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

**FORM 10-Q** 

(Mark One)

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

For the quarterly period ended June 30, 2012

OR

0 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

# **CYTORI THERAPEUTICS, INC.**

(Exact name of Registrant as Specified in Its Charter)

DELAWARE

(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 x No o

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 x No o

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 o

Accelerated Filer x

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

to

Smaller reporting company o

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

As of July 31, 2012, there were 58,711,231 shares of the registrant's common stock outstanding.

92121

33-0827593

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

(Zip Code)

# CYTORI THERAPEUTICS, INC.

# INDEX

Page

# PART I FINANCIAL INFORMATION

	Item 1.	Financial Statements	
		Consolidated Condensed Balance Sheets as of June 30, 2012 and December 31, 2011 (unaudited)	3
		<u>Consolidated Condensed Statements of Operations and Comprehensive Loss for the three and six months ended June</u> <u>30, 2012 and 2011 (unaudited)</u>	4
		Consolidated Condensed Statements of Cash Flows for the six months ended June 30, 2012 and 2011 (unaudited)	5
		Consondated Condensed Statements of Cash Flows for the six months ended suite 50, 2012 and 2011 (unddated)	5
		Notes to Consolidated Condensed Financial Statements (unaudited)	6
	Item 2.	Management's Discussion and Analysis of Financial Condition and Results of Operations	16
	Item 3.	Quantitative and Qualitative Disclosures about Market Risk	26
	item 5.		20
	Item 4.	Controls and Procedures	26
PART II	OTHER INFO	ORMATION	
	Item 1.	Legal Proceedings	27
	Item 1A.	Risk Factors	27
	Item 2.	Unregistered Sales of Equity Securities and Use of Proceeds	35
	Item 3.	Defaults Upon Senior Securities	35
	Item 4.	Mine Safety Disclosures	35
	Item 5.	Other Information	35
	Item 6.	<u>Exhibits</u>	36

# PART I. FINANCIAL INFORMATION

Item 1. Financial Statements

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

	A	s of June 30, 2012	A	s of December 31, 2011
Assets				
Current assets:			-	
Cash and cash equivalents	\$	25,771,000	\$	36,922,000
Accounts receivable, net of reserves of \$220,000 and of \$474,000 in 2012 and 2011, respectively		1,983,000		2,260,000
Inventories, net		3,108,000		3,318,000
Other current assets		1,115,000	_	837,000
Total current assets		31,977,000		43,337,000
Property and equipment, net		2,255,000		1,711,000
Restricted cash and cash equivalents		350,000		350,000
Investment in joint venture		164,000		250,000
Other assets		1,755,000		1,772,000
Intangibles, net		81,000		192,000
Goodwill		3,922,000		3,922,000
Total assets	\$	40,504,000	\$	51,534,000
Liabilities and Stockholders' Equity (Deficit)				
Current liabilities:	*		<b>*</b>	
Accounts payable and accrued expenses	\$	5,066,000	\$	5,334,000
Current portion of long-term obligations	_	7,338,000		2,487,000
Total current liabilities		12,404,000		7,821,000
Deferred revenues, related party		1,107,000		3,520,000
Deferred revenues		5,296,000		5,244,000
Warrant liability		1,008,000		627,000
Option liability		2,100,000		1,910,000
Long-term deferred rent		600,000		504,000
Long-term obligations, net of discount, less current portion		17,441,000		21,962,000
Total liabilities		39,956,000		41,588,000
Commitments and contingencies				
Stockholders' equity:				
Preferred stock, \$0.001 par value; 5,000,000 shares authorized; -0- shares issued and outstanding in 2012 and 2011 Common stock, \$0.001 par value; 95,000,000 shares authorized; 58,706,856 and 56,594,683 shares issued and		—		—
outstanding in 2012 and 2011, respectively		59,000		57,000
Additional paid-in capital		260,146,000		252,338,000
Accumulated deficit		(259,657,000)		(242,449,000)
		(200,007,000)	_	(272,743,000)
Total stockholders' equity	_	548,000	_	9,946,000
Total liabilities and stockholders' equity	\$	40,504,000	\$	51,534,000

SEE NOTES TO UNAUDITED CONSOLIDATED CONDENSED FINANCIAL STATEMENTS

## CYTORI THERAPEUTICS, INC. CONSOLIDATED CONDENSED STATEMENTS OF OPERATIONS (UNAUDITED)

		For the Three Months Ended June 30,			For the Six Mo Ended June 3			
	_	2012	_	2011	_	2012		2011
Product revenues	\$	1,947,000	\$	2,411,000	\$	3,427,000	\$	3,773,000
Cost of product revenues		1,032,000		1,109,000	_	1,885,000		1,950,000
Gross profit		915,000		1,302,000		1,542,000		1,823,000
Development revenues:								
Development, related party		2,413,000				2,413,000		1,231,000
Research grant and other		16,000		11,000		19,000		15,000
		2,429,000		11,000		2,432,000		1,246,000
Operating expenses:					_			
Research and development		3,224,000		3,071,000		6,060,000		6,118,000
Sales and marketing		2,581,000		3,716,000		4,956,000		6,942,000
General and administrative		3,788,000		4,147,000		7,712,000		7,692,000
Change in fair value of warrant liability		251,000		(5,649,000)		381,000		(2,178,000)
Change in fair value of option liability		460,000		400,000		190,000		110,000
Total operating expenses		10,304,000		5,685,000		19,299,000		18,684,000
Operating loss		(6,960,000)		(4,372,000)		(15,325,000)		(15,615,000)
Other income (expense):								
Interest income		1,000		1,000		2,000		4,000
Interest expense		(860,000)		(696,000)		(1,726,000)		(1,434,000)
Other income (expense), net		(27,000)		(15,000)		(73,000)		(62,000)
Equity loss from investment in joint venture		(37,000)		(56,000)		(86,000)		(102,000)
Total other income (expense)		(923,000)		(766,000)		(1,883,000)		(1,594,000)
Net loss	<u>\$</u>	(7,883,000)	\$	(5,138,000)	\$	(17,208,000)	\$	(17,209,000)
Basic and diluted net loss per common share	\$	(0.13)	\$	(0.10)	\$	(0.30)	\$	(0.33)
Basic and diluted weighted average common shares		58,676,092		52,411,642		58,080,541		52,204,348

# SEE NOTES TO UNAUDITED CONSOLIDATED CONDENSED FINANCIAL STATEMENTS

## <u>Index</u>

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

	For t	he Six Month	ıs Er	ıded June 30,
		2012		2011
Cash flows from operating activities:				
Net loss	\$	(17,208,000)	\$	(17,209,000)
Adjustments to reconcile net loss to net cash used in operating activities:				
Depreciation and amortization		453,000		400,000
Amortization of deferred financing costs and debt discount		470,000		471,000
Provision for doubtful accounts		19,000		235,000
Change in fair value of warrants		381,000		(2,178,000)
Change in fair value of option liabilities		190,000		110,000
Share-based compensation expense		1,977,000		1,721,000
Equity loss from investment in joint venture		86,000		102,000
Increases (decreases) in cash caused by changes in operating assets and liabilities:				
Accounts receivable		258,000		(623,000)
Inventories		210,000		(513,000)
Other current assets		(278,000)		(15,000)
Other assets		17,000		(905,000)
Accounts payable and accrued expenses		(268,000)		92,000
Deferred revenues, related party		(2,413,000)		(1,231,000)
Deferred revenues		52,000		35,000
Long-term deferred rent		96,000		(24,000)
				( ) )
Net cash used in operating activities		(15,958,000)		(19,532,000)
		<u>(,</u> )	_	(,,)
Cash flows from investing activities:				
Purchases of property and equipment		(886,000)		(433,000)
		(000,000)		(433,000)
Net cash used in investing activities		(886,000)		(433,000)
		(000,000)		(433,000)
Cash flows from financing activities:				
Principal payments on long-term obligations		(140,000)		(2,230,000)
Proceeds from exercise of employee stock options		951,000		2,756,000
Proceeds from sale of common stock		4,946,000		2,750,000
Costs from sale of common stock		(64,000)		
		(04,000)		
Not each provided by financing activities		5,693,000		526,000
Net cash provided by financing activities		5,095,000		520,000
Net decrease in cash and cash equivalents		(11,151,000)		(19,439,000)
		(11,131,000)		(19,439,000)
Cash and cash equivalents at beginning of period		36.922.000		52,668,000
Cash and Cash equivalents at beginning of period		30,922,000		52,008,000
	¢	25 551 000	¢	22.220.000
Cash and cash equivalents at end of period	\$	25,771,000	\$	33,229,000
Supplemental disclosure of cash flows information:				
Cash paid during period for:				
Interest	\$	1,257,000	\$	989,000
Supplemental schedule of non-cash investing and financing activities:				
Capital equipment lease				94,000
-				

SEE NOTES TO UNAUDITED CONSOLIDATED CONDENSED FINANCIAL STATEMENTS

## CYTORI THERAPEUTICS, INC. NOTES TO CONSOLIDATED CONDENSED FINANCIAL STATEMENTS June 30, 2012 (UNAUDITED)

## 1. Basis of Presentation

Our accompanying unaudited consolidated condensed financial statements as of June 30, 2012 and for the three and six months ended June 30, 2012 and 2011 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 June 30, 2012 has been derived from the audited financial statements at December 31, 2011, but does not include all of the information and footnotes required by accounting principles generally accepted in the United States of America for complete financial statements. In the opinion of management, all adjustments (consisting of normal recurring adjustments) considered necessary for a fair presentation of the financial position and results of operations of Cytori Therapeutics, Inc., and our subsidiaries (the Company) have been included. Operating results for the three and six months ended June 30, 2012 are not necessarily indicative of the results that may be expected for the year ending December 31, 2012. 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, 2011.

## 2. Use of Estimates

The preparation of consolidated financial statements in conformity with accounting principles generally accepted in the United States of America 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, evaluating goodwill for impairment, valuing our put option arrangement with Olympus Corporation, valuing warrants, determining the assumptions used in measuring share-based compensation expense and valuing allowances for doubtful accounts and inventories.

Actual results could differ from these estimates. Current economic conditions, including illiquid credit markets and volatile equity markets, contribute to the inherent uncertainty of such 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. Capital Availability

We incurred net losses of \$7,883,000 and \$17,208,000 for the three and six months ended June 30, 2012 and \$5,138,000 and \$17,209,000 for the three and six months ended June 30, 2011, respectively. We have an accumulated deficit of \$259,657,000 as of June 30, 2012. Additionally, we have used net cash of \$15,958,000 and \$19,532,000 to fund our operating activities for the six months ended June 30, 2012 and 2011, respectively. To date, these operating losses have been funded primarily from outside sources of invested capital.

We believe we have enough cash to fund operations into the first quarter of 2013, which factors in the minimum cash and cash liquidity requirements of the Amended and Restated Loan and Security Agreement with the Lenders, which requires that we maintain at least three months of cash on hand to avoid an event of default under the Loan and Security Agreement. We will continue to seek additional cash through strategic corporate partnership and future sales of equity in addition to our operating profits. We have an established history of raising capital through these platforms, and we are currently involved in negotiations with multiple parties. In the continued absence of positive cash flows from operations, no assurance can be given that we can generate sufficient revenue to cover operating costs or that additional financing will be available to us and, if available, on terms acceptable to us in the future.

During 2011, we expanded our commercialization activities while simultaneously pursuing available financing sources to support operations and growth. We have had, and we will likely continue to have, an ongoing need to raise additional cash from outside sources to fund our future operations. If we cannot do so when required, we would need to reduce our research, development, and administrative operations, including reductions of our employee base, in order to offset lack of available funding. We continue to evaluate market conditions and available financing opportunities as part of our normal course of business.

# 4. Recent Accounting Pronouncements

In May 2011, the FASB revised the fair value measurement and disclosure requirements to align the requirements under GAAP and International Financial Reporting Standards ("IFRS"). The guidance clarifies the FASB's intent about the application of existing fair value measurements and requires enhanced disclosures, most significantly related to unobservable inputs used in a fair value measurement that is categorized within Level 3 of the fair value hierarchy. The guidance is effective prospectively during interim and annual periods beginning after December 15, 2011. The adoption of this guidance did not have a material impact on our consolidated financial statements.

## 5. Warrant Liability

Warrants with exercise price reset features (down-round protection) are accounted for as liabilities, with changes in fair value included in net earnings (loss). The fair value of the liability associated with the warrants with this reset feature increased to \$1,008,000 as of June 30, 2012, which resulted in a \$251,000 and \$381,000 loss from the change in fair value of warrants for the three and six months ended June 30, 2012, respectively.

