

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

Form 8-K

Current Report

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): **May 9, 2013**

**CYTORI THERAPEUTICS, INC.**

(Exact name of registrant as specified in its charter)

**Delaware**

**001-34375**

**33-0827593**

(State or Other Jurisdiction of Incorporation)

(Commission File  
Number)

(I.R.S. Employer Identification Number)

**3020 Callan Road, San Diego, California 92121**  
(Address of principal executive offices, with zip code)

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

**n/a**  
(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions ( see General Instruction A.2. below):

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
  - Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
  - Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
  - Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))
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**Item 2.02 Results of Operations and Financial Condition**

On May 9, 2013 Cytori Therapeutics, Inc. (Company) issued a press release announcing its financial results for the first quarter ended March 31, 2013. A copy of the press release is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

The information disclosed under this Item 2.02 in this report, including Exhibit 99.1 hereto, is being furnished and shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, nor shall it be incorporated by reference into any registration statement or other document pursuant to the Securities Act of 1933, as amended, except as expressly set forth in such filing.

**Item 9.01 Financial Statements and Exhibits**

**(d) Exhibits**

<b>Exhibit No.</b>	<b>Description</b>
99.1	Cytori Therapeutics, Inc. Press Release, dated May 9, 2013 *

\* Exhibit 99.1 hereto is being furnished and shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, nor shall it be incorporated by reference into any registration statement or other document pursuant to the Securities Act of 1933, as amended, except as expressly set forth in such filing.

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**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 hereunto duly authorized.

Date: May 9, 2013

**CYTORI THERAPEUTICS, INC.**

By: /s/ Mark E. Saad  
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Mark E. Saad  
Chief Financial Officer



May 9, 2013

## Cytori Reports First Quarter 2013 Business and Financial Results

San Diego, CA – Cytori Therapeutics (NASDAQ: CYTX) today reports its first quarter 2013 financial results and provides updates on clinical development and commercialization activities.

For the first quarter of 2013, Cytori achieved \$3.8 million in total revenue including \$1.9 million in combined product and government contract revenue. Cytori reiterates guidance for the year of \$15 million of product and contract revenue.

### Milestone Highlights

Cytori's year-to-date accomplishments include the following:

- Entered into an agreement to acquire the remaining interest in the Olympus-Cytori Joint Venture, including all manufacturing rights for the Celution® System
- Continued enrollment in the ATHENA trial of Cytori's cell therapy for chronic ischemic heart failure; goal for completion of enrollment remains summer of this year
- Continued enrollment in the ADVANCE European heart attack trial; the current goal for enrollment is 25 patients by year-end 2013
- Opened new tissue ischemia and intravascular markets for the Celution® System with expanded CE Mark claims for these respective indications
- Submitted report to BARDA containing data demonstrating achievement of the first of three objectives under the BARDA contract by validating the core design elements of the next-generation Celution® System; achievement of the other objectives is anticipated on or ahead of schedule
- On track to have a nationwide Japanese distribution network
- Awarded two patents, including a methods patent for using adipose-derived stem and regenerative cell therapy for treating renal disease
- Recruited Dr. Steven Kesten as Executive Vice President and Chief Medical Officer

“Year-to-date, we have continued to execute on our 2013 priorities,” said Christopher J. Calhoun, Cytori's Chief Executive Officer. “Completion of enrollment in ATHENA, successful execution of our BARDA contract deliverables, and growth in total revenues remain our highest priorities.”

### Financial Performance

Total revenues for the first quarter of 2013 were \$3.8 million, compared to \$1.5 million in the first quarter of 2012. Product and government contract revenues for the first quarter of 2013 were \$1.9 million, compared to \$1.5 million for the first quarter of 2012. Government contract revenues for the first quarter of 2013 were \$0.5 million related almost entirely to work performed under the BARDA contract, for which there were no comparable revenues recognized in the first quarter of 2012. Additionally, \$1.8 million in revenue was recognized for services performed in relation to the Joint Venture with Olympus and the Senko distribution agreement. During the first quarter of 2013, Cytori terminated the Senko distribution agreement and reacquired from Senko the rights to SurgiWrap in Japan.

