

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, 2012

**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))

**Item 2.02 Results of Operations and Financial Condition**

On May 9, 2012 Cytori Therapeutics, Inc. (Company) issued a press release announcing its financial results for the first quarter ended March 31, 2012. A copy of the press release is attached hereto as Exhibit 99.1 and is incorporated herein by reference. In addition, on the same date, the Company has posted further insight into those results of operations in an open letter to its stockholders and other interested parties in the blog on the Investor Relations section of its website. A copy of the letter is attached hereto as exhibit 99.2.

The information disclosed under this Item 2.02 in this report, including Exhibits 99.1 and 99.2 hereto, are 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, 2012 *
99.2	Cytori Therapeutics, Inc. Shareholder Letter, dated May 9, 2012 *

\* Exhibits 99.1 and 99.2 hereto are 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, 2012

**CYTORI THERAPEUTICS, INC.**

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



May 9, 2012

## **Cytori Provides Business Update; Reports First Quarter Results**

San Diego, CA – During the first quarter of 2012, Cytori Therapeutics (NASDAQ: CYTX) advanced its cardiac cell therapy product pipeline, grew the commercial business, and strengthened operational and financial performance, which encompasses management of expenses, strategic partnerships, and regulatory approvals. Of the seven active partnership discussions, the Company is focused on the two most advanced transactions with the goal of completing the first partnership in the near term.

Cytori has accomplished the following milestones year-to-date:

### Pipeline

- Received approval from the FDA to begin the U.S. ATHENA IDE trial for chronic myocardial ischemia (CMI); all five centers have been identified and enrollment of the first patient is anticipated in the second quarter;
- Published clinical data from two company-sponsored European trials: the APOLLO cardiac cell therapy heart attack pilot trial and the RESTORE 2 post-marketing breast reconstruction trial;
- Completed multiple meetings with the European regulatory body to review clinical data, specifics on claims and negotiate details on potential patient registry toward CE Mark approval for no-option CMI; providing additional data upon the Notified Body's request; decision expected in 2012;

### Commercial Business

- Continued to build market access for breast reconstruction in Europe; submitted a medical technology assessment application in the UK;
- Grew commercial business; product revenues increased by 9% compared to Q1 2011; reaffirm \$9 million revenue guidance for 2012;

### Operational and Financial Performance

- Reduced total operating expenses by 31% and the operating cash burn rate by 27% as compared to Q1 2011;
- Ended the quarter with \$34.4 million in cash and cash equivalents, compared with \$36.9 million as of year-end 2011;
- Received U.S. composition patent for soft tissue defects and U.S. device patent for accelerating healing of wounds, bringing the total number of issued patents worldwide to 46 with more than 75 applications under review;
- Continued to advance multiple near term partnerships, focused primarily on the two most advanced transactions;

"For our cardiac pipeline, we are placing greater emphasis on our chronic applications, which include the potential CE Mark approval and the U.S. ATHENA trial," said Christopher J. Calhoun, chief executive officer of Cytori. "We have improved operational efficiencies for the commercial business, including year-over-year revenue growth and reduced sales and marketing expenses. Lastly, we are advancing our partnership negotiations, strengthening our IP position and expanding country approvals."

### **Financial Results**

Product revenues were \$1.5 million in the first quarter of 2012, compared to \$1.4 million in first quarter of 2011. Gross profits were \$0.6 million for the first quarter of 2012, compared to \$0.5 million for the same period in 2011. As stated in the 2011 year-end release, 2012 sales are expected to be weighted toward the second half of the year and based on internal quarterly projections. Cytori reaffirms guidance of \$9 million in product revenue.

Total operating expenses were reduced by 31% to \$9.0 million in the first quarter of 2012, compared to \$13.0 million in the first quarter of 2011. Operating expenses include non cash costs associated with changes in the fair value of option and warrant liabilities. Net cash used in operating activities was reduced by 27% to \$7.7 million in the first quarter of 2012 compared to \$10.6 million in the first quarter of 2011. The improvement in total operating expenses and net cash used in operating activities for the first quarter of 2012 as compared to the first quarter of 2011 was due in part to reduced sales and marketing costs and slightly lower clinical trial expenditures.