All future changes in the fair value of the warrants will be recognized currently in earnings until such time as the warrants are exercised or expire. These warrants are not traded in an active securities market, and as such, we estimated the fair value of these warrants using an option pricing model with the following assumptions:

	As of June 30, 2			As of mber 31, 2011
Expected term		1.12 years		1.61 years
Common stock market price	\$	2.70	\$	2.20
Risk-free interest rate		0.21%		0.19%
Expected volatility		77.29%		69.98%
Resulting fair value (per warrant)	\$	0.50	\$	0.32

Expected volatility is based primarily on historical volatility. Historical volatility was computed using daily pricing observations for recent periods that correspond to the expected term of the warrants. We believe this method produces an estimate that is representative of our expectations of future volatility over the expected term of these warrants. We currently have no reason to believe future volatility over the expected remaining life of these warrants is likely to differ materially from historical volatility. The expected life is based on the remaining contractual term of the warrants. The risk-free interest rate is the interest rate for treasury constant maturity instruments published by the Federal Reserve Board that is closest to the expected term of the warrants. The fair value of these warrants also incorporates our assumptions about future equity issuances and their impact to the down-round protection feature.

Fluctuations in the fair value of the warrants are impacted by unobservable inputs, most significantly the assumption with regards to future equity issuances and their impact to the down-round protection feature. Significant increases (decreases) in this input in isolation would result in a significantly higher (lower) fair value measurement.

# 6. Long-term Debt

On September 9, 2011 we entered into a Second Amendment to the Amended and Restated Loan and Security Agreement (loan agreement) with General Electric Capital Corporation (GECC), Silicon Valley Bank (SVB) and Oxford Finance Corporation (together, the "Lenders"), pursuant to which the Lenders increased the prior term loan made to the Company to a principal amount of \$25.0 million (Term Loan), subject to the terms and conditions set forth in the loan agreement. The Term Loan accrues interest at a fixed rate of 9.87% per annum. Pursuant to the loan agreement, we are required to make (i) twelve (12) equal consecutive monthly principal payments of \$20,833 on the first day of each calendar month, commencing on October 1, 2011, (ii) twenty-nine (29) equal consecutive monthly principal payments of \$825,000 on the first day of each calendar month, commencing on October 1, 2012, and (iii) and one (1) final principal payment of \$825,000 on March 1, 2015. In addition, the maturity date of the Term Loan has been extended until March 1, 2015, and at maturity of the Term Loan. In connection with the Term Loan, on September 9, 2011, we issued to the Lenders warrants to purchase up to an aggregate of 132,891 shares of our common stock at an exercise price of \$3.01 per share. These warrants are immediately exercisable and will expire on September 9, 2018.

The Term Loan amended the Amended and Restated Loan and Security Agreement, of which an aggregate balance of approximately \$15.6 million remained outstanding along with a prorated final payment fee of \$419,000. The net proceeds of the Term Loan, after payment of lender fees and expenses, were approximately \$8.6 million.



We accounted for this amendment as debt modification since the terms of the amended Term Loan and the Original Term Loan were not substantially different and as present value of cash flows of the modified instrument (using a net method of comparing the present value of cash flows related to the lowest common principal balance between the old and the new loans) was within 10% of the original debt instrument. Accordingly, the fees associated with the amended Term Loan of \$300,000, final payment fee of \$1,250,000, and the existing unamortized debt discount from the Original Term Loan of \$332,000 will be amortized as an adjustment of interest expense over the term of the Amended Term Loan using the effective interest method.

We allocated the aggregate proceeds of the Term Loan between the warrants and the debt obligations based on their relative fair values. The fair value of the warrants issued to the Lenders is calculated utilizing the Black-Scholes option-pricing model. We are amortizing the relative fair value of the warrants as a discount of \$267,000 over the term of the loan using the effective interest method, with an effective interest rate of 13.63%. If the maturity of the debt is accelerated due to an event of default, then the amortization would be accelerated. The Term Loan is collateralized by the tangible assets of the company, including a security interest in substantially all of its existing and after-acquired assets, excluding its intellectual property assets; provided however, that if the Company does not maintain certain cash ratios, the security interest automatically will be deemed to include the Company's intellectual property assets. As of June 30, 2012, we were in compliance with our financial and non-financial covenants.

## 7. Revenue Recognition

#### Product Sales

We recognize revenue from product sales when the following fundamental criteria are met: (i) persuasive evidence of an arrangement exists, (ii) delivery has occurred, (iii) the price to the customer is fixed or determinable and (iv) collection of the resulting accounts receivable is reasonably assured.

For all sales, we use a binding purchase order or a signed agreement as evidence of an arrangement. Revenue for these product sales is recognized upon delivery to the customer, as all risks and rewards of ownership have been substantively transferred to the customer at that point. For sales to customers who arrange for and manage the shipping process, we recognize revenue upon shipment from our facilities. Shipping and handling costs that are billed to our customers are classified as revenue. The customer's obligation to pay and the payment terms are set at the time of delivery and are not dependent on the subsequent use or resale of our products.

For sales that include multiple deliverables, such as sales of our StemSource® Cell Bank (cell bank), we allocate arrangement consideration at the inception of the arrangement to all deliverables using the relative selling price method. Stem cell banks typically consist of a complex array of equipment, proprietary knowledge, and services, including one or more StemSource® devices, a cryogenic freezer, measuring and monitoring equipment, and a database patient tracking system. In addition, we typically provide consulting services, installation and training services concurrent with the installation of the cell bank. Web hosting and technical and maintenance services are generally provided for a period of up to one year subsequent to the date of sale. FASB authoritative guidance establishes a selling price hierarchy for determining the selling price of a deliverable, which is based on: (a) vendor-specific objective evidence ("VSOE"); (b) third-party evidence ("TPE"); or (c) management estimates. For our cell bank sales, we establish relative selling prices for all deliverables based on vendor-specific quotes for comparable services when available. In the absence of VSOE, we use competitors' products or services considered largely interchangeable with our own or management's best estimate. A substantial amount of consulting services are provided to customers before the equipment installation and training has been completed, and therefore we treat this as a separate unit of accounting. The equipment with installation and initial training activities are treated as separate units of accounting. Also of standalone value to customers is the transfer of the proprietary knowledge, most notably in the form of standard operating procedures, and any license or exclusivity rights associated with the agreements. Revenue for the various deliverables is calculated and recognized into income during the year following the installation.

#### Concentration of Significant Customers

One direct customer comprised 21% of our revenue recognized for the six months ended June 30, 2012. Our Asia-Pacific region sales accounted for 53% of our revenue recognized for the six months ended June 30, 2012. Additionally, three direct customers accounted for 52% of total outstanding accounts receivable as of June 30, 2012.

For the six months ended June 30, 2011, our sales were concentrated in one direct customer, which comprised 29% of our revenue recognized for the six months ended June 30, 2011. Our Asia-Pacific and North America region sales accounted for 71% of our revenue recognized for the six months ended June 30, 2011. Additionally, one direct customer accounted for 40% of total outstanding accounts receivable as of June 30, 2011.

## Research and Development

We earn revenue for performing tasks under research and development agreements with both commercial enterprises, such as Olympus and Senko, and governmental agencies like the National Institutes of Health ("NIH"). Revenue earned under development agreements is classified as either research grant or development revenues depending on the nature of the arrangement. Revenues derived from reimbursement of direct out-of-pocket expenses for research costs associated with grants are recorded as research grant and other within development revenues. Research grant 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 expenses in our statements of operations. Additionally, research and development arrangements we have with commercial enterprises such as Olympus and Senko are considered a key component of our central and ongoing operations. Accordingly, when recognized, the inflows from such arrangements are presented as revenues in our statements of operations.

We received funds from Olympus and Olympus-Cytori, Inc. during 2005 and 2006. We recorded upfront fees totaling \$28,311,000 as deferred revenues, related party. In exchange for these proceeds, we agreed to (a) provide Olympus-Cytori, Inc. an exclusive and perpetual license to our Celution® System device technology and certain related intellectual property, and (b) provide future development contributions related to commercializing the Celution® System platform. The license and development services are not separable and as a result the recognition of this deferred amount requires achievement of service related milestones, under a proportional performance methodology. If and as such revenues are recognized, deferred revenue will be decreased. Proportional performance methodology was elected due to the nature of our development obligations and efforts in support of the Joint Venture ("JV"), including product development activities and regulatory efforts to support the commercialization of the JV products. The application of this methodology uses the achievement of R&D milestones as outputs of value to the JV. We received up-front, non-refundable payments in connection with these development obligations, which we have broken down into specific R&D milestones that are definable and substantive in nature, and which will result in value to the JV when achieved. As our research and development efforts progress, we periodically evaluate, and modify if necessary, the milestone points in our proportional performance model to ensure that revenue recognition accurately reflects our best estimate of substantive value deliverable to the JV. Revenue will be recognized as the above mentioned R&D milestones are completed. Of the amounts received and deferred, we recognized development revenues of \$0 and \$1,231,000 for the three and six months ended June 30, 2011, respectively. During 2012, we recognized \$2,413,000 for the three and six months ended June 30, 2012. All related development costs are expensed as incurred and are included in research and development expense on our statements of operations. To date under the contract, of the \$28,311,000 originally deferred, we have recognized a total of \$27,204,000 through June 30, 2012.

Under a Distribution Agreement with Senko, we granted to Senko an exclusive license to sell and distribute certain Thin Film products in Japan. We have also earned or will be entitled to earn additional payments under the Distribution Agreement based on achieving certain defined and substantive research and development milestones. There was no development revenue recognized related to this agreement during the three and six months ended June 30, 2012 and 2011, respectively.

#### 8. Inventories

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

Inventories consisted of the following:

	June 30, 2012	December 31, 2011
Raw materials	\$ 1,280,000	\$ 1,503,000
Work in process	761,000	790,000
Finished goods	1,067,000	1,025,000
	\$ 3,108,000	\$ 3,318,000

## 9. Share-Based Compensation

#### **Stock Options**

During the first quarter of 2012, we issued to our directors and executive officers options to purchase an aggregate of up to 690,000 shares of our common stock, with four-year vesting for our officers and two-year vesting for our directors. The grant date fair value of the awards granted to our officers was \$2.10 per share and to our directors was \$1.35 per share. The resulting share-based compensation expense of \$1,373,000, net of estimated forfeitures, will be recognized as expense over the respective vesting periods.



During the first quarter of 2011, we issued to our directors, executive officers and certain non-executive employees options to purchase an aggregate of up to 692,500 shares of our common stock, with four-year vesting for our officers and employees and two-year vesting for our directors. The grant date fair value of the awards granted to our officers and employees was \$3.46 and to our directors was \$3.15 per share. The resulting share-based compensation expense of \$2,375,000, net of estimated forfeitures, will be recognized as expense over the respective vesting periods.

## **Restricted Stock Awards**

During the first quarter of 2012, we issued to our executive officers 190,000 shares of restricted stock. The stock award is scheduled to fully vest on January 10, 2013, subject to the officer's continued employment with the Company through the vesting date. The resulting share-based compensation expense of \$654,000 will be recognized as expense over the respective vesting period.

## Performance-Based Restricted Stock Awards

We granted 246,225 performance-based restricted stock awards under the 2004 Equity Incentive Plan in February 2011. The awards provide certain employees until January 1, 2012 to achieve certain performance goals established by the Compensation Committee. Effective January 2012, the outstanding awards were terminated in their entirety based upon the decision by the Compensation Committee that performance criteria had not been met as of January 1, 2012. No compensation expense was recognized related to these awards.

In January 2012, we granted 276,375 performance-based restricted stock awards under the 2004 Equity Incentive Plan. The awards provide certain employees until December 31, 2012 to achieve certain performance goals established by the Compensation Committee. The performance goals are weighted based on the following achievements: entering into a major collaboration for development and/or commercialization of the Company's products (40%), obtaining certain FDA clearance or approvals, which include FDA approval for and initiation of the ATHENA feasibility trial in chronic myocardial ischemia (40%), obtaining CE mark for certain products (15%), and achieving a targeted revenue increase for the fiscal year ended December 31, 2012 (5%). To the extent that any of the performance goals are partially achieved, the Compensation Committee maintains the discretion to continue the vesting of all or a portion of the awards following December 31, 2012. Once earned, the awards will remain unvested until January 10, 2014. Termination of employment prior to vesting will result in the forfeiture of the awards. During the three and six months ended June 30, 2012, we recognized \$49,000 of compensation expense related to these awards.

The following table summarizes activity with respect to the performance based restricted stock awards during the six months ended June 30, 2012:

		Weighted			
	Restricted Stock Awards	Average Grant- Date Fair Value			
Outstanding at January 1, 2012	246,225	\$ 5.82			
Granted	276,375	\$ 3.44			
Vested	0				
Cancelled/forfeited	(261,300)	\$ 5.68			
Outstanding at June 30, 2012	261,300	\$ 3.44			
Vested at June 30, 2012	0				

## 10. 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, warrants, restricted stock and performance based restricted stock awards for all periods presented.