Gross profit was \$0.6 million, or 46%, in the first quarter of 2013 compared to \$0.6 million, or 42%, in the first quarter of 2012. Gross margins are expected to increase substantially in the second half of 2013 as increased second half revenues are realized.

Research and development expenses were \$3.7 million in the first quarter of 2013 compared to \$2.8 million in the first quarter of 2012. The planned increase in research and development expenses is mostly related to services performed under the BARDA contract, in addition to clinical trial costs. Sales, general and administrative expenses were \$6.1 million for the first quarter of 2013 compared to \$6.3 million in the first quarter of 2012.

Net loss was \$7.7 million, or (\$0.11) per share, for the first quarter of 2013 compared to \$9.3 million, or (\$0.16) per share, in the first quarter of 2012. Cytori ended the first quarter of 2013 with \$16.4 million of cash and cash equivalents and \$3.0 million in accounts receivable. Further, Cytori reduced near and long-term liabilities in the first quarter by approximately \$5.8 million. A substantial portion of Cytori's recent and projected cash needs relate to principal payments on its existing term loan. The Company is in discussions with its lender group to extend the term of the loan and defer principal payments to coincide with anticipated product sales, government contract payments, and other potential cash milestones.

“For the first quarter, R&D expenses increased over last year as we invested in ATHENA and performed services under the BARDA contract which were more than offset in contract revenue,” said Mark E. Saad, Chief Financial Officer of Cytori. “We continued to control SG&A expenses, which remained flat as projected. Additionally, we reaffirm our \$15 million combined product and government contract revenue guidance for 2013, which we previously projected will be weighted toward the second half of 2013 as we realize the effects from recent regulatory approvals in Japan and Europe, anticipated new country approvals and continued work under the BARDA contract.”



## **Cardiovascular Disease Pipeline**

The ATHENA trial evaluating Cytori's cell therapy as a treatment for chronic ischemic heart failure is the Company's primary clinical focus in 2013. Enrollment continued during the first quarter of 2013 and additional sites went live and began screening and treating patients. The Company's goal for completion of enrollment is this summer with six month outcomes reported in the first half of 2014. Additionally, the ADVANCE European pivotal trial for acute myocardial infarction (heart attacks) is actively enrolling patients and ahead of schedule to treat the budgeted 25 patients by the end of the year.

## **BARDA Contract**

Cytori's contract with BARDA, a division of the U.S. Department of Health and Human Services, could provide up to \$106 million to fully fund the regulatory and clinical trials required by FDA to gain approval for Cytori's Celution® System for the treatment of soft tissue injuries. This would be achieved through a series of contract options exercised at BARDA's discretion upon achievement of specified development milestones. Upon FDA approval, or in certain circumstances as deemed appropriate by BARDA prior to approval, the U.S. government has the option to purchase Celution® Systems and consumables as a medical countermeasure for national preparedness. The total amount that may be awarded under the contract is \$106 million, not including the value of any potential purchases. Should FDA approval be received, the Company has the right to commercialize its cell therapy in accordance with the claims allowed by the FDA.

Cytori is currently in the proof-of-concept phase of this contract. As specified in the contract, this phase funds three objectives that if successful could trigger up to \$56 million in the first set of contract options. The three objectives are 1) to validate performance of core design elements incorporated within Cytori's next-generation Celution® System; 2) to demonstrate that Cytori's therapeutic cell population can be obtained from patients with burn injury; and 3) to show efficacy of Cytori's cell therapy in a novel preclinical model of thermal burn with concomitant radiation exposure.

In the first quarter of 2013, Cytori made considerable progress on contract deliverables related to all three objectives. In particular, Cytori has recently submitted data to BARDA that the Company believes demonstrates accomplishment of the contract milestone pertaining to feasibility of the next-generation Celution® System. This has been achieved ahead of schedule. Significant progress is also being made on the two remaining milestones, which Cytori expects to achieve on or ahead of schedule. Additionally, and as previously stated, Cytori recognized \$0.5 million in contract revenue toward the achievement of contract deliverables in the first quarter of 2013. Consistent with previous statements, Cytori continues to expect to achieve all three proof-of-concept milestones as required under the contract by the end of the first quarter of 2014.

