the primary and secondary endpoints of both hand function and scleroderma associated functional disability, for Habeo treated patients compared to placebo, in the subgroup of patients with diffuse cutaneous scleroderma.

With respect to the remainder of our current cellular therapeutics clinical pipeline:

- We completed our Phase II Celution Prepared <u>A</u>dipose Derived Regenerative <u>C</u>ells in the <u>T</u>reatment of <u>O</u>steo<u>A</u>rthritis of the Knee, or ACT-OA clinical trial, in June 2015. The 48-week analysis of the ECCO-50 therapeutic was performed as planned and the top-line data are described in the "Osteoarthritis" section below.
- In July 2015, a Japanese investigator-initiated study of the ECCI-50 therapeutic in men with stress urinary incontinence, or SUI, following prostatic surgery for prostate cancer or benign prostatic hypertrophy, called ADRESU, received



approval to begin enrollment from the Japanese Ministry of Health, Labor and Welfare, or MHLW. In June 2017, the ADRESU trial had over 66% enrolled. The Japan Agency for Medical Research and Development, or AMED, has provided partial funding for the ADRESU trial.

• We are developing the DCCT-10 therapeutic for thermal burns under a contract from the Biomedical Advanced Research Development Authority, or BARDA, a division of the U.S. Department of Health and Human Services. In April 2017, we received approval of an Investigational Device Exemption ("IDE") from the U.S. Food and Drug Administration ("FDA") to conduct a pilot clinical trial of CCT in patients with thermal burn injuries. This trial is referred to as the RELIEF clinical trial. In May 2017, we announced BARDA's exercise of Option 2 of up to approximately \$13.4 million to fund RELIEF. We anticipate initiation of RELIEF in 2017.

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 customers in Europe, Japan and other regions. These customers are a mix of research customers evaluating new therapeutic applications of Cytori Cell Therapy and commercial customers, including our licensing partners, distributors, and end user hospitals, clinics and physicians, that use our Celution cell processing system (as further described in *"Sales, Marketing and Service"* below) mostly for treatment of patients in private pay procedures. In Japan, our largest commercial market, we gained increased utilization of our products in the private pay marketplace in 2016 due to several factors, including increased clarity around the November 2014 Regenerative Medicine Law (implemented in November 2015 as it relates to regenerative medicine products like Cytori Cell Therapy) and we project that our sales of consumable sets and market presence in Japan will continue to grow in 2017. The sale of Celution devices, procedure sets, and ancillary products contribute 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. It also provides us with product and customer feedback.

Habeo Cell Therapy for Impaired Hand Function in Scleroderma and Secondary Raynaud's Phenomenon

Scleroderma is a rare and chronic connective tissue disease generally classified as an autoimmune rheumatic disorder. An estimated 300,000 Americans have scleroderma, about one-third of whom have the systemic form of the disease, known as systemic sclerosis (SSc). SSc is further sub-classified as diffuse cutaneous and limited cutaneous SSc. Diffuse subset has more severe disease with significant hand dysfunction and internal organ involvement. Diffuse scleroderma accounts for between one third and one half of all cases of systemic sclerosis. Women are affected four times more frequently than men and the condition is typically detected between the ages of 30 and 50. More than 90% of scleroderma patients are afflicted with hand involvement that is typically progressive and can result in chronic pain, blood flow changes and severe dysfunction. A small number of treatments are occasionally used off-label for hand scleroderma, but they do little to modify disease progression or substantially improve symptoms. Current 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, prostanoids, Endothelin-1 receptor antagonists, and immunosuppressants may be used but are often accompanied by side effects. If these medications are unsuccessful, health providers may perform a sympathectomy to remove nerves to increase blood flow and decrease long-term pain.

SCLERADEC-I is a completed, investigator-initiated, 12-patient, open-label, Phase I pilot trial sponsored by Assistance Publique-Hôpitaux de Marseille, or AP-HM, in Marseille, France. The SCLERADEC I trial received partial support from Cytori. The six-month 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. Two-year follow up data in the SCLERADEC I trial was presented at the Systemic Sclerosis World Congress in February 2016 and published in the journal *Current Research in Translational Medicine* in November 2016 and demonstrated sustained improvement in the following four key endpoints: CHFS, SHAQ, RCS, and hand pain, as assessed by a standard visual analogue scale.

Further, on December 5, 2016, we released topline results for three-year follow-up data showing sustained benefits materially consistent with those shown in two-year data.

In 2014, Drs. Guy Magalon and Brigitte Granel, under the sponsorship of AP-HM, submitted a study for review for a follow-up randomized, double-blind, placebo-controlled trial in France using Cytori Cell Therapy, to be supported by us. The trial, named SCLERADEC II, received approval from the French government in April 2015. Enrollment of this trial commenced in October 2015 and is ongoing. The trial is currently approaching 75% enrollment and we expect enrollment to be completed in 2017, approximately one year later than originally projected, due to delays in French regulatory approvals of participating sites. Patients will be followed at six-month post-treatment and compared with placebo treated patients. Pending the six-month results patients in the placebo group will be eligible for crossover using Habeo cells stored at the time of the initial procedure. This crossover arm will open after all patients have completed six-month follow up.

Based on the results of the SCLERADEC-I trial, we initiated the US-based STAR trial. The STAR trial is a 48-week, 19 site, randomized, double blind, placebo-controlled pivotal clinical trial of 88 patients in the U.S. for the treatment of impaired hand



function in scleroderma. The trial evaluates the safety and efficacy of a single administration of Habeo Cell Therapy 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 24 weeks and 48 weeks (approximately 6 and 12 months) after a single administration of Habeo Cell Therapy or placebo. Of the 88 patients enrolled in STAR, 51 had diffuse cutaneous scleroderma while 37 had the limited form of the disease.

On July 24, 2017, we announced top-line, preliminary data from the STAR trial. While the primary and secondary endpoints did not reach statistical significance at 24 or 48 weeks, the trial data reported clinically meaningful improvement in the primary and secondary endpoints of both hand function and scleroderma-associated functional disability for Habeo[™] treated patients compared to placebo, in the subgroup of patients with diffuse cutaneous scleroderma.

In November 2016, the US FDA Office of Orphan Products Development granted Cytori an orphan drug designation for cryopreserved or centrally processed ECCS-50 (Habeo) for scleroderma.

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.

ACT-OA, was 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 was 1:1:1 between the control, low and high dose groups. The trial was completed in June 2015. The goal of this proof-of-concept trial was 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.

We completed top-line analysis of the final 48-week data in July 2016. A total of 94 patients were randomized (33 placebo, 30 low dose ECCO-50, 31 high dose ECCO-50). In general, a clear difference between low and high dose ECCO-50 was not observed and therefore the data for both groups have been combined. We evaluated numerous endpoints 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 were 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 were observed in all six pre-specified MRI Osteoarthritis Knee Score (MOAKS) classification scores suggesting a lower degree of target knee joint pathological worsening at 48 weeks for the treated group relative to placebo control group. The differences against placebo favored ADRCs, some parameters achieving statistical significance, specifically in the number of bone marrow lesions, the percentage of the bone marrow lesion that is not a cyst, the size of the bone marrow lesions as a percentage of the total sub-region volume, percentage of full thickness cartilage loss, cartilage loss as a percentage of cartilage surface area and the size of the largest osteophyte.

In summary, the ACT-OA Phase II trial demonstrated feasibility of same day fat harvesting, cell processing and intraarticular administration of autologous ADRCs (ECCO-50) with a potential for a beneficial effect of ECCO-50. The accumulated data and experienced gained will be critical in considering designs of further clinical trials in osteoarthritis and other potential indications. In addition, we are actively pursuing partnering and commercialization opportunities for ECCO-50 to further develop our knee osteoarthritis program and also to support our growing commercial sales into the knee osteoarthritis market in Japan.

Stress Urinary Incontinence

Another therapeutic target under evaluation by Cytori led by the University of Nagoya and three other sites and partially supported by 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 ADRCs prepared by our Celution System. The ADRESU trial is a 45 patient, investigator-initiated, open-label, multi-center, single arm trial that was approved by the Japanese 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. Trial enrollment began in September 2015, and in June 2017, the trial is over 66% enrolled. This clinical trial is primarily sponsored and funded by the Japanese government, including a grant provided by AMED.

Cutaneous and Soft Tissue Thermal and Radiation Injuries

We are also developing Cytori Cell Therapy, or DCCT-10, for the treatment of thermal burns. In the third quarter of 2012, we were awarded a contract by BARDA valued at up to \$106 million to develop a medical countermeasure for thermal burns. The total award under the BARDA contract has been intended to support all clinical, preclinical, regulatory and technology development activities needed to complete the FDA approval process for use of DCCT-10 in thermal burn injury under a device-based pre-market authorization ("PMA") regulatory pathway and to provide preclinical data in burn complicated by radiation exposure.

Pursuant to this contract, BARDA initially awarded us approximately \$4.7 million over the initial two-year base period to fund preclinical research and continued development of our Celution System to improve cell processing. In August 2014, BARDA determined that Cytori had completed the objectives of the initial phase of the contract, and exercised its first contract option in the amount of approximately \$12 million. In December 2014 and September 2016, BARDA exercised additional contract options pursuant to which it provided us with \$2.0 million and \$2.5 million in supplemental funds, respectively. These additional funds supported continuation of our research, regulatory, clinical and other activities required for submission of an IDE request to the FDA for RELIEF, a pilot clinical trial using DCCT-10 for the treatment of thermal burns. In April 2017, we received approval of an IDE from the FDA to conduct a pilot clinical trial of CCT in patients with thermal burn injuries. This trial is referred to as the RELIEF clinical trial. In May 2017, we announced BARDA's exercise of Option 2 of up to approximately \$13.4 million to fund RELIEF.

In accordance with the terms of the Amendments, BARDA will provide us with reimbursement of costs incurred, plus payment of a fixed fee, in the aggregate amount of up to approximately \$13.4 million (the "Funding Amount"). We are responsible for further costs in excess of the Funding Amount, if any, to meet the objectives of the Pilot Trial. The Amendments also extend the term of the BARDA Agreement and the period of performance of Option 2 of the BARDA Agreement to November 30, 2020.

Other recent developments for Cytori Cell 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 systemic sclerosis under Community Register of Orphan Medicinal Products number EU/3/16/1643.
- In February 2017, the U.S. FDA Division of Industry and Consumer Education, or DICE, granted us Small Business status for fiscal year 2017, thus entitling us to receive significant financial incentives, fee reductions, and fee waivers for selective FDA medical device regulatory filings. We anticipate that this grant of small business status will substantially reduce filing fees in 2017 for our planned PMA application for Habeo Cell Therapy, should the STAR Phase III data support filing of this application.

Cytori Nanomedicine

In February 2017, we completed our acquisition of the assets of Azaya Therapeutics, Inc., or Azaya, pursuant to the terms of an Asset Purchase Agreement, dated January 26, 2017. Pursuant to the terms of the agreement, we acquired equipment, certain intellectual property including, a portfolio of investigational therapies and related assets, and assumed certain liabilities, from Azaya in exchange for the issuance of 1,173,241 of shares of our common stock in the amount of \$2.3 million, assumption of approximately \$1.8 million in Azaya's payables, and the obligation to pay Azaya future milestones, earn-outs and licensing fees. The acquisition of Azaya brought two additional product candidates, ATI-0918 and ATI-1123, into the Cytori pipeline and we intend to develop and potentially commercialize both compounds, most likely in conjunction with a commercial and or commercial partner.

ATI-0918 is a complex generic formulation of the market leading DOXIL®/CAELYX®, which is a pegylated liposomal encapsulation of doxorubicin and approved in the United States for use in ovarian cancer, multiple myeloma, and Kaposi's Sarcoma; and in the European Union for breast cancer, ovarian cancer, multiple myeloma, and Kaposi's Sarcoma. The current approval pathway for ATI-0918 is to leverage existing bioequivalence data to CAELYX® for approval in the EU and to demonstrate bioequivalence to Lipodox® in the U.S. A study to demonstrate ATI-0918's bioequivalence to CAELYX®, for purposes of EMA approval, has been completed and we intend for these data to serve as the basis for our submission of a marketing authorization application for ATI-0918 to the EMA. We are also making plans to perform a bioequivalence study of ATI-0918 to the U.S. Reference Standard (RS) to serve as the basis for submission of an ANDA for U.S. FDA approval. We currently anticipate that any U.S. bioequivalence trial for ATI-0918 would be funded by a development partner or licensee.

ATI-1123 is a novel liposomal formulation of docetaxel. Docetaxel is currently approved for non-small cell lung cancer, breast cancer, squamous cell carcinoma of the head and neck cancer, gastric adenocarcinoma, and hormone refractory prostate cancer. Its side effects include hair loss, bone marrow suppression, and allergic reactions. It is currently available as a generic drug and there is no form of docetaxel as a liposomal formulation. There is a protein (albumin) bound form of a similar chemotherapeutic drug,



paclitaxel known as Abraxane®, which demonstrated some clinical advantages to paclitaxel. ATI-1123 has shown promising results in preclinical animal models that suggest it may have superior qualities to doxetaxel, including actions against some tumor types that are not amenable to treatment by doxetaxel. A Phase I study of ATI-1123 has been completed in late stage refractory patients and has shown some activity in several tumor types (mostly stable disease). We are currently evaluating clinical scenarios to bring into Phase II studies in several indications and potential development partnerships.

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, 2017 and 2016 (in thousands):

	Fo	For the three months ended June 30,			For the six months ended June 30,			ended	
	2	017		2016		2017		2016	
oduct revenues - third party	\$	969	\$	1,126	\$	1,560	\$	2,459	

We experienced a decrease of \$0.2 million and \$0.9 million in product revenue during the three and six months ended June 30, 2017 as compared to the same period in 2016. The decrease in the three-month period is due to lower sales in the Americas of \$0.3 million partially offset by increased revenues in Japan of \$0.1 million. The decrease in the six-month period is due to lower sales in the Americas of \$0.4 million and Japan of \$0.5 million. The lower sales in the Americas for the three and six months periods is primarily due to the completion of a customer's clinical trial, for which Cytori was suppling the products.

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 investigatorinitiated and funded studies focused on, but not limited to, hand scleroderma, Crohn's disease, peripheral artery disease, erectile dysfunction, and diabetic foot ulcers. Habeo Cell Therapy for hand scleroderma will continue to be accessible to patients and physicians through a managed access program, or MAP. We announced in mid-June of 2017 that we ended our MAP agreement with IDIS (initiated in 2016) and partnered with a new vendor, myTomorrows, with expanded geographical coverage for MAP, including Europe, Middle East and Latin America (excluding of Chile). myTomorrows is an innovative and fully integrated organization dedicated to providing fully compliant early access to innovative therapeutics in advance of the products full marketing authorization in the countries that it serves.

Cost of product revenues

Cost of product revenues relate primarily to Cytori Cell Therapy-related products and includes material, manufacturing labor, and overhead costs, as well as amortization of intangible assets. The following table summarizes the components of our cost of revenues for the three and six months ended June 30, 2017 and 2016 (in thousands):

	For the three months ended June 30,					For the six me June	ended
		2017		2016	2017		 2016
Cost of product revenues (excluding amortization of intangible							
assets and share-based compensation)	\$	396	\$	494	\$	798	\$ 946
Amortization of intangible assets		306		82		612	181
Share-based compensation		5		9		13	25
Total cost of product revenues	\$	707	\$	585	\$	1,423	\$ 1,152
Total cost of product revenues as % of product revenues		73.0%		52.0%		91.2%	 46.8%

Cost of product revenues as a percentage of product revenues was 73.0% and 91.2% for the three and six months ended June 30, 2017 and 52.0% and 46.8% for the three and six months ended June 30, 2016. Fluctuation in this percentage is due to our product mix, distributor and direct sales mix, geographic mix, foreign exchange rates, idle capacity, allocation of overhead, and higher intangible amortization expense.

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. We are investigating various pricing options for our cellular therapeutics, which may help to increase our gross profit margins in 2017 and beyond.



Development revenues

Under our government contract with BARDA, we recognized a total of \$0.5 million and \$1.5 million in revenues for the three and six months ended June 30, 2017 which included allowable fees as well as cost reimbursements. During the three and six months ended June 30, 2017, we incurred \$0.5 million and \$1.4 million in qualified expenditures. During the three and six months ended June 30, 2016, we recognized revenue of \$1.7 million and \$3.3 million and incurred \$1.6 million and \$3.1 million in qualified expenditures, respectively. The decrease in revenues for the three and six months ended June 30, 2017 as compared to the same periods in 2016 is primarily due to slight decreases in research and development activities related to BARDA.

The future: We entered into an amendment with BARDA in May 2017 for the initiation of a pilot clinical trial of DCCT-10 in thermal burn injury. The amendment extends the term of the BARDA Agreement and the period of performance of Option 2 of the BARDA Agreement to November 30, 2020.

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, 2017 and 2016 (in thousands):

	For the three months ended June 30,					For the six months ender June 30,			
		2017	2016		2017		2016		
General research and development	\$	2,950	\$	5,121	\$	6,192	\$	9,113	
Share-based compensation		42		126		89		261	
Total research and development expenses	\$	2,992	\$	5,247	\$	6,281	\$	9,374	

The decrease in research and development expenses, excluding share-based compensation, for the three and six months ended June 30, 2017 as compared to the same period in 2016 is due to a decrease of approximately \$1.8 million and \$2.4 million for the three and six months periods in clinical study expenses as well as a decrease of approximately \$0.2 million and \$0.5 million in salaries and benefits as a result of completion of enrollment in our U.S. clinical trials enrolling in 2016.

The future: We expect aggregate research and development expenditures remain consistent at current levels for the balance of 2017, as we complete the STAR clinical trial and begin our activities on the RELIEF clinical trial as well as our development efforts of the recently acquired assets from Azaya.

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, 2017 and 2016 (in thousands):

	For the three months ended June 30,			For the six months ended June 30,		
	 2017		2016	 2017		2016
Sales and marketing	\$ 1,233	\$	846	\$ 2,140	\$	1,832
Share-based compensation	30		43	62		92
Total sales and marketing expenses	\$ 1,263	\$	889	\$ 2,202	\$	1,924

Sales and marketing expenses excluding share-based compensation increased by approximately \$0.4 million and \$0.3 million during the three and six months ended June 30, 2017 as compared to the same period in 2016 due to increases in professional services mostly related to our operations in Japan, commercial planning activities for scleroderma in the United States and investments in the EMEA managed access program.

The future: We expect sales and marketing expenditures to slightly decrease during the second half of 2017, as we delay efforts on commercial readiness activities for hand scleroderma in the United States.



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, 2017 and 2016 (in thousands):

	For the three months ended June 30,			For the six months ended June 30,				
	2017		2016		2017		2016	
General and administrative	\$ 1,985	\$	2,178	\$	3,981	\$	4,347	
Share-based compensation	134		150		246		267	
Total general and administrative expenses	\$ 2,119	\$	2,328	\$	4,227	\$	4,614	

General and administrative expenses excluding share-based compensation decreased by \$0.2 million and \$0.4 million during the three and six months ended June 30, 2017, as compared to the same periods in 2016 is primarily due to decreases in salary and related benefits expense consistent with our ongoing cost curtailment efforts.

The future: We expect general and administrative expenditures to moderately increase with the acquisition of Azaya assets and as we integrate its operations under the Cytori Therapeutics umbrella.

Share-based compensation expenses

Share-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, 2017 and 2016 (in thousands):

	For the three months ended June 30,			For the six months ended June 30,			
	2017		2016		2017		2016
Cost of product revenues	\$ 5	\$	9	\$	13	\$	25
Research and development-related	42		126		89		261
Sales and marketing-related	30		43		62		92
General and administrative-related	134		150		246		267
Total share-based compensation	\$ 211	\$	328	\$	410	\$	645

The decrease in share-based compensation expenses for the three and six months ended June 30, 2017 as compared to the same periods in 2016 is primarily related to a lower annual grant activities caused by reductions in headcount and due to the decline in the stock price during 2017 as compared to the same period in 2016, and its corresponding impact on share-based compensation.

The future: We expect to continue to grant options and stock awards (which will result in an expense) to our employees, directors, and, as appropriate, to non-employee service providers. In addition, previously-granted options will continue to vest in accordance with their original terms. As of June 30, 2017, the total compensation cost related to non-vested stock options and stock awards not yet recognized for all our plans is approximately \$1.2 million which is expected to be recognized as a result of vesting under service conditions over a weighted average period of 1.64 years.

In process research and development acquired from Azaya Therapeutics

In February 2017, we entered into an agreement to acquire assets, including in process research and development ("IPR&D) related to two drug candidates, from Azaya Therapeutics. In connection with this agreement, we recorded an IPR&D charge totaling \$1.7 million. The acquired IPR&D is in the early stage of development and has no alternative use. Additional research, pre-clinical studies, and regulatory approvals must be successfully completed prior to commercialization of any product.

Financing items

The following table summarizes interest income, interest expense, and other income and expense for the three and six months ended June 30, 2017 and 2016 (in thousands):

	For	For the three months ended June 30,			For the six months ended June 30,			
	201	17	2016	2	017		2016	
Interest income	\$	7 \$	2	\$	18	\$	4	
Interest expense		(538)	(645)		(1,129)		(1,302)	
Other income, net		63	462		228		876	
Total	\$	(468) \$	(181)	\$	(883)	\$	(422)	

• Interest expense decreased for the three and six months ended June 30, 2017 as compared to the same period in 2016, due to the commencement of principal payments on our debt.

• The changes in other income during the three and six months ended June 30, 2017 as compared to the same period in 2016 resulted primarily from changes in exchange rates related to transactions in foreign currency.

The future: We expect interest expense in 2017 to decrease as we continue to make payments on the principal balance of the Loan and Security Agreement, dated May 29, 2015, or the Loan and Security Agreement, with Oxford Finance LLC, or Oxford.