We have excluded all potentially dilutive securities from the calculation of diluted loss per share attributable to common stockholders for the three and six months ended June 30, 2012 and 2011, as their inclusion would be antidilutive. Potentially dilutive common shares excluded from the calculations of diluted loss per share were 18,401,231 for the three and six month periods ended June 30, 2012 and 19,196,482 for the three and six month periods ended June 30, 2011, respectively.



## 11. 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 was estimated based on current schedules of pre-clinical and clinical studies in progress. As of June 30, 2012, we have pre-clinical research study obligations of \$60,000 (which are expected to be fully completed within a year) and clinical research study obligations of \$11,900,000 (\$3,700,000 of which are expected to be completed within a year). Should the timing or the budgets of the pre-clinical and clinical trials change, the timing and amounts of the payments for these obligations would also change.

During 2008, we entered into a supply agreement with a minimum purchase requirements clause. As of June 30, 2012, we have minimum purchase obligations of \$2,191,000 (\$1,341,000 of which are expected to be paid within a year).

We have entered into several lease agreements for our headquarters office location as well as international office locations and corporate housing for our employees on international assignments. As of June 30, 2012, we have remaining lease obligations of \$9,824,000 (\$1,843,000 of which are 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. When evaluating contingencies, we may be unable to provide a meaningful estimate due to a number of factors, including the procedural status of the matter in question, the presence of complex or novel legal theories, and/or the ongoing discovery and development of information important to the matters. In addition, damage amounts claimed in litigation against us may be unsupported, exaggerated or unrelated to possible outcomes, and as such are not meaningful indicators of our potential liability. We regularly review contingencies to determine the adequacy of our accruals and related disclosures. The amount of ultimate loss may differ from these estimates, and it is possible that cash flows or results of operations could be materially affected in any particular period by the unfavorable resolution of one or more of these contingencies. Whether any losses finally determined in any claim, action, investigation or proceeding could reasonably have a material effect on our business, financial condition, results of operations or cash flows will depend on a number of variables, including: the timing and amount of such losses; the structure and type of any remedies; the significance of the impact any such losses, damages or remedies may have on our consolidated financial statements; and the unique facts and circumstances of the particular matter that may give rise to additional factors. 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.

Refer to note 6 for a discussion of our commitments and contingencies related to our long-term obligations.

Refer to note 12 for a discussion of our commitments and contingencies related to our transactions with Olympus, including (a) our obligation to the Joint Venture in future periods and (b) certain put and call rights embedded in the arrangements with Olympus.

## 12. Transactions with Olympus Corporation

## Initial Investment by Olympus Corporation in Cytori

In 2005, we entered into a common stock purchase agreement with Olympus in which we received \$11,000,000 in cash proceeds. We received an additional \$11,000,000 from Olympus in August 2006 for the issuance of approximately 1,900,000 shares of our common stock at \$5.75 per share. We received an additional \$6,000,000 from Olympus in August 2008 for the issuance of 1,000,000 unregistered shares of our common stock at \$6.00 per share and 500,000 common stock warrants (with an original exercise price of \$8.50 per share) under a private placement offering.

As of June 30, 2012, Olympus holds approximately 6.8% of our issued and outstanding shares. Additionally, Olympus has a right, which it has not yet exercised, to designate a director to serve on our Board of Directors.

## Formation of the Olympus-Cytori Joint Venture

In 2005, we entered into a joint venture and other related agreements (the "Joint Venture Agreements") with Olympus. The Joint Venture is owned equally by Olympus and us. We have determined that the Joint Venture is a variable interest entity or VIE, but that Cytori is not the VIE's primary beneficiary. Accordingly, we have accounted for our interests in the Joint Venture using the equity method of accounting, since we can exert significant influence over the Joint Venture's operations. At June 30, 2012, the carrying value of our investment in the Joint Venture is \$164,000. We are under no obligation to provide additional funding to the Joint Venture, but may choose to do so. We made no cash contributions to the Joint Venture during the three and six months ended June 30, 2012 and 2011.

## Put/Calls and Guarantees

The Shareholders' Agreement between Cytori and Olympus provides that in certain specified circumstances of our insolvency or if we experience a change in control, Olympus will have the rights to (i) repurchase our interests in the Joint Venture at the fair value of such interests or (ii) sell its own interests in the Joint Venture to Cytori (the "Put") at the higher of (a) \$22,000,000 or (b) the Put's fair value.

At June 30, 2012 and December 31, 2011, the estimated fair value of the Put was \$2,100,000 and \$1,910,000, respectively. Fluctuations in the Put value are recorded in the consolidated condensed statements of operations as a component of change in fair value of option liabilities. The estimated fair value of the Put has been recorded as a long-term liability in the caption option liability in our consolidated condensed balance sheets.

The valuations of the Put were completed using an option pricing theory based simulation analysis (i.e., a Monte Carlo simulation). The valuations are based on assumptions as of the valuation date with regard to the market value of Cytori and the estimated fair value of the Joint Venture, the expected correlation between the values of Cytori and the Joint Venture, the expected volatility of Cytori and the Joint Venture, the bankruptcy recovery rate for Cytori, the bankruptcy threshold for Cytori, the probability of a change of control event for Cytori, and the risk free interest rate. Fluctuations in the fair value of the Put are impacted by unobservable inputs, most significantly the fair value of Cytori and the Joint Venture and the bankruptcy threshold for Cytori. Generally, a change in the assumption used for the fair value of Cytori and the Joint Venture is accompanied by a directionally opposite change in the fair value of the Put, whereas a change in assumption used for the bankruptcy threshold for Cytori is accompanied by a directionally similar change in the fair value of the Put.

The following assumptions were employed in estimating the value of the Put:

	 June 30, 2012	Г 	December 31, 2011
Expected volatility of Cytori	77.40%		76.07%
Expected volatility of the Joint Venture	77.40%		76.07%
Bankruptcy recovery rate for Cytori	28.00%		28.00%
Bankruptcy threshold for Cytori	\$ 13,277,000	\$	8,594,000
Probability of a change of control event for Cytori	3.18%		3.33%
Expected correlation between fair values of Cytori and the Joint Venture in the future	99.00%		99.00%
Risk free interest rate	1.67%		1.89%

The Put has no expiration date. Accordingly, we will continue to recognize a liability for the Put and mark it to market each quarter until it is exercised or until the arrangements with Olympus are amended.

## **13. 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.

The following table provides a summary of the recognized assets and liabilities that we measure at fair value on a recurring basis:

	Balance as of Basis of			Fair	r Value Measu	irem	rements		
	Ju	ıne 30, 2012		Level 1		Level 2		Level 3	
Assets:									
Cash equivalents	\$	22,645,000	\$	22,645,000	\$	—	\$	—	
Liabilities:									
Put option liability	\$	(2,100,000)	\$	—	\$		\$	(2,100,000)	
Warrant liability	\$	(1,008,000)	\$	—	\$		\$	(1,008,000)	

	Ba	alance as of	Basis of Fair Value Meas			irer	nents	
	Dece	mber 31, 2011		Level 1		Level 2		Level 3
Assets:								
Cash equivalents	\$	30,646,000	\$	30,646,000	\$		\$	—
Liabilities:								
Put option liability	\$	(1,910,000)	\$	—	\$		\$	(1,910,000)
Warrant liability	\$	(627,000)	\$	—	\$	—	\$	(627,000)

We use quoted market prices to determine the fair value of our cash equivalents, which consist of money market funds that are classified in Level 1 of the fair value hierarchy.

We value our put liability using an option pricing theory based simulation analysis (i.e., a Monte Carlo simulation) (see note 12). Because some of the inputs to our valuation model are either not observable quoted prices or are not derived principally from or corroborated by observable market data by correlation or other means, the put option liability is classified as Level 3 in the fair value hierarchy.

The following table summarizes the change in our Level 3 put option liability value:

Put option liability		nonths ended ne 30, 2012	Three months ende June 30, 2012			
Beginning balance	\$	(1,910,000)	\$	(1,640,000)		
Decrease (increase) in fair value recognized in operating expenses		(190,000)		(460,000)		
Ending balance	\$	(2,100,000)	\$	(2,100,000)		
Put option liability						
Put option liability	0	nonths ended ne 30, 2011		e months ended une 30, 2011		
Put option liability Beginning balance	0	ionuio ended	J	e montilo enaca		
<b>k</b>	Ju	ne 30, 2011	J	une 30, 2011		

Common stock purchase warrants issued in connection with our August 2008 private equity placement do not trade in an active securities market, and as such, we estimate the fair value of these warrants using the option pricing model. Some of the significant inputs are observable in active markets, such as common stock market price, volatility, and risk free rate. The fair value of these warrants also incorporate our assumptions about future equity issuances and their impact to the down-round protection feature. Because some of the inputs to our valuation model are either not observable quoted prices or are not derived principally from or corroborated by observable market data by correlation or other means, the warrant liability is classified as Level 3 in the fair value hierarchy.

The following table summarizes the change in our Level 3 warrant liability value:

Warrant liability		nonths ended ne 30, 2012	Three months ended June 30, 2012			
Beginning balance	\$	(627,000)	\$	(757,000)		
Decrease (increase) in fair value recognized in operating expenses		(381,000)		(251,000)		
Ending balance	\$	(1,008,000)	\$	(1,008,000)		
Varrant liability Six months ended June 30, 2011		inonitio ciraca		e months ended une 30, 2011		
warrant naomty				<u> </u>		
Beginning balance	\$	(4,987,000)		(8,458,000)		
		<u> </u>		(8,458,000) 5,649,000		

No other assets or liabilities are measured at fair value on a recurring basis, or have been measured at fair value on a non-recurring basis subsequent to initial recognition, on the accompanying consolidated condensed balance sheet as of June 30, 2012.

#### 14. Fair Value

## **Financial Instruments**

We disclose fair value information about all financial instruments, whether or not recognized in the balance sheet, for which it is practicable to estimate fair value. The disclosures of estimated fair value of financial instruments at June 30, 2012 and December 31, 2011, were determined using available market information and appropriate valuation methods. Considerable judgment is necessary to interpret market data and develop estimated fair value. The use of different market assumptions or estimation methods may have a material effect on the estimated fair value amounts.

The carrying amounts for cash and cash equivalents, accounts receivable, inventories, other current assets, accounts payable, accrued expenses and other liabilities approximate fair value due to the short-term nature of these instruments.

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

At June 30, 2012 and December 31, 2011, the aggregate fair value and the carrying value of the Company's fixed rate long-term debt were as follows:

	June	30, 2012	Decem	ber 31, 2011
	Fair Value	Carrying Value	Fair Value	Carrying Value
Fixed rate long-term debt	\$ 24,499,000	\$ 24,686,000	\$ 24,211,000	\$ 24,341,000

Carrying value is net of debt discount of \$1,377,000 and \$1,847,000 as of June 30, 2012 and December 31, 2011, respectively.

## 15. Stockholders' Equity

#### **Common Stock**

On December 13, 2010 we raised \$10,000,000 in gross proceeds from a sale of 1,428,571 shares of unregistered common stock to Astellas Pharma Inc. for \$7.00 per share in a private stock placement. Pursuant to the terms of the purchase agreement, we granted Astellas Pharma Inc. a two year right of first refusal to enter into a development and commercialization collaboration with us regarding the use of our technology, on a worldwide basis, for the treatment of liver conditions. In addition, we have agreed to use reasonable efforts to file a registration statement with the Securities and Exchange Commission to register the shares of common stock for resale upon the request of Astellas Pharma Inc. We also granted Astellas Pharma Inc. a non-voting observer seat on our Board of Directors and the right to designate a representative member to our Scientific Advisory Board. The \$10,000,000 in total proceeds we received exceeded the market value of our stock at the completion of the purchase agreement. The \$2,526,000 difference between the proceeds received and the fair market values of our common stock was recorded as a component of deferred revenues in the accompanying balance sheets. This difference was recorded as deferred revenue since, conceptually, the excess proceeds represent a value paid by Astellas Pharma Inc. attributable to the scientific advisory board seat, the non-voting observer seat on our Board of Directors, and the two year right of first refusal to enter into a development and commercialization with us regarding the use of our technology, on a worldwide basis, for the treatment of liver conditions, rather than an additional equity investment in Cytori. The recognition of this deferred amount is expected to occur upon the earlier of the expiration of the two year period or the termination of the agreement.

On July 11, 2011, we entered into a common stock purchase agreement with Seaside 88, LP relating to the offering and sale of a total of up to 6,326,262 shares of our common stock. The agreement required us to issue and Seaside to buy 1,326,262 shares of our common stock at an initial closing and 250,000 shares of our common stock once every two weeks, commencing 30 days after the initial closing, for up to an additional 20 closings, subject to the satisfaction of customary closing conditions. At the initial closing, the offering price was \$4.52, which equaled to 88% of our common stock's volume-weighted average trading prices, or VWAP, during the ten-day trading period immediately prior to the initial closing date, raising approximately \$6,000,000 in gross proceeds. At subsequent closings, the offering price was 90.25% of our common stock's volume-weighted average trading prico to each subsequent closing date. We raised approximately \$18,233,000 in gross proceeds from the sale of 5,826,262 shares in our scheduled closings through April 9th, 2012. Effective, April 30<sup>th</sup>, 2012, we terminated the agreement with Seaside 88, LP and we will not sell the remaining and final 500,000 shares that would otherwise have been sold under this agreement.

