

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): **March 7, 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 March 7, 2013 Cytori Therapeutics, Inc. (Company) issued a press release announcing its financial results for the year ended December 31, 2012. 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 March 7, 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.

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: March 7, 2013

CYTORI THERAPEUTICS, INC.

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

Cytori Reports 2012 Business and Financial Results; Provides Outlook for 2013

- U.S. ATHENA trial on track for mid-2013 completion of enrollment with 1st data in 1H 2014 -
 - BARDA: Contract activities underway -
 - Achieved \$9.1 million in product and contract revenue for 2012 -
- Recent approvals in Japan and EU to drive continued revenue growth in 2013 and beyond -

SAN DIEGO—Cytori Therapeutics (NASDAQ: CYTX) reports its 2012 business and financial results and provides an outlook for 2013. The Company achieved record total revenues for the year and fourth quarter ended December 31, 2012 of \$14.5 million and \$7.3 million, respectively, compared to \$10.0 million and \$2.8 million, respectively, for the same periods in 2011.

Milestone Highlights

Cytori's 2012 and year-to-date milestones include the following:

- Initiated enrollment in the ATHENA U.S. refractory heart failure trial; all six centers are actively screening patients, enrollment is on track to be complete mid-summer
- Awarded contract with BARDA, a division of the U.S. Health and Human Services, worth up to \$106 million to develop a novel cell-based treatment of thermal burns combined with radiation injury
- Obtained Class I device clearance in Japan, opening the Japanese market and increasing fourth quarter revenues
- Opened EU vascular market with CE Mark claims for intravascular delivery (Intravase®)
- Expanded CE Mark claims for multiple indications including cryptoglandular fistulae and tissue ischemia
- Amended and resumed enrollment in the ADVANCE European heart attack trial
- Achieved \$9.1 million in product and contract revenue, including a record \$4.3 million in the fourth quarter
- Grew Celution® and StemSource® System shipments by 46% year-over-year
- Increased patent portfolio year-over-year by 36% with the issuance of 15 patents worldwide, bringing the total number of global patents to 57 with 75 additional applications under review
- Recruited Steven Kesten, M.D., as Executive Vice President and Chief Medical Officer
- Raised \$21.4 million in net proceeds from public offering of shares, including \$2.8 million in net proceeds in January 2013 from the exercise of the full over-allotment option

“We made substantial progress in 2012 across three key areas of our business: our cardiac pipeline, our recently awarded government contract and our commercial operations,” said Chris Calhoun, Chief Executive Officer of Cytori. “The specific developments include the initiation of the ATHENA trial, a significant contract with the Biomedical Advanced Research Authority (BARDA) related to thermal burns, and growing revenue opportunities through important European and Japanese regulatory approvals, which was reflected in strong fourth quarter sales and which we see significantly contributing to revenue growth in 2013 and beyond.

“These three areas will be the priorities we intend to focus on in the next 12 to 18 months. We believe these objectives provide the greatest potential to impact shareholder value and make the most efficient use of our capital. Given the platform nature of our products, there are several other compelling medical applications and geographies in which we have made progress. We expect to move these opportunities forward as additional resources become available with an emphasis on grant and contract funding, organic customer demand or partnerships.”

Financial Performance and Guidance

Product and contract revenues more than doubled in the fourth quarter of 2012 to \$4.3 million compared to \$2.1 million for the same period in 2011. For the full year 2012, we saw 14% growth in product and contract revenues to \$9.1 million as compared to \$8.0 million for the prior year. The increase in product revenue in the fourth quarter (\$4.0 million in 2012 compared to \$2.1 million in 2011) was primarily a result of sales under the Class I device clearance in Japan achieved in September 2012.

Cytori recognized \$0.4 million in contract revenue related to the BARDA agreement for the year and fourth quarter of 2012 for which there was no comparable revenue recognized in 2011. Total development revenues, including contract revenue, were \$5.8 million and \$3.4 million for the year and fourth quarter of 2012 compared to \$2.0 million and \$0.8 million in the same periods of 2011. The balance of development revenue is the result of the recognition of deferred revenue in connection with the Astellas 2010 equity agreement and the recognition of clinical and regulatory milestones related to the Company's Joint Venture with Olympos Corporation.