Liquidity and Capital Resources

Short-term and long-term liquidity

The following is a summary of our key liquidity measures at June 30, 2017 and December 31, 2016 (in thousands):

	As	of June 30, 2017	As of December 31, 2016		
Cash and cash equivalents	\$	9,028	\$	12,560	
Current assets	\$	15,623	\$	18,747	
Current liabilities		13,229		12,501	
Working capital	\$	2,394	\$	6,246	

We incurred net losses of \$6.0 million and \$13.6 million for the three and six months ended June 30, 2017, and \$6.4 million and \$11.7 million for the three and six months ended June 30, 2016, respectively. We have an accumulated deficit of \$392.7 million as of June 30, 2017. Additionally, we have used net cash of \$9.9 million and \$10.7 million to fund our operating activities for the six months ended June 30, 2017, and 2016, respectively.

Further, our Loan and Security Agreement with Oxford requires us to maintain a minimum of \$5.0 million in unrestricted cash and cash equivalents on hand to avoid an event of default under the Loan and Security Agreement. Based on our cash and cash equivalents on hand of approximately \$9.0 million at June 30, 2017, and our obligation to make payments of principal of \$0.6 million plus accrued interest in monthly installments, we estimate that we must raise additional capital and/or obtain a waiver or restructure the Loan and Security Agreement in September 2017 to avoid defaulting under our \$5.0 million minimum cash/cash equivalents covenant.

To date, these operating losses have been funded primarily from outside sources of invested capital including our recently completed underwritten public offering, our Lincoln Park Purchase Agreement ("Lincoln Park Purchase Agreement") with Lincoln Park Capital Fund, LLC ("Lincoln Park") and the Rights Offering (each defined below), our at-the-market ("ATM") equity facility, the Loan and Security Agreement and gross profits. We have had, and we will likely continue to have, an ongoing need to raise additional cash from outside sources to fund our future clinical development programs and other operations.



On June 15, 2016, the Company closed a rights offering originally filed under Form S-1 registration statement in April 2016 ("Rights Offering"). 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 us of \$17.1 million.

During the six months ended June 30, 2017, we sold 894,050 shares of our common stock under our ATM offering program, receiving total net proceeds of approximately \$1.5 million. Although sales of our common stock have taken place pursuant to our ATM offering program, there can be no assurance that we will be successful in consummating future sales based on prevailing market conditions or in the quantities or at the prices that we deem appropriate. In addition, under current SEC regulations, at any time during which the aggregate market value of our common stock held by non-affiliates, or public float, is less than \$75.0 million, the amount we can raise through primary public offerings of securities in any twelve-month period using shelf registration statements, including sales under our ATM offering program, is limited to an aggregate of one-third of our public float. As of December 31, 2016, our public float was 21.5 million shares, the value of which was \$32.5 million based upon the closing price of our common stock of \$1.51 on such date. The value of our public float calculated on the same basis was approximately \$11.0 million.

On December 22, 2016, we entered into the Lincoln Park Purchase Agreement and a registration rights agreement, with Lincoln Park pursuant to which we have the right to sell to Lincoln Park and Lincoln Park is obligated to purchase up to \$20.0 million in amounts of shares, of our common stock, over the 30-month period commencing on the date that a registration statement, that we filed with the Securities and Exchange Commission (the "SEC") in December 2016. We may direct Lincoln Park, at its sole discretion and subject to certain conditions, to purchase up to 100,000 shares of common stock on any business day but in no event will the amount of a single Regular Purchase exceed \$1.0 million. The purchase price of shares of common stock related to the Regular Purchases will be based on the prevailing market prices of such shares at the time of sales. Our sales of shares of common stock to Lincoln Park and its affiliates, at any single point in time, of more than 9.99% of the then outstanding shares of the common stock. There are no trading volume requirements or restrictions under the Lincoln Park Purchase Agreement. There is no upper limit on the price per share that Lincoln Park must pay for common stock under a Regular Purchase or an accelerated purchase and in no event will shares be sold to Lincoln Park on a day our closing price is less than the floor price of \$0.50 per share as set forth in the Lincoln Park Purchase Agreement. On December 22, 2016, we issued to Lincoln Park 127,419 shares of common stock as commitment shares in consideration for entering into the Lincoln Park Purchase Agreement. Through June 30, 2017, we sold a total of 103,000 shares under the Lincoln Park Purchase Agreement, for proceeds of approximately \$0.2 million. We will issue up to an additional 279,258 shares of common stock on a pro rata basis to Lincoln Park only as and when shares are sold under the Lincoln Park Purchase Agreement to Lincoln Park.

Pursuant to this securities transaction and related equity issuance, as well as anticipated gross profits and potential outside sources of capital, we believe we have sufficient cash to fund operations through at least the third quarter of 2017. We continue to seek additional capital through product revenues, strategic transactions, including extension opportunities under the awarded BARDA contract, and from other financing alternatives. However, there can be no assurance that we will be successful in securing additional resources when needed, on terms acceptable to us or at all. Therefore, there exists substantial doubt about our ability to continue as a going concern.

On April 11, 2017, we entered into an underwriting agreement (the "Underwriting Agreement") with Maxim Group LLC ("Maxim") relating to the issuance and sale of 8.6 million shares of our common stock, par value \$0.001 per share. The price to the public in this offering is \$1.10 per share. Maxim agreed to purchase the shares from us pursuant to the Underwriting Agreement at a price of \$1.0395 per share. The net proceeds to us from the offering were approximately \$8.7 million, after deducting underwriting discounts and commissions and estimated offering expenses payable by the Company. The offering closed on April 17, 2017. In addition, under the terms of the Underwriting Agreement, we granted Maxim a 45-day option to purchase up to 944,000 additional shares of common stock. On May 31, 2017, Maxim exercised their overallotment option and purchased 849,000 shares at \$1.10 per share. The net proceeds to us were \$0.8 million, after deducting underwriting costs and offering expenses payable by us.

Our inability to raise additional cash will have a material and adverse impact on operations and will cause us to default on our loan.

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

As of June 30, 2017, 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, 2016.

Cash (used in) provided by operating, investing, and financing activities for the six months ended June 30, 2017 and 2016 is summarized as follows (in thousands):

	 For the six months ended June 30,				
	 2017	2016			
Net cash used in operating activities	\$ (9,855)	\$	(10,735)		
Net cash used in investing activities	(1,375)		(105)		
Net cash provided by financing activities	7,685		16,405		
Effect of exchange rate changes on cash and cash equivalents	13		139		
Net decrease in cash and cash equivalents	\$ (3,532)	\$	5,704		

Operating activities

Net cash used in operating activities for the six months ended June 30, 2017 was \$9.9 million. Overall, our operational cash use decreased during the six months ended June 30, 2017 as compared to the same period in 2016, due primarily to a decrease in losses from operations (when adjusted for non-cash items) of \$0.3 million and by \$0.5 million in working capital improvements.

Investing activities

Net cash used in investing activities for the six months ended June 30, 2017 resulted primarily from cash outflows for payment for long-lived assets purchased as part of Azaya's acquisition of \$1.2 million.

Financing Activities

The net cash provided by financing activities for the six months ended June 30, 2017 related primarily to sale of common stock of \$11.2 million offset by cash used in principal payments on our debt of \$3.5 million.

Critical Accounting Policies and Significant Estimates

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

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

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, 2016.

Item 3. Quantitative and Qualitative Disclosures about Market Risk

As of June 30, 2017, there have been no material changes in our market risks from those described in Item 7A "Quantitative and Qualitative Disclosures About Market Risk" in our Annual Report on Form 10-K for the fiscal year ended December 31, 2016.

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, 2017 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, 2017, 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, 2016 filed with the SEC on March 24, 2017, 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.

Our success depends in large part upon the successful development and commercialization of our cellular therapeutics, especially Habeo Cell Therapy, which recently failed to achieve its primary or secondary endpoints in a Phase III clinical trial assessing the safety and efficacy of Habeo Cell Therapy in the treatment of finger and hand dysfunction due to scleroderma. While we are continuing to assess the topline data from the trial, we may be unable to identify a viable path forward for continued development of this product candidate, which in turn could materially and adversely affect our business and operations.

Our success in large part is dependent upon our ability to develop our Cytori Cell Therapy products, and in particular, our Habeo Cell Therapy product. Habeo Cell Therapy is our lead product candidate. In July 2017, we announced topline results from our Phase III STAR clinical trial that evaluated the efficacy and safety of Habeo Cell Therapy in the treatment of finger and hand dysfunction due to scleroderma. In this trial, Habeo Cell Therapy did not achieve its primary endpoint of improvement in hand dysfunction, compared to placebo, in patients with scleroderma, as measured by the Cochin Hand Function Score, or CHFS, at twenty-four (24) and forty-eight (48) weeks, nor did it achieve its secondary endpoints of improvement in the Raynaud's Condition Score, or RCS, and the Scleroderma Health Assessment Questionnaire, or SHAQ, at forty-eight (48) weeks, compared to placebo. The Company does not believe that this STAR clinical data is sufficient to submit a pre-market approval, or PMA, application for Habeo Cell Therapy to the FDA for hand manifestations of scleroderma.

Analysis of the Phase III data indicated that within a pre-specified subgroup analysis, the STAR patients within the diffuse cutaneous scleroderma subset indicated improvements in the Cochin Hand Function Score and the Health Assessment Questionnaire-Disability Index, or HAQ-DI (a measure of functional disability), that met or exceeded the published criteria for minimally important clinical differences in these measures as compared to STAR patients within the limited cutaneous scleroderma subset. However, these differences may not be deemed sufficient to continue development of Habeo Cell Therapy for scleroderma. Thorough analysis of our Phase III data may result in the determination that there is not a viable plan for continued development of Habeo Cell Therapy for scleroderma. Further, anticipated discussions with the FDA and with other regulatory authorities regarding our Phase III data and Habeo Cell Therapy may be unsuccessful or may result in imposition of onerous requirements should we pursue further development of this therapy. Even if we desire to design further trials and continue to pursue a path toward potential regulatory approval of Habeo Cell Therapy, any such development will likely require significant financial and personnel resources. We may be unable to obtain sufficient capital to fund such further trials, and any such trials, if funded, may fail to yield positive results. Further, the failure to achieve our primary or secondary endpoints in the STAR Phase III trial will likely have an adverse effect on our current commercial sales of our cellular therapeutics, and on our efforts to find additional partners to develop and commercialize our cellular therapeutics, and on our efforts to find additional partners to develop and commercialize our cellular therapeutics.



There can be no assurance that we will be able to further develop Habeo Cell Therapy. Our continuing analyses of data from the Phase III trial may produce negative or inconclusive results, or may be inconsistent with our previously announced top-line results. Because our cell therapy business is in substantial part dependent on the success of Habeo Cell Therapy, if we are unable to identify, fund and ultimately execute an alternative development strategy for this product candidate or our other cell therapy candidates, we may be required to reduce or curtail our cell therapy activities, which would materially and adversely affect our business and operations, and could require us to liquidate, dissolve or otherwise wind down our operations. Further, if we decide to sell or otherwise dispose of our cell therapy platform, we may be unable to identify a suitable acquirer, or may be unable to negotiate and consummate a transaction on terms acceptable to us.

If we are unable to successfully partner with other companies to commercialize our product candidates, our business could materially suffer.

A key part of our business strategy is to leverage strategic partnerships/collaborations to commercialize our product candidates. We do not have the financial, human or other resources necessary to develop, commercialize, launch or sell our therapeutic offerings in all of the geographies that we are targeting, and thus it is important that we identify and partner with third parties who possess the necessary resources to bring our products to market. We expect that any such partners will provide regulatory and reimbursement/pricing expertise, sales and marketing resources, and other expertise and resources vital to the success of our product offerings in their territories. We further expect, but cannot guarantee, that any such partnering arrangements will include upfront cash payments to us in return for the rights to develop, manufacture, and/or sell our products in specified territories, as well as downstream revenues in the form of milestone payments and royalties.

We are currently prioritizing our efforts to find a strategic partner for our Habeo Cell Therapy, formerly ECCS-50, which is specifically intended for treatment of hand dysfunction in scleroderma patients. For various reasons, including the preliminary topline data from our U.S. Phase III STAR clinical trial announced in July 2017 and the novelty of our cellular therapeutic approach, the regulatory and reimbursement environments for Habeo Cell Therapy in certain markets, including Europe and the Asia-Pacific region, are complex and uncertain. There can be no assurance that regulatory agencies or authorities in the U.S., Europe, the Asia-Pacific region or elsewhere will grant conditional or full regulatory approval for Habeo Cell Therapy on the timeframes we anticipate, or at all, nor can we guarantee that government or commercial payers will grant us favorable reimbursement for use of Habeo Cell Therapy. In fact, we anticipate that our preliminary topline STAR Phase III clinical data will result in delays in our regulatory approval efforts of our Habeo Cell Therapy efforts, or cause us to abandon or materially alter our regulatory approval strategies for Habeo Cell Therapy. Further, even if we receive regulatory approval and favorable reimbursement, there is no guarantee that a market will develop for Habeo Cell Therapy at our intended price points, or at all. These commercialization risks could affect prospective partners' or collaborators' willingness to enter into partnering arrangements on terms acceptable to us, or at all. Prospective partners may be unwilling to enter into Habeo collaboration/partnering agreements with us in light of our topline STAR clinical trial data. We anticipate that it will be difficult to find a commercialization partner for our Habeo Cell Therapy on favorable terms, if at all. Further, if data from the currently enrolling French investigator-initiated SCLERADEC II trial are not positive, or if the trial is discontinued prior to receipt of data, the regulatory and commercial hurdl

We are also prioritizing our efforts to find a strategic partner to help commercialize and sell our ATI-0918 drug candidate, initially in Europe, and secondarily, to fund development and commercialization of our ATI-1123 product candidate. We do not currently have the commercial expertise or resources to market and sell either ATI-0918 or ATI-1123. There can be no assurance that we will enter into partnering agreements for either ATI-0918 or ATI-1123 with suitable partners on terms acceptable to us, or at all. At present, we do not intend to expend significant resources on development of ATI-1123. However, regardless of whether we enter into a partnering agreement for ATI-0918, we will still incur significant costs and expenses in manufacturing, testing and validating it and in performing necessary regulatory and clinical work to ready our EMA marketing dossier for submission. If we cannot find a suitable partner for our ATI-0918 product candidate, our business could be significantly harmed.

We are also soliciting partnering interest in our ECCO-50 therapeutic for use in knee osteoarthritis, but we anticipate that our partnering efforts with respect to this indication will be subordinate to our Habeo Cell Therapy and ATI-0918 partnering efforts. Further, while consistent trends were observed in most secondary endpoints relative to the placebo group in our ACT-OA knee osteoarthritis trial, the 12-week endpoint of single pain on walking question did not achieve statistical significance, so there can be no assurance that our partnering efforts for our ECCS-50 therapeutics will be successful.

In addition, we may seek development and/or commercial partners for the other therapeutic indications set forth in our clinical pipeline, including:

• use of Cytori Cell Therapy in stress urinary incontinence, or SUI, in men following surgical removal of the prostate gland (this therapeutic indication is currently the subject of a Phase III, investigator-initiated trial in Japan, called ADRESU); and



development of Cytori Cell Therapy for Secondary Raynaud's Phenomenon, or SRP (this therapeutic indication is currently in the pre-clinical stage).

There can be no assurance that these male SUI and SRP pipeline indications will be attractive to prospective partners. The male SUI market is small (approximately \$45.0 million), and the viability of both indications, especially SRP, is in substantial part dependent upon receipt of positive STAR and/or SCLERADEC II clinical data. We anticipate that the failure to achieve the primary and secondary endpoints in our STAR Phase III trial could materially hamper our efforts to identify prospective cell therapy partners or to negotiate cell therapy partnering transactions on terms favorable to us, or at all.

Even if we succeed in securing partners for our lead or other product candidates, our partners may fail to develop or effectively commercialize our product candidates. Partnerships and collaborations involving our products and product candidates pose a number of risks, including the following:

- partners may not have sufficient resources or may decide not to devote the necessary resources due to internal constraints such as budget limitations, lack of human resources, or a change in strategic focus;
- partners may believe our intellectual property is not valid or is unenforceable or unprotectable, or the product or product candidate infringes on the intellectual property rights of others;
- partners may dispute their responsibility to conduct development and commercialization activities pursuant to the applicable collaboration, including the payment of related costs or the division of any revenues;
- partners may decide to pursue a competitive product developed outside of the partnering arrangement;
- partners may not be able to obtain, or believe they cannot obtain, the necessary regulatory approvals or reimbursement rates for the product candidates; and
- partners may decide to terminate or not to renew their agreement with us for these reasons or other reasons.

As a result, partnering agreements may not lead to development or commercialization of our lead product candidates or other product candidates in the most efficient manner or at all.

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

We have had, and we will continue to have, an ongoing need to raise additional cash from outside sources to continue funding our operations to profitability, including our continuing substantial research and development expenses. We do not currently believe that our cash balance and the revenues from our operations will be sufficient to fund the development and marketing efforts required to reach profitability without raising additional capital from accessible sources of financing in the near future. Although it is difficult to predict future liquidity requirements, we believe that our \$9 million in cash and cash equivalents on hand as of June 30, 2017 will be sufficient to fund our currently contemplated operations at least through October 2017. Our future capital requirements will depend on many factors, including:

- our ability to raise capital to fund our operations on terms acceptable to us, or at all;
- our perceived capital needs with respect to development of our Cytori Cell Therapy and Cytori Nanomedicines development programs, and any delays in, adverse events of, and excessive costs of such programs beyond what we currently anticipate;
- our ability to establish and maintain collaborative and other arrangements with third parties to assist in bringing our products to market and the cost of such arrangements at the time;
- costs associated with the integration and operation of our newly acquired Cytori Nanomedicine business, including hiring of as many as 20 or more new employees to operate the Cytori Nanomedicine business, and costs of validation, requalification and recommencement of the Cytori Nanomedicine manufacturing operations at our San Antonio, Texas facility;
- the cost of manufacturing our product candidates, including compliance with good manufacturing practices, or GMP, applicable to our product candidates;



- expenses related to the establishment of sales and marketing capabilities for product candidates awaiting approval or products that have been approved;
- the level of our sales and marketing expenses;
- competing technological and market developments; and
- our ability to introduce and sell new products.

We have secured capital historically from grant revenues, collaboration proceeds, and debt and equity offerings. We will need to secure substantial additional capital to fund our future operations. We cannot be certain that additional capital will be available on terms acceptable to us, or at all. Our ability to raise capital was adversely affected when the FDA put a hold on our ATHENA cardiac trials in mid-2014, which had an adverse impact to stock price performance and our corresponding ability to restructure our debt. Subsequently, a continued downward trend in our stock price resulting from a number of factors, including (i) general economic and industry conditions, (ii) challenges faced by the regenerative medicine industry as a whole, (iii) the market's unfavorable view of certain of our recent equity financings conducted in 2014 and 2015 (which financings were priced at a discount to market and included 100% warrant coverage), (iv) market concerns regarding our continued need for capital (and the effects of any future capital raising transactions we may consummate), (v) market perceptions of our ATHENA and ACT-OA clinical trial data, and (vi) our recent NASDAQ Stock Market LLC, or Nasdaq, listing deficiency issues and resultant 1-for-15 reverse stock split, made it more difficult to procure additional capital on terms reasonably acceptable to us. Most recently, the release in July 2017 of the top-line data from our STAR Phase III trial, in which we announced the failure to achieve the trial's primary and secondary endpoints, resulted in a further substantial decrease in our stock price. Though our recent acquisition of the Cytori Nanomedicine business from Azaya Therapeutics, including our ATI-0918 and ATI-1123 drug candidates, appear to have been viewed favorably by our investors and the marketplace, we cannot assure you that this acquisition will not ultimately be viewed negatively and thus further hamper our efforts to attract additional capital. If we are unsuccessful in our efforts to raise any such additional capital, we may be required to take actions that could materially and adversely harm our business, including a possible significant reduction in our research, development and administrative operations (including reduction of our employee base), surrendering of our rights to some technologies or product opportunities, delaying of our clinical trials or regulatory and reimbursement efforts, or curtailing of or even ceasing operations.

Our financing plans include pursuing additional cash through use of our at-the-market, or ATM, offering program, strategic corporate partnerships, licensing and sales of equity. In addition, in December 2016, we entered into a purchase agreement, or the Lincoln Park Purchase Agreement, with Lincoln Park Capital Fund, LLC, or Lincoln Park, pursuant to which we may direct Lincoln Park to purchase up to \$20.0 million in shares of our common stock from time to time over a 30-month period, subject to satisfaction of certain conditions. While we have an established history of raising capital through these platforms, and we are currently involved in negotiations with multiple parties, there is no guarantee that adequate funds will be available when needed from additional debt or equity financing, development and commercialization partnerships or from other sources or on terms acceptable to us. In addition, under current SEC regulations, at any time during which the aggregate market value of our common stock held by non-affiliates, or public float, is less than \$75.0 million, the amount we can raise through primary public offerings of securities in any twelve-month period using shelf registration statements, including sales under our ATM offering program, is limited to an aggregate of one-third of our public float. As of June 30, 2017, our public float was 33.1 million shares, the value of which was \$36.4 million based upon the closing price of our common stock of \$1.10 on such date. The value of one-third of our public float calculated on the same basis was approximately \$12.1 million.

Further, our Loan and Security Agreement with Oxford Finance, LLC, or Oxford, as further described below, requires us to maintain a minimum of \$5.0 million in unrestricted cash and cash equivalents on hand to avoid an event of default under the Loan and Security Agreement. Based on our cash and cash equivalents on hand of approximately \$9 million at June 30, 2017, and our obligation to make payments of principal of \$590,000 plus accrued interest in monthly installments, we estimate that we must raise additional capital and/or obtain a waiver or restructure the Loan and Security Agreement in September 2017 to avoid defaulting under our \$5 million minimum cash/cash equivalents covenant. If we are unable to avoid an event of default under the Loan and Security Agreement, our business could be severely harmed.