## **Commercial Business**

Cytori's product revenues were more heavily weighted by orders from Japan in the first quarter of 2013. For the remainder of 2013, it is expected that product revenue growth will be driven by expanded research and general clinical use based on recent regulatory approvals in Japan and Europe. This is driven in Japan based on the recent Class I approval and in Europe by the Celution® System CE Mark for intravascular delivery and tissue ischemia.

Cytori is seeing growing interest in the number of investigator-initiated studies, the number of multi-center studies and the number of patients anticipated to be treated in those trials. Financially, these trials are funded primarily by government grants or funds from specific healthcare institutions. Recently, a ¥500 million (approximately \$5 million) grant from the Ministry of Health, Labour and Welfare (MHLW) in Japan was issued to support a multi-center trial that could lead to approval and reimbursement for Cytori's cell therapy for stress urinary incontinence. In Europe, Cytori has been informed by an investigator in France that an ongoing pilot study in patients with hand complications from scleroderma is being considered for a multi-center trial based on encouraging preliminary results.

Finally, the Puregraft® product line continues its positive sales trends. Record Puregraft® revenues were reported with growth in both sales and units shipped in sequential quarters as well as quarter over year ago quarter. This trend reflects the increasing demand for this product as well as the overall growth in fat grafting amongst plastic and reconstructive surgeons. Cytori expects to accelerate Puregraft® sales with the launch of an important product line extension later this year, targeting a significant market for small volume fat grafting procedures.

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## Olympus Joint Venture

Cytori has finalized an agreement with Olympus Corporation to acquire all of Olympus' rights to the Olympus-Cytori Joint Venture, including Celution® product manufacturing and patent rights and eliminating any royalty obligations to the Joint Venture. Regaining full control of manufacturing rights provides Cytori with greater flexibility on the manufacturing process and associated costs, enables higher margins, and speeds the transition to the smaller next-generation system. As part of the agreement, the Olympus-Cytori Joint Venture will return all rights to Cytori at closing in exchange for alternative payment options including: \$4.5 million within one year or \$6 million within two years.

“In 2011, following unforeseen disruptions to Olympus' business and corporate governance, we took immediate and proactive measures to protect our business interests associated with the Joint Venture, which ultimately resulted in our acquisition of Olympus' interest in the Celution® technology and the JV,” said Mr. Calhoun. “We are grateful for the strategic, technological and financial support Olympus has provided Cytori over the years. In partnership with them, we were able to enhance the performance of the Celution® technology, improve our operational capability and increase our presence in Japan. Based on our internal capabilities to miniaturize and directly manufacture the next-generation system and the importance of protecting and controlling our supply chain and related economics, we believe this action is in the best near and long-term interest of our business.”

## Upcoming Milestones

Cytori's core milestones for the next 12 months include the following:

- Complete enrollment in the ATHENA trial
- Achieve proof-of-concept milestones in the BARDA contract and qualify Cytori for up to \$56 million in additional development funding
- Publish the 18 month outcomes from the PRECISE European chronic ischemic heart failure trial
- Continue to strengthen the Company's patent position
- Generate product and contract revenue of \$15 million in 2013

## Management Conference Call Webcast and Shareholder Letter Information

Cytori will host a management conference call at 5:00 p.m. Eastern Time today to further discuss the Company's progress. The [webcast](#) will be available live and by replay two hours after the call and may be accessed under “Webcasts” in the [Investor Relations section](#) of Cytori's website. If you are unable to access the webcast, you may dial in to the call at +1-877-402-3914, Conference ID: 51847937.