#### Warrant Adjustments

Our March 2009 offering of 4,771,174 shares of our common stock and warrants to purchase up to a total of 6,679,644 additional shares of our common stock with an exercise price of \$2.59 per share, our May 2009 equity offering of 1,864,783 shares of our common stock and warrants to purchase up to a total of 3,263,380 additional shares of our common stock with an exercise price of \$2.62 per share, our closings with Seaside 88, LP through June 30, 2012, our October 2010 offering of 4,600,000 shares of our common stock and our December 2010 sale of 1,428,571 shares of our common stock triggered an adjustment to the exercise price and number of shares issuable under the warrants issued to investors in our August 2008 private placement financing. As a result, as of June 30, 2012, the common stock warrants issued on August 11, 2008 are currently exercisable for 2,021,543 shares of our common stock at an exercise price of \$5.73 per share.

## **Other Related Party Transactions**

As of June 30, 2012 and December 31, 2011, Green Hospital Supply, Inc., our distribution partner in Japan and a related party, was a beneficial owner of 5.1% and 5.3%, respectively, of our outstanding shares of common stock.

During the three and six months ended June 30, 2012, we incurred approximately \$24,000 and \$51,000, respectively, and \$34,000 and \$62,000 during the three and six months ended June 30, 2011, respectively, in royalty costs in connection with our sales of our Celution® 800/CRS System products to the European and Asia-Pacific reconstructive surgery market, pursuant to our License and Royalty Agreement and the Amended License/Commercial Agreement with the Olympus-Cytori, Inc. joint venture, respectively. Additionally, in February 2012, we purchased second generation Celution ® Systems and consumable sets from Olympus-Cytori, Inc. joint venture, at a formula-based transfer price aggregating to \$1,048,000. As of June 30, 2012 and December 31, 2011, Olympus Corporation was a beneficial owner of 6.8% and 7.1%, respectively, of our outstanding shares of common stock and a beneficial owner of 50% of Olympus-Cytori, Inc. joint venture.

#### <u>Index</u>

## 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, 2011.

## CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING STATEMENTS

This report contains certain statements that may be deemed "forward-looking statements" within the meaning of United States of America 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 those related to clinical research studies 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 revenues or effectively manage our gross profit margins; our ability to obtain regulatory clearance; expectations as to our future performance; the "Liquidity and Capital Resources" section of this report, including our potential need for additional financing and the availability thereof; 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: our need and ability to raise additional cash, our joint ventures, 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 in our filings with the Securities and Exchange Commission and under the "Risk Factors" section in Part II below.

We encourage you to read the risks described under Part II, Item 1A "Risk Factors" carefully. We caution you not to place undue reliance on the forwardlooking 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.

## Overview

Cytori Therapeutics, Inc. is developing cell therapies based on autologous adipose-derived stem and regenerative cells (ADRCs) to treat cardiovascular disease and repair soft tissue defects. Our scientific data suggest ADRCs improve blood flow, moderate the immune response and keep tissue at risk of dying alive. As a result, we believe these cells can be applied across multiple "ischemic" conditions. These therapies are made available by our proprietary device, the Celution® System, which automates the extraction and preparation of clinical grade ADRCs at the point-of-care.

Our goal is to build shareholder value by focusing on novel, 'high-value' cell-based therapeutics to market in core geographies: Europe, Asia, and the Americas. Celution® is a platform technology that we believe could potentially address multiple diseases and conditions. To take advantage of our limited resources, we are committing our internal resources to cardiovascular disease and soft tissue defect repair, offering the technology to customers and/or partners to identify and explore additional potential indications, and are seeking partners to accelerate core or non-core opportunities.



## <u>Pipeline</u>

The primary therapeutic area within our clinical development pipeline is cardiovascular disease. We have completed and reported results from three clinical trials, moved from APOLLO to ADVANCE in Europe for heart attacks, have been approved to initiate a feasibility trial in the U.S. for chronic myocardial ischemia, and are seeking approval in Europe for chronic myocardial ischemia.

In the U.S., we received approval to begin our ATHENA feasibility trial in chronic myocardial ischemia, which will be a prospective, double blind, placebo-controlled, multi-center trial in up to 45 patients. The ATHENA trial will utilize our Celution® One device that was developed and manufactured by the Olympus-Cytori, Inc. joint venture. Enrollment is expected to begin in the third quarter of 2012 and be completed within 12 to 18 months.

In our ADVANCE trial, we are amending our European clinical protocol to conform to the evolving country-specific regulatory policies for good manufacturing practices, harmonize our regulatory, reimbursement and market access strategies, while simplifying the trial to a single arm pivotal design and optimizing enrollment criteria. In aggregate, these protocol amendments should accelerate country approvals and enrollment rates and increase the likelihood of success in this trial. We are also implementing a protocol change of the cell processing system used in the study from Celution® One to Celution® 800. The Celution® 800 platform is the system that was successfully used to support the APOLLO (acute STEMI) and PRECISE (chronic myocardial ischemia) pilot studies. The encouraging safety and feasibility results from APOLLO and PRECISE give us confidence that the Celution® 800 System gives us the best opportunity for a successful trial from both an operational and clinical perspective. Additionally, several improvements in software and hardware have been incorporated to further improve this system's performance. This change is being implemented for a number of reasons, including those described above, and our expectation that the Celution 800 device will receive a CE Mark approval for No Option Chronic Myocardial Ischemia claims sometime this year. Submissions are currently underway and we expect to have a revised timeline for the trial by the end of the third quarter.

Our CE Mark application for the Celution® System in no-option chronic myocardial ischemia patients is currently under review. Barring delays or requests for further data, we anticipate a decision before the end of the year. Should we receive approval, we would target select hospital customers in the G5 countries and likely implement a patient registry. This registry will allow us to collect further data to support reimbursement and government payors, and help expand market access.

## **Commercial Business**

The 2012 goals for our commercial business are twofold. The first is to expand market access so that we can grow product revenue significantly over time and the second is to achieve a positive contribution margin in the near term. Today, our sales activities remain largely opportunistic and focused on obtaining and maintaining successful early clinical adopters of our products. Looking forward, we intend to target larger market segments and grow therapeutically oriented consumable revenue. To accomplish this goal, we are focusing on driving essential market access elements such as published clinical and health economics data, physician education and indication-specific therapeutic claims, while maintaining a critical eye on expenses. In late 2011, Cytori reduced its sales and marketing headcount. The impact of this reduction along with other sales and marketing costs will result in reduced overall spending in 2012, while maintaining our ability to achieve 2012 growth objectives.

Our most advanced therapeutic indication is breast reconstruction. In Europe, the NHS National Innovation Centre in the UK indicated that our technology may be cost-effective for lumpectomy breast reconstruction. Furthermore, the use of ADRCs was acknowledged by the British Association of Plastic, Reconstructive & Aesthetic Surgeons (BPRAS) in their latest breast surgery guidelines, demonstrating progress in developing market access. In May, we submitted a technology assessment application in the UK specific to our Celution® System for the RESTORE procedure as a way to both improve healthcare and lower the overall costs of breast reconstruction for women who have had a lumpectomy for breast cancer. This will help support our reimbursement efforts in the UK. In a similar fashion to the UK, we are working with other key competent authorities in Europe to expand coverage. In Japan, we are working with the Pharmaceuticals and Medical Devices Agency (PMDA), to utilize our global clinical data for Japanese approval of our technology for breast reconstruction. In other geographic markets, we intend to grow product sales where we are approved to sell.

#### Corporate

Our corporate priorities are to expand global regulatory approvals, complete strategic development and commercialization partnerships, strengthen the balance sheet and continue to manage expenses.

One of our top priorities is to establish a strategic partnership, which could accelerate core or non-core opportunities and potentially bring in significant additional capital. We believe completing one or more substantive partnerships is achievable this year. Due to the platform nature of our technology and products, we are able to simultaneously pursue transactions for multiple indications in core areas like cardiovascular disease and other non-core areas such as liver disease for which Astellas Pharma has acquired negotiation rights through December 2012.



We have been actively streamlining our operations and reducing costs wherever possible, focusing the company and seeking to minimize cash operating costs. Our 2012 budget calls for a reduction in combined Sales & Marketing and General and Administrative expenses for 2012 as compared to 2011, which will support an anticipated increase in R&D expenses for 2012, principally to fund our cardiac cell therapy clinical trials.

Regulatory processes are well underway in the US, Canada, the EU, Australia, Japan, and other countries. We received regulatory approval for Celution® in Russia and continue to expect progress in many of these markets during 2012 that could expand our commercial opportunities. In the US, receiving the IDE approval was a key development for the company that signals a positive and clearer pathway with the FDA. We also feel that the multiple opportunities we have in other countries increase the possibility that one or more meaningful markets could open up for Cytori. Two countries of note where we have made recent progress include Australia and India. We will provide greater detail on these markets as these opportunities mature and grow.

## Olympus Partnership

On November 4, 2005, we entered into a strategic development and manufacturing joint venture agreement and other related agreements with Olympus. As part of the terms of these agreements, we formed a joint venture, Olympus-Cytori, Inc. (Joint Venture), to develop and manufacture future generation devices based on our Celution® System platform.

Under the Joint Venture Agreements:

- Olympus paid \$30,000,000 for its 50% interest in the Joint Venture. Moreover, Olympus simultaneously entered into a License/Joint Development Agreement with the Joint Venture and us to develop a second generation commercial system and manufacturing capabilities.
- We licensed our device technology, including the Celution® System platform and certain related intellectual property, to the Joint Venture for use in future generation devices. These devices will process and purify adult stem and regenerative cells residing in adipose (fat) tissue for various therapeutic clinical applications. In exchange for this license, we received a 50% interest in the Joint Venture, as well as an initial \$11,000,000 payment from the Joint Venture; the source of this payment was the \$30,000,000 contributed to the Joint Venture by Olympus. Moreover, upon receipt of a CE Mark for the first generation Celution® System platform in January 2006, we received an additional \$11,000,000 development milestone payment from the Joint Venture.

The Joint Venture currently has exclusive access to our Celution® System device technology for the development, manufacture, and supply of such systems to us. Once a second generation Celution® System is developed and approved by regulatory agencies, the Joint Venture will exclusively supply us with these systems at a formula-based transfer price. We have retained all marketing rights (subject to our various distribution agreements and regulatory rights) to sell the Celution® System devices for all therapeutic applications of adipose stem and regenerative cells.

We have worked closely with Olympus' team of scientists and engineers to design the future generations of the Celution® System so that it will contain certain product enhancements and that can be manufactured in a streamlined manner.

In August 2007, we entered into a License and Royalty Agreement with the Joint Venture which provides us the ability to commercially launch the Celution® System platform earlier than we could have otherwise done so under the terms of the Joint Venture Agreements. Subsequently, in November 2007, we amended the License/Commercial Agreement to substantially incorporate the terms of the Royalty Agreement (effective on the expiration of the Royalty Agreement) to continue to allow us to manufacture the Cytori-developed Celution® System platform, including the Celution® 800/CRS, until such time as the Joint Venture's products are commercially available for the same market served by the Cytori platform, subject to a reasonable royalty that will be payable to the Joint Venture for all such sales.

In 2011 Olympus experienced serious internal issues which have led to a significant change in the management structure at Olympus. In 2012 these changes have continued to develop, with a total restructuring of the Olympus board of directors, its management team, and aspects of its operations. In light of these events, we are engaged in ongoing discussions with Olympus relating to the future of the Joint Venture relationship. Throughout the discussions, both parties are committed to ensure that any changes to the Joint Venture structure that occur would be beneficial to both parties.

## **Results of Operations**

#### Product revenues

Product revenues consisted of revenues primarily from our Celution® and Puregraft® Systems and StemSource® Cell Banks.

The following table summarizes the components for the three and six months ended June 30, 2012 and 2011:

	 For the th ended J	 		nths 80,		
	 2012	 2011		2012		2011
Product revenues - third party	\$ 1,947,000	\$ 2,411,000	\$	3,427,000	\$	3,773,000

Beginning in March of 2008, we began sales and shipments of our Celution® 800/CRS System to the European and Asia-Pacific reconstructive surgery markets and during 2010 we began sales of our Puregraft® System in the United States and Europe. Assuming all other applicable revenue recognition criteria have been met, revenue for these product sales is recognized upon delivery to the customer, as all risks and rewards of ownership have been substantively transferred to the customer at that point. For product sales to customers who arrange for and manage all aspects of the shipping process, we recognize revenue upon shipment from our facilities. Beginning in 2011, for product sales that include a combination of equipment, services, or other multiple deliverables that will be provided in the future, we defer an estimate based on relative selling price method for those future deliverables from product revenue until such deliverables have been provided or earned. Shipping and handling costs that are billed to our customers are classified as revenue.

