

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 12, 2014**

CYTORI THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

Delaware

(State or Other Jurisdiction of Incorporation)

001-34375

(Commission File
Number)

33-0827593

(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 12, 2014 Cytori Therapeutics, Inc. (Company) issued a press release announcing its financial results for the first quarter ended March 31, 2014. 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

Exhibit No.	Description
99.1	Cytori Therapeutics, Inc. Press Release, dated May 12, 2014 *

* 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.

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.

CYTORI THERAPEUTICS, INC.

Date: May 12, 2014

By: /s/ Mark E. Saad

Mark E. Saad
Chief Financial Officer



CYTORI THERAPEUTICS CONTACT

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Cytori Reports First Quarter 2014 Business and Financial Results

San Diego, CA, May 12, 2014 – Cytori Therapeutics (NASDAQ: CYTX) today reports its first quarter 2014 financial results and provides updates on clinical development and commercialization activities.

Cytori achieved total product and government contract revenues for the first quarter ended March 31, 2014 of \$1.4 million, compared to \$1.9 million for the same period in 2013. As a result of previously implemented revisions to the revenue recognition policy, product revenues do not include \$3.4 million in shipments to customers in the fourth quarter of 2013 and the first quarter of 2014, which are expected to be recognized as revenue in 2014. The Company did not record non-cash development revenue in the first quarter of 2014 as compared to \$1.8 million in the first quarter of 2013. Total net loss was \$10.4 million in the first quarter of 2014 compared with \$7.7 million in the same period of 2013. Cytori ended the first quarter of 2014 with \$12.8 million of cash and cash equivalents and \$3.6 million in accounts receivable.

Year-To-Date Highlights

- Expanded ATHENA I to ten sites including Swedish Medical Center in Seattle and Christ Hospital in Cincinnati, enrollment continues at current sites;
- Initiated enrollment in ATHENA II at the first site with the total site complement expanded up to 12;
- Published European PRECISE heart failure trial data in the *American Heart Journal*;
- Scheduled In-Process Review (IPR) meeting to review completed BARDA deliverables for June 10, 2014; and
- Expanded global patent portfolio to a total of 125 patents, including two cardiovascular disease patents in select EU countries and a U.S. patent for wound healing.

“Our ATHENA trial enrollment is trending higher with the site specific support we are providing and additional sites coming online soon,” said Dr. Marc Hedrick, President and CEO of Cytori. “In addition, our In-Process Review meeting with BARDA has been scheduled in June to review the data showing the successful completion of our base objectives. Executing on these two top corporate priorities and enhancing the financial strength of the Company are my primary near term objectives.”

Financial Performance

Product and contract revenues for the first quarter of 2014 were \$1.4 million, consisting of \$1.0 million in product revenues and \$0.4 million in contract revenues. This compares to \$1.9 million in combined product and contract revenues for the first quarter of 2013, consisting of \$1.4 million of product revenues and \$0.5 million of contract revenues. As a result of the revised revenue recognition policy, first quarter revenues do not include \$3.4 million of product orders shipped to customers in the fourth quarter of 2013 and in the first quarter of 2014. \$0.5 million of shipments from the fourth quarter were recognized in the first quarter of 2014 and an additional \$0.3 million of shipments in the first quarter were deferred. Cytori anticipates recognizing these remaining shipments as revenue in 2014. In the first quarter of 2013, the Company also recorded \$1.8 million in non-cash development revenue for which there was no equivalent in 2014. Gross profit was \$0.6 million in the first quarter of 2014 compared to \$0.6 million in the first quarter of 2013.

Total operating expenses rose from \$9.7 million in the first quarter of 2013 to \$10.6 million in the first quarter of 2014. Research and development expenses were \$4.3 million in the first quarter of 2014 compared with \$3.7 million in the first quarter of 2013. This increase is related largely to increased patient enrollment for the ATHENA trial and reimbursable activities related to the BARDA contract. Sales and marketing expenses declined to \$1.9 million from \$2.3 million in the first quarter of 2013 as a result of reductions in the 2013 headcount and other expenses in the U.S. and Europe. General and administrative expenses rose from \$3.8 million in the first quarter 2013 to \$4.3 million, largely as the result of \$0.8 million in one-time professional services charges and an increase in non-cash bad debt reserve related to 2012 sales.