In addition to the funding sources previously mentioned, we continue to seek additional capital through product revenues and state and federal development programs, including additional funding opportunities though our current BARDA contract.

We may be or become the target of securities litigation, which is costly and time-consuming to defend.

In the past, following periods of market volatility in the price of a company's securities, the reporting of unfavorable news or continued decline in a company's stock price, security holders have often instituted class action litigation. The market value of our securities has steadily declined over the past several years for a variety of reasons, including the announcement of the results of our Phase III clinical trial in July 2017, and for other reasons discussed elsewhere in this "Risk Factors" section, which heightens our



litigation risk. If we face such litigation, we could incur substantial legal costs and our management's attention could be diverted from the operation of our business, causing our business to suffer. Any adverse determination in any such litigation or any amounts paid to settle any such actual or threatened litigation could require that we make significant payments.

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.

- By: /s/ Marc H. Hedrick Marc H. Hedrick President & Chief Executive Officer
- By: /s/ Tiago Girao Tiago Girao VP of Finance and Chief Financial Officer

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Dated: August 11, 2017

Dated: August 11, 2017

Exhibit Index

- 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 Warrant by and between Cytori Therapeutics, Inc. and Maxim Group LLC (incorporated by reference to our Current Report on Form 8-K, filed with the Commission on April 12, 2017)
- 4.2 Form of Restated Warrant by and between Cytori Therapeutics, Inc. and Broadridge Corporate Issuer Solutions, Inc. (filed herein)
- 10.1 Sixth Amendment of Solicitation/Modification of Contract, effective April 14, 2017, by and between ASPR-BARDA and Cytori Therapeutics, Inc. (incorporated by reference to our Quarterly Report on Form 10-Q filed with the Commission on May 12, 2017)
- 10.2# 2014 Equity Incentive Plan of Cytori Therapeutics, Inc. as Amended and Restated (incorporated by reference to Appendix A of our Definitive Proxy Statement on Schedule 14A filed with the Commission on April 10, 2017)
- 10.3+ Seventh Amendment of Solicitation/Modification of Contract, effective May 19, 2017, by and between ASPR-BARDA and Cytori Therapeutics, Inc. (filed herewith)
- 10.4+ Eighth Amendment of Solicitation/Modification of Contract, effective May 23, 2017, by and between ASPR-BARDA and Cytori Therapeutics, Inc. (filed herewith)
- 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

Exhibit No.

Description

- 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.
- # Indicates management contract or compensatory plan or arrangement.
- + Confidential treatment has been requested with respect to certain portions of this exhibit. Omitted portions have been filed separately with the Securities and Exchange Commission.

RESTATED WARRANT AGENT AGREEMENT

RESTATED WARRANT AGENT AGREEMENT ("<u>Warrant Agreement</u>") made effective as of the completion of the Offering, as defined below (the "<u>Issuance Date</u>"), between Cytori Therapeutics, Inc., a Delaware corporation (the "<u>Company</u>"), and Broadridge Corporate Issuer Solutions, Inc., a corporation having its principal offices in Philadelphia, Pennsylvania (the "<u>Warrant Agent</u>").

WHEREAS, the Company is engaged in a public rights offering (the "<u>Offering</u>") of the Company's Common Stock (as defined below) together with Warrants (as defined below) to purchase Common Stock and, in connection therewith, has distributed to holders of its common stock, par value \$0.001 per share ("<u>Common Stock</u>"), rights to subscribe to purchase units in the Offering (the "Units"). Each Unit consists of one share of Common Stock (the "<u>Shares</u>") and 0.5 of a "Series R" warrant (the "<u>Warrants</u>" and, together with the Units, the Shares and the Warrant Shares (as defined below), the "<u>Securities</u>"). Each whole Warrant represents the right to purchase one share of Common Stock. Each Warrant entitles the holder thereof to purchase one share of Common Stock at an exercise price of \$3.06 per share, subject to adjustment as described herein; and

WHEREAS, the Company has filed with the U.S. Securities and Exchange Commission a Registration Statement, No. 333-210628 on Form S-1 (as the same may be amended from time to time, the "<u>Registration Statement</u>") for the registration, under the Securities Act of 1933, as amended (the "<u>Act</u>") of the Securities, including the Warrants and the Common Stock issuable upon exercise of the Warrants (the "<u>Warrant Shares</u>"); and

WHEREAS, the Company desires the Warrant Agent to act on behalf of the Company, and the Warrant Agent is willing to so act, in connection with the issuance, registration, transfer, exchange and exercise of the Warrants; and

WHEREAS, the Company desires to provide for the form and provisions of the Warrants, the terms upon which they shall be issued and exercised, and the respective rights, limitation of rights, and immunities of the Company, the Warrant Agent, and the holders of the Warrants or if the Warrants are held in "street name", a Participant (as defined below) or a designee appointed by such Participant (each, a "<u>Holder</u>" or "<u>Registered Holder</u>"); and

WHEREAS, all acts and things have been done and performed which are necessary to make the Warrants, when executed on behalf of the Company and countersigned by or on behalf of the Warrant Agent, as provided herein, the valid, binding and legal obligations of the Company, and to authorize the execution and delivery of this Warrant Agreement.

NOW, THEREFORE, in consideration of the mutual agreements herein contained, the parties hereto agree as follows:

1. <u>Appointment of Warrant Agent</u>. The Company hereby appoints the Warrant Agent to act as agent for the Company for the Warrants, and the Warrant Agent hereby accepts such appointment and agrees to perform the same in accordance with the terms and conditions set forth in this Warrant Agreement.

2. Warrants.

2.1 <u>Form of Warrant</u>. Each Warrant shall be issued in registered form only, shall be in substantially the form of <u>Exhibit A</u> hereto, the provisions of which are incorporated herein, and shall be signed by, or bear the facsimile or electronic signature of, the Chief Executive Officer, President, Chief Financial Officer or Treasurer, Secretary or Assistant Secretary of the Company. In the event the person whose facsimile signature has been placed upon any Warrant shall have ceased to serve in the capacity in which such person signed the Warrant before such Warrant is issued, it may be issued with the same effect as if he or she had not ceased to be such at the date of issuance. All of the Warrants shall initially be represented by one or more book-entry certificates (each a "<u>Book-Entry Warrant Certificate</u>").

2.2. <u>Effect of Countersignature</u>. Unless and until countersigned by the Warrant Agent pursuant to this Warrant Agreement, a Warrant shall be invalid and of no effect and may not be exercised by the holder thereof.

2.3. Registration.

2.3.1. <u>Warrant Register</u>. The Warrant Agent shall maintain books ("<u>Warrant Register</u>"), for the registration of original issuance and the registration of transfer of the Warrants. Upon the initial issuance of the Warrants, the

Warrant Agent shall issue and register the Warrants in the names of the respective holders thereof in such denominations and otherwise in accordance with instructions delivered to the Warrant Agent by the Company. To the extent the Warrants are eligible for the book entry and depository services of The Depository Trust Company ("<u>DTC eligible</u>") as of the Issuance Date (as defined below), all of the Warrants shall be represented by one or more Book-Entry Warrant Certificates deposited with The Depository Trust Company (the "<u>Depository</u>") and registered in the name of Cede & Co., a nominee of the Depository. Ownership of beneficial interests in the Book-Entry Warrant Certificates shall be shown on, and the transfer of such ownership shall be effected through, records maintained (i) by the Depository or its nominee for each Book-Entry Warrant Certificate; (ii) by institutions that have accounts with the Depository (such institution, with respect to a Warrant in its account, a "<u>Participant</u>"); or (iii) directly on the book-entry records of the Warrant Agent with respect only to owners of beneficial interests represented by such direct registration.

If the Warrants are not DTC eligible as of the Issuance Date or the Depository subsequently ceases to make its book-entry settlement system available for the Warrants, the Company may instruct the Warrant Agent regarding making other arrangements for book-entry settlement within ten (10) days after the Depository ceases to make its book-entry settlement available. In the event that the Company does not make alternative arrangements for book-entry settlement within ten (10) days or the Warrants are not eligible for, or it is no longer necessary to have the Warrants available in, book-entry form, the Warrant Agent shall provide written instructions to the Depository to deliver to the Warrant Agent for cancellation each Book-Entry Warrant Certificate, and the Company shall instruct the Warrant Agent to deliver to the Depository definitive certificates ("<u>Warrant Certificates</u>") in physical form evidencing such Warrants. Such Warrant Certificates shall be in substantially the form annexed hereto as <u>Exhibit A</u>.

2.3.2. <u>Beneficial Owner; Registered Holder</u>. The term "beneficial owner" shall mean any person in whose name ownership of a beneficial interest in the Warrants evidenced by a Book-Entry Warrant Certificate is recorded in the records maintained by the Depository or its nominee. Prior to due presentment for registration of transfer of any Warrant, the Company and the Warrant Agent may deem and treat the person in whose name such Warrant shall be registered upon the Warrant Register ("<u>registered holder</u>"), as the absolute owner of such Warrant and of each Warrant represented thereby (notwithstanding any notation of ownership or other writing on the Warrant Certificate made by anyone other than the Company or the Warrant Agent), for the purpose of any exercise thereof and for all other purposes, and neither the Company nor the Warrant Agent shall be affected by any notice to the contrary.

2.4. <u>FAST Program</u>. If the Company's transfer agent is not participating in the Depository's Fast Automated Securities Transfer Program and the registered holder requests that the shares of Common Stock be issued or registered to a holder other than the registered holder, then an ink-original Election to Purchase and a medallion guarantee shall be required.

2.5 <u>Separate Transferability of Warrants</u>. The Warrants will be issued as a separate security from any Common Stock issued concurrently in the offering of the Warrants and will be separately transferable immediately upon issuance.

2.6 <u>Uncertificated Warrants</u>. Notwithstanding the foregoing and anything else herein to the contrary, the Warrants may be issued in uncertificated form.

3. Terms and Exercise of Warrants.

3.1. <u>Exercise Price</u>. Each Warrant shall, when countersigned by the Warrant Agent, entitle the registered holder thereof, subject to the provisions of such Warrant and of this Warrant Agreement, to purchase from the Company the number of shares of Common Stock stated therein, at the price of \$3.06 per whole share, subject to the subsequent adjustments provided in Section 5 hereof. The term "Exercise Price" as used in this Warrant Agreement refers to the price per share at which Common Stock may be purchased at the time a Warrant is exercised.

3.2. <u>Duration of Warrants</u>. A Warrant may be exercised only during the period ("<u>Exercise Period</u>") commencing immediately following the closing of the Offering (the "<u>Issuance Date</u>") and terminating at 5:00 P.M., New York City time on the date that is thirty (30) months after the closing date of the Offering ("<u>Expiration Date</u>") *provided, however*, that the exercise of any Warrant shall be subject to the satisfaction of any applicable conditions, as set forth in Section 3.3.7 or with respect to an effective registration statement. Each Warrant not exercised on or before the Expiration Date shall become void, and all rights thereunder and all rights in respect thereof under this Warrant Agreement shall cease at 5:00 P.M. New York City time on the Expiration Date. Notwithstanding the foregoing or anything else herein to the contrary, for so long as the holder continues to hold a Warrant, such holder shall not enter into any short sale or similar

transaction with respect to the Common Stock. Any violation of this provision may result in the Warrant being terminated at the Company's option.

3.3. Exercise of Warrants.

3.3.1. Exercise and Payment. A registered holder may exercise a Warrant by delivering, not later than 5:00 P.M., New York City time, on any business day during the Exercise Period (the "<u>Exercise Date</u>") to the Warrant Agent at its corporate trust department (i) the Warrant Certificate evidencing the Warrants to be exercised, or, in the case of a Book-Entry Warrant Certificate, the Warrants to be exercised (the "<u>Book-Entry Warrants</u>") shown on the records of the Depository to an account of the Warrant Agent at the Depository designated for such purpose in writing by the Warrant Agent to the Depository from time to time, (ii) an election to purchase the Warrant Shares underlying the Warrants to be exercised ("<u>Election to Purchase</u>"), properly completed and executed by the registered holder on the reverse of the Warrant Certificate or, in the case of a Book-Entry Warrant Certificate, properly delivered by the Participant in accordance with the Depository's procedures, and (iii) the Exercise Price for each Warrant to be exercised in lawful money of the United States of America by certified or official bank check or by bank wire transfer in immediately available funds. The Registered Holder shall not be required to deliver the original Warrant in order to effect an exercise hereunder.

If any of (A) the Warrant Certificate or the Book-Entry Warrants, (B) the Election to Purchase, or (C) the Exercise Price therefor, is received by the Warrant Agent after 5:00 P.M., New York City time, on the specified Exercise Date, the Warrants will be deemed to be received and exercised on the business day next succeeding the Exercise Date. If the date specified as the Exercise Date is not a business day, the Warrants will be deemed to be received and exercise thereof will be null and void and any funds delivered to the Warrant Agent will be returned to the registered holder or Participant, as the case may be, as soon as practicable. In no event will interest accrue on funds deposited with the Warrant Agent in respect of an exercise or attempted exercise of Warrants. The validity of any exercise of Warrants will be determined by the Company in its sole discretion and such determination will be final and binding upon the registered holder or Participant, as applicable, and the Warrant Agent. Neither the Company nor the Warrant Agent shall have any obligation to inform a registered holder or the Participant, as applicable, of the invalidity of any exercise of Warrants.

The Warrant Agent shall deposit all funds received by it in payment of the Exercise Price in the account of the Company maintained with the Warrant Agent for such purpose and shall confirm the balance in the account at any time following such request from the Company.

3.3.2. <u>Issuance of Certificates</u>. The Warrant Agent shall, by 11:00 A.M. New York City time on the third business day following the Exercise Date of any Warrant, advise the Company or the transfer agent and registrar in respect of (a) the Warrant Shares issuable upon such exercise as to the number of Warrants exercised in accordance with the terms and conditions of this Agreement, (b) the instructions of each registered holder or Participant, as the case may be, with respect to delivery of the Warrant Shares issuable upon such exercise, and the delivery of definitive Warrant Certificates, as appropriate, evidencing the balance, if any, of the Warrants remaining after such exercise, (c) in case of a Book-Entry Warrant Certificate, the notation that shall be made to the records maintained by the Depository, its nominee for each Book-Entry Warrant Certificate, or a Participant, as appropriate, evidencing the balance, if any, of the warrants remaining after such exercise and (d) such other information as the Company or such transfer agent and registrar shall reasonably require.

The Company shall, by 5:00 P.M., New York City time, on the third business day next succeeding the Exercise Date of any Warrant and the clearance of the funds in payment of the Exercise Price, execute, issue and deliver to the Warrant Agent the Warrant Shares to which such registered holder or Participant, as the case may be, is entitled, in fully registered form, registered in such name or names as may be directed by such registered holder or the Participant, as the case may be. Upon receipt of such Warrant Shares, the Warrant Agent shall, by 5:00 P.M., New York City time, on the fifth Business Day next succeeding such Exercise Date, transmit such Warrant Shares to or upon the order of the registered holder or Participant, as the case may be.

In lieu of delivering physical certificates representing the Warrant Shares issuable upon exercise, provided the Company's transfer agent is participating in the Depository's Fast Automated Securities Transfer program, the Company shall use its reasonable best efforts to cause its transfer agent to electronically transmit the Warrant Shares issuable upon exercise to the Depository by crediting the account of the Depository or of the Participant through its Deposit Withdrawal Agent Commission system. The time periods for delivery described in the immediately preceding paragraph shall apply to the electronic transmittals described herein. If the Company's transfer agent is not participating in the Depository's Fast Automated Securities Transfer Program and the Registered Holder requests that the shares of Common Stock be issued

or registered to a holder other than the registered holder, then an ink-original Election to Purchase and a medallion guarantee shall be required.

3.3.3. <u>Valid Issuance</u>. All shares of Common Stock issued upon the proper exercise of a Warrant in conformity with this Warrant Agreement shall be validly issued, fully paid and nonassessable.

3.3.4. <u>No Fractional Exercise</u>. Warrants may be exercised only in whole numbers of Warrant Shares. No fractional Warrant Shares are to be issued upon the exercise of the Warrant, but rather the number of Warrant Shares to be issued shall be rounded up to the nearest whole number. If fewer than all of the Warrants evidenced by a Warrant Certificate are exercised, a new Warrant Certificate for the number of unexercised Warrants remaining shall be executed by the Company and countersigned by the Warrant Agent as provided in Section 2 of this Warrant Agreement, and delivered to the holder of this Warrant Certificate at the address specified on the books of the Warrant Agent or as otherwise specified by such registered holder. If fewer than all the Warrants evidenced by a Book-Entry Warrant Certificate are exercised, a notation shall be made to the records maintained by the Depository, its nominee for each Book-Entry Warrant Certificate, or a Participant, as appropriate, evidencing the balance of the Warrants remaining after such exercise.

3.3.5 <u>No Transfer Taxes</u>. The Company shall not be required to pay any stamp or other tax or governmental charge required to be paid in connection with any transfer involved in the issue of the Warrant Shares upon the exercise of Warrants; and in the event that any such transfer is involved, the Company shall not be required to issue or deliver any Warrant Shares until such tax or other charge shall have been paid or it has been established to the Company's satisfaction that no such tax or other charge is due.

3.3.6 Date of Issuance. Each person in whose name any such certificate for shares of Common Stock is issued or to whom shares of Common Stock are credited to such person's account at the Depository shall for all purposes be deemed to have become the holder of record of such Common Stock as of the time that a duly executed Election to Purchase is delivered in accordance with Section 3.3.1, provided that, in the case of a cash exercise, payment of the Aggregate Exercise Price is made within two (2) Trading Days after the delivery of the Election to Purchase, and if the payment of the Aggregate Exercise Price is not made within two (2) Trading Day after the delivery of the Election to Purchase, the Holder shall be deemed to have become the holder of record of such Common Stock on the first Trading Day after the date on which the Aggregate Exercise Price has been paid,, irrespective of the date of delivery of such certificate or the date the shares of Common Stock are credited to such person's account at the Depository, except that, if the date of such delivery and/or payment is a date when the stock transfer books of the Company are closed, such person shall be deemed to have become the holder of such shares at the close of business on the next succeeding date on which the stock transfer books are open.

3.3.7 Cashless Exercise Under Certain Circumstances.

(i) The Company shall provide to the registered holder prompt written notice of any time that the Company is unable to issue the Warrant Shares via a transfer effected by the Depository or otherwise (without restrictive legend), because (A) the Commission has issued a stop order with respect to the Registration Statement, (B) the Commission otherwise has suspended or withdrawn the effectiveness of the Registration Statement, either temporarily or permanently, (C) the Company has suspended or withdrawn the effectiveness of the Registration Statement, either temporarily or (D) otherwise (each a "<u>Restrictive Legend Event</u>"). To the extent that a Restrictive Legend Event occurs after the registered holder has exercised a Warrant in accordance with the terms of the Warrants but prior to the delivery of the Warrant Shares, the Company shall, at the election of the registered holder to be given within five (5) days of receipt of notice of the Restrictive Legend Event, either (A) rescind the previously submitted Election to Purchase and the Company shall return all consideration paid by registered holder for such shares upon such rescission or (B) treat the attempted exercise as a cashless exercise as described in the next paragraph and refund the cash portion of the exercise price to the registered holder.

(ii) If a Restrictive Legend Event has occurred [and no exemption from the registration requirements is available], the Warrant shall only be exercisable on a cashless basis. Notwithstanding anything herein to the contrary, the Company shall not be required to make any cash payments or net cash settlement to the registered holder in lieu of issuance of the Warrant Shares. Upon a "cashless exercise", the Holder shall be entitled to receive a certificate (or book entry) for the number of Warrant Shares equal to the quotient obtained by dividing [(A x B) - (A x C)] by (B), where:

(A) = the total number of shares with respect to which this Warrant is then being exercised;

- (B) = the arithmetic average of the Closing Sale Prices (as defined below) of the Common Stock for the five (5) consecutive trading days ending on the date immediately preceding the date of the Election to Purchase; and
- (X) = the Exercise Price then in effect for the applicable shares of Common Stock at the time of such exercise.

Upon receipt of an Election to Purchase for a cashless exercise, the Warrant Agent will promptly deliver a copy of the Election to Purchase to the Company to confirm the number of Warrant Shares issuable in connection with the cashless exercise. The Company shall calculate and transmit to the Warrant Agent, and the Warrant Agent shall have no obligation under this section to calculate, the number of Warrant Shares issuable in connection with the cashless exercise.

"<u>Closing Sale Price</u>" means, for any security as of any date, the last closing bid price and last closing trade price, respectively, for such security on the NASDAQ Capital Market, as reported by Bloomberg, or, if the NASDAQ Capital Market begins to operate on an extended hours basis and does not designate the closing bid price or the closing trade price, as the case may be, then the last bid price or the last trade price, respectively, of such security prior to 4:00:00 p.m., New York time, as reported by Bloomberg, or, if the NASDAQ Capital Market is not the principal securities exchange or trading market for such security, the last closing bid price or last trade price, respectively, of such security is listed or traded as reported by Bloomberg, or if the foregoing do not apply, the last closing bid price or last trade price, respectively, of such security in the over-the-counter market on the electronic bulletin board for such security as reported by Bloomberg, or, if no closing bid price or last trade price, respectively, is reported for such security by Bloomberg, the average of the bid prices, or the ask prices, respectively, of any market makers for such security as reported in the OTC Link or "pink sheets" by OTC Markets Group Inc. (formerly Pink OTC Markets Inc.). If the Closing Sale Price cannot be calculated for a security on a particular date on any of the foregoing bases, the Closing Sale Price of such security on such date shall be the fair market value as determined in good faith by the Company. All such determinations to be appropriately adjusted for any stock dividend, stock split, stock combination or other similar transaction during the applicable calculation period.