Gross profit was \$2.6 million for the fourth quarter ended December 31, 2012, compared to \$1.1 million in the fourth quarter in 2011, representing a 126% increase in gross profit and exceeding sales and marketing expenses in the quarter by \$0.5 million. Gross profit was \$4.7 million for the full year 2012 as compared to \$4.1 million in 2011.

Research and development expenses were \$13.6 million and \$4.0 million for the year and fourth quarter ended December 31, 2012, compared to \$10.9 million and \$2.0 million for the same periods in 2011. This planned increase was principally associated with the initiation of the ATHENA trial. In contrast, sales, general and administrative expenses were reduced to \$25.2 million and \$6.3 million for the year and fourth quarter ended December 31, 2012, compared to \$28.3 million and \$6.5 million for the respective periods in 2011. The decrease in SG&A expenses was the result of planned reductions in expenses based on the establishment of a more efficient commercial operations structure.

Net loss was \$32.3 million, or (\$0.55) per share, and \$3.8 million, or (\$0.06) per share, for the year and fourth quarter ended 2012, respectively. This compares to \$32.5 million, or (\$0.61) per share, and \$6.9 million, or (\$0.12) per share for the same periods of 2011, respectively. Net loss for year end 2012 includes a net non-cash charge of \$0.1 million compared to a net non-cash credit of \$3.6 million in 2011. Net non-cash charges include the change in the fair value of warrant and option liabilities.

At the end of 2012, Cytori had \$25.7 million of cash and cash equivalents and \$3.9 million of accounts receivable, net. In addition, in January 2013 the Company received \$2.8 million in net proceeds from the exercise of the over-allotment option as part of the public equity offering Cytori executed in December 2012.

"We are focusing our variable expenditures on key areas that are expected to provide substantial near and medium term value," said Mark Saad, Chief Financial Officer. "Our greatest single investment will be the U.S. ATHENA trial, for which we expect the first data readout in the first half of 2014. We believe the BARDA contract represents a potentially fully funded pathway to U.S. commercialization with a near term opportunity to qualify for the next option phases within twelve months. And lastly, we expect to accelerate revenue growth in 2013 based on recent regulatory approvals to achieve at least \$15 million in combined product and contract revenue, while maintaining sales, general and administrative expenses at their current levels. Similar to 2012, the majority of the total revenue estimate is expected to be achieved in the second half of the year."

Cardiovascular Disease Pipeline

The ATHENA trial is Cytori's primary clinical focus in 2013. For this trial, all six centers have received institutional review board approval to begin screening and enrolling patients. We believe low screen failure rates and positive feedback from investigators have contributed to relatively rapid enrollment per active site thus far. The trial currently remains on track for completion of enrollment by mid-summer with six month results anticipated in the first half of 2014.

In 2012, Cytori amended the ADVANCE trial and enrolled patients across a small number of European trial centers. The Company is encouraged by the long term data from the pilot trial APOLLO, which led to the initiation of ADVANCE. 15 patients have been enrolled in ADVANCE to date. In light of the required resources to complete enrollment in an accelerated fashion and competing corporate priorities at this time, Cytori is prepared only to commit a minimal level of investment in ADVANCE for 2013. The goal for 2013 is to bring the total ADVANCE enrollment to 25 patients with an interim analysis to be performed after the first 72 patients.

Thermal Burns Combined with Radiation Injury

We believe Cytori's contract with BARDA provides a potentially fully funded path to market and a likely customer for Cytori technology, the U.S. government. In the fourth quarter, the first quarter under contract, Cytori recognized \$0.4 million in contract revenue toward the achievement of contract deliverables including development of the next-generation Celution® device. Cytori expects to achieve proof-of-concept milestones as required under the contract in the first quarter of 2014.