“Following the management transition in April, we anticipate focusing on top strategic priorities and streamlining expenses throughout the year,” said Mark Saad, Chief Financial Officer. “Such changes will include the elimination of certain non-core activities and studies, reduction of certain infrastructure costs in Europe and Japan and non-transaction related professional services.”

Net loss was \$10.4 million, or (\$0.14) per share, for the first quarter of 2014 compared to \$7.7 million, or (\$0.11) per share, in the first quarter of 2013. Cytori ended the first quarter of 2014 with \$12.8 million of cash and cash equivalents and \$3.6 million in accounts receivable. The Company intends to raise additional cash in the near term to meet both operating and debt obligations and is in discussions with both financial and strategic parties.

Cardiovascular Disease

Cytori is presently enrolling patients in two prospective, multi-center, double-blind, randomized and placebo-controlled Phase I/II clinical trials investigating Cytori Cell Therapy for heart failure due to ischemic heart disease (the ATHENA I and II trials). Long term follow up data from the European PRECISE trial, the predecessor trial to ATHENA I and II, has been accepted for publication by the *American Heart Journal* and is currently available online. The PRECISE trial was a 27-patient, prospective, randomized, double-blind, placebo-controlled, feasibility trial. The publication showed 36 month safety and 18 month efficacy data, including sustained statistically significant improvements in cardiac functional capacity, as measured by maximum oxygen consumption (MVO₂), a measure of exercise capacity, at six and 18 months. Per the protocol, MVO₂ was measured only at six and 18 months.

In ATHENA I, ten trial centers have been approved by FDA and eight are initiated. Data is anticipated to be available approximately eight months following the completion of enrollment, anticipated to be later this year. The ATHENA II trial, which studies a higher cell dose in the same patient population as ATHENA I, is enrolling at the first site and has been expanded by FDA up to 12 sites. Top enrolling ATHENA I sites will transition immediately to ATHENA II once ATHENA I enrollment has reached 45 patients. Data from ATHENA II is anticipated to be available in 2015.

Thermal Burn & Radiation Injury: BARDA Contract Revenue

In September 2012, Cytori was awarded a master contract with the U.S. government for the development of Cytori Cell Therapy for thermal burns combined with radiation injury. Thus far, approximately \$4 million of that contract revenue has been received and the Company believes that the associated three base contract objectives have been met. Cytori and BARDA have scheduled an In-Process Review meeting on June 10, 2014 to consider expanded funding to Cytori under the contract. Favorable review from this meeting may lead to additional contract revenue for a U.S. clinical trial program in thermal burn injury, further support for ongoing development of the next generation Celution® System, and expanded preclinical studies. Additionally, Cytori is seeking to leverage data gathered as part of the BARDA project to date to enable additional contract opportunities for the Company.

Product Revenue

Cytori’s commercial activity focuses on surgeons and hospitals conducting clinical research in cell therapy. This market segment generates relevant clinical safety and efficacy data, which extends Cytori’s research and development pipeline, drives potential new corporate sponsored trials or business development opportunities with the goal of providing a positive contribution margin to Cytori. Cytori projects modest year-over-year sales growth in 2014 without an increase in annual sales related costs. 2014 activities associated with the Lorem Vascular partnership will largely relate to achieving Chinese regulatory approval with commercial efforts anticipated to follow in 2015. Cytori will provide updates on the future revenue implications of international activities as regulatory and commercial milestones are met.