3.3.8 <u>Disputes</u>. In the case of a dispute as to the determination of the Exercise Price or the arithmetic calculation of the Warrant Shares, the Company shall promptly issue to the registered holder the number of Warrant Shares that are not disputed.

4. Share Delivery Failure. If the Company shall fail, for any reason or for no reason, to issue to the Holder within three (3) trading days after receipt of the applicable Election to Purchase (the "Share Delivery Deadline"), a certificate for the number of shares of Common Stock to which the Holder is entitled upon the Holder's exercise of a Warrant or credit the Holder's balance account with the Depository for such number of shares of Common Stock to which the Holder is entitled upon the Holder's exercise of this Warrant (as the case may be, but in each case without a restrictive legend) (a "Delivery Failure"), and if on or after such Share Delivery Deadline the Holder purchases (in an open market transaction or otherwise) shares of Common Stock to deliver in satisfaction of a sale by the Holder of all or any portion of the number of shares of Common Stock issuable upon such exercise that the Holder so anticipated receiving from the Company, then, in addition to all other remedies available to it, the Company shall, within three (3) Business Days (as defined below) after the Holder's request and in the Holder's discretion, either (i) pay cash to the Holder in an amount equal to 100% of the Holder's total purchase price (including brokerage commissions and other out-of-pocket expenses, if any) for the shares of Common Stock so purchased (including, without limitation, by any other person in respect, or on behalf, of the Holder) (the "Buy-In Price"), at which point the Company's obligation to so issue and deliver such certificate or credit the Holder's balance account with the Depository for the number of shares of Common Stock to which the Holder is entitled upon the Holder's exercise hereunder (as the case may be) (and to issue such shares of Common Stock) shall terminate, or (ii) promptly honor its obligation to so issue and deliver to the Holder a certificate or certificates representing such shares of Common Stock or credit the Holder's balance account with the Depository for the number of shares of Common Stock to which the Holder is entitled upon the Holder's exercise hereunder (as the case may be) and pay cash to the Holder in an amount equal to the excess (if any) of the Buy-In Price over the product of (A) such number of shares of Common Stock multiplied by (B) the lowest Closing Sale Price of the shares of Common Stock on any trading day during the period commencing on the date of the applicable Election to Purchase and ending on the date immediately preceding the date of such issuance and payment under this clause (ii). The term "Business Day" as used in this Agreement shall mean any day except a Saturday, a Sunday or any other day on which commercial banks are required or authorized to close in the City of New York, State of New York. If the Company fails for any reason to deliver to the Holder the Common Stock subject to an Election to Purchase by the Share Delivery Deadline, the Company shall pay to the Holder, in cash, as liquidated damages and not as a penalty, for each \$1,000 of Common Stock subject to such exercise (based on the VWAP of the Common Stock on the date of the applicable Election to Purchase), \$10 per trading day (increasing to \$20 per trading day on the fifth trading day after such liquidated damages begin to accrue) for each Trading Day after such Share Delivery Deadline until such shares of Common Stock are delivered or Holder rescinds such exercise. For the purposes of this provision "<u>VWAP</u>" means, for any date, the price determined by

the first of the following clauses that applies: (a) if the Common Stock is then listed or quoted on the Nasdaq Capital Market, the daily volume weighted average price of the Common Stock for such date (or the nearest preceding date) on the Nasdaq Capital Market on which the Common Stock is then listed or quoted as reported by Bloomberg L.P. (based on a trading day from 9:30 a.m. (New York City time) to 4:02 p.m. (New York City time)), (b) if the Common Stock is listed or quoted on the OTCQB or OTCQX, the volume weighted average price of the Common Stock for such date (or the nearest preceding date) on OTCQB or OTCQX as applicable, (c) if the Common Stock is not then listed or quoted for trading on OTCQB or OTCQX and if prices for the Common Stock are then reported in the "Pink Sheets" published by OTC Markets Group, Inc. (or a similar organization or agency succeeding to its functions of reporting prices), the most recent bid price per share of the Common Stock so reported, or (d) in all other cases, the fair market value of a share of Common Stock as determined by an independent appraiser selected in good faith by the Holders of a majority in interest of the Warrants then outstanding and reasonably acceptable to the Company, the fees and expenses of which shall be paid by the Company.

5. Adjustments.

5.1 Stock Dividends.

5.1.1 <u>Split-Ups</u>. If after the date hereof, and subject to the provisions of Section 5.5 below, the number of outstanding shares of Common Stock is increased by a stock dividend payable in shares of Common Stock on Common Stock, or by a split-up of shares of Common Stock or other similar event, then, on the effective date of such stock dividend, split-up or similar event, the number of shares of Common Stock issuable on exercise of each Warrant shall be increased in proportion to such increase in the outstanding shares of Common Stock and the Exercise Price shall be proportionally decreased such that the aggregate Exercise Price, after such adjustments, remains the same for each Warrant.

5.1.2 Extraordinary Dividends. If the Company, at any time while the Warrants are outstanding and unexpired, shall pay a dividend or make a distribution in cash, securities or other assets to the holders of the Common Stock as a class on account of such shares of Common Stock (or other shares of the Company's capital stock into which the Warrants are convertible), other than as described in subsection 5.1.1 (any such non-excluded event being referred to herein as an "Extraordinary Dividend"), then the Warrant Price shall be decreased, effective immediately after the effective date of such Extraordinary Dividend, by the amount of cash and/or the fair market value (as determined by the Board, in good faith) of any securities or other assets paid on each share of Common Stock (or other shares of the Company's capital stock into which the Warrants are convertible) in respect of such Extraordinary Dividend.

5.2 <u>Aggregation of Shares.</u> If after the date hereof, and subject to the provisions of Section 5.5, the number of outstanding shares of Common Stock is decreased by a consolidation, combination, reverse stock split or reclassification of shares of Common Stock or other similar event, then, on the effective date of such consolidation, combination, reverse stock split, reclassification or similar event, the number of shares of Common Stock issuable on exercise of each Warrant shall be decreased in proportion to such decrease in outstanding shares of Common Stock.

5.3. <u>Adjustments in Warrant Price</u>. Whenever the number of shares of Common Stock purchasable upon the exercise of the Warrants is adjusted, the Warrant Price shall be adjusted (to the nearest cent) by multiplying such Warrant Price immediately prior to such adjustment by a fraction (x) the numerator of which shall be the number of shares of Common Stock purchasable upon the exercise of the Warrants immediately prior to such adjustment, and (y) the denominator of which shall be the number of shares of Common Stock so purchasable immediately thereafter.

5.4. <u>Notices of Changes in Warrant</u>. Upon every adjustment of the Exercise Price or the number of shares issuable upon exercise of a Warrant, the Company shall give written notice thereof to the Warrant Agent, which notice shall state the Exercise Price resulting from such adjustment and the increase or decrease, if any, in the number of shares purchasable at such price upon the exercise of a Warrant, setting forth in reasonable detail the method of calculation and the facts upon which such calculation is based. Upon the occurrence of any event specified in Sections 5.1 or 5.2, then, in any such event, the Company shall give written notice to each registered holder, at the last address set forth for such holder in the warrant register, of the record date or the effective date of the event. Failure to give such notice, or any defect therein, shall not affect the legality or validity of such event.

5.5. <u>No Fractional Shares</u>. Notwithstanding any provision contained in this Agreement to the contrary, the Company shall not issue fractional shares or scrip representing fractional shares upon the exercise of Warrants. If, by reason of any adjustment made pursuant to this Section 5, the holder of any Warrant would be entitled, upon the exercise of such Warrant, to receive a fractional interest in a share, the Company shall, upon such exercise and at its sole election, either (i) pay a cash adjustment in respect of such final fraction in an amount equal to such fraction multiplied by the Warrant Price, or

(ii) round up to the nearest whole number the number of shares of Common Stock to be issued to such Holder.

5.6. Form of Warrant. The form of Warrant need not be changed because of any adjustment pursuant to this Section 5, and Warrants issued after such adjustment may state the same Warrant Price and the same number of shares as is stated in the Warrants initially issued pursuant to this Agreement; provided, however, that the Company may at any time in its sole discretion make any change in the form of Warrant that the Company may deem appropriate and that does not affect the substance thereof, and any Warrant thereafter issued or countersigned, whether in exchange or substitution for an outstanding Warrant or otherwise, may be in the form as so changed.

6. Transfer and Exchange of Warrants.

6.1. <u>Registration of Transfer</u>. The Warrant Agent shall register the transfer, from time to time, of any outstanding Warrant upon the Warrant Register, upon surrender of such Warrant for transfer, properly endorsed with signatures properly guaranteed and accompanied by appropriate instructions for transfer. Upon any such transfer, a new Warrant representing an equal aggregate number of Warrants shall be issued and the old Warrant shall be cancelled by the Warrant Agent. The Warrants so cancelled shall be delivered by the Warrant Agent to the Company from time to time upon request.

6.2. <u>Procedure for Surrender of Warrants</u>. Warrants may be surrendered to the Warrant Agent, together with a written request for exchange or transfer reasonably acceptable to Warrant Agent, duly executed by the registered holder thereof, or by a duly authorized attorney, and thereupon the Warrant Agent shall issue in exchange therefor one or more new Warrants as requested by the registered holder of the Warrants so surrendered, representing an equal aggregate number of Warrants; provided, however, that except as otherwise provided herein or in any Book-Entry Warrant Certificate, each Book-Entry Warrant Certificate may be transferred only in whole and only to the Depository, to another nominee of the Depository, to a successor depository, or to a nominee of a successor depository; provided further, however, that in the event that a Warrant surrendered for transfer bears a restrictive legend, the Warrant Agent shall not cancel such Warrant and issue new Warrants in exchange therefor until the Warrant Agent has received an opinion of counsel for the Company stating that such transfer may be made and indicating whether the new Warrants must also bear a restrictive legend. Upon any such registration of transfer, the Company shall execute, and the Warrant Agent shall countersign and deliver, in the name of the designated transferee a new Warrant Certificate or Warrant Certificates of any authorized denomination evidencing in the aggregate a like number of unexercised Warrants.

6.3. <u>Fractional Warrants</u>. The Warrant Agent shall not be required to effect any registration of transfer or exchange which will result in the issuance of a Warrant Certificate for a fraction of a Warrant.

6.4. <u>Service Charges</u>. A service charge shall be made for any exchange or registration of transfer of Warrants, as negotiated between Company and Warrant Agent.

6.5. <u>Warrant Execution and Countersignature</u>. The Warrant Agent is hereby authorized to countersign and to deliver, in accordance with the terms of this Warrant Agreement, the Warrants required to be issued pursuant to the provisions of this Section 6, and the Company, whenever required by the Warrant Agent, will supply the Warrant Agent with Warrants duly executed on behalf of the Company for such purpose.

7. <u>Limitations on Exercise</u>. Neither the Warrant Agent nor the Company shall effect any exercise of any Warrant, and a registered holder shall not have the right to exercise any portion of a Warrant, to the extent that after giving effect to the issuance of shares of Common Stock after exercise as set forth on the applicable Election to Purchase, the registered holder (together with such registered holder's Affiliates (as defined in Rule 405 under Act), and any other persons acting as a group together with the registered holder or any of the registered holder's Affiliates), would beneficially own in excess of 4.99% of the Company's Common Stock (the "<u>Maximum Percentage</u>"). For purposes of the foregoing sentence, the number of shares of Common Stock beneficially owned by the registered holder and its Affiliates shall include the number of shares of Common Stock which would be issuable upon exercise of the remaining, nonexercised portion of any Other securities of the Company beneficially owned by the registered Holder or any of its affiliates (including, without limitation, any convertible notes or convertible preferred stock or warrants) subject to a limitation on conversion or exercise analogous to the limitation contained herein.. Except as set forth in the preceding sentence, for purposes of this Section 7, beneficial ownership shall be calculated in accordance with Section 13(d) of the Exchange Act and the rules and regulations promulgated thereunder, it being acknowledged by the registered holder that

neither the Warrant Agent nor the Company is representing to the registered holder that such calculation is in compliance with Section 13(d) of the Exchange Act and the registered holder is solely responsible for any schedules required to be filed in accordance therewith. To the extent that the limitation contained in this Section 7 applies, the determination of whether a Warrant is exercisable (in relation to other securities owned by the registered holder together with any Affiliates) and of which portion of a Warrant is exercisable shall be in the sole discretion of the registered holder, and the submission of an Election to Purchase shall be deemed to be the registered holder's determination of whether such Warrant is exercisable (in relation to other securities owned by the registered holder together with any Affiliates) and of which portion of a Warrant is exercisable, and neither the Warrant Agent nor the Company shall have any obligation to verify or confirm the accuracy of such determination and neither of them shall have any liability for any error made by the registered holder. In addition, a determination as to any group status as contemplated above shall be determining in accordance with Section 13(d) of the Exchange Act and the rules and regulations promulgated thereunder. For purposes of this Section 7, in determining the number of outstanding shares of Common Stock as reflected in (A) the Company's most recent periodic or annual report filed with the Securities and Exchange Commission, as the case may be, (B) a more recent public announcement by the Company or (C) a more recent written notice by the Company or the Company's transfer agent setting forth the number of shares of Common Stock outstanding. The provisions of this Section 7 shall be construed and implemented in a manner otherwise than in strict conformity with the terms of this Section 6 to correct this subsection (or any portion hereof) which may be defective or inconsistent with the intended beneficial ownership limitation herein con

8. Other Provisions Relating to Rights of Holders of Warrants.

8.1. <u>No Rights as Stockholder</u>. Except as otherwise specifically provided herein, a registered holder, solely in its capacity as a holder of a Warrant, shall not be entitled to vote or receive dividends or be deemed the holder of share capital of the Company for any purpose, nor shall anything contained in this Warrant Agreement be construed to confer upon a registered holder, solely in its capacity as the registered holder of a Warrant, any of the rights of a stockholder of the Company or any right to vote, give or withhold consent to any corporate action (whether any reorganization, issue of stock, reclassification of stock, consolidation, merger, conveyance or otherwise), receive notice of meetings, receive dividends or subscription rights, or otherwise, prior to the issuance to the registered holder of the Warrant Shares which it is then entitled to receive upon the due exercise of a Warrant. A Warrant does not entitle the registered holder thereof to any of the rights of a stockholder.

8.2. Lost, Stolen, Mutilated, or Destroyed Warrants. If any Warrant is lost, stolen, mutilated, or destroyed, the Company and the Warrant Agent may on such terms as to indemnity (including obtaining an open penalty bond protecting the Warrant Agent) or otherwise as they may in their discretion impose (which shall, in the case of a mutilated Warrant, include the surrender thereof), issue a new Warrant of like denomination, tenor, and date as the Warrant so lost, stolen, mutilated, or destroyed. Any such new Warrant shall constitute a substitute contractual obligation of the Company, whether or not the allegedly lost, stolen, mutilated, or destroyed Warrant shall be at any time enforceable by anyone.

8.3. <u>Reservation of Common Stock</u>. The Company shall at all times reserve and keep available a number of its authorized but unissued shares of Common Stock that will be sufficient to permit the exercise in full of all outstanding Warrants issued pursuant to this Warrant Agreement.

8.4 <u>Registration of Common Stock</u>. The Company will use commercially reasonable efforts to maintain the effectiveness of the Registration Statement and the current status of the Prospectus or to file and maintain the effectiveness of another registration statement and another current prospectus covering the Warrants and the Warrant Shares until all Warrant Shares covered by such registration statement may be sold without restriction or limitation pursuant to Rule 144 and without the requirement to be in compliance with Rule 144(c)(1).

9. Redemption.

9.1 <u>Right of Redemption</u>. Not less than all of the outstanding Warrants may be redeemed, at the option of the Company, at any time following the first anniversary of closing of the Offering and prior to the Expiration Date, at the office of the Warrant Agent, upon the notice referred to in <u>Section 9.2</u>, at the price of \$0.01 per Warrant (subject to adjustment proportionate to any adjustment to the Warrant Price pursuant to Section 5.3) (the "<u>Redemption Price</u>"), provided, however, that the last reported sales price of the Common Stock has been equal to or greater than the \$7.65 per share (subject to adjustment proportionate to any adjustment to Section 5.3) for any period of 10 consecutive

trading days ending prior to the notice of redemption to the Registered Holders and there is an effective registration statement covering the shares of Common Stock issuable upon exercise of the Warrants current and available,.

9.2 Date Fixed for, and Notice of, Redemption. In the event the Company shall elect to redeem all of the Warrants pursuant to Section 9.1 (the "Redeemable Warrants"), the Company shall fix a date for the redemption. Notice of redemption shall be mailed by first class mail, postage prepaid, by the Company not less than 30 days prior to the date fixed for redemption to the Registered Holders of the Redeemable Warrants at their last addresses as they shall appear on the registration books. Any notice mailed in the manner herein provided shall be conclusively presumed to have been duly given on the date sent whether or not the Registered Holder received such notice.

9.3 Exercise After Notice of Redemption. The Redeemable Warrants may be exercised for cash in accordance with Section 3.3.1 of this Warrant Agreement at any time after notice of redemption shall have been given by the Company pursuant to Section 9.2 hereof and prior to the time and date fixed for redemption. On and after the redemption date, the record holders of the Redeemable Warrants shall have no further rights except to receive the Redemption Price upon surrender of the Redeemable Warrants.

10. Concerning the Warrant Agent and Other Matters.

10.1. Concerning the Warrant Agent. The Warrant Agent:

i)

shall have no duties or obligations other than those set forth herein and no duties or obligations shall be inferred or

implied;

may rely on and shall be held harmless by the Company in acting upon any certificate, statement, instrument, opinion, ii) notice, letter, facsimile or electronic transmission, telegram or other document, or any security delivered to it, and reasonably believed by it to be genuine and to have been made or signed by the proper party or parties;

iii) may rely on and shall be held harmless by the Company in acting upon written or oral instructions or statements from the Company with respect to any matter relating to its acting as Warrant Agent;

may consult with counsel satisfactory to it (including counsel for the Company) and shall be held harmless by the iv) Company in relying on the advice or opinion of such counsel in respect of any action taken, suffered or omitted by it hereunder in good faith and in accordance with such advice or opinion of such counsel;

solely shall make the final determination as to whether or not a Warrant received by Warrant Agent is duly, completely v) and correctly executed, and Warrant Agent shall be held harmless by the Company in respect of any action taken, suffered or omitted by Warrant Agent hereunder in good faith and in accordance with its determination;

shall not be obligated to take any legal or other action hereunder which might, in its judgment subject or expose it to vi) any expense or liability unless it shall have been furnished with an indemnity satisfactory to it; and

shall not be liable or responsible for any failure of the Company to comply with any of its obligations relating to the vii) Registration Statement or this Warrant Agreement, including without limitation obligations under applicable regulation or law.

10.2 Payment of Taxes. The Company will from time to time promptly pay all taxes and charges that may be imposed upon the Company or the Warrant Agent in respect of the issuance or delivery of shares of Common Stock upon the exercise of Warrants, but the Company shall not be obligated to pay any transfer taxes in respect of the Warrants or such shares. The Warrant Agent shall not register any transfer or issue or deliver any Warrant Certificate(s) or Warrant Shares unless or until the persons requesting the registration or issuance shall have paid to the Warrant Agent for the account of the Company the amount of such tax, if any, or shall have established to the reasonable satisfaction of the Company that such tax, if any, has been paid.

10.3 Resignation, Consolidation, or Merger of Warrant Agent.

10.3.1. <u>Appointment of Successor Warrant Agent</u>. The Warrant Agent, or any successor to it hereafter appointed, may resign its duties and be discharged from all further duties and liabilities hereunder after giving sixty (60) days' notice in writing to the Company. If the office of the Warrant Agent becomes vacant by resignation or incapacity to act

or otherwise, the Company shall appoint in writing a successor Warrant Agent in place of the Warrant Agent. If the Company shall fail to make such appointment within a period of 30 days after it has been notified in writing of such resignation or incapacity by the Warrant Agent or by the holder of the Warrant (who shall, with such notice, submit his Warrant for inspection by the Company), then the holder of any Warrant may apply to the Supreme Court of the State of New York for the County of New York for the appointment of a successor Warrant Agent at the Company's cost. Any successor Warrant Agent (but not including the initial Warrant Agent), whether appointed by the Company or by such court, shall be a corporation organized and existing under the laws of the State of Delaware, in good standing and having its principal office in the State of New York, and authorized under such laws to exercise corporate trust powers and subject to supervision or examination by federal or state authority. After appointment, any successor Warrant Agent shall be vested with all the authority, powers, rights, immunities, duties, and obligations of its predecessor Warrant Agent with like effect as if originally named as Warrant Agent hereunder, without any further act or deed; but if for any reason it becomes necessary or appropriate, the predecessor Warrant Agent shall execute and deliver, at the expense of the Company, an instrument transferring to such successor Warrant Agent all the authority, powers, and rights of such predecessor Warrant Agent hereunder; and upon request of any successor Warrant Agent the Company shall make, execute, acknowledge, and deliver any and all instruments in writing for more fully and effectually vesting in and confirming to such successor Warrant Agent all such authority, powers, rights, immunities, duties, and obligations.

10.2.2. <u>Notice of Successor Warrant Agent</u>. In the event a successor Warrant Agent shall be appointed, the Company shall give notice thereof to the predecessor Warrant Agent and the transfer agent for the Common Stock not later than the effective date of any such appointment.

10.2.3. <u>Merger or Consolidation of Warrant Agent</u>. Any corporation into which the Warrant Agent may be merged or with which it may be consolidated or any corporation resulting from any merger or consolidation to which the Warrant Agent shall be a party shall be the successor Warrant Agent under this Warrant Agreement without any further act.