We experienced a decrease in product revenue during the three and six months ended June 30, 2012 as compared to the same periods in 2011, due principally to the product mix comprising revenue for each period and anticipated timing associated with larger system related sales.

*The future*: We expect to continue to generate product revenues from a mix of Celution ® and StemSource® System and consumables sales as well as Puregraft® orders. We will sell the products to a diverse group of customers in Europe, Asia and the U.S., who may apply the products towards reconstructive surgery, soft tissue repair, research, aesthetics, and cell and tissue banking as approved in each country.

## Cost of product revenues

Cost of product revenues relate primarily to Celution<sup>®</sup> System products and StemSource<sup>®</sup> Cell Banks and includes material, manufacturing labor, and overhead costs. The following table summarizes the components of our cost of revenues for the three and six months ended June 30, 2012 and 2011:

	 For the th ended			For the six months ended June 30,					
	 2012		2011		2012		2011		
Cost of product revenues Share-based compensation	\$ 1,013,000 19.000	\$	1,092,000 17,000	\$	1,849,000 36,000	\$	1,916,000 34,000		
Total cost of product revenues	\$ 1,032,000	\$	1,109,000	\$	1,885,000	\$	1,950,000		
Total cost of product revenues as % of product revenues	 53.0%	, 5	46.0%	)	55.0%	, 	51.7%		

Cost of product revenues as a percentage of product revenues was 53.0% and 55.0% for the three and six months ended June 30, 2012 and 46.0% and 51.7% for the three and six months ended June 30, 2011, respectively. Fluctuation in this percentage is to be expected due to the product mix, distributor and direct sales mix, and allocating of overhead.

The future: We expect to continue to see variation in our gross profit margin as the product mix comprising revenues fluctuates.

## Development revenues

The following table summarizes the components of our development revenues for the three and six months ended June 30, 2012 and 2011:

	 For the the ended J	 	For the six months ended June 30,			
	 2012	 2011		2012		2011
Development (Olympus)	\$ 2,413,000	\$ _	\$	2,413,000	\$	1,231,000
Research grant and other	16,000	11,000		19,000		15,000
Total	\$ 2,429,000	\$ 11,000	\$	2,432,000	\$	1,246,000

We recognize deferred revenues, related party, as development revenue when certain performance obligations are met (i.e., using a proportional performance approach). During the quarter ended June 30, 2012, we recognized \$2,413,000 of revenue associated with our arrangements with Olympus as a result of completion of two remaining clinical milestones for the APOLLO and PRECISE clinical trials. During the quarter ended March 31, 2011, we recognized \$1,231,000 of revenue associated with our arrangements with Olympus as a result of achieving a product development milestone related to the preproduction development of the next-generation Celution® One System.

*The future:* We may recognize additional development revenues during 2012, as the anticipated completion for the next revenue recognition milestone related to our Joint Venture with Olympus is in 2012. The exact timing of whether additional development revenue will be recognized and when amounts will be reported in revenue will depend on certain factors including obtaining certain regulatory clearances and/or approvals related to the Celution® System. However, the cash related to the joint venture agreements was received when these agreements were signed and no further related cash payments will be made to us even if we recognize additional development revenue related to the joint venture. To date, of the \$28,311,000 originally deferred, we have recognized a total of \$27,204,000 through June 30, 2012.

We will continue to recognize revenue from the Thin Film development work we are performing on behalf of Senko, based on the relative fair value of the milestones completed as compared to the total efforts expected to be necessary to obtain regulatory clearance from the MHLW. We have determined that we will need to conduct a clinical trial to receive an approval from the MHLW in order for initial commercialization to occur. We are currently working on the trial design, timeline and budget for the trial. Accordingly, we expect to recognize approximately \$1,129,000 (consisting of \$879,000 in deferred revenues plus a non-refundable payment of \$250,000 to be received upon commercialization) in revenues associated with this milestone arrangement if and when regulatory approval is achieved. Moreover, we expect to recognize \$500,000 per year associated with deferred Senko license fees over a three-year period following commercialization, if achieved, as the refund rights associated with the license payment expire. There can be no assurance given of whether, or when, this regulatory approval might be received to allow us to proceed with commercialization.

#### Research and development expenses

Research and development expenses include costs associated with the design, development, testing and enhancement of our products, regulatory fees, the purchase of 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, 2012 and 2011:

	 For the thr ended .	 		nths 30,		
	 2012	 2011		2012		2011
General research and development	\$ 3,015,000	\$ 2,633,000	\$	5,595,000	\$	5,205,000
Development milestone (Joint Venture)	23,000	324,000		124,000		680,000
Share-based compensation	186,000	114,000		341,000		233,000
Total research and development expenses	\$ 3,224,000	\$ 3,071,000	\$	6,060,000	\$	6,118,000

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. These expenses, in conjunction with continued development efforts related to our Celution® System, result primarily from the broad expansion of our research and development efforts enabled by the funding we received from Olympus in 2005 and 2006 and from other investors during the last few years.

Research and development expenses for the three and six months ended June 30, 2012 as compared to the same periods in 2011 remained relatively consistent as we have not started enrollment in our US trial ATHENA as of June 30, 2012.

Expenditures related to the Joint Venture with Olympus, which are included in the variation analysis above, include costs that are necessary to support the commercialization of our products, including the next generation Celution® System. These development activities, include performing pre-clinical and clinical studies, seeking regulatory approval, and performing product development related to therapeutic applications for adipose stem and regenerative cells for multiple large markets. The costs associated with the development of the device were comprised of labor and related benefits, consulting and other professional services, supplies and other miscellaneous expenses.

The future: We expect research and development expenditures to increase in the remainder of 2012 as we are scheduled to continue enrollment in the ADVANCE cardiac trial, start enrollment in our US trial ATHENA, seek additional regulatory clearances and potentially seek to initiate additional trials or patient registries during 2012.

#### Sales and marketing expenses

Sales and marketing expenses include costs associated with sales and marketing personnel, tradeshows, physician training, and promotional activities and materials. The following table summarizes the components of our sales and marketing expenses for the three and six months ended June 30, 2012 and 2011:

		For the th ended				onths 30,		
		2012		2011		2012		2011
Sales and marketing	\$	2,392,000	\$	3,467,000	\$	4,571,000	\$	6,446,000
Share-based compensation	Φ	189,000	Ф	249,000	Φ	385,000	φ	496,000
Total sales and marketing expenses	\$	2,581,000	\$	3,716,000	\$	4,956,000	\$	6,942,000

The decrease in sales and marketing expense during the three and six months ended June 30, 2012 as compared to the same periods in 2011 was mainly attributed to the decrease in salary and related benefits expense (excluding share-based compensation) of \$668,000 and \$1,113,000 due to a decrease in headcount, decrease in travel related expenses of \$168,000 and \$336,000, and a decrease in professional services expenses of \$136,000 and \$110,000, respectively, as a result of targeted reductions in staff and external costs made prior to year end in 2011 as well as subsequent reductions made in early 2012.

The future: We expect sales and marketing expenditures to remain relatively stable during remainder of 2012.

## 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, 2012 and 2011:

	 For the the ended	 		onths 30,		
	 2012	 2011		2012		2011
General and administrative	\$ 3,146,000	\$ 3,687,000	\$	6,497,000	\$	6,734,000
Share-based compensation	642,000	460,000		1,215,000		958,000
Total general and administrative expenses	\$ 3,788,000	\$ 4,147,000	\$	7,712,000	\$	7,692,000

For the three and six months ended June 30, 2012 as compared to the same periods in 2011, the decrease in general and administrative expenses (excluding share-based compensation) occurred primarily due to a decrease in professional services expense (such as consulting and compliance expenses) of \$676,000 and \$711,000, respectively.

*The future:* We expect general and administrative expenses to remain relatively stable through the remainder of 2012.

## Share-based compensation expenses

Stock-based compensation expenses include charges related to options issued to employees, directors and non-employees. We measure stock-based compensation expense based on the grant-date fair value of any awards granted to our employees. Such expense is recognized over the period of time that employees provide service to us and earn all rights to the awards.

The following table summarizes the components of our share-based compensation expenses for the three and six months ended June 30, 2012 and 2011:

	 For the the ended			For the six months ended June 30,				
	 2012	_	2011		2012		2011	
Cost of product revenues	\$ 19,000	\$	17,000	\$	36,000	\$	34,000	
Research and development-related	186,000		114,000		341,000		233,000	
Sales and marketing-related	189,000		249,000		385,000		496,000	
General and administrative-related	642,000		460,000		1,215,000		958,000	
Total share-based compensation	\$ 1,036,000	\$	840,000	\$	1,977,000	\$	1,721,000	

Most of the share-based compensation expenses for the three and six months ended June 30, 2012 and 2011 related to the vesting of stock option awards to employees. The increase in share-based compensation for the three and six months ended June 30, 2012 as compared to the same periods in 2011 is primarily due to the grant of restricted stock awards and performance based stock awards. See Note 9 to the Consolidated Condensed Financial Statements included elsewhere herein for disclosure and discussion of 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, 2012, the total compensation cost related to non-vested stock options and stock awards not yet recognized for all our plans is approximately \$6,650,000. Of this amount, \$5,976,000 is expected to be recognized as a result of vesting under service conditions over a weighted average period of 1.67 years.

#### Change in fair value of warrant liability

The following is a table summarizing the change in fair value of our warrant liability for the three and six months ended June 30, 2012 and 2011:

	 For the the conded J	 	For the six months ended June 30,				
	 2012	 2011		2012		2011	
Change in fair value of warrant liability	\$ 251,000	\$ (5,649,000)	\$	381,000	\$	(2,178,000)	

Changes in fair value of our warrant liability are primarily due to fluctuations in the valuation inputs, such as stock price, volatility, remaining life and others. See Note 5 to the Consolidated Condensed Financial Statements included elsewhere herein for disclosure and discussion of our warrant liability.

*The future:* Future changes in the fair value of the warrant liability will be recognized currently in earnings until such time as the warrants are exercised or expire.

## Change in fair value of option liability

The following is a table summarizing the change in fair value of our put option liability for the three and six months ended June 30, 2012 and 2011:

	 For the the ended	 		onths 30,		
	 2012	 2011		2012		2011
Change in fair value of put option liability	\$ 460,000	\$ 400,000	\$	190,000	\$	110,000

*The future:* The Put has no expiration date. Accordingly, we will continue to recognize a liability for the Put until it is exercised or until the arrangements with Olympus are amended.

## Financing items

The following table summarizes interest income, interest expense, and other income and expense for the three and six months ended June 30, 2012 and 2011:

	 For the the ended .	 	For the six months ended June 30,			
	 2012	 2011		2012		2011
Interest income	\$ 1,000	\$ 1,000	\$	2,000	\$	4,000
Interest expense	(860,000)	(696,000)		(1,726,000)		(1,434,000)
Other income (expense)	(27,000)	(15,000)		(73,000)		(62,000)
Total	\$ (886,000)	\$ (710,000)	\$	(1,797,000)	\$	(1,492,000)

Interest expense increased for the three and six months ended June 30, 2012 as compared to the same periods in 2011 due to cash interest and non-cash amortization of debt issuance costs and debt discount for our \$25.0 million term loan. In September 2011, we entered into a second amendment to the Amended and Restated Loan and Security Agreement, pursuant to which the lenders funded an additional principal increasing the total principal balance to \$25.0 million.

*The future:* Interest income earned in 2012 will be dependent on our levels of funds available for investment as well as general economic conditions. Subject to our future financing activities, we expect interest expense in 2012 to increase as we continue to pay interest on the \$25.0 million term loan that was amended in September 2011.

## Equity loss from investment in Joint Venture

The following table summarizes our equity loss from investment in joint venture for the three and six months ended June 30, 2012 and 2011:

		ree months June 30,		nonths ended ne 30,
	2012	2011	2012	2011
Equity loss in investment	\$ (37,000)	\$ (56,000)	\$ (86,000)	\$ (102,000)

The losses relate entirely to our 50% equity interest in the Joint Venture, which we account for using the equity method of accounting.

*The future:* We do not expect to recognize significant losses from the activities of the Joint Venture in the foreseeable future. Over the next one to two years, the Joint Venture is expected to incur labor costs related to the development of our second generation commercial system as well as general and administrative expenses, offset by royalty and other revenue expected to be generated by our current Celution® 800/CRS and future generation devices. Though we have no obligation to do so, we may contribute funding to the Joint Venture to cover any costs should the Joint Venture deplete its cash balance.