Therapeutic pipeline

Cytori’s customers are conducting a number of early stage clinical studies that represent potential pipeline opportunities using Cytori Cell Therapy. Some of the most promising indications under evaluation include: (1) stress urinary incontinence in Japan, (2) ACL repair in Spain, and (3) scleroderma related sclerodactyly in Europe. Cytori intends to provide updates on these studies as they become available and is currently evaluating which of these opportunities should receive increased development support and emphasis.

Upcoming Milestones

During the remainder of 2014, Cytori intends to:

- Strengthen the balance sheet, lower expenses and narrow operating burn and negative contribution margin from product sales activities
- Complete ATHENA enrollment and transition to enrollment in ATHENA II
- Expand BARDA government contract
- File for Celution® System approval in China
- Focus pipeline activities on a few targeted indications that can be developed in a cost effective and timely manner
- Grow research product sales and increase contract related revenues

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: 37177533.

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

Cautionary Statement Regarding Forward-Looking Statements

This press release includes forward-looking statements that involve known and unknown risks and uncertainties. All statements, other than historical facts, including statements regarding the expected timing of the completion of enrollment of the ATHENA clinical trials, our ability to obtain expanded contract options with BARDA, our ability to leverage BARDA data for additional contract opportunities, our expectation of continuing demand from investigator initiated trial customers, our ability to reduce expenses, and our outlook and financial guidance for 2014 are forward looking statements. 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 our need to raise more cash in the future, our level of indebtedness and covenant restrictions under such indebtedness, 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 contract options, 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 Cytori's Securities and Exchange Commission Filings, including in its most recent annual and quarterly reports.

There may be events in the future that we are unable to predict, or over which we have no control, and our business, financial condition, results of operations and prospects may change in the future. We assume no responsibility to update or revise any forward-looking statements to reflect events, trends or circumstances after the date they are made unless we have an obligation under U.S. Federal securities laws to do so.

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

	As of March 31, 2014	As of December 31, 2013
Assets		
Current assets:		
Cash and cash equivalents	\$ 12,800,000	\$ 15,506,000
Accounts receivable, net of reserves of \$1,687,000 and of \$1,445,000 in 2014 and 2013, respectively	3,636,000	4,152,000
Inventories, net	4,225,000	3,694,000
Other current assets	1,391,000	1,225,000
Total current assets	22,052,000	24,577,000
Property and equipment, net	1,192,000	1,054,000
Restricted cash and cash equivalents	350,000	350,000
Other assets	2,412,000	2,812,000
Intangibles, net	9,494,000	9,345,000
Goodwill	3,922,000	3,922,000
Total assets	\$ 39,422,000	\$ 42,060,000
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable and accrued expenses	\$ 6,443,000	\$ 6,077,000
Current portion of long-term obligations, net of discount	5,241,000	3,191,000
Termination fee obligation	200,000	400,000
Puregraft divestiture obligation	388,000	547,000
Joint Venture purchase obligation	2,553,000	4,691,000
Total current liabilities	14,825,000	14,906,000
Deferred revenues	206,000	212,000
Long-term deferred rent and other	664,000	710,000
Long-term obligations, net of discount, less current portion	21,325,000	23,100,000
Total liabilities	37,020,000	38,928,000
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, \$0.001 par value; 5,000,000 shares authorized; -0- shares issued and outstanding in 2014 and 2013	—	—
Common stock, \$0.001 par value; 145,000,000 shares authorized; 75,458,551 and 71,305,375 shares issued and outstanding in 2014 and 2013, respectively	75,000	71,000
Additional paid-in capital	313,426,000	303,710,000
Accumulated other comprehensive loss	206,000	256,000
Accumulated deficit	(311,305,000)	(300,905,000)
Total stockholders' equity	2,402,000	3,132,000
Total liabilities and stockholders' equity	\$ 39,422,000	\$ 42,060,000