Net loss was \$9.3 million, or (\$0.16) per share, for the first quarter of 2012 compared to \$12.1 million, or (\$0.23) per share, for the first quarter of 2011. At the end of the first quarter of 2012, Cytori had \$34.4 million in cash and cash equivalents and \$1.4 million in account receivable, net of reserves. This compares to ending 2011 with \$36.9 million in cash and cash equivalents and \$2.3 million in accounts receivable, net of reserves. Cytori recently terminated its financing agreement with Seaside 88, which raised a total of \$18.2 million since we entered the agreement. The primary emphasis is to strengthen the balance sheet by executing one or more development and commercialization partnership agreement(s).

### **Conference Call, Shareholder Letter and Slide Presentation Information**

Cytori will host a management conference call at 5:00 p.m. Eastern Time today to further discuss these results. The live webcast of the conference call may be accessed under "Webcasts" in the Investor Relations section (<http://ir.cytori.com>) of Cytori's website. The webcast will be available live and by replay two

hours after the call. If you are unable to access the webcast, you may dial in to the call at +1.888.208.1815, Passcode: 6625514. More details on our business are contained in the 'May 2012 Shareholder Letter' posted on the homepage of our Investor Relations website.

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## About Cytori

Cytori Therapeutics is developing cell therapies based on autologous adipose-derived 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 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)

## 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 the successful initiation of the ATHENA clinical trial of the Company's Celution® system for chronic myocardial ischemia, our efforts to expand our CE Mark, achieve our revenue projection for 2012, and execute a commercialization partnership agreement. 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 clinical and regulatory uncertainties, such as those associated with the ATHENA clinical trial, 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 "Risk Factors" in Cytori's Securities and Exchange Commission Filings. 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:

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

	<u>As of March 31, 2012</u>	<u>As of December 31, 2011</u>
<b>Assets</b>		
<b>Current assets:</b>		
Cash and cash equivalents	\$ 34,399,000	\$ 36,922,000
Accounts receivable, net of reserves of \$187,000 and of \$474,000 in 2012 and 2011, respectively	1,425,000	2,260,000
Inventories, net	3,374,000	3,318,000
Other current assets	1,135,000	837,000
<b>Total current assets</b>	<b>40,333,000</b>	<b>43,337,000</b>
Property and equipment, net	2,367,000	1,711,000
Restricted cash and cash equivalents	350,000	350,000
Investment in joint venture	200,000	250,000
Other assets	1,794,000	1,772,000
Intangibles, net	136,000	192,000
Goodwill	3,922,000	3,922,000
<b>Total assets</b>	<b>\$ 49,102,000</b>	<b>\$ 51,534,000</b>
<b>Liabilities and Stockholders' Equity (Deficit)</b>		
<b>Current liabilities:</b>		
Accounts payable and accrued expenses	\$ 6,046,000	\$ 5,334,000
Current portion of long-term obligations	4,911,000	2,487,000
<b>Total current liabilities</b>	<b>10,957,000</b>	<b>7,821,000</b>
Deferred revenues, related party	3,520,000	3,520,000
Deferred revenues	5,176,000	5,244,000
Warrant liability	757,000	627,000
Option liability	1,640,000	1,910,000
Long-term deferred rent	498,000	504,000
Long-term obligations, net of discount, less current portion	19,704,000	21,962,000
<b>Total liabilities</b>	<b>42,252,000</b>	<b>41,588,000</b>
<b>Commitments and contingencies</b>		
<b>Stockholders' equity:</b>		
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; 58,428,606 and 56,594,683 shares issued and outstanding in 2012 and 2011, respectively	58,000	57,000
Additional paid-in capital	258,566,000	252,338,000
Accumulated deficit	(251,774,000)	(242,449,000)
<b>Total stockholders' equity</b>	<b>6,850,000</b>	<b>9,946,000</b>
<b>Total liabilities and stockholders' equity</b>	<b>\$ 49,102,000</b>	<b>\$ 51,534,000</b>