10.4. Fees and Expenses of Warrant Agent.

10.4.1. <u>Remuneration</u>. The Company agrees to pay the Warrant Agent reasonable remuneration in an amount separately agreed to between Company and Warrant Agent for its services as Warrant Agent hereunder and will reimburse the Warrant Agent upon demand for all expenditures that the Warrant Agent may reasonably incur in the execution of its duties hereunder. One half of the total Warrant Agent fees (not including postage) must be paid upon execution of this Warrant Agreement. The remaining half must be paid within fifteen (15) business days thereafter. An invoice for any out-of-pocket and/or per item fees incurred will be rendered to and payable by the Company within fifteen (15) days of the date of said invoice. It is understood and agreed that all services to be performed by Warrant Agent shall cease if full payment for its services has not been received in accordance with the above schedule, and said services will not commence thereafter until all payment due has been received by Warrant Agent.

10.4.2. <u>Further Assurances</u>. The Company agrees to perform, execute, acknowledge, and deliver or cause to be performed, executed, acknowledged, and delivered all such further and other acts, instruments, and assurances as may reasonably be required by the Warrant Agent for the carrying out or performing of the provisions of this Warrant Agreement.

10.5. Liability of Warrant Agent.

10.5.1. <u>Reliance on Company Statement</u>. Whenever in the performance of its duties under this Warrant Agreement, the Warrant Agent shall deem it necessary or desirable that any fact or matter be proved or established by the Company prior to taking or suffering any action hereunder, such fact or matter (unless other evidence in respect thereof be herein specifically prescribed) may be deemed to be conclusively proved and established by a statement signed by the President, Chief Executive Officer, Chief Financial Officer, Secretary or other principal officer of the Company and delivered to the Warrant Agent may rely upon such statement for any action taken or suffered in good faith by it pursuant to the provisions of this Warrant Agreement.

10.5.2. <u>Indemnity</u>. The Warrant Agent shall be liable hereunder only for its own gross negligence, willful misconduct or bad faith. The Company agrees to indemnify the Warrant Agent and save it harmless against any and all liabilities, including judgments, claims, losses, damages, costs and reasonable counsel fees, for anything done or omitted by the Warrant Agent in the execution of this Warrant Agreement except as a result of the Warrant Agent's gross negligence, willful misconduct, or bad faith.

10.5.3. <u>Limitation of Liability</u>. The Warrant Agent's aggregate liability, if any, during the term of this Warrant Agreement with respect to, arising from, or arising in connection with this Warrant Agreement, or from all services provided or omitted to be provided under this Warrant Agreement, whether in contract, or in tort, or otherwise, is limited to, and shall not exceed, the amounts paid or payable hereunder by the Company to Warrant Agent as fees and charges, but not including reimbursable expenses.

10.5.4 <u>Disputes</u>. In the event any question or dispute arises with respect to the proper interpretation of this Warrant Agreement or the Warrant Agent's duties hereunder or the rights of the Company or of any holder of a Warrant, the Warrant Agent shall not be required to act and shall not be held liable or responsible for refusing to act until the question or dispute has been judicially settled (and the Warrant Agent may, if it deems it advisable, but shall not be obligated to, file a suit in interpleader or for a declaratory judgment for such purpose) by final judgment rendered by a court of competent jurisdiction, binding on all parties interested in the matter which is no longer subject to review or appeal, or settled by a written document in form and substance satisfactory to the Warrant Agent and executed by the Company and each other interested party. In addition, the Warrant Agent may require for such purpose, but shall not be obligated to require, the execution of such written settlement by all the Warrant holders, as applicable, and all other parties that may have an interest in the settlement.

10.5.5 Exclusions. The Warrant Agent shall have no responsibility with respect to the validity of this Warrant Agreement or with respect to the validity or execution of any Warrant (except its countersignature thereof); nor shall it be responsible for any breach by the Company of any covenant or condition contained in this Warrant Agreement or in any Warrant; nor shall it be responsible to make any adjustments required under the provisions of Section 4 hereof or responsible for the manner, method, or amount of any such adjustment or the ascertaining of the existence of facts that would require any such adjustment; nor shall it by any act hereunder be deemed to make any representation or warranty as to the authorization or reservation of any shares of Common Stock to be issued pursuant to this Warrant Agreement or any Warrant or as to whether any shares of Common Stock will when issued be valid and fully paid and nonassessable.

10.6. <u>Acceptance of Agency</u>. The Warrant Agent hereby accepts the agency established by this Warrant Agreement and agrees to perform the same upon the terms and conditions herein set forth and among other things, shall account promptly to the Company with respect to Warrants exercised and concurrently account for, and pay to the Company, all moneys received by the Warrant Agent for the purchase of shares of Common Stock through the exercise of Warrants.

11. Miscellaneous Provisions.

11.1. <u>Successors</u>. All the covenants and provisions of this Warrant Agreement by or for the benefit of the Company or the Warrant Agent shall bind and inure to the benefit of their respective successors and assigns.

11.2. <u>Notices</u>. Any notice, statement or demand authorized by this Warrant Agreement to be given or made by the Warrant Agent or by the holder of any Warrant to or on the Company shall be sufficiently given (i) when so delivered if by hand or overnight delivery, (ii) when sent, if delivered by facsimile (provided that confirmation of transmission is mechanically or electronically generated and kept on file by the sending party) or by electronic mail, or (iii) if sent by certified mail or private courier service, within five (5) days after deposit of such notice, postage prepaid, addressed (until another address is filed in writing by the Company with the Warrant Agent), as follows:

Cytori Therapeutics, Inc. 3020 Callan Road San Diego, CA 92121 Attn: Marc H. Hedrick

With a copy to:

DLA Piper LLP (US) 4365 Executive Dr., Suite 1100 San Diego, CA 92121 Attention: Jeffrey Baglio, Esq.

Any notice, statement or demand authorized by this Warrant Agreement to be given or made by the holder of any Warrant or by the Company to or on the Warrant Agent shall be sufficiently given (a) upon receipt if by hand or overnight delivery, (b) when sent, if delivered by facsimile (provided that confirmation of transmission is mechanically or electronically generated and kept on file by the sending party) or by electronic mail, or (c) if by hand or overnight delivery or

Exhibit 4.2

if sent by certified mail or private courier service, within five (5) days after deposit of such notice, postage prepaid, addressed (until another address is filed in writing by the Warrant Agent with the Company), as follows:

Broadridge Corporate Issuer Solutions, Inc. 1717 Arch Street Suite 1300 Philadelphia, Pennsylvania 19103 Attn: Compliance Department

With a copy to:

Broadridge Financial Solutions, Inc. 2 Journal Square Plaza Jersey City, New Jersey 07306 Attention: General Counsel

11.3. <u>Applicable Law</u>. The validity, interpretation, and performance of this Warrant Agreement and of the Warrants shall be governed in all respects by the laws of the State of New York, without giving effect to conflicts of law principles that would result in the application of the substantive laws of another jurisdiction. The Company hereby agrees that any action, proceeding or claim against it arising out of or relating in any way to this Warrant Agreement shall be brought and enforced in the courts of the State of New York or the United States District Court for the Southern District of New York, and irrevocably submits to such jurisdiction, which jurisdiction shall be exclusive. The Company hereby waives any objection to such exclusive jurisdiction and that such courts represent an inconvenience forum. Any such process or summons to be served upon the Company may be served by transmitting a copy thereof by registered or certified mail, return receipt requested, postage prepaid, addressed to it at the address set forth in Section 11.2 hereof. Such mailing shall be deemed personal service and shall be legal and binding upon the Company in any action, proceeding or claim.

11.4. <u>Persons Having Rights under this Warrant Agreement</u>. Nothing in this Agreement shall be construed to confer upon, or give to, any person or entity other than the parties hereto and the Registered Holders of the Warrants any right, remedy, or claim under or by reason of this Agreement or of any covenant, condition, stipulation, promise, or agreement hereof. All covenants, conditions, stipulations, promises, and agreements contained in this Agreement shall be for the sole and exclusive benefit of the parties hereto and their successors and assigns and of the Registered Holders of the Warrants.

11.5. <u>Examination of the Warrant Agreement</u>. A copy of this Warrant Agreement shall be available at all reasonable times at the office of the Warrant Agent in the city of Philadelphia, Commonwealth of Pennsylvania, for inspection by the registered holder of any Warrant. The Warrant Agent may require any such holder to submit his Warrant for inspection by it.

11.6. <u>Counterparts</u>. This Warrant Agreement may be executed in any number of counterparts and each of such counterparts shall for all purposes be deemed to be an original, and all such counterparts shall together constitute but one and the same instrument. Such counterparts may be delivered electronically.

11.7. <u>Effect of Headings</u>. The Section headings herein are for convenience only and are not part of this Warrant Agreement and shall not affect the interpretation thereof.

11.8 <u>Amendments</u>. This Warrant Agreement may be amended by the parties hereto without the consent of any registered holder for the purpose of curing any ambiguity, or of curing, correcting or supplementing any defective provision contained herein or adding or changing any other provisions with respect to matters or questions arising under this Warrant Agreement as the parties may deem necessary or desirable and that the parties deem shall not adversely affect the interest of the registered holders. All other modifications or amendments, including any amendment to increase the Exercise Price or shorten the Exercise Period, shall require the written consent of the registered holders of a majority of the then outstanding Warrants.

11.9 <u>Severability</u>. This Warrant Agreement shall be deemed severable, and the invalidity or unenforceability of any term or provision hereof shall not affect the validity or enforceability of this Warrant Agreement or of any other term or provision hereof. Furthermore, in lieu of any such invalid or unenforceable term or provision, the parties hereto intend that there shall be added as a part of this Warrant Agreement a provision as similar in terms to such invalid or unenforceable provision as may be possible and be valid and enforceable.

11.10 <u>Force Majeure</u>. In the event either party is unable to perform its obligations under the terms of this Warrant Agreement because of acts of God, strikes, failure of carrier or utilities, equipment or transmission failure or damage that is reasonably beyond its control, or any other cause that is reasonably beyond its control, such party shall not be liable for damages to the other for any damages resulting from such failure to perform or otherwise from such causes. Performance under this Warrant Agreement shall resume when the affected party or parties are able to perform substantially that party's duties.

11.11 <u>Consequential Damages</u>. Notwithstanding anything in this Warrant Agreement to the contrary, neither party to this Warrant Agreement shall be liable to the other party for any consequential, indirect, special or incidental damages under any provision of this Agreement or for any consequential, indirect, punitive, special or incidental damages arising out of any act or failure to act hereunder even if that party has been advised of or has foreseen the possibility of such damages.

[Signature Page Follows.]

IN WITNESS WHEREOF, this Restated Warrant Agreement has been duly executed by the parties effective as of the Issuance Date.

CYTORI THERAPEUTICS, INC.

By: Name: Tiago Girao Title: Chief Financial Officer

BROADRIDGE CORPORATE ISSUER SOLUTIONS, INC.

By: Name: Title:

Signature Page to Warrant Agency Agreement

<u>EXHIBIT A</u>

[Form of Warrant Certificate]

[REVERSE]

[Form of Warrant Certificate]

[FACE]

Number: R-____

THIS WARRANT SHALL BE VOID IF NOT EXERCISED PRIOR TO THE EXPIRATION OF THE EXERCISE PERIOD PROVIDED FOR IN THE RESTATED WARRANT AGREEMENT DESCRIBED BELOW CYTORI THERAPEUTICS, INC.

Incorporated Under the Laws of the State of Delaware

CUSIP [___]

Series R Warrant Certificate

The Warrants evidenced by this Warrant Certificate are part of a duly authorized issue of Warrants entitling the holder on exercise to receive shares of Common Stock and are issued or to be issued pursuant to a Restated Warrant Agreement dated as of [_____], 2016 (the "*Warrant Agreement*"), duly executed and delivered by the Company to Broadridge Corporate Issuer Solutions, Inc., a corporation having its principal offices in Philadelphia, Pennsylvania, as warrant agent (the "*Warrant Agreem*"), which Warrant Agreement is hereby incorporated by reference in and made a part of this instrument and is hereby referred to for a description of the rights, limitation of rights, obligations, duties and immunities thereunder of the Warrant Agreement may be obtained by the holder hereof upon written request to the Company. Defined terms used in this Warrant Certificate but not defined herein shall have the meanings given to them in the Warrant Agreement.

Warrants may be exercised at any time during the Exercise Period set forth in the Warrant Agreement. Notwithstanding the foregoing or anything else herein or in the Warrant Agreement to the contrary, for so long as the holder continues to hold the Warrant, such holder shall not enter into any short sale or similar transaction with respect to the Common Stock. Any violation of this provision may result in the Warrant being terminated at the Company's option. The holder of Warrants evidenced by this Warrant Certificate may exercise them by delivering (i) this Warrant Certificate, or, in the case of a Book-Entry Warrant Certificate (as defined in the Warrant Agreement), the Warrants to be exercised (the "*Book-Entry Warrants*") as shown on the records of The Depository Trust Company (the "*Depository*") to an account of the Warrant Agent at the Depository designated for such purpose in writing by the Warrant Agent to the Depository, (ii) an election to purchase ("*Exercise Notice*"), properly executed by the holder hereof on the reverse of this Warrant Certificate or properly executed by the institution in whose account the Warrant is recorded on the records of the Depository (the "*Participant*"), and substantially in the form included on the reverse of this Warrant Certificate and (iii) the Warrant Price for each Warrant to be exercised in lawful money of the United States by certified or official bank check or by bank wire transfer in immediately available funds, in each case payable to the Warrant Agent, unless a "*cashless exercise*" is permitted under the Warrant Agreement.

In the event that upon any exercise of Warrants evidenced hereby the number of Warrants exercised shall be less than the total number of Warrants evidenced hereby, there shall be issued to the holder hereof or his, her or its assignee, a new Warrant Certificate evidencing the number of Warrants not exercised. If fewer than all the Warrants evidenced by a Book-Entry Warrant Certificate are exercised, a notation shall be made to the records maintained by the Depository, its nominee for each Book-Entry Warrant Certificate, or a Participant, as appropriate, evidencing the balance of the Warrants remaining after such exercise.

Notwithstanding anything else in this Warrant Certificate or the Warrant Agreement, no Warrant may be exercised unless at the time of exercise (i) a registration statement covering the shares of Common Stock to be issued upon exercise is effective under the Securities Act and (ii) a prospectus thereunder relating to the shares of

Common Stock is current, except through "cashless exercise" as provided for in the Warrant Agreement.

The Warrant Agreement provides that upon the occurrence of certain events the number of shares of Common Stock issuable upon exercise of the Warrants set forth on the face hereof may, subject to certain conditions, be adjusted. If, upon exercise of a Warrant, the holder thereof would be entitled to receive a fractional interest in a share of Common Stock, the Company shall, upon exercise, either round up to the nearest whole number of shares of Common Stock to be issued to the holder of the Warrant or pay such holder cash for such fractional share in the Company's sole discretion.

Warrant Certificates, when surrendered at the office of the Warrant Agent designated for such purposes by the Registered Holder thereof in person or by legal representative or attorney duly authorized in writing, may be exchanged, in the manner and subject to the limitations provided in the Warrant Agreement, but without payment of any service charge, for another Warrant Certificate or Warrant Certificates of like tenor evidencing in the aggregate a like number of Warrants.

Upon due presentation for registration of transfer of this Warrant Certificate at the office of the Warrant Agent, a new Warrant Certificate or Warrant Certificates of like tenor and evidencing in the aggregate a like number of Warrants shall be issued to the transferee(s) in exchange for this Warrant Certificate, subject to the limitations provided in the Warrant Agreement, without charge except for any tax or other governmental charge imposed in connection therewith.

The Company and the Warrant Agent may deem and treat the Registered Holder(s) hereof as the absolute owner(s) of this Warrant Certificate (notwithstanding any notation of ownership or other writing hereon made by anyone), for the purpose of any exercise hereof, of any distribution to the holder(s) hereof, and for all other purposes, and neither the Company nor the Warrant Agent shall be affected by any notice to the contrary. Neither the Warrants nor this Warrant Certificate entitles any holder hereof to any rights of a stockholder of the Company.

NOTICE OF EXERCISE

(To Be Executed Upon Exercise of Warrant)

CASH EXERCISE:

The undersigned hereby irrevocably elects to exercise the rights represented by this Warrant Certificate to receive _______ shares of Common Stock and herewith tenders payment for such shares to the order of Cytori Therapeutics, Inc. (the "*Company*") in the amount of \$_____ in accordance with the terms hereof. The undersigned requests that a certificate for such shares be registered in the name of ______, whose address is ______ and that such shares be delivered to ______ whose address is ______. If said number of shares is less than all of the shares of Common Stock purchasable hereunder, the undersigned requests that a new Warrant Certificate representing the remaining balance of such shares be registered in the name of ______, whose address is ______, and that such Warrant Certificate be delivered to ______, whose address is ______.

CASHLESS EXERCISE:

In the event that the Warrant may be exercised, to the extent allowed by the Restated Warrant Agreement, through cashless exercise, (i) the number of shares that this Warrant is exercisable for would be determined in accordance with section 3.3.2 of the Restated Warrant Agreement which allows for such cashless exercise and (ii) the holder hereof shall complete the following:

The undersigned hereby irrevocably elects to exercise the right, represented by this Warrant Certificate, through the cashless exercise provisions of the Restated Warrant Agreement, to receive shares of Common Stock. If said number of shares is less than all of the shares of Common Stock purchasable hereunder (after giving effect to the cashless exercise), the undersigned requests that a new Warrant Certificate representing the remaining balance of such shares be registered in the name of ______, whose address is ______, and that such Warrant Certificate be delivered to ______, whose address is ______.

Date:_____, 20___

(Signature)

(Address)

(Tax Identification Number)

Signature must conform in all respects to the name of the holder as specified on the face of this Warrant Certificate. If Warrant Shares, or a Warrant Certificate evidencing unexercised Warrants, are to be issued in a name other than that of the registered holder hereof or are to be delivered to an address other than the address of such holder as shown on the books of the Warrant Agent, the above signature must be guaranteed by a an Eligible Guarantor Institution (as that term is defined in Rule 17Ad-15 of the Securities Exchange Act of 1934, as amended).

Signature Guaranteed:

THE SIGNATURE(S) SHOULD BE GUARANTEED BY AN ELIGIBLE GUARANTOR INSTITUTION (BANKS, STOCKBROKERS, SAVINGS AND LOAN ASSOCIATIONS AND CREDIT UNIONS WITH MEMBERSHIP IN AN APPROVED SIGNATURE GUARANTEE MEDALLION PROGRAM, PURSUANT TO RULE 17Ad-15).

ASSIGNMENT

(FORM OF ASSIGNMENT TO BE EXECUTED IF WARRANT HOLDER DESIRES TO TRANSFER WARRANTS EVIDENCED HEREBY)

FOR VALUE RECEIVED, _____ HEREBY SELL(S), ASSIGN(S) AND TRANSFER(S) UNTO

(Please print name and address including zip code of assignee)

the rights represented by the within Warrant Certificate and does hereby irrevocably constitute and appoint ______ Attorney to transfer said Warrant Certificate on the books of the Warrant Agent with full power of substitution in the premises.

Date: _____, 20___

(Signature)

(Address)

(Tax Identification Number)

Signature must conform in all respects to the name of the holder as specified on the face of this Warrant Certificate and must bear a signature guarantee by an Eligible Guarantor Institution (as that term is defined in Rule 17Ad-15 of the Securities Exchange Act of 1934, as amended).

Signature Guaranteed:

THE SIGNATURE(S) SHOULD BE GUARANTEED BY AN ELIGIBLE GUARANTOR INSTITUTION (BANKS, STOCKBROKERS, SAVINGS AND LOAN ASSOCIATIONS AND CREDIT UNIONS WITH MEMBERSHIP IN AN APPROVED SIGNATURE GUARANTEE MEDALLION PROGRAM, PURSUANT TO RULE 17Ad-15).

WEST\268940956.6 367298-000020 (Please insert social security or other identifying number of assignee)

_____ (Please i ______ other ide

<u>Exhibit B</u>

AGENT AND FEE SCHEDULE

Exchange:

Project Management Fees for up to 100 record stockholders:

• \$500.00 per month, Agent Fee

Covers all services listed in "AGENT SERVICES COVERED" as set forth in Exhibit B for all record date Stockholders.

Warrant Agent shall be entitled to reimbursement of all reasonable out-of-pocket expenses including but not limited to postage, stationery and supplies, which will be billed as incurred during the performance of Warrant Agent's duties hereunder, including without limitation:

Out of pocket expenses

- Postage with shared Pre-Sort savings (to be paid in advance) 1
- Overnight delivery / courier service / photocopy service
- Envelopes outer and BRE (Business Reply Envelopes) 1
- Brochures and enrollment materials
- Insurance and courier fees
- Printing of check forms and blank stock certificates

Although Warrant Agent may advance payment for these expenses and then invoice Company, there are occasions when Warrant Agent may require advance payment toward large expense items.

11 Rates are subject to change upon U.S. and foreign postage rate increases.

CERTAIN MATERIAL (INDICATED BY ASTERISKS) HAS BEEN OMITTED FROM THIS DOCUMENT PURSUANT TO A REQUEST FOR CONFIDENTIAL TREATMENT. THE OMITTED MATERIAL HAS BEEN FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION.