## Liquidity and Capital Resources

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## Short-term and long-term liquidity

The following is a summary of our key liquidity measures at June 30, 2012 and December 31, 2011:

	As of June 30, 2012		As of December 31, 2011		
Cash and cash equivalents	\$	25,771,000	\$	36,922,000	
Current assets	\$	31,977,000	\$	43,337,000	
Current liabilities		12,404,000		7,821,000	
Working capital	\$	19,573,000	\$	35,516,000	

We incurred net losses of \$7,883,000 and \$17,208,000 for the three and six months ended June 30, 2012 and \$5,138,000 and \$17,209,000 for the three and six months ended June 30, 2011, respectively. We have an accumulated deficit of \$259,657,000 as of June 30, 2012. Additionally, we have used net cash of \$15,958,000 and \$19,532,000 to fund our operating activities for the six months ended June 30, 2012 and 2011, respectively. To date, these operating losses have been funded primarily from outside sources of invested capital.

We believe we have enough cash to fund operations into the first quarter of 2013, which factors in the minimum cash and cash liquidity requirements of the Amended and Restated Loan and Security Agreement with the Lenders, which requires that we maintain at least three months of cash on hand to avoid an event of default under the Loan and Security Agreement. We will continue to seek additional cash through strategic corporate partnership and future sales of equity in addition to our operating profits. We have an established history of raising capital through these platforms, and we are currently involved in negotiations with multiple parties. In the continued absence of positive cash flows from operations, no assurance can be given that we can generate sufficient revenue to cover operating costs or that additional financing will be available to us and, if available, on terms acceptable to us in the future.

During 2011, we expanded our commercialization activities while simultaneously pursuing available financing sources to support operations and growth. We have had, and we will likely continue to have, an ongoing need to raise additional cash from outside sources to fund our future operations. If we cannot do so when required, we would need to reduce our research, development, and administrative operations, including reductions of our employee base, in order to offset lack of available funding. We continue to evaluate market conditions and available financing opportunities as part of our normal course of business.

The following summarizes our contractual obligations and other commitments at June 30, 2012, and the effect such obligations could have on our liquidity and cash flow in future periods:

	Payments due by period									
	Less than 1			More than						
Contractual Obligations	Total		year 1 – 3 years		1 – 3 years	3 – 5 years		5 years		
	<b>.</b>		<i>•</i>	<b>E E 2</b> 4 0 0 0	<b>.</b>	10 610 000	<i>•</i>	10.000	<b>.</b>	
Long-term obligations	\$	26,158,000	\$	7,521,000	\$	18,618,000	\$	19,000	\$	—
Interest commitment on long-term obligations		3,846,000		2,252,000		1,593,000		1,000		
Operating lease obligations		9,824,000		1,843,000		3,605,000		3,740,000		636,000
Minimum purchase requirements		2,191,000		1,341,000		850,000		—		
Pre-clinical research study obligations		60,000		60,000		_		_		
Clinical research study obligations		11,900,000		3,700,000		6,000,000		2,200,000		—
Total	\$	53,979,000	\$	16,717,000	\$	30,666,000	\$	5,960,000	\$	636,000

Cash (used in) provided by operating, investing, and financing activities for the three and six months ended June 30, 2012 and 2011 is summarized as follows:

	F	For the six months ended June 30,			
	_	2012 2011			
Net cash used in operating activities	\$	(15,958,000)	\$	(19,532,000)	
Net cash used in investing activities		(886,000)		(433,000)	
Net cash provided by financing activities		5,693,000		526,000	

## **Operating** activities

Operational activities, inclusive of research and development, sales and marketing, and general and administrative efforts, offset in part by product sales, generated an operating loss of \$15,325,000 for the six months ended June 30, 2012. The operating cash impact of this loss was \$15,958,000, after adjusting for the consideration of non-cash share-based compensation and other adjustments for material non-cash activities, such as depreciation, amortization, change in fair value of option and warrant liabilities, and changes in working capital due to timing of product shipments (accounts receivable) and payment of liabilities.

Operational activities, inclusive of research and development, sales and marketing, and general and administrative efforts, offset in part by product sales, generated an operating loss of \$15,615,000 for the six months ended June 30, 2011. The operating cash impact of this loss was \$19,532,000, after adjusting for the recognition of non-cash development revenue of \$1,231,000, the consideration of non-cash share-based compensation, other adjustments for material non-cash activities, such as depreciation and amortization, change in fair value of option liabilities and warrants, changes in working capital due to timing of product shipments (accounts receivable) and payment of liabilities.

#### **Investing** activities

Net cash used in investing activities for the six months ended June 30, 2012 and 2011 resulted from cash outflow for purchases of property and equipment.

#### **Financing** Activities

The net cash provided by financing activities for the six months ended June 30, 2012 related primarily to a sale of 1,750,000 shares for approximately \$4,946,000 in gross proceeds in connection with our common stock purchase agreement with Seaside entered into on July 11, 2011 and proceeds from exercise of warrants and employee stock options of \$951,000.

The net cash provided by financing activities for the six months ended June 30, 2011 related to proceeds from exercise of warrants and employee stock options of \$2,756,000 offset by the principal payments on long-term obligations of \$2,230,000.

## **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. These are our policies that require us to make our most significant judgments and, as a result, could have the greatest impact on our future financial results.

#### Warrant Liability

See Notes to Consolidated Condensed Financial Statements included elsewhere herein for disclosure and discussion of our warrant liability.

#### **Revenue Recognition**

See Notes to Consolidated Condensed Financial Statements included elsewhere herein for disclosure and discussion of revenue recognition.

## Goodwill Impairment Testing

In late 2002, we purchased StemSource, Inc. and recognized over \$4,600,000 in goodwill associated with the acquisition, of which \$3,922,000 remains on our balance sheet as of June 30, 2012. We test this goodwill at least annually, as of November 30, for impairment as well as when an event occurs or circumstances change such that it is reasonably possible that impairment may exist. The application of the goodwill impairment test involves a substantial amount of judgment. The judgments employed may have an effect on whether a goodwill impairment loss is recognized.



No impairment triggering events occurred during the three and six months ended June 30, 2012 that would require us to perform an impairment test.

### Variable Interest Entity (Olympus-Cytori Joint Venture)

See Notes to Consolidated Condensed Financial Statements included elsewhere herein for disclosure and discussion of the Olympus-Cytori Joint Venture.

## Income Taxes

Income taxes are accounted for under the asset and liability method. Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases and operating loss and tax credit carry forwards. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income (loss) in the years in which those temporary differences are expected to be recovered or settled. Due to our history of losses, a full valuation allowance is recognized against our deferred tax assets.

#### **Recently Adopted Accounting Pronouncements**

See Notes to Consolidated Condensed Financial Statements included elsewhere herein for disclosure and discussion of new accounting standards.

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

We are exposed to market risk related to fluctuations in interest rates and in foreign currency exchange rates.

#### **Interest Rate Exposure**

We are not subject to market risk due to fluctuations in interest rates on our long-term obligations as they bear a fixed rate of interest. Our exposure relates primarily to short-term investments, including funds classified as cash equivalents. As of June 30, 2012, all excess funds were invested in money market funds and other highly liquid investments, therefore our interest rate exposure is not considered to be material.

## Foreign Currency Exchange Rate Exposure

Our exposure to market risk due to fluctuations in foreign currency exchange rates relates primarily to our activities in Europe and Japan. Transaction gains or losses resulting from cash balances and revenues have not been significant in the past and we are not currently engaged in any hedging activity in the Euro, the Yen or other currencies. Based on our cash balances and revenues derived from markets other than the United States for the three and six months ended June 30, 2012, a hypothetical 10% adverse change in the Euro or Yen against the U.S. dollar would not result in a material foreign currency exchange loss. Consequently, we do not expect that reductions in the value of such sales denominated in foreign currencies resulting from even a sudden or significant fluctuation in foreign exchange rates would have a direct material impact on our financial position, results of operations or cash flows.

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

Under our Japanese Thin Film agreement with Senko, we would receive payments in the nature of royalties based on Senko's net sales, which would be Yen denominated.

#### **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 of 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, 2012 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, 2012, we were not a party to any material legal proceeding. See Note 11 to the Consolidated Condensed Financial Statements included elsewhere herein for a discussion of our loss contingencies.

#### Item 1A. Risk Factors

In analyzing our company, you should consider carefully the following risk factors together with all of the other information included in this quarterly report on Form 10-Q, including our unaudited Consolidated Condensed Financial Statements and the related notes and "Management's Discussion and Analysis of Financial Conditions and Results of Operations". If any of the risks described below occur, our business, operating results, and financial condition could be adversely affected and the value of our common stock could decline.

We have marked with an asterisk (\*) those risks described below that reflect new risks or substantive changes from the risks described under Part I, Item 1A "Risk Factors" included in our Annual Report on Form 10-K for the year ended December 31, 2011.

### We will likely need to raise more cash in the future

We have almost always had negative cash flows from operations. Our business will continue to result in a substantial requirement for research and development expenses for several years, during which we may not be able to bring in sufficient cash and/or revenues to offset these expenses. We will likely be required to raise capital from one or more sources in the future to continue funding our operations to profitability. 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 future. In addition, our Amended and Restated Loan and Security Agreement with General Electric Capital Corporation, Silicon Valley Bank and Oxford Finance Corporation requires us to maintain certain minimum cash requirements, and if our cash reserves fall below those minimum requirements, then we could be in default under our loan agreement and subject to potential adverse remedies by the lenders, which would have a substantial and material adverse effect on our business, financial condition, results of operations, the value of our common stock and warrants and our ability to raise capital. There is no guarantee that adequate funds will be available when needed from additional debt or equity financing, arrangements with development and commercialization partners, increased results of operations, or from other sources, or on terms attractive to us. Our inability to obtain sufficient additional funds in the future would, at a minimum, require us to delay, scale back, or eliminate some or all of our research or product development, manufacturing operations, clinical or regulatory activities, which could have a substantial negative effect on our results of operations and financial condition.

## Continued turmoil in the economy could harm our business

Negative trends in the general economy, including trends resulting from an actual or perceived recession, tightening credit markets, increased cost of commodities, including oil, actual or threatened military action by the United States and threats of terrorist attacks in the United States and abroad, could cause a reduction of investment in and available funding for companies in certain industries, including ours and our customers. Our ability to raise capital has been and may in the future be adversely affected by downturns in current credit conditions, financial markets and the global economy.

#### We have never been profitable on an operational basis and expect significant operating losses for the next few years

We have incurred net operating losses in each year since we started business. As our focus on the Celution® System platform and development of therapeutic applications for its cellular output has increased, losses have resulted primarily from expenses associated with research and development activities and general and administrative expenses. While we work continuously to implement cost reduction measures where possible, we nonetheless expect to continue operating in a loss position on a consolidated basis and that recurring operating expenses will be at high levels for the next several years, in order to perform clinical trials, additional pre-clinical research, product development, and marketing. As a result of our historic losses, we have been, and are likely to continue to be, reliant on raising outside capital to fund our operations.

#### Our business strategy is high-risk

We are focusing our resources and efforts primarily on development of the Celution® System family of products and the therapeutic applications of its cellular output, which requires extensive cash needs for research, development, and commercialization activities. This is a high-risk strategy because there is no assurance that our future products will ever become commercially viable (commercial risk), that we will prevent other companies from depriving us of market share and profit margins by selling products based on our inventions and developments (legal risk), that we will successfully manage a company in a new area of business (regenerative medicine) and on a different scale than we have operated in the past (operational risk), that we will be able to achieve the desired therapeutic results using stem and regenerative cells (scientific risk), or that our cash resources will be adequate to develop our products until we become profitable, if ever (financial risk). We are using our cash in one of the riskiest industries in the economy (strategic risk). This may make our stock an unsuitable investment for many investors.

## The development and manufacture of future generation Celution ® System devices is important to us

We have given Olympus-Cytori, Inc. an exclusive license to manufacture future generation Celution® System devices. If Olympus-Cytori, Inc. does not successfully develop and manufacture these devices, we may experience disruptions and/or delays of our commercialization of these devices into the market. Any significant disruption of our commercialization of these devices could affect our operations and commercialization efforts (clinical, regulatory and/or commercial sales), and be harmful to our business.

We and Olympus must overcome contractual and cultural barriers. Although our relationship is formally measured by a set of complex contracts, many aspects of the relationship will be non-contractual and must be worked out between the parties and the responsible individuals. The joint venture is intended to have a long life, and it is difficult to maintain cooperative relationships over a long period of time in the face of various kinds of change. Cultural differences, including language barrier to some degree, may affect the efficiency of the relationship.

Olympus-Cytori, Inc. is 50% owned by us and 50% owned by Olympus. By contract, each side must consent before any of a wide variety of important business actions can occur. This situation possesses a risk of potentially time-consuming and difficult negotiations which could at some point delay the joint venture from pursuing its business strategies.

Olympus is entitled to designate the joint venture's chief executive officer and a majority of its board of directors, which means that day-to-day decisions which are not subject to a contractual veto are subject to be controlled by Olympus. In addition, Olympus-Cytori, Inc. may require more money than its current capitalization in order to complete development and production of future generation devices. If we are unable to help provide future financing for Olympus-Cytori, Inc., our relative equity interest in Olympus-Cytori, Inc. may decrease.