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

	<b>For the Three Months</b>	
	<b>Ended March 31,</b>	
	<b>2012</b>	<b>2011</b>
Product revenues	\$ 1,481,000	\$ 1,362,000
Cost of product revenues	853,000	842,000
Gross profit	628,000	520,000
Development revenues:		
Development, related party	—	1,231,000
Research grants and other	3,000	4,000
	3,000	1,235,000
Operating expenses:		
Research and development	2,836,000	3,047,000
Sales and marketing	2,376,000	3,226,000
General and administrative	3,924,000	3,544,000
Change in fair value of warrant liability	130,000	3,471,000
Change in fair value of option liability	(270,000)	(290,000)
Total operating expenses	8,996,000	12,998,000
Operating loss	(8,365,000)	(11,243,000)
Other income (expense):		
Interest income	2,000	2,000
Interest expense	(865,000)	(738,000)
Other expense, net	(47,000)	(47,000)
Equity loss from investment in joint venture	(50,000)	(46,000)
Total other expense	(960,000)	(829,000)
Net loss	\$ (9,325,000)	\$ (12,072,000)
Basic and diluted net loss per common share	\$ (0.16)	\$ (0.23)
Basic and diluted weighted average common shares	57,484,990	51,994,708



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

	<b>For the Three Months Ended</b>	
	<b>March 31,</b>	
	<b>2012</b>	<b>2011</b>
<b>Cash flows from operating activities:</b>		
Net loss	\$ (9,325,000)	\$ (12,072,000)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	220,000	194,000
Amortization of deferred financing costs and debt discount	237,000	240,000
Increase (decrease) in allowance for doubtful accounts	(24,000)	21,000
Change in fair value of warrant liability	130,000	3,471,000
Change in fair value of option liability	(270,000)	(290,000)
Stock-based compensation	942,000	881,000
Equity loss from investment in joint venture	50,000	46,000
Increases (decreases) in cash caused by changes in operating assets and liabilities:		
Accounts receivable	859,000	278,000
Inventories	(56,000)	(174,000)
Other current assets	(298,000)	(130,000)
Other assets	(22,000)	(922,000)
Accounts payable and accrued expenses	(83,000)	(854,000)
Deferred revenues, related party	—	(1,231,000)
Deferred revenues	(68,000)	(10,000)
Long-term deferred rent	(6,000)	(12,000)
Net cash used in operating activities	<u>(7,714,000)</u>	<u>(10,564,000)</u>
<b>Cash flows from investing activities:</b>		
Purchases of property and equipment	<u>(25,000)</u>	<u>(131,000)</u>
Net cash used in investing activities	<u>(25,000)</u>	<u>(131,000)</u>
<b>Cash flows from financing activities:</b>		
Principal payments on long-term obligations	(71,000)	—
Proceeds from exercise of employee stock options and warrants	947,000	674,000
Proceeds from sale of common stock	4,396,000	—
Costs from sale of common stock	<u>(56,000)</u>	<u>—</u>
Net cash provided by financing activities	<u>5,216,000</u>	<u>674,000</u>
Net decrease in cash and cash equivalents	(2,523,000)	(10,021,000)
Cash and cash equivalents at beginning of period	<u>36,922,000</u>	<u>52,668,000</u>
Cash and cash equivalents at end of period	<u>\$ 34,399,000</u>	<u>\$ 42,647,000</u>





May 9, 2012

Dear Investors,

Management is focusing on delivering strong results in each of our three business areas and achieving the goals established for 2012, setting the foundation for leadership and growth in the cell therapy field. The following will detail accomplishments and updated information in each of the three categories.

### **Cardiovascular Disease Product Pipeline**

Six-month data from the European acute heart attack trial, APOLLO, was published in the peer-reviewed *Journal of the American College of Cardiology* during the first quarter. Manuscripts describing the long term (18-month) results for both the APOLLO and the PRECISE trials are in late stage review. Peer-reviewed publications of the data are anticipated later this year.