## About Cytori

Cytori Therapeutics is developing cell therapies based on autologous adipose-derived regenerative cells (ADRCs) to treat cardiovascular disease and other medical conditions. Our scientific data suggest ADRCs improve blood flow, moderate the inflammatory 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 to the physician and patient at the point-of-care by Cytori's proprietary technologies and products, including the Celution® System product family. [www.cytori.com](http://www.cytori.com)

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## **Cautionary Statement Regarding Forward-Looking Statements**

This press release includes forward-looking statements regarding events, trends and business prospects, which may affect our future operating results and financial position, such as our expectation of completion of enrollment of the ATHENA clinical trial by mid-summer with six month results in the first half of 2014, our ability to meet the BARDA proof-of-concept milestones by the first quarter of 2014, the potential for the BARDA contract to represent a fully funded pathway to U.S. commercialization, our expectation of continuing demand from investigator-initiated trial customers, the ability of an investigator-initiated study to lead to MHLW approval and reimbursement of our cell therapy in Japan, our ability to pursue additional grant funding and partnership opportunities, our publication of 18-month trial outcomes from the PRECISE trial, our ability to maintain our sales, general and administrative expenses at current levels, and our revenue guidance of \$15 million in product and contract revenue for the year. Such statements are subject to risks and uncertainties that could cause our actual results and financial position to differ materially. Some of these risks include the level of future interest in our products by Japan research institutions, performance of our Japan distribution network, clinical, pre-clinical and regulatory uncertainties, such as those associated with the ATHENA clinical trial and the BARDA proof-of-concept milestones, including risks in the collection and results of clinical data, final clinical outcomes, dependence on third party performance, performance and acceptance of our products in the marketplace, and other risks and uncertainties described under the "Risk Factors" in our annual and quarterly Securities and Exchange Commission Filings on Forms 10-K and 10-Q. We assume no responsibility to update or revise any forward-looking statements to reflect events, trends or circumstances after the date they are made.

### **Contact:**

<i>Investors</i>	<i>Media</i>
Tom Baker	Megan McCormick
+1.858.875.5258	+1.858.875.5279
<a href="mailto:tbaker@cytori.com">tbaker@cytori.com</a>	<a href="mailto:mmccormick@cytori.com">mmccormick@cytori.com</a>

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

	<u>As of March 31, 2013</u>	<u>As of December 31, 2012</u>
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 16,404,000	\$ 25,717,000
Accounts receivable, net of reserves of \$374,000 and of \$278,000 in 2013 and 2012, respectively	2,961,000	3,926,000
Inventories, net	3,646,000	3,175,000
Other current assets	1,189,000	1,161,000
	<u>24,200,000</u>	<u>33,979,000</u>
Total current assets	24,200,000	33,979,000
Property and equipment, net	2,049,000	2,174,000
Restricted cash and cash equivalents	350,000	350,000
Investment in joint venture	37,000	85,000
Other assets	2,808,000	2,740,000
Goodwill	3,922,000	3,922,000
	<u>33,366,000</u>	<u>43,250,000</u>
Total assets	\$ 33,366,000	\$ 43,250,000
<b>Liabilities and Stockholders' Equity</b>		
Current liabilities:		
Accounts payable and accrued expenses	\$ 6,000,000	\$ 7,411,000
Current portion of long-term obligations, net of discount	9,800,000	9,784,000
Current portion of termination fee obligation	800,000	—
Warrant liability	84,000	418,000
	<u>16,684,000</u>	<u>17,613,000</u>
Total current liabilities	16,684,000	17,613,000
Deferred revenues, related party	—	638,000
Deferred revenues	232,000	2,635,000
Option liability	2,500,000	2,250,000
Long-term deferred rent and other	988,000	756,000
Long-term obligations, net of discount, less current portion	10,594,000	12,903,000
	<u>30,998,000</u>	<u>36,795,000</u>
Total liabilities	30,998,000	36,795,000
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, \$0.001 par value; 5,000,000 shares authorized; -0- shares issued and outstanding in 2013 and 2012	—	—
Common stock, \$0.001 par value; 95,000,000 shares authorized; 67,173,050 and 65,914,050 shares issued and outstanding in 2013 and 2012, respectively	67,000	66,000
Additional paid-in capital	284,806,000	281,117,000
Accumulated other comprehensive loss	(110,000)	—
Accumulated deficit	(282,395,000)	(274,728,000)
	<u>2,368,000</u>	<u>6,455,000</u>
Total stockholders' equity	2,368,000	6,455,000
Total liabilities and stockholders' equity	\$ 33,366,000	\$ 43,250,000