Furthermore, under a License/Joint Development Agreement among Olympus-Cytori, Inc., Olympus, and us, Olympus may have a significant role in the development of Olympus-Cytori, Inc.'s next generation devices. Although Olympus has extensive experience in developing medical devices, this arrangement has resulted in a reduction of our control over the development and manufacturing of the next generation devices. Any significant disruption of activity by Olympus in connection with our business relationship and/or the development of Olympus-Cytori's next generation devices and our joint venture could be harmful to our business.

In 2011 Olympus experienced serious internal issues which have led to a significant change in the management structure at Olympus. In 2012 these changes have continued to develop, with a total restructuring of the Olympus board of directors, its management team, and aspects of its operations. In light of these events, we are engaged in ongoing discussions with Olympus relating to the future of the joint venture relationship. Throughout the discussions, both parties are committed to ensure that any changes to the joint venture structure that occur would be beneficial to both parties. Notwithstanding our discussions, if our relationship were to change in a manner that significantly disrupts our operations and commercialization efforts (clinical, regulatory and/or commercial sales), then our business would likely be harmed.

#### <u>Index</u>

#### We have a limited operating history; operating results and stock price can be volatile like many life science companies

Our prospects must be evaluated in light of the risks and difficulties frequently encountered by emerging companies and particularly by such companies in rapidly evolving and technologically advanced biotech and medical device fields. From time to time, we have tried to update our investors' expectations as to our operating results by periodically announcing financial guidance. However, we have in the past been forced to revise or withdraw such guidance due to lack of visibility and predictability of product demand. Our stock price has a history of significant volatility, which may harm our ability to raise additional capital and may cause an investment in Cytori to be unsuitable for some investors.

#### We are vulnerable to competition and technological change, and also to physicians' inertia

We compete with many domestic and foreign companies in developing our technology and products, including biotechnology, medical device, and pharmaceutical companies. Many current and potential competitors have substantially greater financial, technological, research and development, marketing, and personnel resources. There is no assurance that our competitors will not succeed in developing alternative products that are more effective, easier to use, or more economical than those which we have developed or are in the process of developing, or that would render our products obsolete and noncompetitive. In general, we may not be able to prevent others from developing and marketing competitive products similar to ours or which perform similar functions.

Competitors may have greater experience in developing therapies or devices, conducting clinical trials, obtaining regulatory clearances or approvals, manufacturing and commercialization. It is possible that competitors may obtain patent protection, approval, or clearance from the FDA or achieve commercialization earlier than we can, any of which could have a substantial negative effect on our business. Finally, Olympus and our other partners might pursue parallel development of other technologies or products, which may result in a partner developing additional products competitive with ours.

We compete against cell-based therapies derived from alternate sources, such as bone marrow, umbilical cord blood and potentially embryos. Doctors historically are slow to adopt new technologies like ours, regardless of the perceived merits, when older technologies continue to be supported by established providers. Overcoming such inertia often requires very significant marketing expenditures or definitive product performance and/or pricing superiority.

We expect physicians' inertia and skepticism to also be a significant barrier as we attempt to gain market penetration with our future products. We believe we will continue to need to finance lengthy time-consuming clinical studies to provide evidence of the medical benefit of our products and resulting therapies in order to overcome this inertia and skepticism particularly in reconstructive surgery, cell preservation, the cardiovascular area and many other indications.

#### Most potential applications of our technology are pre-commercialization, which subjects us to development and marketing risks

We are in a relatively early stage of the path to commercialization with many of our products. We believe that our long-term viability and growth will depend in large part on our ability to develop commercial quality cell processing devices and useful procedure-specific consumables, and to establish the safety and efficacy of our therapies through clinical trials and studies. With our Celution® System platform, we are pursuing new approaches for reconstructive surgery, preservation of stem and regenerative cells for potential future use, therapies for cardiovascular disease, soft tissue defects, and other conditions. There is no assurance that our development programs will be successfully completed or that required regulatory clearances or approvals will be obtained on a timely basis, if at all.

There is no proven path for commercializing the Celution® System platform in a way to earn a durable profit commensurate with the medical benefit. Although we began to commercialize our reconstructive surgery products in Europe and certain Asian markets, and our cell banking products in Japan, Europe, and certain Asian markets in 2008, additional market opportunities for many of our products and/or services may not materialize for a number of years.

Successful development and market acceptance of our products is subject to developmental risks, including failure of inventive imagination, ineffectiveness, lack of safety, unreliability, failure to receive necessary regulatory clearances or approvals, high commercial cost, preclusion or obsolescence resulting from third parties' proprietary rights or superior or equivalent products, competition from copycat products, and general economic conditions affecting purchasing patterns. There is no assurance that we or our partners will successfully develop and commercialize our products, or that our competitors will not develop competing technologies that are less expensive or superior. Failure to successfully develop and market our products would have a substantial negative effect on our results of operations and financial condition.



## Market acceptance of new technology such as ours can be difficult to obtain

New and emerging cell therapy and cell banking technologies, such as those provided by the Celution® System family of products, may have difficulty or encounter significant delays in obtaining market acceptance in some or all countries around the world due to the novelty of our cell therapy and cell banking technologies. Therefore, the market adoption of our cell therapy and cell banking technologies may be slow and lengthy with no assurances that significant market adoption will be successful. The lack of market adoption or reduced or minimal market adoption of our cell therapy and cell banking technologies may have a significant impact on our ability to successfully sell our product(s) into a country or region.

## Future clinical trial results may differ significantly from our expectations

While we have proceeded incrementally with our clinical trials in an effort to gauge the risks of proceeding with larger and more expensive trials, we cannot guarantee that we will not experience negative results larger and much more expensive clinical trials than we have conducted to date, such as the new ADVANCE acute heart attack trial in Europe, and the coming ATHENA feasibility trial in chronic myocardial ischemia. Poor results in our clinical trials could result in substantial delays in commercialization, substantial negative effects on the perception of our products, and substantial additional costs. These risks are increased by our reliance on third parties in the performance of many of the clinical trial functions, including the clinical investigators, hospitals, and other third party service providers.

## Manufacturing Risk

Although we have significant experience in manufacturing the Celution® System platform or its consumables at a commercial level, and although Olympus is a highly capable and experienced manufacturer of medical devices, there can be no guarantee that we or the Olympus-Cytori Joint Venture will be able to successfully develop and manufacture future generation Celution® Systems in a manner that is cost-effective or commercially viable, or that development and manufacturing capabilities might not take much longer than currently anticipated to be ready for the market.

Although we have been manufacturing the the Celution<sup>®</sup> 800 System and the StemSource<sup>®</sup> 900-based Cell Bank since 2008, we cannot assure that we will be able to manufacture sufficient numbers of such products to meet the demand, or that we will be able to overcome unforeseen manufacturing difficulties for these sophisticated medical devices.

In the event that the Olympus-Cytori Joint Venture is not successful in the development and manufacture of the next generation Celution® One System, Cytori may not have the resources or ability to self-manufacture sufficient numbers of devices and consumables to meet market demand, and this failure may substantially extend the time it would take for us to bring a more advanced commercial device to market.

## We may not be able to protect our proprietary rights

Our success depends in part on whether we can maintain our existing patents, obtain additional patents, maintain trade secret protection, and operate without infringing on the proprietary rights of third parties.

There can be no assurance that any of our pending patent applications will be approved or that we will develop additional proprietary products that are patentable. There is also no assurance that any patents issued to us will not become the subject of a re-examination, will provide us with competitive advantages, will not be challenged by any third parties, or that the patents of others will not prevent the commercialization of products incorporating our technology. Furthermore, there can be no guarantee that others will not independently develop similar products, duplicate any of our products, or design around our patents.

Our commercial success will also depend, in part, on our ability to avoid infringing on patents issued to others. If we were judicially determined to be infringing on any third-party patent, we could be required to pay damages, alter our products or processes, obtain licenses, or cease certain activities. If we are required in the future to obtain any licenses from third parties for some of our products, there can be no guarantee that we would be able to do so on commercially favorable terms, if at all. U.S. patent applications are not immediately made public, so we might be surprised by the grant to someone else of a patent on a technology we are actively using. As noted above and in the case of the University of Pittsburgh lawsuit, even patents issued to us or our licensors might be judicially determined to belong in full or in part to third parties.

Litigation, which would result in substantial costs to us and diversion of effort on our part, may be necessary to enforce or confirm the ownership of any patents issued or licensed to us, or to determine the scope and validity of third-party proprietary rights. If our competitors claim technology also claimed by us and prepare and file patent applications in the United States, we may have to participate in interference proceedings declared by the U.S. Patent and Trademark Office or a foreign patent office to determine priority of invention, which could result in substantial costs to and diversion of effort, even if the eventual outcome is favorable to us. Any such litigation or interference proceeding, regardless of outcome, could be expensive and time-consuming.

Successful challenges to our patents through oppositions, reexamination proceedings or interference proceedings could result in a loss of patent rights in the relevant jurisdiction. If we are unsuccessful in actions we bring against the patents of other parties and it is determined that we infringe the patents of third-parties, we may be subject to litigation, or otherwise prevented from commercializing potential products in the relevant jurisdiction, or may be required to obtain licenses to those patents or develop or obtain alternative technologies, any of which could harm our business. Furthermore, if such challenges to our patent rights are not resolved in our favor, we could be delayed or prevented from entering into new collaborations or from commercializing certain products, which could adversely affect our business and results of operations.

Competitors or third parties may infringe our patents. We may be required to file patent infringement claims, which can be expensive and timeconsuming. In addition, in an infringement proceeding, a court may decide that a patent of ours is not valid or is unenforceable, or that the third party's technology does not in fact infringe upon our patents. An adverse determination of any litigation or defense proceedings could put one or more of our patents at risk of being invalidated or interpreted narrowly and could put our related pending patent applications at risk of not issuing. Litigation may fail and, even if successful, may result in substantial costs and be a distraction to our management. We may not be able to prevent misappropriation of our proprietary rights, particularly in countries outside the U.S. where patent rights may be more difficult to enforce. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential or sensitive information could be compromised by disclosure in the event of litigation. In addition, during the course of litigation there could be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock.

In addition to patents, which alone may not be able to protect the fundamentals of our business, we also rely on unpatented trade secrets and proprietary technological expertise. Some of our intended future cell-related therapeutic products may fit into this category. We rely, in part, on confidentiality agreements with our partners, employees, advisors, vendors, and consultants to protect our trade secrets and proprietary technological expertise. There can be no guarantee that these agreements will not be breached, or that we will have adequate remedies for any breach, or that our unpatented trade secrets and proprietary technological expertise will not otherwise become known or be independently discovered by competitors.

Our amended regenerative cell technology license agreement with the Regents of the University of California (UC) which includes issued U.S. patent number 7,470,537, contains certain developmental milestones, which if not achieved could result in the loss of exclusivity or loss of the license rights. The loss of such rights could impact our ability to develop certain regenerative cell technology products. Also, our power as licensee to successfully use these rights to exclude competitors from the market is untested.

Failure to obtain or maintain patent protection, or protect trade secrets, for any reason (or third-party claims against our patents, trade secrets, or proprietary rights, or our involvement in disputes over our patents, trade secrets, or proprietary rights, including involvement in litigation), could have a substantial negative effect on our results of operations and financial condition.

## We may not be able to protect our intellectual property in countries outside the United States

Intellectual property law outside the United States is uncertain and in many countries is currently undergoing review and revisions. The laws of some countries do not protect our patent and other intellectual property rights to the same extent as United States laws. This is particularly relevant to us as most of our current commercial product sales and clinical trials are outside of the United States. Third parties may attempt to oppose the issuance of patents to us in foreign countries by initiating opposition proceedings. Opposition proceedings against any of our patent filings in a foreign country could have an adverse effect on our corresponding patents that are issued or pending in the United States. It may be necessary or useful for us to participate in proceedings to determine the validity of our patents or our competitors' patents that have been issued in countries other than the U.S. This could result in substantial costs, divert our efforts and attention from other aspects of our business, and could have a material adverse effect on our results of operations and financial condition. We currently have pending patent applications in Europe, Australia, Japan, Canada, China, Korea, and Singapore, among others.

#### We and our Olympus-Cytori, Inc. joint venture are subject to FDA regulation

As medical devices, the Celution® System family of products, Puregraft ® family of products and the Celbrush® must receive regulatory clearances or approvals from the FDA and, in many instances, from non-U.S. and state governments prior to their sale. The Celution® System family of products is subject to stringent government regulation in the United States by the FDA under the Federal Food, Drug and Cosmetic Act. The FDA regulates the design/development process, clinical testing, manufacture, safety, labeling, sale, distribution, and promotion of medical devices and drugs. Included among these regulations are pre-market clearance and pre-market approval requirements, design control requirements, and the Quality System Regulations/Good Manufacturing Practices. Other statutory and regulatory requirements govern, among other things, establishment registration and inspection, medical device listing, prohibitions against misbranding and adulteration, labeling and post-market reporting.