#### Claims Expansion for No-Option Chronic Myocardial Ischemia (CMI)

Our application to expand Celution® system CE Mark claims to include no-option CMI patients is under active review. This subset of heart failure patients is refractory to interventional, surgical and medical management. CE Mark expansion would enable us to sell into hospitals and allow physicians to offer a Celution®-based procedure to this select group of patients, either through private pay or special budget allocations ahead of formal reimbursement. Additionally, the updated ADVANCE trial described below will have 35 centers trained with Celution® and able to treat patients, all of which represent potential accounts should we receive expanded claims.

In the first quarter, we conducted multiple meetings with our governing regulatory authority and provided responses to requests for additional information. Many open items have now been resolved. There are three key open items remaining, including the details of a proposed post market patient registry, a request for additional supportive data to further assess the risk/benefit ratio of cell therapy in this patient population, and agreement on specific indications for use and claims. Our response to these remaining items will be submitted shortly, followed by a meeting in the upcoming weeks. Due to the complexity of the evaluation process, requests for additional information and the landmark importance of this first-in-class approval, we now anticipate the decision coming in the second half of the year. We are confident in our ability to supply our Notified Body with the requisite information to address the remaining open items.

#### ATHENA Trial

The U.S. ATHENA trial for refractory heart failure (including chronic myocardial ischemia patients) is ahead of schedule. We received FDA approval in January to begin the 45 patient, double blind, placebo-controlled trial. Five trial centers have been selected, including Texas Heart Institute and the Minneapolis Heart Institute. All sites were chosen based upon their experience in cell-based trials, academic and clinical leadership in interventional cardiology and their practice demographics, which includes their ability to rapidly recruit target patients. Patient enrollment will begin this quarter and is anticipated to be completed by mid-2013.

#### ADVANCE Trial

The pan-European ADVANCE pivotal trial for acute myocardial infarction is being amended. Thus far, complex and evolving tissue and cell therapy guidelines across Europe and within individual countries have negatively impacted our ability to bring new trial sites online. In recognition of the trends, we are revising the trial protocol to uniformly conform to each country's regulations, which primarily comprise implementing good manufacturing practices unique to each G5 nation, and to incorporate the latest knowledge from recent cell therapy trial outcomes.

Our changes are geared to meet current regulatory standards, improve the trial design and to expand the utility of the trial toward reimbursement. Other refinements include: longer-term analysis of cost-effectiveness data, modification of inclusion and exclusion criteria to accelerate enrollment and moving to a single dose vs. standard-of-care control design. The primary endpoint in the trial remains the reduction in infarct size as measured by MRI at six-months.

The updated protocol will be ready to submit to competent country authorities by June. Enrollment should resume in earnest as early as September 2012. We will provide an updated enrollment timeline at our next quarterly management update in August.

### **Commercial Business**

We commercialize several product lines into the soft tissue market across Europe, Asia-Pacific and the U.S. They include devices for soft tissue defect repair and aesthetics, cell and tissue storage solutions, and systems for cell-based translational research. Simultaneously, we are directing specific activities toward market access and reimbursement for breast reconstruction.

The 12-month data from RESTORE 2, the European multi-center breast reconstruction trial, was published in the peer-reviewed *European Journal of Surgical Oncology* during the quarter. This publication, together with the inclusion of the RESTORE procedure in the recently issued guidelines by the British Association of Plastic, Reconstructive and Aesthetic Surgeons, are two critical inputs in the application for a recommendation from the Medical Technology Advisory Committee (MTAC) of the UK's National Institute for Health and Clinical Excellence (NICE). Our MTAC application was recently submitted. Applicants are typically notified if they have been selected for full review within two to three months. If chosen to be included in the program, additional information will be required and a thorough evaluation will be conducted during a period of approximately ten months. We would then anticipate publication of their decision in the form of a guidance document during the first half of 2013.

Recommendation by NICE is primarily based on the technology's potential to provide significant benefit to patients or the UK National Healthcare System. If recommended, this designation could have considerable influence over the adoption and utilization of Cytori technology for breast cancer reconstruction both in the UK and potentially more broadly in Europe.