Exhibit 10.3

				1. CONTRACT ID CODE	PAGE OF		
AMENDMENT	OF SOLICITATION/MODIFICA	FION OF CONTRACT			PAGES		
2. AMENDMEN	T/MODIFICATION NO.	3. EFFECTIVE DATE	4. REQUISIT	ION/PURCHASE REQ. NO.	5. PROJECT NO. (If applicable)		
0007		See Block 16C					
6. ISSUED BY	CODE	ASPR-BARDA	7. ADMINIS	TERED BY (if other than Item 6)	CODE ASPR-BARDA01		
ASPR-BARDA 200 Independence Ave., S.W. Room 640-G Washington DC 20201			ASPR-BAR 330 Indepen Washington	dence Ave, SW, Rm G644			
8. NAME AND A	ADDRESS OF CONTRACTOR (No,	street, count, State and ZIP Code)	(x)	9A. AMENDMENT OF SOLICITATION	NO.		
CVTODI TUEDA	APEUTICS, INC 1386447						
	APEUTICS, INC. 3020 RD			9B. DATED (SEE ITEM 11)			
			Х	10A. MODIFICATION OF CONTRACT/ORDER NO. HHSO100201200008C			
CODE 1300 447			_	10B. DATED <i>(SEE ITEM 13)</i> 09/28/2012			
CODE 1386447		FACILITY CODE					
		11. THIS ITEM ONLY APPLIE forth in Item 14. The hour and date sp			t extended. Offers must acknowledge rece		
numbers. FAILUF SPECIFIED MAY provided each tele	ŘE OF YOUŘ AČKNÓWLEDGEM Y RESULT IN REJECTION OF YO	ENT TO BE RECEIVED AT THE PL UR OFFER. If by virtue of this amend e solicitation and this amendment, and	ACE DESIGN	y separate letter or telegram which includes a ATED FOR THE RECEIPT OF OFFERS PF to change an offer already submitted, such or to the opening hour and date specified.	IOR TO THE HOUR AND DATE		
	IS ITEM ONLY APPLIES TO MO	DDIFICATION OF CONTRACTS/	ORDERS. IT N	AODIFIES THE CONTRACT/ORDER N	O. AS DESCRIBED IN ITEM 14.		
CHECK ONE	A. THIS CHANGE ORDER IS I ITEM 10A.	SSUED PURSUANT TO: (Specify au	thority) THE C	HANGES SET FORTH IN ITEM 14 ARE M	IADE IN THE CONTRACT ORDER NO		
	B. THE ABOVE NUMBERED C date, etc.) SET FORTH IN IT	CONTRACT/ORDER IS MODIFIED EM 14, PURSUANT TO THE AUTH	TO REFLECT IORITY OF FA	THE ADMINISTRATIVE CHANGES (such R 43.103(b).	as changes in paying office, appropriatio		
Х		REEMENT IS ENTERED INTO PUR 1987) Changes - cost-reimbursement a					
	D. OTHER (Specify type of modi	fication and authority)					
E. IMPORTANT	: Contractor 🛛 is not. 🗵 is re	quired to sign this document and retur	m <u>1</u>	copies to the issuing office.			
Tax ID Number: 3 DUNS Number: 1 The purpose of th 1.Update the Statt 2.Update the Cost 3.Update the Peri 4.Add Advancend 5.Update ARTICI 6.Update of total 7.Update addition	33-0827593	N 2. N004/OPTION 2. O100201200008C.	neadings, inclu	ıding solicitation/contract subject matter wl	eere țeasible)		
				ofore changed, remains unchanged and in ful			
15A. NAME ANI Tiago M. Gir	D TITLE OF SIGNER (Type or print rao CEO	t)		E AND TITLE OF CONTRACTING OFFIC	CER (Type or print)		
		15C DATE SIGNED		CONYERS ED STATES OF AMERICA	16C DATE SIGNED		
15B. CONTRAC /s/ Tiago M. (15C. DATE SIGNED 05/19/17	TOB. UNIT	Will Com	16C. DATE SIGNED 5/19/2017		
US-DOCS\92204	364.1						

(Signature of person authorized to sign)
--

NSN 7540-01-152-8070 Previous edition unusable

CONTINUATION SHEET REFERENCE NO. OF DOCUMENT BEING CONTINUED HISO10 0201200008C/0007						
NAME OF OFFEROR OR CONTRACTOR CYTORI THERAPEUTICS, INC 1386447						
ITEM NO.	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT	
(A)	(B)	(C)	(D)	(E)	(F)	
	FOB: Destination Period of Performance: 09/28/2012 to 11/30/2020					
	Add Item 4 as follows :					
4	Option 2 – PILOT IDE CLINICAL TRIAL (Period of Performance: May 23, 2017 thru November 30, 2020) Amount: \$13,358,679.00 (Option Line Item)				0.00	
NSN 7540-01-15	2-8067				OPTIONAL FORM 336 (4-86) Sponsored by GSA FAR (48 CFR) 53.110	

SUMMARY OF CHANGES

- SECTION J STATEMENT OF WORK; OPTION 2: PILOT CLINICAL TRIAL EXECUTION is hereby deleted in its entirety and replaced with OPTION 2: REVISED PILOT CLINICAL TRIAL EXECUTION - STATEMENT OF WORK (CLIN004/OPTION 2; 5/19/2017) - ATTACHMENT 1).
- 2. ARTICLE B.3. OPTION PRICES, is hereby deleted in its entirety and replaced with the following:
 - a. Unless the government exercises its option pursuant to the option clause contained in ARTICLE I.2, the contract consists only of the Base Work segment specified in the Statement of Work as defined in SECTIONS C and F, for the price set forth in ARTICLE B.2 of the contract.
 - b. Pursuant to FAR Clause 52.2017-9 (Option to Extend the Term of the Contract), the Government may, by unilateral contract modification, require the Contractor to perform the Option Work Segments specified in the Statement of Work as defined in SECTIONS C and F of this contract. If the Government exercises the/these option (s), written notice must be given to the Contractor within 30 days after the Government has completed its analysis of the deliverables associated with the applicable GO/NO GO Decision gate; and the Government must give the Contractor a preliminary written notice of its intent to exercise the option at least 30 days before the contract expires. Specific information regarding the time frame for this notice is set forth in the OPTION CLAUSE Article in SECTION G of this contract. The estimated cost of the contract will be increased as set forth below:

CLIN/ Option	Estimated Period of Performance	Supplies/Services	Total Estimated Cost	Fixed Fee	Total Estimated Cost Plus Fixed Fee	Exercised Y/N
0002/1	Aug 18, 2014 thru June 15, 2017	Research and Development, Regulatory, Clinical and other tasks required for initiation of a Pilot Clinical Trial of Celution System in thermal burn injury.	[***]	[***]	\$16,579,415	Yes
0004/2	May 19, 2017 thru Nov 30, 2020	Research and Development, Regulatory, Clinical and other tasks required for completion of a Pilot Clinical Trial of the Celution System in thermal burn injury.	[***]	[***]	\$13,358,679	Yes
0005/3	September 28, 2015 to September 27, 2017	Clinical, regulatory, and other tasks required for completion of a Pivotal Clinical Trial leading to FDA licensure for use of the Celution System in thermal burn injury.	[***]	[***]	\$45,501,320	No
0006/4	September 28, 2013 to September 27, 2017	Research and development, clinical regulatory and other tasks required to develop and obtain FDA clearance for a wound dressing that has ease of use and other characteristics suitable for use in thermal burn injury following a mass casualty event.	[***]	[***]	\$23,420,322	No

3. The Period of Performance for contract HHS0100201200008C has changed:

From: September 28, 2012 through September 27, 2017 To: September 28, 2012 through November 30, 2020

- 4. ARTICLE B.5. ADVANCE UNDERSTANDINGS, is hereby amended by adding paragraph (I) as show below:
 - I. Option 2 will fund a clinical study design in accordance with the SOW for CLIN 4/Option 2, as incorporated into the Contract upon execution of this modification. It is Cytori's responsibility to meet the objectives of the clinical study as defined in the SOW by supporting additional funds required beyond the amount provided under this Option in the contract as a means of sharing the cost for development of the product for the intended use. Cytori's cost-share will not be required if the USG funds invested for this Option in the contract prove to be sufficient for meeting the objectives of the clinical study. All funds must be tracked and managed using the clinical management tools established under project management effort.

5. Update ARTICLE G.7. INDIRECT COST RATES:

The following rates will be utilized for billing purposes until during the period of performance of this contract periods: Fringe benefits at [***]%, and a general and administrative expense rate (G&A) of [***]% (until audit is completed). The billing rates for the option period will be based on the incurred cost submission for the previous calendar year, subject to Government audit adjustments. <u>Final rate proposals must</u> <u>be sent to the Contracting Officer, within 6 months subsequent to the fiscal year end. (See FAR Clause 52.216-7 incorporated herein).</u>

- 6. ARTICLE I.2.a.(c), is hereby deleted and replaced with the following:
 - (c) The total duration of this contract, including the exercise of any options under this clause, shall not exceed 8 years and 6 months.
- 7. The following clauses hereby supersede and replace their predecessor clauses:

ARTICLE H.2. PROTECTION OF HUMAN SUBJECTS, HHSAR 352.270-4 (b) (December 18, 2015)

a. The Contractor agrees that the rights and welfare of human subjects involved in research under this contract shall be protected in accordance with 45 CFR Part 46 and with the Contractor's current Federal-wide Assurance (FWA) on file with the Office for Human Research Protections (OHRP), Department of Health and Human Services. The Contractor further agrees to provide certification at least annually that the Institutional Review Board has reviewed and approved the procedures, which involve human subjects in accordance with 45 CFR Part 46 and the Assurance of Compliance

b. The Contractor shall bear full responsibility for the performance of all work and services involving the use of human subjects under this contract and shall ensure that work is conducted in a proper manner and as safely as is feasible. The parties hereto agree that the Contractor retains the right to control and direct the performance of all work under this contract. Nothing in this contract shall create an agency or employee relationship between the Government and the Contractor, or any subcontractor, agent or employee of the Contractor, or any other person, organization, institution, or group of any kind whatsoever. The Contractor agrees that it has entered into this contract and will discharge its obligations, duties, and undertakings and the work pursuant thereto, whether requiring professional judgment or otherwise, as an independent Contractor without creating liability on the part of the Government for the acts of the Contractor or its employees.

c. Contractors involving other agencies or institutions in activities considered to be engaged in research involving human subjects must ensure that such other agencies or institutions obtain their own FWA if they are routinely engaged in research involving human subjects or ensure that such agencies or institutions are covered by the Contractors' FWA via designation as agents of the institution or via individual investigator agreements (see OHRP website at: http://www.hhs.gov/ohrp/policy/guidanceonalternativetofwa.pdf).

d. If at any time during the performance of this contract the Contractor is not in compliance with any of the requirements and or standards stated in paragraphs (a) and (b) above, the Contracting Officer may immediately suspend, in whole or in part, work and further payments under this contract until the Contractor corrects the noncompliance. The Contracting Officer may communicate the notice of suspension by telephone with confirmation in writing. If the Contractor fails to complete corrective action within the period of time designated in the Contracting Officer's written notice of suspension, the Contracting Officer may, after consultation with OHRP, terminate this contract in whole or in part.

ARTICLE H.6. CARE OF LIVE VERTEBRATE ANIMALS, HHSAR 352.270-5b (December 18, 2015)

a. Before undertaking performance of any contract involving animal-related activities where the species is regulated by USDA, the Contractor shall register with the Secretary of Agriculture of the United States in accordance with 7 U.S.C. 2136 and 9 CFR sections 2.25 through 2.28. The Contractor shall furnish evidence of the registration to the Contracting Officer.

b. The Contractor shall acquire vertebrate animals used in research from a dealer licensed by the Secretary of Agriculture under 7 U.S.C. 2133 and 9 CFR Sections 2.1-2.11, or from a source that is exempt from licensing under those sections.

c. The Contractor agrees that the care, use and intended use of any live vertebrate animals in the performance of this contract shall conform with the Public Health Service (PHS) Policy on Humane Care of Use of Laboratory Animals (PHS Policy), the current Animal Welfare Assurance (Assurance), the Guide for the Care and Use of Laboratory Animals (National Academy Press, Washington, DC) and the pertinent laws and regulations of the United States Department of Agriculture (see 7 U.S.C. 2131 et seq. and 9 CFR Subchapter A, Parts 1-4). In case of conflict between standards, the more stringent standard shall govern.

d. If at any time during performance of this contract, the Contracting Officer determines, in consultation with the Office of Laboratory Animal Welfare (OLAW), National Institutes of Health (NIH), that the Contractor is not in compliance with any of the requirements and standards stated in paragraphs (a) through (c) above, the Contracting Officer may immediately suspend, in whole or in part, work and further payments under this contract until the Contractor corrects the noncompliance. Notice of the suspension may be communicated by telephone and confirmed in writing. If the Contractor fails to complete corrective action within the period of time designated in the Contracting Officer's written notice of suspension, the Contracting Officer may, in consultation with OLAW, NIH, terminate this contract in whole or in part, and the Contractor's name may be removed from the list of those contractors with approved Assurances.

Note: The Contractor may request registration of its facility and a current listing of licensed dealers from the Regional Office of the Animal and Plant Health Inspection Service (APHIS), USDA, for the region in which its research facility is located. The location of the appropriate APHIS Regional Office, as well as information concerning this program may be obtained by contacting the Animal Care Staff, USDA/APHIS, 4700 River Road, Riverdale, Maryland 20737 (E-mail: <u>ace@aphis.usda.gov</u>;

Web site: (http://www.aphis.usda.gov/animal welfare).

ARTICLE H.23. ACKNOWLEDGMENT OF FEDERAL FUNDING

Section 507 of P.L. 104-208 mandates that Contractors funded with Federal dollars, in whole or in part, acknowledge Federal funding when issuing statements, press releases, requests for proposals, bid solicitations and other documents. This requirement is in addition to the continuing requirement to provide an acknowledgment of support and disclaimer on any publication reporting the results of a contract funded activity.

A. Publication and Publicity

No information related to data obtained under this contract shall be released or publicized without providing the COR with at least thirty (30) days advanced notice and an opportunity to review the proposed release or publication.

In addition to the requirements set forth in HHSAR Clause 352.227-70, Publications and Publicity incorporated by reference in SECTION I of this contract, Section 507 of P.L. 104-208 mandates that Contractors funded with Federal dollars, in whole or in part, acknowledge Federal funding when issuing statements, press releases, requests for proposals, bid solicitations and other documents. Contractors are required to state: (1) the percentage and dollar amounts of the total program or project costs financed with Federal money and; (2) the percentage and dollar amount of the total costs financed by nongovernmental sources. For purposes of this contract "publication" is defined as an issue of printed material offered for distribution or any communication or oral presentation of information, including any manuscript or scientific meeting abstract. Any publication containing data generated under this contract must be submitted for the COR review no less than thirty (30) calendar days for manuscripts and fifteen (15) calendar days for abstracts before submission for public presentation or publication. Contract support shall be acknowledged in all such publications substantially as follows:

"This project has been funded in whole or in part with Federal funds from the Department of Health and Human Services; Office of the Assistant Secretary for Preparedness and Response; Biomedical Advanced Research and Development Authority, under Contract No. HHS0100201200008C.

B. Press Releases

Misrepresenting contract results or releasing information that is injurious to the integrity of the Government may be construed as improper conduct. Press releases shall be considered to include the public release of information to any medium, excluding peer-reviewed scientific publications. With the exception of ad-hoc press releases required by applicable law or regulations, the Contractor shall ensure that the COR has received an advance copy of any press release related to the contract not less than five (5) business days prior to the issuance of the press release.

The Contractor shall acknowledge the support of the Department of Health and Human Service, Office of the Assistant Secretary for Preparedness and Response, Biomedical Advanced Research and Development Authority, whenever publicizing the work under this contract in any media by including an acknowledgment substantially as follows:

"This project has been funded in whole or in part with Federal funds from the Department of Health and Human Services; Office of the Assistant Secretary for Preparedness and Response; Biomedical Advanced Research and Development Authority, under Contract No. HHS0100201200008C.

ARTICLE H.24. PROHIBITION ON THE USE OF APPROPRIATED FUNDS FOR LOBBYING ACTIVITIES AND HHSAR 352.203-70 ANTI-LOBBYING (December 18, 2015)

The Contractor is hereby notified of the restrictions on the use of Department of Health and Human Service's funding for lobbying of Federal, State and Local legislative bodies.

Section 1352 of Title 31, United States Code (Public Law 101-121, effective 12/23/89), among other things, prohibits a recipient (and their subcontractors) of a Federal contract, grant, loan, or cooperative agreement from using appropriated funds (other than profits from a federal contract) to pay any person for influencing or attempting to influence an officer or employee of any agency, a Member of Congress, an officer or employee of Congress, or an employee of a Member of Congress in connection with any of the following covered Federal actions; the awarding of any Federal contract; the making of any Federal grant; the making of any Federal loan; the entering into of any cooperative agreement; or the modification of any Federal contract, grant, loan, or cooperative agreement. For additional information of prohibitions against lobbying activities, see FAR Subpart 3.8 and FAR Clause 52.203-12.

In addition, as set forth in HHSAR 352.203-70 "Anti-Lobbying" (December 18, 2015), the current Department of Health and Human Services Appropriations Act provides that no part of any appropriation contained in this Act shall be used, other than for normal and recognized executive- legislative relationships, for publicity or propaganda purposes, for the preparation, distribution, or use of any kit, pamphlet, booklet, publication, radio, television, or video presentation designed to support, or defeat legislation pending before the Congress, or any State or Local legislature except in presentation to the Congress, or any State or Local legislative body itself.

The current Department of Health and Human Services Appropriations Act also provides that no part of any appropriation contained in this Act shall be used to pay the salary or expenses of any contract or grant recipient, or agent acting for such recipient, related to any activity designed to influence legislation or appropriations pending before the Congress, or any State or Local legislature.

ARTICLE H.19 DISSEMINATION OF FALSE OR DELIBERATELY MISLEADING INFORMATION

The Contractor shall not use contract funds to disseminate information that is deliberately false or misleading.

The Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals (PHS Policy) establishes a number of requirements for research activities involving animals. Before award may be made to an applicant organization, the organization shall file, with the Office of Laboratory Animal Welfare (OLAW), National Institutes of Health (NIH), a written Animal Welfare Assurance (Assurance) which commits the organization to comply with the provisions of the PHS Policy, the Animal Welfare Act, and the Guide for the Care and Use of Laboratory Animals (National Academy Press, Washington, DC). In accordance with the PHS Policy, applicant organizations must establish an Institutional Animal Care & Use Committee (IACUC), qualified through the experience and expertise of its members, to oversee the institution's animal program, facilities and procedures. Applicant organizations are required to provide verification of IACUC approval prior to release of an award involving live vertebrate animals. No award involving the use of animals shall be made unless OLAW approves the Assurance and verification of IACUC approval for the proposed animal activities has been provided to the Contracting Officer. Prior to award, the Contracting Officer will notify Contractor(s) selected for projects that involve live vertebrate animals that an Assurance and verification of IACUC approval are required. The Contracting Officer will request that OLAW negotiate an acceptable Assurance with those Contractor(s) and request verification of IACUC approval. For further information, contact OLAW at NIH, 6705 Rockledge Drive, RKL1, Suite 360, MSC 7982 Bethesda, Maryland 20892-7982 (E-mail: olaw@od.nih.gov; Phone: 301-496-7163).

No PHS supported work for research involving vertebrate animals will be conducted by an organization, unless that organization is operating in accordance with an approved Animal Welfare Assurance and provides verification that the Institutional Animal Care and Use Committee (IACUC) has reviewed and approved the proposed activity in accordance with the PHS policy. Applications may be referred by the PHS back to the institution for further review in the case of apparent or potential violations of the PHS Policy. No award to an individual will be made unless that individual is affiliated with an assured organization that accepts responsibility for compliance with the PHS Policy. Foreign applicant organizations applying for PHS awards for activities involving vertebrate animals are required to comply with PHS Policy or provide evidence that acceptable standards for the humane care and use of animals will be met. Foreign applicant organizations are not required to submit IACUC approval, but should provide information that is satisfactory to the USG to provide assurances for the humane care of such animals.

ARTICLE H.23. INSTITUTIONAL RESPONSIBILITY REGARDING INVESTIGATOR FINANCIAL CONFLICTS OF INTEREST

The Contractor shall comply with the requirements of 45 CFR Part 94, Responsible Prospective Contractors, which promotes objectivity in research by establishing standards to ensure that Investigators (defined as the project director or principal Investigator and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research funded under BARDA contracts, or proposed for such funding, which may include, for example, collaborators or consultants) will not be biased by any Investigator financial conflicts of interest.

If the failure of an Investigator to comply with an Institution's financial conflicts of interest policy or a financial conflict of interest management plan appears to have biased the design, conduct, or reporting of the BARDA-funded research, the Contractor must promptly notify the Contracting Officer of the corrective action taken or to be taken. The Contracting Officer will consider the situation and, as necessary, take appropriate action or refer the matter to the Contractor for further action, which may include directions to the Contractor on how to maintain appropriate objectivity in the BARDA-funded research project.

The Contracting Officer and/or HHS may inquire at any time before, during, or after award into any Investigator disclosure of financial interests, and the Contractor's review of, and response to, such disclosure, regardless of whether the disclosure resulted in the Contractor's determination of a financial conflict of interests. The Contracting Officer may require submission of the records or review them on site. On the basis of this review of records or other information that may be available, the Contracting Officer may decide that a particular financial conflict of interest will bias the objectivity of the BARDA-funded research to such an extent that further corrective action is needed or that the Institution has not managed the financial conflict of interest in accordance with 45 CFR Part 94. The issuance of a Stop Work Order by the Contracting Officer may be necessary until the matter is resolved.

If the Contracting Officer determines that BARDA-funded clinical research, whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment, has been designed, conducted, or reported by an Investigator with a financial conflict of interest that was not disclosed managed or reported the Contractor shall require the Investigator involved to disclose the financial conflict of interest in each public presentation of the results of the research and to request an addendum to previously published presentations.

ARTICLE H.24. QUALITY ASSURANCE (QA) AUDIT REPORTS

The Government reserves the right to participate in QA audits. Upon completion of the audit/site visit the Contractor shall provide a report capturing the findings, results and next steps in proceeding with the subcontractor. If action is requested of the subcontractor, detailed concerns for addressing areas of non-conformance to FDA regulations for GLP, GMP, or GCP guidelines, as identified in the audit report, must be provided to the COR. The Contractor shall provide responses from the subcontractors to address these concerns and plans for corrective action execution.

- Contractor shall notify CO and COR of upcoming, ongoing, or recent audits/site visits of subcontractors as part of weekly communications.
- Contractor shall notify the COR and CO within five (5) business days of report completion.