#### <u>Index</u>

The regulatory process can be lengthy, expensive, and uncertain. Before any new medical device may be introduced to the U.S. market, the manufacturer generally must obtain FDA clearance or approval through either the 510(k) pre-market notification process or the lengthier pre-market approval application, or PMA, process. It generally takes from three to 12 months from submission to obtain 510(k) pre-market clearance, although it may take longer. Approval of a PMA could take four or more years from the time the process is initiated. The 510(k) and PMA processes can be expensive, uncertain, and lengthy, and there is no guarantee of ultimate clearance or approval. We expect that some of our products under development today or in the future, as well as Olympus-Cytori's, will be subject to the lengthier PMA process. Securing FDA clearances and approvals may require the submission of extensive clinical data and supporting information to the FDA, and there can be no guarantee of ultimate clearance or approval. Failure to comply with applicable requirements can result in application integrity proceedings, fines, recalls or seizures of products, injunctions, civil penalties, total or partial suspensions of production, withdrawals of existing product approvals or clearances, refusals to approve or clear new applications or notifications, and criminal prosecution.

Medical devices are also subject to post-market reporting requirements for deaths or serious injuries when the device may have caused or contributed to the death or serious injury, and for certain device malfunctions that would be likely to cause or contribute to a death or serious injury if the malfunction were to recur. If safety or effectiveness problems occur after the product reaches the market, the FDA may take steps to prevent or limit further marketing of the product. Additionally, the FDA actively enforces regulations prohibiting marketing and promotion of devices for indications or uses that have not been cleared or approved by the FDA.

There can be no guarantee that we will be able to obtain the necessary 510(k) clearances or PMA approvals to market and manufacture our other products in the United States for their intended use on a timely basis, if at all. Delays in receipt of or failure to receive such clearances or approvals, the loss of previously received clearances or approvals, or failure to comply with existing or future regulatory requirements could have a substantial negative effect on our results of operations and financial condition.

## To sell in international markets, we will be subject to regulation in foreign countries

In cooperation with our distribution partners, we intend to market our current and future products both domestically and in many foreign markets. A number of risks are inherent in international transactions. In order for us to market our products in Europe, Canada, Japan and certain other non-U.S. jurisdictions, we need to obtain and maintain required regulatory approvals or clearances and must comply with extensive regulations regarding safety, manufacturing processes and quality. For example, we still have not obtained regulatory approval for our Thin Film products in Japan. These regulations, including the requirements for approvals or clearances to market, may differ from the FDA regulatory scheme. International sales also may be limited or disrupted by political instability, price controls, trade restrictions and changes in tariffs. Additionally, fluctuations in currency exchange rates may adversely affect demand for our products by increasing the price of our products in the currency of the countries in which the products are sold.

There can be no assurance that we will obtain regulatory approvals or clearances in all of the countries where we intend to market our products, or that we will not incur significant costs in obtaining or maintaining foreign regulatory approvals or clearances, or that we will be able to successfully commercialize current or future products in various foreign markets. Delays in receipt of approvals or clearances to market our products in foreign countries, failure to receive such approvals or clearances or the future loss of previously received approvals or clearances could have a substantial negative effect on our results of operations and financial condition.

## Changing, new and/or emerging government regulations may adversely affect us

Government regulations can change without notice. Given the fact that Cytori operates in various international markets, our access to such markets could change with little to no warning due to a change in government regulations that suddenly up-regulate our product(s) and create greater regulatory burden for our cell therapy and cell banking technology products.

Due to the fact that there are new and emerging cell therapy and cell banking regulations that have recently been drafted and/or implemented in various countries around the world, the application and subsequent implementation of these new and emerging regulations have little to no precedence. Therefore, the level of complexity and stringency is not known and may vary from country to country, creating greater uncertainty for the international regulatory process.

Anticipated or unanticipated changes in the way or manner in which the FDA regulates products or classes/groups of products can delay, further burden, or alleviate regulatory pathways that were once available to other products. There are no guarantees that such changes in FDA's approach to the regulatory process will not deleteriously affect some or all of our products or product applications.

We do not know if the current FDA proposed changes to the 510(k) system will have any material effect on any of our current or future 510(k) applications. Depending on if and how these proposed changes are ultimately adopted and implemented, our current or future applications for FDA approval for our products may be adversely affected and our business could be harmed as a result.

#### We may have difficulty obtaining health insurance reimbursement for our products

New and emerging cell therapy and cell banking technologies, such as those provided by the Celution® System family of products, may have difficulty or encounter significant delays in obtaining health care reimbursement in some or all countries around the world due to the novelty of our cell therapy and cell banking technology and subsequent lack of existing reimbursement schemes / pathways. Therefore, the creation of new reimbursement pathways may be complex and lengthy with no assurances that such reimbursements will be successful. The lack of health insurance reimbursement or reduced or minimal reimbursement pricing may have a significant impact on our ability to successfully sell our cell therapy and cell banking technology product(s) into a county or region, which would negatively impact our operating results.

## Our concentration of sales in Japan may enhance the negative effects on our business of any crisis in that region

We have a significant concentration of sales in Japan, the United States, and Europe given our early stage of commercialization. As a result of this regional concentration of sales, changes in the regulatory environment in these countries, or any other countries in which we have a significant concentration of sales, could adversely impact our sales. If the government of any of these countries significantly curtailed or prohibited the sale of our products, our revenues would be adversely affected. Recently, the earthquake, tsunami and subsequent problems affecting nuclear power plants in Japan have dramatically impacted Japan's manufacturing capacity and business activities. The long-term effect of these issues is still uncertain. While we expect that the situation has stabilized and will improve, if it does not, these circumstances could be harmful to our business since a substantial portion of our sales have come from Japan.

#### Our global operations expose us to additional risk and uncertainties.

We have operations in a number of regions around the world, including the United States, Japan, and Europe. Our global operations may be subject to risks that may limit our ability to operate our business. We sell our products globally, which exposes us to a number of risks that can arise from international trade transactions, local business practices and cultural considerations, including:

- political unrest, terrorism and economic or financial instability;
- · unexpected changes and uncertainty in regulatory requirements and systems related
- · nationalization programs that may be implemented by foreign governments;
- import-export regulations;
- · difficulties in enforcing agreements and collecting receivables;
- · difficulties in ensuring compliance with the laws and regulations of multiple jurisdictions;
- · changes in labor practices, including wage inflation, labor unrest and unionization policies;
- · longer payment cycles by international customers;
- currency exchange fluctuations;
- · disruptions of service from utilities or telecommunications providers, including electricity shortages;
- difficulties in staffing foreign branches and subsidiaries and in managing an expatriate workforce, and differing employment practices and labor issues;
- · potentially adverse tax consequences;



We also face risks associated with currency exchange and convertibility, inflation and repatriation of earnings as a result of our foreign operations. We are also vulnerable to appreciation or depreciation of foreign currencies against the U.S. dollar. Although we have significant operations in Asia, a substantial portion of transactions are denominated in U.S. dollars. As appreciation against the U.S. dollar increases, it will result in an increase in the cost of our business expenses abroad. Conversely, downward fluctuations in the value of foreign currencies relative to the U.S. dollar may make our products less price competitive than local solutions. From time to time, we may engage in currency hedging activities, but such activities may not be able to limit the risks of currency fluctuations.

#### We and our joint venture with Olympus have to maintain quality assurance certification and manufacturing approvals

The manufacture of our products are, and the manufacture of any future cell-related therapeutic products would be, subject to periodic inspection by regulatory authorities and distribution partners. The manufacture of devices and products for human use is subject to regulation and inspection from time to time by the FDA for compliance with the FDA's Quality System Regulation, or QSR, requirements, as well as equivalent requirements and inspections by state and non-U.S. regulatory authorities. There can be no guarantee that the FDA or other authorities will not, during the course of an inspection of existing or new facilities, identify what they consider to be deficiencies in our compliance with QSRs or other requirements and request, or seek remedial action.

Failure to comply with such regulations or a potential delay in attaining compliance may adversely affect our manufacturing activities and could result in, among other things, injunctions, civil penalties, FDA refusal to grant pre-market approvals or clearances of future or pending product submissions, fines, recalls or seizures of products, total or partial suspensions of production, and criminal prosecution. There can be no assurance after such occurrences that we will be able to obtain additional necessary regulatory approvals or clearances on a timely basis, if at all. Delays in receipt of or failure to receive such approvals or clearances, or the loss of previously received approvals or clearances could have a substantial negative effect on our results of operations and financial condition.

## We depend on a few key officers

Our performance is substantially dependent on the performance of our executive officers and other key scientific and sales staff, including Christopher J. Calhoun, our Chief Executive Officer, and Marc Hedrick, MD, our President. We rely upon them for strategic business decisions and guidance. We believe that our future success in developing marketable products and achieving a competitive position will depend in large part upon whether we can attract and retain additional qualified management and scientific personnel. Competition for such personnel is intense, and there can be no assurance that we will be able to continue to attract and retain such personnel. The loss of the services of one or more of our executive officers or key scientific staff, or the inability to attract and retain additional personnel and develop expertise as needed could have a substantial negative effect on our results of operations and financial condition.

## We may not have enough product liability insurance

The testing, manufacturing, marketing, and sale of our regenerative cell products involve an inherent risk that product liability claims will be asserted against us, our distribution partners, or licensees. There can be no guarantee that our clinical trial and commercial product liability insurance is adequate or will continue to be available in sufficient amounts or at an acceptable cost, if at all. A product liability claim, product recall, or other claim, as well as any claims for uninsured liabilities or in excess of insured liabilities, could have a substantial negative effect on our results of operations and financial condition. Also, well-publicized claims could cause our stock to fall sharply, even before the merits of the claims are decided by a court.

## Our charter documents contain anti-takeover provisions and we have adopted a Stockholder Rights Plan to prevent hostile takeovers

Our Amended and Restated Certificate of Incorporation and Bylaws contain certain provisions that could prevent or delay the acquisition of Cytori by means of a tender offer, proxy contest, or otherwise. They could discourage a third party from attempting to acquire control of Cytori, even if such events would be beneficial to the interests of our stockholders. Such provisions may have the effect of delaying, deferring, or preventing a change of control of Cytori and consequently could adversely affect the market price of our shares. Also, in 2003 we adopted a Stockholder Rights Plan of the kind often referred to as a poison pill. The purpose of the Stockholder Rights Plan is to prevent coercive takeover tactics that may otherwise be utilized in takeover attempts. The existence of such a rights plan may also prevent or delay a change in control of Cytori, and this prevention or delay adversely affect the market price of our shares.

## We pay no dividends

We have never paid cash dividends in the past, and currently do not intend to pay any cash dividends in the foreseeable future. This could make an investment in our company inappropriate for some investors, and may serve to narrow our potential sources of additional capital.

## <u>Index</u>

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

None

# Item 3. Defaults Upon Senior Securities

None

# Item 4. Mine Safety Disclosures

None

# Item 5. Other Information

None

# Item 6. Exhibits

<u>Index</u>

Item 0. LA	
Exhibit No.	Description
<u>31.1</u>	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).
<u>31.2</u>	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).
<u>32.1*</u>	Certifications Pursuant to 18 U.S.C. Section 1350/ Securities Exchange Act Rule 13a-14(b), as adopted pursuant to Section 906 of the Sarbanes - Oxley Act of 2002 (filed herewith).
101.INS	XBRL Instance Document
101.SCH	XBRL Schema Document
101.CAL	XBRL Calculation Linkbase Document
101.DEF	XBRL Definition Linkbase Document
101.LAB	XBRL Label Linkbase Document
101.PRE	XBRL Presentation Linkbase Document

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

# SIGNATURES

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

# CYTORI THERAPEUTICS, INC.

Dated: August 9, 2012	By: /s/ Christopher J. Calhoun Christopher J. Calhoun Chief Executive Officer
Dated: August 9, 2012	By: /s/ Mark E. Saad Mark E. Saad Chief Financial Officer
	37

## 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, Christopher J. Calhoun, 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 9, 2012 /s/ Christopher J. Calhoun Christopher J. Calhoun, 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, Mark E. Saad, 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 9, 2012 /s/ Mark E. Saad Mark E. Saad Chief Financial Officer

## **EXHIBIT 32.1**

# 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, 2012 as filed with the Securities and Exchange Commission on the date hereof, Christopher J. Calhoun, as Chief Executive Officer of Cytori Therapeutics, Inc., and Mark E. Saad, as 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 9, 2012

By: /s/ Christopher J. Calhoun Christopher J. Calhoun

Chief Executive Officer

By: /s/ Mark E. Saad

Mark E. Saad Chief Financial Officer

Dated: August 9, 2012