Based on first quarter sales and our sales funnel, we reaffirm our \$9 million product revenue target for 2012. First quarter product sales were \$1.5 million compared to \$1.4 million in the first quarter of 2011, an increase of 9%. As stated in the 2011 year-end release, 2012 sales are expected to be weighted toward the second half of the year. Our strategy to drive hospital-based selling and consumable utilization is working. Celution® consumable sales were the highest in the past five quarters and second highest in company history. In addition, we achieved record Puregraft® sales.

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## Operational and Financial Performance

For the quarter, Cytori achieved improvement in our operational efficiency and financial performance. Total operating expenses were reduced by 31% compared to the same period in 2011 (\$9.0 million vs. \$13.0 million). Correspondingly, operating cash burn was reduced by 27% with net cash used in operating activities of \$7.7 million in the quarter compared to \$10.6 million in the first quarter of 2011. The improvement in total operating expenses and net cash used in operating activities is due in part to reduced sales and marketing costs and slightly lower clinical trial expenditures.

We are actively negotiating strategic partnerships to develop and commercialize Celution® cell therapy for specific indications and markets. While a number of these transactions are progressing, management is particularly focused on closing one of the two most advanced opportunities, which we believe can be completed in the near term.

The company ended the first quarter with \$34.4 million in cash and cash equivalents plus \$1.4 million in accounts receivable. Recently, we terminated the financing agreement with Seaside 88. The Company raised approximately \$18 million through that agreement.

Cytori now has 46 issued patents with more than 75 additional applications under review. Our intellectual property position was strengthened during the quarter with the receipt of two U.S. patents including a composition patent for ADRC-enriched fat grafting for soft tissue applications, and a device-based patent for using cells to accelerate the healing of wounds. We anticipate our IP portfolio of issued patents worldwide will grow by at least 15% during the year.

## Summary

Significant clinical, regulatory, commercial and corporate accomplishments set the stage for a milestone-rich year. The key value drivers for 2012 that we have achieved or expect to achieve include the following:

2012 Milestones	Completed
Execute strategic partnership	
Approval to initiate ATHENA	P
Begin enrollment in ATHENA	
No-option chronic myocardial ischemia CE Mark expansion	
Puregraft® 850 FDA clearance and CE Mark	P
Publish RESTORE 2 12-month results	P
UK breast reconstruction medical technology assessment application	P
Publish APOLLO primary endpoints (6-months)	P
Publish APOLLO long term (18-month) outcomes	
Publish PRECISE primary endpoints (6-months)	
Publish PRECISE long term (18-month) outcomes	
\$9 million in product revenue	

Sincerely,



Christopher J. Calhoun

\*ADRCs, or adipose-derived regenerative cells, are the output of the Celution® system.

## Cautionary Statement Regarding Forward-Looking Statement

This shareholder letter includes forward-looking statements regarding events, trends and business prospects, which may affect our future operating results and financial position. Such statements, including, but not limited to, those regarding our ability to achieve our revenue growth targets, obtain European no-option chronic myocardial ischemia claims, obtain recommendation from the UK National Institute for Health for breast reconstruction, optimize and resume enrollment in the ADVANCE trial, obtain additional publications for APOLLO and PRECISE trials, begin enrollment in the ATHENA trial, and complete a strategic corporate partnership, are all subject to risks and uncertainties that could cause our actual results and financial position to differ materially. Some of these risks and uncertainties include, but are not limited to, risks related to our history of operating losses, the need for further financing and our ability to access the necessary additional capital for our business, inherent risk and uncertainty in the protection of intellectual property rights, regulatory uncertainties regarding the collection and results of clinical data, our ability to obtain sufficient data to support reimbursement, uncertainties relating to the success of our sales and marketing programs, changing and unpredictable regulatory environment, dependence on third party performance and the risk of natural disasters and other occurrences that may disrupt the normal business cycles in areas of our global operations, as well as other risks and uncertainties described under "Risk Factors" in Cytori's 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.