ARTICLE H.25. TECHNICAL AUDITS

Contractor shall accommodate periodic or ad hoc site visits by the USG with forty-eight (48) hours advance notice. If the USG, the Contractor, or other parties identifies any issues during an audit, the Contractor shall capture the issues, identify potential solutions, and provide a report to the USG.

- If issues are identified during the audit, Contractor shall submit a report to the CO and COR detailing the finding and proposed corrective action(s) within 10 business days of the audit.
- COR and CO will review the report and provide a response to the Contractor with ten (10) business days.
- Once corrective action is completed, the Contractor will provide a final report to the CO and COR.

ARTICLE H.3. HUMAN MATERIALS (ASSURANCE OF OHRP COMPLIANCE)

The acquisition and supply of all human specimen material (including fetal material) used under this contract shall be obtained by the Contractor in full compliance with applicable Federal, State and Local laws and the provisions of the Uniform Anatomical Gift Act in the United States, and no undue inducements, monetary or otherwise, will be offered to any person to influence their donation of human material.

The Contractor shall provide written documentation that all human materials obtained as a result of research involving human subjects conducted under this contract, by collaborating sites, or by subcontractors identified under this contract, were obtained with prior approval by the Office for Human Research Protections (OHRP) of an Assurance to comply with the requirements of 45 CFR 46 to protect human research subjects. This restriction applies to all collaborating sites without OHRP- approved Assurances, whether domestic or foreign, and compliance must be ensured by the Contractor.

Provision by the Contractor to the Contracting Officer of a properly completed "Protection of Human Subjects Assurance Identification/IRB Certification/Declaration of Exemption", Form OMB No. 0990-0263 (formerly Optional Form 310), certifying IRB review and approval of the protocol from which the human materials were obtained constitutes the written documentation required. The human subject certification can be met by submission of a self-designated form provided that it contains the information required by the "Protection of Human Subjects Assurance Identification/IRB Certification/Declaration of Exemption", Form OMB No. 0990-0263 (formerly Optional Form 310).

ARTICLE H.4. RESEARCH INVOLVING HUMAN FETAL TISSUE

All research involving human fetal tissue shall be conducted in accordance with the Public Health Service Act, 42 U.S.C. 289g-l and 289g-2. Implementing regulations and guidance for conducting research on human fetal tissue may be found at 45 CFR 46, Subpart B and <u>http://grantsl.nih.gov/grants/quide/notice-files/not93-235.html</u> and any subsequent revisions to this NIH Guide to Grants and Contracts ("Guide") Notice.

The Contractor shall make available, for audit by the Secretary, HHS, the physician statements and informed consents required by 42 USC 289g-l (b) and (c), or ensure HHS access to those records, if maintained by an entity other than the Contractor.

ARTICLE H.6. ANIMAL WELFARE

All research involving live, vertebrate animals shall be conducted in accordance with the Public Health Service Policy on Humane Care and Use of Laboratory Animals. This policy may be accessed at:

http://grantsl.nih.gov/grants/olaw/references/phspol.htm

ARTICLE H.7. INFORMATION ON COMPLIANCE WITH ANIMAL CARE REQUIREMENTS

Registration with the U. S. Dept, of Agriculture (USDA) is required to use regulated species of animals for biomedical purposes. USDA is responsible for the enforcement of the Animal Welfare Act (7 U.S.C. 2131 et. seq.), <u>https://awic.nal.usda.gov/</u>.

The Public Health Service (PHS) Policy is administered by the Office of Laboratory Animal Welfare (OLAW) <u>http://grants2.nih.gov/grants/olaw/olaw.htm</u>. An essential requirement of the PHS Policy <u>http://grants2.nih.gov/grants/olaw/references/phspol.htm</u> is that every institution using live vertebrate animals must obtain an approved assurance from OLAW before they can receive funding from any component of the U. S. Public Health Service.

The PHS Policy requires that Assured institutions base their programs of animal care and use on the Guide for the Care and Use of Laboratory Animals <u>http://www.nap.edu/readingroom/books/labrats/</u> and that they comply with the regulations (9 CFR, Subchapter A) https://awic.nal.usda.gov/final-rules-animal-welfare-9-cfr-parts-l-2-and-3

issued by the U.S. Department of Agriculture (USDA) under the Animal Welfare Act. The Guide may differ from USDA regulations in some respects. Compliance with the USDA regulations is an absolute requirement of this Policy.

The Association for Assessment and Accreditation of Laboratory Animal Care International (AAALAC) <u>http://www.aaalac.org/</u> is a professional organization that inspects and evaluates programs of animal care for institutions at their request. Those that meet the high standards are given the accredited status. As of the 2002 revision of the PHS Policy, the only accrediting body recognized by PHS is the AAALAC. While AAALAC Accreditation is not required to conduct biomedical research, it is highly desirable. AAALAC uses the Guide as their primary evaluation tool. They also use the Guide for the Care and Use of Agricultural Animals in Agricultural Research and Teaching. It is published by the Federated of Animal Science Societies <u>http://www.fass.org/</u>.

ARTICLE H.9. APPROVAL OF REQUIRED ASSURANCE BY OLAW

Under governing regulations, federal funds which are administered by the Department of Health and Human Services, Office of Biomedical Advanced Research and Development Authority (BARDA) shall not be expended by the Contractor for research involving live vertebrate animals, nor shall live vertebrate animals be involved in research activities by the Contractor under this award unless a satisfactory assurance of compliance with 7 U.S.C. 2316 and 9 CFR Sections 2.25-2.27 is submitted within 30 days of the date of this award and approved by the Office of Laboratory Animal Welfare (OLAW). Each performance site (if any) must also assure compliance with 7 U.S.C. 2316 and 9 CFR Sections 2.25-2.27 with the following restriction: Only activities which do not directly involve live vertebrate animals (i.e. are clearly severable and independent from those activities that do involve live vertebrate animals) may be conducted by the Contractor or individual performance sites pending OLAW approval of their respective assurance of compliance with 7 U.S.C. 2316 and 9 CFR Sections 2.25-2.27. Additional information regarding OLAW may be obtained via the Internet at <u>http://grants2.nih.gov/grants/olaw/references/phspol.htm</u>

ARTICLE H.12. IDENTIFICATION AND DISPOSITION OF DATA

The Contractor will be required to provide certain data generated under this contract to the Department of Health and Human Services (DHHS). DHHS reserves the right to review any other data determined by DHHS to be relevant to this contract in accordance with FAR 52.227-14, Alternate II. The Contractor shall keep copies of all data required by the Food and Drug Administration (FDA) relevant to this contract for the time specified by the FDA.

ARTICLE H.13. EXPORT CONTROL NOTIFICATION

Contractors are responsible for ensuring compliance with all export control laws and regulations that may be applicable to the export of and foreign access to their proposed technologies.

Contractors may consult with the Department of State with any questions regarding the International Traffic in Arms Regulation (ITAR) (22 C.F.R. Parts 120-130) and/or the Department of Commerce regarding the Export Administration Regulations (15 C.F.R. Parts 730-774).

ARTICLE H.17. RESTRICTION ON ABORTIONS

The Contractor shall not use contract funds for any abortion.

ARTICLE H.18. CONTINUED BAN ON FUNDING OF HUMAN EMBRYO RESEARCH

The Contractor shall not use contract funds for (1) the creation of a human embryo or embryos for research purposes; or (2) research in which a human embryo or embryos are destroyed, discarded, or knowingly subjected to risk of injury or death greater than that allowed for research on fetuses in utero under 45 CFR 46.204(b) and Section 498(b) of the Public Health Service Act (42 U.S.C. 289g (b)). The term "human embryo or embryos" includes any organism, not protected as a human subject under 45 CFR 46 as of the date of the enactment of this Act, that is derived by fertilization, parthenogenesis, cloning, or any other means from one or more human gametes or human diploid cells.

Additionally, in accordance with a March 4, 1997 Presidential Memorandum, Federal funds may not be used for cloning of human beings.

ARTICLE H.20. CONFIDENTIALITY OF INFORMATION

a. Confidential information, as used in this article, means information or data of a personal nature about an individual, or proprietary information or data submitted by or pertaining to an institution or organization.

b. The Contracting Officer and the Contractor may, by mutual consent, identify elsewhere in this contract specific information and/or categories of information which the USG will furnish to the Contractor or that the Contractor is expected to generate which is confidential and providing further that the Government is not entitled to unlimited rights to that information pursuant to FAR 52.227-14, Alternate II. Similarly, the Contracting Officer and the Contractor may, by mutual consent, identify such confidential information from time to time during the performance of the contract. Failure to agree will be settled pursuant to the "Disputes" clause.

c. If it is established elsewhere in this contract that information to be utilized under this contract, or a portion thereof, is subject to the Privacy Act, the Contractor will follow the rules and procedures of disclosure set forth in the Privacy Act of 1974, 5 U.S.C. 552a, and implementing regulations and policies, with respect to systems of records determined to be subject to the Privacy Act.

d. Confidential information, as defined in paragraph (a) of this article, shall not be disclosed without the prior written consent of the individual, institution, or organization.

e. Whenever the Contractor is uncertain with regard to the proper handling of material under the contract, or if the material in question is subject to the Privacy Act or is confidential information subject to the provisions of this article, the Contractor should obtain a written determination from the Contracting Officer prior to any release, disclosure, dissemination, or publication.

f. The provisions of paragraph (d) of this article shall not apply to conflicting or overlapping provisions in other Federal, State or local laws.

ARTICLE H.21. ACCESS TO DOCUMENTATION/DATA

The USG shall have physical and electronic access to all documentation and data generated under this contract, including: all data documenting Contractor performance; all data generated; all communications and correspondence with regulatory agencies and bodies to include all audit observations, inspection reports, milestone completion documents, and all Offeror commitments and responses. Contractor shall provide the USG with an electronic copy of all correspondence and submissions to the FDA within 5 business days of receipt. The USG shall acquire unlimited rights to all data funded under this contract in accordance with FAR Subpart 27.4 and FAR Clause 52.227-14, Alternate II.

ARTICLE H.29. RESTRICTION ON EMPLOYMENT OF UNAUTHORIZED ALIEN WORKERS

The Contractor shall not use contract funds to employ workers described in section 274A (h)(3) of the Immigration and Nationality Act, which reads as follows:

"(3) Definition of unauthorized alien - As used in this section, the term 'unauthorized alien' with respect to the employment of an alien at a particular time, that the alien is not at that time either an alien lawfully admitted for permanent residence, or (B) authorized to be so employed by this Act or by the Attorney General."

ARTICLE H.30. NOTIFICATION OF CRITICAL PROGRAMMATIC CONCERNS, RISKS, OR POTENTIAL RISKS

If any action occurs that creates a cause for critical programmatic concern, risk, or potential risk to the Government or the Contractor and Incident Report shall be delivered to the CO and COR.

- Within 48 hours of activity or incident or within 24 hours for a security related activity or incident, Contractor must notify the CO and COR.
- Additional updates due to COR and CO within 48 hours of additional developments.
- Contractor shall submit within 5 business days a Corrective Action Plan (if deemed necessary by either party) to address any potential issues.

If corrective action is deemed necessary, Contractor must address in writing, its consideration of concerns raised by the CO or COR within 5 business days.

ARTICLE H.31. PERSON IN PLANT

With seven (7) business days advance notice to the Contractor in writing from the Contracting Officer, the USG may place a person-in-plant in the Contractor's or subcontractor's facility, who shall be subject to the Contractor's or subcontractor's policies and procedures regarding security and facility access at all times while in the facility.

An article substantially similar to this Person-in-Plant article shall be incorporated into any subcontract for experimental or manufacturing work.

ARTICLE H.32. PROTECTION OF PERSONNEL WHO WORK WITH NONHUMAN PRIMATES

All Contractor personnel who work with nonhuman primates or enter rooms or areas containing nonhuman primates shall comply with the procedures set forth in NIH Policy Manual 3044-2, entitled, "Protection of NIH Personnel Who Work with Nonhuman Primates," located at the following URL: http://wwwl.od.nih.gov/oma/manualchapters/intramural/3044-2/

ARTICLE H.34. REGISTRATION WITH THE SELECT AGENT PROGRAM FOR WORK INVOLVING THE POSSESSION, USE, AND/OR TRANSFER OF SELECT BIOLOGICAL AGENTS OR TOXINS

Work involving select biological agents or toxins shall not be conducted under this contract until the Contractor and any affected subcontractor(s) are granted a certificate of registration or are authorized to work with the applicable select agents.

For prime or subcontract awards to domestic institutions who possess, use, and/or transfer Select Agents under this contract, the institution must complete registration with the Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (DHHS) or the Animal and Plant Health Inspection Services (APHIS), U.S. Department of Agriculture (USDA), as applicable, before performing work involving Select Agents, in accordance with 42 CFR 73. No Government funds can be used for work involving Select Agents, as defined in 42 CFR 73, if the final registration certificate is denied.

For prime or subcontract awards to foreign institutions who possess, use, and/or transfer Select Agents under this contract, the institution must provide information satisfactory to the Government that a process equivalent to that described in 42 CFR 73 (<u>http://www.selectagents.gov/Regulations.html</u>) for U.S. institutions is in place and will be administered on behalf of all Select Agent work sponsored by these funds before using these funds for any work directly involving the Select Agents. The Contractor must provide information addressing the following key elements appropriate for the foreign institution: safety, security, training, procedures for ensuring that only approved/appropriate individuals have access to the Select Agents, and any applicable laws, regulations and policies equivalent to 42 CFR 73. The Government will assess the policies and procedures for comparability to the U.S. requirements described in 42 CFR Part 73. When requested by the contracting officer, the Contractor shall provide key information delineating any laws, regulations, policies, and procedures applicable to the foreign institution for the safe and secure possession, use, and transfer of Select Agents. This includes summaries of safety, security, and training plans, and applicable laws, regulations, and policies. For the purpose of security risk assessments, the Contractor must provide the names of all individuals at the foreign institution who will have access to the Select Agents and procedures for ensuring that only approved and appropriate individuals have access to Select Agents under the contract.

Listings of HHS select agents and toxins, biologic agents and toxins, and overlap agents or toxins as well as information about the registration process, can be obtained on the Select Agent Program Web site at <u>http://www.selectagents.gov</u>

ARTICLE H.35. MANUFACTURING STANDARDS

The Good Manufacturing Practice Regulations (GMP) (21 CFR Parts 210-211) will be the standard to be applied for manufacturing, processing, packaging, storage and delivery of this product.

If at any time during the life of the contract, the Contractor fails to comply with GMP in the manufacturing, processing, packaging, storage, stability and other testing of the manufactured drug substance or product and delivery of this product and such failure results in a material adverse effect on the safety, purity or potency of the product (a material failure) as identified by the FDA, the Contractor shall have thirty (30) calendar days from the time such material failure is identified to cure such material failure. If, within the thirty (30) calendar day period, the Contractor fails to take such an action to the satisfaction of the USG Project Officer, or fails to provide a remediation plan that is acceptable to the COR, then the contract may be terminated.

ARTICLE H.36. IN-PROCESS REVIEW

In Process Reviews (IPR) will be conducted at the discretion of the USG to discuss the progression of the milestones. The USG reserves the right to revise the milestones and budget pending the development of the project. Deliverables such as an overall project summary report and/or slides will be required when the IPRs are conducted. The Contractor's success in completing the required tasks under each work segment must be demonstrated through the Deliverables and Milestones specified under SECTION F. Those deliverables will constitute the basis for the USG's decision, at its sole discretion, to proceed with the work segment, or institute changes to the work segment, or terminate the work segment as otherwise permitted by this contract.

IPRs may be scheduled at the discretion of the USG to discuss progression of the contract. The Contractor shall provide a presentation following a prescribed template which will be provided by the USG at least 30 business days prior to the IPR. Subsequently, the contractor will be requested to provide a revised/final presentation to the Contracting Officer at least 10 business days prior to the IPR.

H. 37. PUBLIC ACCESS TO ARCHIVED PUBLICATIONS RESULTING FROM ASPR FUNDED RESEARCH

All ASPR-funded investigators shall submit to the NIH National Library of Medicine's (NLM) PubMed Central (PMC) an electronic version of the author's final manuscript, upon acceptance for publication, of any peer-reviewed scientific publications resulting from research supported in whole or in part with Federal funds from the Department of Health and Human Services; Office of the Assistant Secretary for Preparedness and Response. ASPR defines the author's final manuscript as the final version accepted for journal publication, and includes all modifications from the publishing peer review process. The PMC archive will preserve permanently these manuscripts for use by the public, health care providers, educators, scientists, and ASPR. The Policy directs electronic submissions to the NIH/NLM/PMC: http://www.pubmedcentral.nih.gov.

Additional information is available at

http://www.phe.gov/Preparedness/planning/science/Pages/AccessPlan.aspx

b. DEPARTMENT OF HEALTH AND HUMAN SERVICES ACQUISITION REGULATION (HHSAR) (48 CFR CHAPTER 3) CLAUSES:

HHSAR CLAUSE NO.	DATE	TITLE
352.211-3	Dec 2015	Paperwork Reduction Act
352.203-70	Dec 2015	Anti-Lobbying
352.222-70	Dec 2015	Contractor Cooperation in Equal Employment Opportunity Investigations
352.223-70	Dec 2015	Safety and Health
352.224-70	Dec 2015	Privacy Act
352.227-70	Dec 2015	Publications and Publicity
352.231-70	Dec 2015	Salary Rate Limitation
352.233-71	Dec 2015	Litigation and Claims
352.237-75	Dec 2015	Key Personnel
352.270-6	Dec 2015	Restriction on use of Human Subjects

a. FAR Clause 52.217-9, Option to Extend the Term of the Contract (Mar 2000) (a) The Government may extend the term of this contract by written notice to the Contractor within 30 days after the Government has completed its analysis of the deliverables associated with the applicable GO/NO GO Decision gate; provided that the Government gives the Contractor a preliminary written notice of its intent to extend at least 30 days before the contract expires. The preliminary notice does not commit the Government to an extension. (b) If the Government exercises this option, the extended contract shall be considered to include this option clause. (c) The total duration of this contract, including the exercise of any options under this clause, shall not exceed 5 years.

OPTION 2: REVISED PILOT CLINICAL TRIAL EXECUTION - STATEMENT OF WORK (CLIN004/OPTION 2; 5/19/2017) ATTACHMENT 1

BARDA Broad Agency Announcement (BAA)

(BAA-11-100-SOL-00009) Advanced Research and Development of Chemical, Biological, Radiological, and Nuclear Medical Countermeasures

Medical Countermeasures

CELUTION SYSTEM

Use: Full Thickness Burn Wound Treatment Contract #: HHSO100201200008C Period: CLIN 4/Option 2

Contractual Statement of Work

PREAMBLE

Independently and not as an agency 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 the BARDA Broad Agency Announcement (BAA) CBRN-BAA-11-100-SOL-00009.

The overall goal of this project is to advance the development of the Celution System as an autologous cell-based countermeasure for the treatment of full and deep-partial thickness burn wounds. The scope of work for this contract includes activities that fall into the following areas: non-clinical efficacy studies; clinical activities; manufacturing activities; and all associated regulatory, quality assurance, management, and administrative activities. The Research and Development (R&D) effort for the Celution System will progress in specific stages that cover the base performance (I) segment and two (I to II) option segment as specified in the contract. The Contractor has completed specific tasks required for the Base and Option 1 periods. This statement of work describes the activities to be performed as part of Option 2.

Objective

Execution of a Pilot IDE Clinical Trial for treatment of deep-partial and full thickness thermal burn wounds in conjunction with standard of care.

Deliverables

- 1. Clinical Study Report
- 2. Written report from a pre-submission meeting held with FDA to discuss a potential pivotal clinical trial that could follow the trial to be executed in accordance with this Statement of Work. This deliverable will be deemed met should the results of the clinical trial to be executed under Option 2 indicate that the treatment approach is not safe or not feasible.

4. OPTION 2: PILOT IDE CLINICAL TRIAL

The objective of Option 2 is to obtain clinical data sufficient to make an assessment of the safety and feasibility of use of intravenous delivery of autologous ADRCs as an adjunct to treatment of full and deep partial thickness thermal burn wounds treated with a meshed autologous split thickness skin graft (STSG) such that, in the event that the approach is deemed safe and feasible, feedback can be obtained from FDA regarding design and endpoints of a potential follow-on pivotal clinical trial sufficient to inform design and budgeting for said trial.

4.1 Program Management

The Contractor shall provide for the following as outlined below:

- 4.1.1 The overall management, integration and coordination of all contract activities, including a technical and administrative infrastructure to ensure the efficient planning, initiation, implementation, and direction of all contract activities;
- 4.1.2 A Principal Investigator (PI) responsible for project management, communication, tracking, monitoring and reporting on status and progress, and modification to the project requirements and timelines, including projects undertaken by subcontractors; The contract deliverables list (reference), identifies all contract deliverables and reporting requirements for this contract.
- 4.1.3 Project Manager with responsibility for monitoring and tracking day-to-day progress and timelines, coordinating communication and project activities; costs incurred; and program management; The contract deliverables list (reference), identifies all contract deliverables and reporting requirements for this contract.