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

	<b>For the Three Months Ended March 31,</b>	
	<b>2013</b>	<b>2012</b>
Product revenues	\$ 1,392,000	\$ 1,481,000
Cost of product revenues	<u>756,000</u>	<u>853,000</u>
Gross profit	<u>636,000</u>	<u>628,000</u>
Development revenues:		
Development, related party	638,000	—
Development revenue	1,179,000	—
Government contracts and other	549,000	3,000
	<u>2,366,000</u>	<u>3,000</u>
Operating expenses:		
Research and development	3,720,000	2,836,000
Sales and marketing	2,257,000	2,376,000
General and administrative	3,846,000	3,924,000
Change in fair value of warrant liability	(334,000)	130,000
Change in fair value of option liability	250,000	(270,000)
	<u>9,739,000</u>	<u>8,996,000</u>
Total operating expenses	<u>9,739,000</u>	<u>8,996,000</u>
Operating loss	<u>(6,737,000)</u>	<u>(8,365,000)</u>
Other income (expense):		
Interest income	—	2,000
Interest expense	(709,000)	(865,000)
Other expense, net	(173,000)	(47,000)
Equity loss from investment in joint venture	(48,000)	(50,000)
	<u>(930,000)</u>	<u>(960,000)</u>
Total other expense	<u>(930,000)</u>	<u>(960,000)</u>
Net loss	<u>(7,667,000)</u>	<u>(9,325,000)</u>
Other comprehensive loss – foreign currency translation adjustments	<u>(110,000)</u>	<u>—</u>
Comprehensive loss	<u>\$ (7,777,000)</u>	<u>\$ (9,325,000)</u>
Basic and diluted net loss per common share	<u>\$ (0.11)</u>	<u>\$ (0.16)</u>
Basic and diluted weighted average common shares	<u>66,990,950</u>	<u>57,484,990</u>

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

	<b>For the Three Months Ended</b>	
	<b>March 31,</b>	
	<b>2013</b>	<b>2012</b>
<b>Cash flows from operating activities:</b>		
Net loss	\$ (7,667,000)	\$ (9,325,000)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	200,000	220,000
Amortization of deferred financing costs and debt discount	192,000	237,000
Increase (decrease) in allowance for doubtful accounts	87,000	(24,000)
Change in fair value of warrant liability	(334,000)	130,000
Change in fair value of option liability	250,000	(270,000)
Stock-based compensation	873,000	942,000
Equity loss from investment in joint venture	48,000	50,000
Increases (decreases) in cash caused by changes in operating assets and liabilities:		
Accounts receivable	868,000	859,000
Inventories	(477,000)	(56,000)
Other current assets	(28,000)	(298,000)
Other assets	(974,000)	(22,000)
Accounts payable and accrued expenses	(523,000)	(83,000)
Deferred revenues, related party	(638,000)	—
Deferred revenues	(1,203,000)	(68,000)
Long-term deferred rent	32,000	(6,000)
	<u>(9,294,000)</u>	<u>(7,714,000)</u>
<b>Cash flows from investing activities:</b>		
Purchases of property and equipment	(81,000)	(25,000)
License agreement termination fee	(200,000)	—
	<u>(281,000)</u>	<u>(25,000)</u>
<b>Cash flows from financing activities:</b>		
Principal payments on long-term obligations	(2,485,000)	(71,000)
Proceeds from exercise of employee stock options and warrants	—	947,000
Proceeds from sale of common stock	3,001,000	4,396,000
Costs from sale of common stock	(184,000)	(56,000)
	<u>332,000</u>	<u>5,216,000</u>
Effect of exchange rate changes on cash and cash equivalents	(70,000)	—
	<u>(9,313,000)</u>	<u>(2,523,000)</u>
Cash and cash equivalents at beginning of period	<u>25,717,000</u>	<u>36,922,000</u>
Cash and cash equivalents at end of period	<u>\$ 16,404,000</u>	<u>\$ 34,399,000</u>