Revenue Growth

The commercial operations in 2012 delivered by increasing revenues despite the implementation of substantial cost reductions:

- Total product and contract revenues grew 14% year-over-year, with \$4.4 million coming from Japan
- System shipments grew 46% year-over-year, due mostly to the Class I device clearance in Japan in September 2012
- Puregraft® sales grew 46% in 2012 during which time more than 5,000 units were shipped
- Demonstrated leverage of commercial infrastructure as fourth quarter gross profit of \$2.6 million exceeded sales and marketing expenses of \$2.1 million

In the second half of 2012, we achieved Class I device clearance in Japan. This contributed to an increase in total product sales in the fourth quarter of 2012 based on demand that has continued into 2013. Demand for Cytori's products as a result of this approval is coming primarily from hospitals seeking to perform self or government funded investigator-initiated research or trials with Celution® cell therapy. At present, there are 40 investigator-initiated clinical studies in development, in process or now complete utilizing Cytori's cell therapy technology. Future customers will include groups beginning new investigator-initiated trials and current customers expanding existing studies involving more centers and patients and a related increase in systems and consumables. Reflective of this model is a stress urinary incontinence pilot study that was approved to begin in May 2011 at Nagoya University. The University was recently awarded a ¥500 million (approximately \$5 million) grant from the Ministry of Health, Labour and Welfare (MHLW) to fund a multi-center trial that we believe could lead to approval and reimbursement for Cytori's cell therapy for that indication.

In 2012, Cytori expanded its CE Mark to include treatment of ischemic tissue and recently (February 2013) received certification of its Intravase® product specifically for the safe infusion of ADRCs into the intravascular system. These expanded certifications enable commercial sales of Celution® for ischemic tissue and vascular delivery. The ongoing commercial launch will target ADVANCE centers as well as other select hospitals in Europe and other regions that recognize the CE Mark. Further claims expansion and reimbursement is expected upon completion of ATHENA, a subsequent U.S. pivotal study and further clinical experience, including registries, in key countries.

Upcoming Milestones

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

- Complete enrollment in the ATHENA trial in mid-summer; six month data in the first half of 2014
- Achieve proof-of-concept under the first option of the BARDA contract, which will qualify Cytori for up to \$56 million in additional development funding
- Publish the 18 month outcomes from the PRECISE European refractory heart failure trial
- Continue to strengthen the Company's patent position
- Increase product and contract revenue by at least 65% (at least \$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: 11509895.

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 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 the Nagoya University trial to lead to approval and reimbursement of our cell therapy in Japan, our ability to pursue additional grant funding and partnership opportunities, our establishment of a patient registry, 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 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.

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

	As of December 31,	
	2012	2011
Assets		
Current assets:		
Cash and cash equivalents	\$ 25,717,000	\$ 36,922,000
Accounts receivable, net of reserves of \$278,000 and of \$474,000 in 2012 and 2011, respectively	3,926,000	2,260,000
Inventories, net	3,175,000	3,318,000
Other current assets	1,161,000	837,000
Total current assets	33,979,000	43,337,000
Property and equipment, net	2,174,000	1,711,000
Restricted cash and cash equivalents	350,000	350,000
Investment in joint venture	85,000	250,000
Other assets	2,740,000	1,772,000
Intangibles, net	—	192,000
Goodwill	3,922,000	3,922,000
Total assets	\$ 43,250,000	\$ 51,534,000
Liabilities and Stockholders' Equity (Deficit)		
Current liabilities:		
Accounts payable and accrued expenses	\$ 7,411,000	\$ 5,334,000
Current portion of long-term obligations	9,784,000	2,487,000
Warrant liability, current	418,000	—
Total current liabilities	17,613,000	7,821,000
Deferred revenues, related party	638,000	3,520,000
Deferred revenues	2,635,000	5,244,000
Warrant liability, long-term	—	627,000
Option liability	2,250,000	1,910,000
Long-term deferred rent	756,000	504,000
Long-term obligations, net of discount, less current portion	12,903,000	21,962,000
Total liabilities	36,795,000	41,588,000
Commitments and contingencies		
Stockholders' equity (deficit):		
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; 65,914,050 and 56,594,683 shares issued and outstanding in 2012 and 2011, respectively	66,000	57,000
Additional paid-in capital	281,117,000	252,338,000
Accumulated deficit	(274,728,000)	(242,449,000)
Total stockholders' equity	6,455,000	9,946,000
Total liabilities and stockholders' equity	\$ 43,250,000	\$ 51,534,000