- 4.1.4 A BARDA Liaison with responsibility for effective communication with the Project Officer and Contracting Officer. May be the PI or Project Manager.
- 4.1.5 Administrative and legal staff to provide development of compliant subcontracts, consulting, and other legal agreements, and ensure timely acquisition of all proprietary rights, including IP rights, and reporting all inventions made in the performance of the project.
- 4.1.6 Administrative staff with responsibility for financial management and reporting on all activities conducted by the Contractor and any subcontractors.
- 4.1.7 Contract Review Meetings
 - 4.1.7.1 The Contractor shall participate in regular meetings to coordinate and oversee the contract effort as directed by the Contracting and Project Officers. Such meetings may include, but are not limited to, meeting of the Contractors and subcontractors to discuss clinical progress, product and regulatory issues; meetings with individual contractors and other HHS officials to discuss the technical, regulatory, and ethical aspects of the program; and meeting with technical consultants to discuss technical data provided by the Contractor.
 - 4.1.7.2 The Contractor shall participate in teleconferences twice a month between the Contractor and BARDA to review technical progress. Teleconferences or additional face-to-face meetings shall be more frequent at the request of BARDA.
- 4.1.8 Integrated Master Schedule
 - 4.1.8.1 Within 60 calendar days of the effective date of the contract, the Contractor shall submit a first draft of an updated Integrated Master Schedule in a format agreed upon by BARDA to the Project Officer and the Contracting Officer for review and comment. The Integrated Master Schedule shall be incorporated into the contract, and will be used to monitor performance of the contract. Contractor shall include the key milestones. The IMS for the period of performance will be accepted by BARDA at the PMBR
- 4.1.9 Integrated Master Plan
 - 4.1.9.1 Work Breakdown Structure: The Contractor shall utilize a WBS template agreed upon by BARDA for reporting on the contact. The Contractor shall expand and delineate the Contract Work Breakdown Structure (CWBS) to a level agreed upon by BARDA as part of their Integrated Master Plan for contract reporting. The CWBS shall be discernable and consistent. BARDA may require Contractor to furnish WBS data at the work package level or at a lower level if there is significant complexity and risk associated with the task.
 - 4.1.9.2 Earned Value Management System Plan: Subject to the requirements under HHSAR Clause 352.234-4, the Contractor shall use principles of Earned Value Management System (EVMS) in the management of this contract. The Seven Principles are:
 - I. Plan all work scope for the program to completion.
 - II. Break down the program work scope into finite pieces that can be assigned to a responsible person or organization for control of technical, schedule, and cost objectives.
 - III. Integrate program work scope, schedule, and cost objectives into a performance measurement baseline plan against which accomplishments may be measured. Control Changes to the baseline.
 - IV. Use actual cost incurred and recorded in accomplishing the work performed.
 - V. Objectively assess accomplishments at the work performance level.
 - VI. Analyze significant variances from the plan, forecast impacts, and prepare an estimate at completion based on performance to date and work to be performed.
 - VII. Use earned value information in the company's management processes.
- 4.1.10 *Risk Management Plan:* The Contractor shall provide an updated risk management plan and risk register bi-annually highlighting potential problems and/or issues that may arise during the life of the contract, their impact on cost, schedule and performance, and appropriate remediation plans. The plan references relevant WBS elements where appropriate.
- 4.1.11 *Performance Measurement Baseline Review (PMBR):* The Contractor shall submit a plan for a PMBR to occur within 90 days of contract award. At the PMBR, the Contractor and BARDA shall mutually agree upon the budget, schedule and technical plan baselines (Performance Measurement Baseline). These baselines shall be the basis for monitoring and reporting progress throughout the life of the contract. The PMBR is conducted to achieve confidence that the baselines accurately capture the entire technical scope of work, are consistent with contract schedule requirements, are reasonably and

logically planned, and have adequate resources assigned. The goals of the PMBR are as follows:

- I. Jointly assess areas such as the Contractor's planning for complete coverage of the SOW, logical scheduling of the work activities, adequate resources, and identification of inherent risks
- II. Confirm the integrity of the Performance Measurement Baseline (PMB)
- III. Foster the use of EVM as a means of communication
- IV. Provide confidence in the validity of Contractor reporting
- V. Identify risks associated with the PMB
- VI. Present any revised PMBs for mutual agreement
- VII. Present an Integrated Master Schedule: The Contractor shall deliver an initial program level Integrated Master Schedule (IMS) that rolls up all time-phased WBS elements down to the activity level. This IMS shall include the dependencies that exist between tasks. This IMS will be agreed to and finalized at the PMBR. DI-MGMT-81650 may be referenced as guidance in creation of the IMS (see http://www.acq.osd.mil/pm/).
- VIII. Present the Risk Management Plan
- 4.1.12 *Deviation Request:* During the course of contract performance, in response to a need to change IMS activities as baselined at the PMBR, the Contractor shall submit a Deviation Report. This report shall request a change in the agreed- upon IMS and timelines. This report shall include: (i) discussion of the justification/rationale for the proposed change; (ii) options for addressing the needed changes from the agreed upon timelines, including a cost-benefit analysis of each option; and (iii) recommendations for the preferred option that includes a full analysis and discussion of the effect of the change on the entire product development program, timelines, and budget.
- 4.1.13 *Monthly and Annual Reports:* The Contractor shall deliver Project Status Reports on a monthly basis. The reports shall address the items below cross referenced to the WBS, SOW, IMS, and EVM:
 - I. Executive summary highlighting the progress, issues, and relevant activities in manufacturing, non-clinical, clinical, and regulatory;
 - II. Progress in meeting contract milestones, detailing the planned progress and actual progress during the reporting period, explaining any differences between the two and corrective steps;
 - III. Updated IMS;
 - IV. Updated EVM;
 - V. Updated Risk Management Plan (Every 3 months);
 - VI. Three month rolling forecast of planned activities;
 - VII. Progress of regulatory submissions;
 - VIII. Estimated and actual expenses;
- 4.1.14 Data Management: The Contractor shall develop and implement data management and quality control systems/procedures, including transmission, storage, confidentiality, and retrieval of all contract data;
 - 4.1.14.1 Provide for the statistical design and analysis of data resulting from the research;
 - 4.1.14.2 Provide raw data or specific analyses of data generated with contract funding to the Project Officer, upon request.
- 4.2 Non-Clinical Toxicology (WBS 4.2) N/A
- 4.3 Non-Clinical Studies (WBS 4.3) N/A

4.4 Clinical Studies (WBS 4.4)

- 4.4.1 Develop and execute a contract with a contract research organization for the execution of the clinical study ("RELIEF"). The contract should specify roles and responsibilities for Cytori and the CRO throughout study execution;
- 4.4.2 Develop and execute site contracts, gain IRB approvals and initiate clinical study sites;
- 4.4.3 Provide interim data reports to be presented to BARDA for the purpose of determination of the achievement of the objectives set forth herein.

- 4.4.4 Complete final study report for the "RELIEF" clinical trial.
- 4.4.5 "*RELIEF*" *Clinical Study Summary:* Cytori will execute a prospective, open-label, parallel group, usual care controlled, multi-center randomized clinical study targeting thermal burns. Subjects will have at least one deep partial or full thickness burn wound of ≥ 250 cm² that is to be autografted with a meshed split thickness skin graft (STSG). Subjects will be randomized to receive either usual care or usual care supplemented with intravenous administration of ADRCs. Subjects who receive ADRCs will undergo small volume fat harvest (100 to 150 mL) under general anesthesia. Harvested tissue will be processed in the Celution® System to isolate and concentrate ADRCs which will then be delivered intravenously. All enrolled subjects will be assessed for end points specified within the clinical protocol.
- 4.4.6 The objective of this trial is to obtain data that will allow assessment of the safety and feasibility of intravenous delivery of autologous ADRCs as an adjunct to treatment of full and deep partial thickness thermal burn wounds treated with a meshed autologous split thickness skin graft (STSG). Safety and feasibility will be assessed on an ongoing basis that will include assessment following enrollment and treatment of each of the first five subjects treated in the study and at intervals thereafter.

4.4.6.1	[***]
4.4.6.2	[***]
4.4.6.3	[***]
4.4.6.4	[***]

- 4.4.7 Preparation of materials for a possible FDA pre-submission package.
 - 4.4.7.1 Because the trial applies an open-label design it will be possible to monitor both primary (safety and feasibility) and secondary/exploratory (preliminary/potential efficacy) end points on an ongoing basis. Subsequent to adequate enrollment and prior to completion of the full and final clinical study report these data may be compiled and submitted to FDA as part of a presubmission package pertaining to a possible follow-on pivotal trial of this approach. This package may include an outline of a proposed design of said potential pivotal trial.
 - 4.4.7.2 This task (4.4.7) shall not be required in the event that a final determination is made that the treatment approach is not safe or is not feasible.

4.5 Regulatory (WBS 4.5)

- 4.5.1 Engaging the FDA on a path to support the use of the product for the specific indication;
- 4.5.2 Preparing materials for and requesting, scheduling and participating in all meetings with the FDA, including meetings to review EUA and/or all other data packages;
- 4.5.3 Providing BARDA with (i) the initial draft minutes and final draft minutes of any formal meeting with the FDA; (ii) final draft minutes of any informal meeting with the FDA;
- 4.5.4 Generating all necessary data and preparing documentation for IDE submissions to regulatory agencies;
- 4.5.5 Execution of reporting of adverse events to FDA in accordance with relevant FDA requirements and the IDE approval;
- 4.5.6 Submitting IDE documentation to the FDA in a timely manner, consistent with timelines set out in the contract and by the FDA.
- 4.5.7 Preparation and submission, if indicated by safety and feasibility data, to FDA of a pre-submission package pertaining to a possible follow-on clinical trial.
- 4.5.8 Scheduling and execution of a meeting with FDA, if indicated, and, if held, generation of a written report based on said pre-submission package.
- 4.5.9 This task (4.5) shall not be required in the event the results of the clinical trial indicate that the treatment approach is not safe or is not feasible.

4.6 CMC (WBS 1.6) - N/A

CERTAIN MATERIAL (INDICATED BY ASTERISKS) HAS BEEN OMITTED FROM THIS DOCUMENT PURSUANT TO A REQUEST FOR CONFIDENTIAL TREATMENT. THE OMITTED MATERIAL HAS BEEN FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION.

Exhibit 10.4

AMENDMENT OF SOLICITATION/MODIFIC	CATION OF CONTRACT		1. CONTRACT ID CODE	PAGE OF PAGES			
		i		1 8			
2. AMENDMENT/MODIFICATION NO. 0008	3. EFFECTIVE DATE See Block 16C	4. REQUISITION/PUR OS196591	RCHASE REQ. NO.	5. PROJECT NO. (If applicable)			
6. ISSUED BY CODE	E ASPR-BARDA	7. ADMINISTERED B	Y (if other than Item 6)	CODE ASPR-BARDA01			
ASPR-BARDA 200 Independence Ave., S.W. Room 640-G Washington DC 20201		ASPR-BARDA 330 Independence Ave Washington DC 20201					
8. NAME AND ADDRESS OF CONTRACTOR (No, street, county. State and ZIP Code)	(x) 9A. AMENDME	ENT OF SOLICITATION NO.				
CYTORI THERAPEUTICS, INC 1386447 CYTORI THERAPEUTICS, INC. 3020 3020 CALLAN RD SAN DIEGO CA 921211109		, ,	9B. DATED (SEE ITEM 11)				
		X 10A. MODIFICA HHSO10020120	ATION OF CONTRACT/ORDE 0008C	R NO.			
CODE 1386447	FACILITY CODE	10B. DATED (SI 09/28/2012	EE ITEM 13)				
	11. THIS ITEM ONLY APPLIE	S TO AMENDMENTS OF S	SOLICITATIONS				
numbers. FAILURE OF YOUR ACKNOWLEDGI SPECIFIED MAY RESULT IN REJECTION OF V provided each telegram or letter makes reference to 12. ACCOUNTING AND APPROPRIATION DAY 2017.1992017.25106 13. THIS ITEM ONLY APPLIES TO CHECK ONE A. THIS CHANGE ORDER IS ITEM 10A	YOUR OFFER. If by virtue of this amend o the solicitation and this amendment, and TA (If required) MODIFICATION OF CONTRACTS/	dment you desire to change an d is received prior to the openi Net Increase: ORDERS. IT MODIFIES TI	offer already submitted, such ch ng hour and date specified. \$13,358,679 HE CONTRACT/ORDER NO	hange may be made by telegram or letter,			
	CONTRACT/ORDER IS MODIFIED T TEM 14, PURSUANT TO THE AUTHO		TRATIVE CHANGES (such as	changes in paying office, appropriation			
C. THIS SUPPLEMENTAL AG	REEMENT IS ENTERED INTO PURS	UANT TO AUTHORITY OF:					
D. OTHER (Specify type of mod X 52.217-9, Option to Extend the T	Terms of the Contract						
	s required to sign this document and retur	1	he issuing office.				
14. DESCRIPTION OF AMENDMENT/MODE Tax ID Number: 33-0827593	FICATION (Organized by UCF section	headings, including solicitati	ion/contract subject matter whe	re feasible)			
DUNS Number: 111029179		(m) · · -					
Proof of Concept for Use of the Celution	System as a Medical Counterme	easure for Thermal Burn					
A.The purpose of this modification is for	the Government to exercise CL	IN004/option 2 of contra	act HHS0100201200008C				
Continued							
Except as provided herein, all terms and conditions							
15A. NAME AND TITLE OF SIGNER (Type or p	rint)	16A. NAME AND TITLE	E OF CONTRACTING OFFICE	ER (Type or print)			

Tiago M. Girao CFO		WENDELL CONYERS	
15B. CONTRACTOR/OFFEROR /s/ Tiago M. Girao	15C. DATE SIGNED 5/23/17	16B. UNITED STATES OF AMERICA	16C. DATE SIGNED 5/23/2017
(Sianature of person authorized to sian)	Ĩ	(Sianature of Contractina Officer)	

CONTINUATION SHEET REFERENCE NO. OF DOCUMENT BEING CONTINUED HHSO100201200008C/0008						PAGE 2	OF 8
AME OF OFFER	ROR OR CONTRA PEUTICS, INC 138	CTOR					
ITEM NO. (A)		SUPPLIES/SERVICES (B)	QUANTITY (C)	UNIT (D)	UNIT PRICE (E)	AMOUNT (F)	
	Period of Performan	Code: HHS Avenue, SW				13,358,679.00	

OPTIONAL FORM 336 (4-86) Sponsored by GSA FAR (48 CFR) 53.110

US-DOCS\92204410.1

Contract No. HHSO100201200008C	Continuation Sheet	Page 3 of 8
Modification No.8	Block 14	

SUMMARY OF CHANGES

- 1. The purpose of this modification is as follow: to exercise the Government's unilateral right to exercise option in accordance with the contract's clause FAR 52.217-9, option to Extend the Term of the Contract.
- 2. The Government hereby exercises CLIN 4/Option 2:Pilot IDE Clinical Trial for treatment of deep-partial and full thickness thermal burn wounds in conjuction with standard of care as priced in Article B.3.
- 3. Funding and Contract Total summary: the total funded amount on the contract is hereby increased by \$13,358,679 from \$21,263,095.00 to \$34,621,774.00.
- 4. The Period of Performance for: Option 2(CLIN 0004): May 23,2017 thru November 30,2020
- 5. The period of performance (PoP) of the Contract has changed:

From: September 28, 2012 thru June 15, 2017 To: September 28, 2012 thru November 30,2020

6. Under SECTION J (SEE ATTACHMENT #1), the statement of Work dated May 1,2017(6 pages):

BARDA Broad Agency Announcement (BAA) (BAA-11-100-SOL-00009)

Advanced Research and Development of Chemical, Biological, Radiological, and Nuclear Medical Countermeasures

CELUTION SYSTEM Use: Full Thickness Burn Wound Treatment Contract #: HHS0100201200008C Period: CLIN4/Option 2

Contractual Statement of Work

PREAMBLE

Independently and not as an agency 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 the BARDA Broad Agency Announcement (BAA) CBRN-BAA-11-100-SOL-00009.

The overall goal of this project is to advance the development of the Celution System as an autologous cell-based countermeasure for the treatment of full and deep-partial thickness burn wounds. The scope of work for this contract includes activities that fall into the following areas: non-clinical efficacy studies; clinical activities; manufacturing activities; and all associated regulatory, quality assurance, management, and administrative activities. The Research and Development (R&D) effort for the Celution System will progress in specific stages that cover the base performance (I) segment and two (I to II) option segment as specified in the contract. The Contractor has completed specific tasks required for the Base and Option 1 periods. This statement of work describes the activities to be performed as part of Option 2.

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1

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- 4.1.4 A BARDA Liaison with responsibility for effective communication with the Project Officer and Contracting Officer. May be the PI or Project Manager.
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4.1.9 Integrated Master Plan

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2

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 - VIII. Present the Risk Management Plan
- 4.1.12 *Deviation Request:* During the course of contract performance, in response to a need to change IMS activities as baselined at the PMBR, the Contractor shall submit a Deviation Report. This report shall request a change in the agreed-upon IMS and timelines. This report shall include: (i) discussion of the justification/rationale for the proposed change; (ii) options for addressing the needed changes from the agreed upon timelines, including a cost-benefit analysis of each option; and (iii) recommendations for the preferred option that includes a full analysis and discussion of the effect of the change on the entire product development program, timelines, and budget.
- 4.1.13 *Monthly and Annual Reports:* The Contractor shall deliver Project Status Reports on a monthly basis. The reports shall address the items below cross referenced to the WBS, SOW, IMS, and EVM:
 - I. Executive summary highlighting the progress, issues, and relevant activities in manufacturing, non-clinical, clinical, and regulatory;
 - II. Progress in meeting contract milestones, detailing the planned progress and actual progress during the reporting period, explaining any differences between the two and corrective steps;
 - III. Updated IMS;
 - IV. Updated EVM;
 - V. Updated Risk Management Plan (Every 3 months);
 - VI. Three month rolling forecast of planned activities;
 - VII. Progress of regulatory submissions;
 - VIII. Estimated and actual expenses;
- 4.1.14 *Data Management:* The Contractor shall develop and implement data management and quality control systems/procedures, including transmission, storage, confidentiality, and retrieval of all contract data;
- 4.1.14.1 Provide for the statistical design and analysis of data resulting from the research;
- 4.1.14.2 Provide raw data or specific analyses of data generated with contract funding to the Project Officer, upon request.
- 4.2 Non-Clinical Toxicology (WBS 4.2) N/A
- 4.3 Non-Clinical Studies (WBS 4.3) N/A
- 4.4 Clinical Studies (WBS 4.4)

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- 4.4.1 Develop and execute a contract with a contract research organization for the execution of the clinical study ("RELIEF"). The contract should specify roles and responsibilities for Cytori and the CRO throughout study execution;
- 4.4.2 Develop and execute site contracts, gain IRB approvals and initiate clinical study sites;
- 4.4.3 Provide interim data reports to be presented to BARDA for the purpose of determination of the achievement of the objectives set forth herein.
- 4.4.4 Complete final study report for the "RELIEF" clinical trial.
- 4.4.5 "RELIEF" Clinical Study Summary: Cytori will execute a prospective, open-label, paralle group, usual care controlled, multi-center randomized clinical study targeting thermal burns. Subjects will have at least one deep partial or full thickness burn wound of \geq 250 cm² that is to be autografted with a meshed split thickness skin graft (STSG). Subjects will be randomized to receive either usual care or usual care supplemented with intravenous administration of ADRCs. Subjects who receive ADRCs will undergo small volume fat harvest (100 to 150 mL) under general anesthesia. Harvested tissue will be processed in the Celution System to isolate and concentrate ADRCs which will then be delivered intravenously. All enrolled subjects will be assessed for end points specified within the clinical protocol.
- 4.4.6 The objective of this trial is to obtain data that will allow assessment of the safety and feasibility of intravenous delivery of autologous ADRCs as an adjunct to treatment of full and deep partial thickness thermal burn wounds treated with a meshed autologous split thickness skin graft (STSG). Safety and feasibility will be assessed on an ongoing basis that will include assessment following enrollment and treatment of each of the first five subjects treated in the study and at intervals thereafter.
 - 4.4.6.1 [***]
 - 4.4.6.2 [***]
 - 4.4.6.3 [***]
 - 4.4.6.4 [***]
- 4.4.7 Preparation of materials for a possible FDA pre-submission package.
 - 4.4.7.1 Because the trial applies an open-label design it will be possible to monitor both primary (safety and feasibility) and secondary/exploratory (preliminary/potential efficacy) end points on an ongoing basis. Subsequent to adequate enrollment and prior to completion of the full and final clinical study report these data may be compiled and submitted to FDA as part of a pre-submission package pertaining to a possible follow-on pivotal trial of this approach. This package may include an outline of a proposed design of said potential pivotal trial.
 - 4.4.7.2 This task (4.4.7) shall not be required in the event that a final determination is made that the treatment approach is not safe or is not feasible.

4.5 Regulatory (WBS 4.5)

- 4.5.1 Engaging the FDA on a path to support the use of the product for the specific indication;
- 4.5.2 Preparing materials for and requesting, scheduling and participating in all meetings with the FDA, including meetings to review EUA and/or all other data packages;
- 4.5.3 Providing BARDA with (i) the initial draft minutes and final draft minutes of any formal meeting with the FDA; (ii) final draft minutes of any informal meeting with the FDA;
- 4.5.4 Generating all necessary data and preparing documentation for IDE submissions to regulatory agencies;
- 4.5.5 Execution of reporting of adverse events to FDA in accordance with relevant FDA requirements and the IDE approval;
- 4.5.6 Submitting IDE documentation to the FDA in a timely manner, consistent with timelines set out in the contract and by the FDA.
- 4.5.7 Preparation and submission, if indicated by safety and feasibility data, to FDA of a pre-submission package pertaining to a possible follow-on clinical trial.

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- 4.5.8 Scheduling and execution of a meeting with FDA, if indicated, and, if held, generation of a written report based on said pre-submission package.
- 4.5.9 This task (4.5) shall not be required in the event the results of the clinical trial indicate that the treatment approach is not safe or is not feasible.

4.6 CMC (WBS 1.6) - N/A

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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 11, 2017 /s/ Marc H. Hedrick Marc H. Hedrick, President & Chief Executive Officer

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

I, 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 11, 2017 /s/ Tiago Girao 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, 2017 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 11, 2017

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

Dated: August 11, 2017

By: /s/ Tiago Girao

Tiago Girao VP of Finance and Chief Financial Officer