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

	For the Three Months Ended March 31,	
	2014	2013
Product revenues	\$ 1,031,000	\$ 1,392,000
Cost of product revenues	<u>421,000</u>	<u>756,000</u>
Gross profit	<u>610,000</u>	<u>636,000</u>
Development revenues:		
Development, related party	—	638,000
Development revenue	—	1,179,000
Government contracts and other	<u>403,000</u>	<u>549,000</u>
	<u>403,000</u>	<u>2,366,000</u>
Operating expenses:		
Research and development	4,292,000	3,720,000
Sales and marketing	1,928,000	2,257,000
General and administrative	4,340,000	3,846,000
Change in fair value of warrant liability	—	(334,000)
Change in fair value of option liability	—	250,000
Total operating expenses	<u>10,560,000</u>	<u>9,739,000</u>
Operating loss	<u>(9,547,000)</u>	<u>(6,737,000)</u>
Other income (expense):		
Interest income	2,000	—
Interest expense	(941,000)	(709,000)
Other income (expense), net	86,000	(173,000)
Equity loss from investment in joint venture	—	(48,000)
Total other income (expense)	<u>(853,000)</u>	<u>(930,000)</u>
Net loss	<u>\$ (10,400,000)</u>	<u>\$ (7,667,000)</u>
Other comprehensive income (loss) – foreign currency translation adjustments	<u>(50,000)</u>	<u>(110,000)</u>
Net comprehensive loss	<u>\$ (10,450,000)</u>	<u>\$ (7,777,000)</u>
Basic and diluted net loss per common share	<u>\$ (0.14)</u>	<u>\$ (0.11)</u>
Basic and diluted weighted average common shares	<u>74,102,396</u>	<u>66,990,950</u>

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

	For the Three Months Ended	
	March 31,	
	2014	2013
Cash flows from operating activities:		
Net loss	\$ (10,400,000)	\$ (7,667,000)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	160,000	200,000
Amortization of deferred financing costs and debt discount	281,000	192,000
Increase (decrease) in allowance for doubtful accounts	465,000	87,000
Change in fair value of warrant liability	—	(334,000)
Change in fair value of option liability	—	250,000
Stock-based compensation	687,000	873,000
Equity loss from investment in joint venture	—	48,000
Increases (decreases) in cash caused by changes in operating assets and liabilities:		
Accounts receivable	49,000	868,000
Inventories	(551,000)	(477,000)
Other current assets	(172,000)	(28,000)
Other assets	379,000	(974,000)
Accounts payable and accrued expenses	351,000	(523,000)
Deferred revenues, related party	—	(638,000)
Deferred revenues	(165,000)	(1,203,000)
Long-term deferred rent	(46,000)	32,000
	<u>(8,962,000)</u>	<u>(9,294,000)</u>
Net cash used in operating activities	<u>(8,962,000)</u>	<u>(9,294,000)</u>
Cash flows from investing activities:		
Purchases of property and equipment	(287,000)	(81,000)
Expenditures for intellectual property	(155,000)	—
License agreement termination fee	(200,000)	(200,000)
	<u>(642,000)</u>	<u>(281,000)</u>
Net cash used in investing activities	<u>(642,000)</u>	<u>(281,000)</u>
Cash flows from financing activities:		
Principal payments on long-term obligations	—	(2,485,000)
Joint Venture purchase payments	(2,138,000)	—
Proceeds from exercise of employee stock options and warrants	33,000	—
Proceeds from sale of common stock	9,000,000	3,001,000
Costs from sale of common stock	—	(184,000)
	<u>6,895,000</u>	<u>332,000</u>
Net cash provided by financing activities	<u>6,895,000</u>	<u>332,000</u>
Effect of exchange rate changes on cash and cash equivalents	<u>3,000</u>	<u>(70,000)</u>
Net decrease in cash and cash equivalents	<u>(2,706,000)</u>	<u>(9,313,000)</u>
Cash and cash equivalents at beginning of period	<u>15,506,000</u>	<u>25,717,000</u>
Cash and cash equivalents at end of period	<u>\$ 12,800,000</u>	<u>\$ 16,404,000</u>
Supplemental disclosure of cash flows information:		
Cash paid during period for:		
Interest	\$ 659,000	\$ 520,000