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

	For the Three Months Ended December 31,		For the Twelve Months Ended December 31,	
	2012	2011	2012	2011
Product revenues	\$ 3,967,000	\$ 2,076,000	\$ 8,709,000	\$ 7,983,000
Cost of product revenues	1,412,000	944,000	4,000,000	3,837,000
Gross profit	2,555,000	1,132,000	4,709,000	4,146,000
Development revenues:				
Development, related party	469,000	761,000	2,882,000	1,992,000
Development	2,529,000	—	2,529,000	—
Government contract and other	360,000	1,000	381,000	21,000
	3,358,000	762,000	5,792,000	2,013,000
Operating expenses:				
Research and development	4,013,000	1,956,000	13,628,000	10,904,000
Sales and marketing	2,081,000	3,000,000	9,488,000	13,560,000
General and administrative	4,183,000	3,498,000	15,672,000	14,727,000
Change in fair value of warrant liability	(1,453,000)	(646,000)	(209,000)	(4,360,000)
Change in fair value of option liability	(150,000)	60,000	340,000	740,000
Total operating expenses	8,674,000	7,868,000	38,919,000	35,571,000
Operating loss	(2,761,000)	(5,974,000)	(28,418,000)	(29,412,000)
Other income (expense):				
Interest income	1,000	3,000	4,000	9,000
Interest expense	(804,000)	(861,000)	(3,386,000)	(2,784,000)
Other income (expense), net	(223,000)	(18,000)	(314,000)	(55,000)
Equity loss from investment in joint venture	(36,000)	(56,000)	(165,000)	(209,000)
Total other income (expense)	(1,062,000)	(932,000)	(3,861,000)	(3,039,000)
Net loss	\$ (3,823,000)	\$ (6,906,000)	\$ (32,279,000)	\$ (32,451,000)
Basic and diluted net loss per common share	\$ (0.06)	\$ (0.12)	\$ (0.55)	\$ (0.61)
Basic and diluted weighted average common shares	59,581,607	55,664,792	58,679,687	53,504,030

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

	For the Years Ended December 31,	
	2012	2011
Cash flows from operating activities:		
Net loss	\$ (32,279,000)	\$ (32,451,000)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	933,000	855,000
Amortization of deferred financing costs and debt discount	930,000	711,000
Increase in allowance for doubtful accounts	144,000	483,000
Change in fair value of warrants	(209,000)	(4,360,000)
Change in fair value of option liability	340,000	740,000
Stock-based compensation	3,904,000	3,316,000
Equity loss from investment in joint venture	165,000	209,000
Increases (decreases) in cash caused by changes in operating assets and liabilities:		
Accounts receivable	(1,810,000)	(670,000)
Inventories	143,000	60,000
Other current assets	(324,000)	(3,000)
Other assets	(74,000)	(1,206,000)
Accounts payable and accrued expenses	1,183,000	(1,436,000)
Deferred revenues, related party	(2,882,000)	(1,992,000)
Deferred revenues	(2,609,000)	315,000
Long-term deferred rent	252,000	106,000
	<u>(32,193,000)</u>	<u>(35,323,000)</u>
Cash flows from investing activities:		
Purchases of property and equipment	(1,204,000)	(560,000)
	<u>(1,204,000)</u>	<u>(560,000)</u>
Cash flows from financing activities:		
Principal payments on long-term obligations	(2,692,000)	(4,529,000)
Proceeds from long-term obligations	—	9,444,000
Debt issuance costs and loan fees	—	(719,000)
Proceeds from exercise of employee stock options and warrants and stock purchase plan	1,413,000	2,849,000
Proceeds from sale of common stock	24,953,000	13,286,000
Costs from sale of common stock	(1,482,000)	(194,000)
	<u>22,192,000</u>	<u>20,137,000</u>
Net (decrease) increase in cash and cash equivalents	(11,205,000)	(15,746,000)
Cash and cash equivalents at beginning of year	<u>36,922,000</u>	<u>52,668,000</u>
Cash and cash equivalents at end of year	<u>\$ 25,717,000</u>	<u>\$ 36,922,000</u>

