

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): **November 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 November 7, 2013 Cytori Therapeutics, Inc. (Company) issued a press release announcing its financial results for the third quarter ended September 30, 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

| Exhibit No. | Description |
|--------------------|---|
| 99.1 | Cytori Therapeutics, Inc. Press Release, dated November 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.

CYTORI THERAPEUTICS, INC.

Date: November 7, 2013

By: /s/ Mark E. Saad

Mark E. Saad
Chief Financial Officer



November 7, 2013

Cytori Reports Nine Month and Third Quarter 2013 Business and Financial Results

San Diego, CA - Cytori Therapeutics (NASDAQ: CYTX) today reports its nine month and third quarter 2013 financial results and provides updates on clinical development, commercialization and corporate development activities.

Total revenue for the nine months and quarter ended September 30, 2013 were \$8.7 million and \$2.7 million, respectively. Net loss for the nine months and quarter ended September 30, 2013 was \$16.1 million and \$5.3 million, respectively.

Milestone Highlights

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

- Formed a commercialization partnership for select emerging markets, including \$24 million in equity, a long term supply agreement with an initial \$7 million product purchase commitment, and up to \$500 million in commercial milestones
- Under the BARDA contract, the Company made significant progress toward the achievement of critical preclinical milestones needed to seek up to \$56 million in additional funding
- Expanded the number of actively recruiting centers in the ATHENA clinical trial program to seven and identified additional sites for ATHENA II
- Received approvals for the Celution® System in Australia and Singapore
- Awarded seven patents, including a methods patent for using adipose-derived regenerative cell therapy for treating renal disease and licensed exclusive rights to a patent related to adipose-derived regenerative cells for the treatment of autoimmune diseases

"The recently signed partnership significantly strengthens our balance sheet, accelerates the expansion of our international cardiovascular business, and positions us for future revenue growth," said Christopher J. Calhoun, Cytori's Chief Executive Officer. "Year-to-date, we continued to make progress globally in our heart failure program and U.S. trials and are close to achieving all three objectives under the BARDA contract to qualify for the next phase worth up to \$56 million."

Financial Performance

Total revenues for the first nine months of 2013 were \$8.7 million compared to \$7.2 million for the first nine months of 2012. Total product and contract revenues for the first nine months of 2013 were \$6.9 million, which consisted of \$4.4 million in product sales and \$2.5 million in contract revenue. Total product and contract revenues for the first nine months of 2012 were \$4.8 million, which consisted of \$4.7 million in product sales and negligible contract revenues. Total product and cash contract revenues for the third quarter of 2013 were \$2.7 million, compared to \$1.3 million in the third quarter of 2012. Based on projected sales in the fourth quarter of 2013, Cytori reiterates its 2013 revenue objective of \$14 million in combined product and contract revenue.

Gross profit for the first nine months and quarter ended September 30, 2013 were \$2.1 million and \$0.7 million respectively compared to \$2.2 million and \$0.6 million respectively for the first nine months and quarter ended September 30, 2012.

Research and development expenses for the first nine months and quarter ended September 30, 2013 were \$12.0 million and \$4.1 million compared to \$9.6 million and \$3.6 million respectively for the first nine months and quarter ended September 30, 2012. The planned increase in research and development expenses is predominately related to reimbursed services performed under the BARDA contract, in addition to increased clinical trial costs. Sales, general and administrative expenses for the first nine months and quarter ended September 30, 2013 were \$18.7 million and \$6.1 million respectively compared to \$18.9 million and \$6.2 million respectively for the first nine months and quarter ended September 30, 2012.

Net loss for the first nine months of 2013 was \$16.1 million, or (\$0.24) per share, compared to \$28.5 million, or (\$0.49) per share, in the first nine months of 2012. Net loss for the third quarter of 2013 was \$5.3 million, or (\$0.08) per share, compared to \$11.2 million, or (\$0.19) per share, in the third quarter of 2012. The reduction of net loss for the first nine months of 2013 is predominately attributable to gains totaling \$9.3 million from the sale of Puregraft® in the third quarter of 2013 and from the gain on previously held equity interest in the Olympus-Cytori Joint Venture in the second quarter of 2013.

Cytori ended the third quarter of 2013 with \$10.2 million of cash and cash equivalents and \$2.6 million in accounts receivable. Subsequent to the end of the quarter, Cytori entered into a strategic partnership that will bring in \$24 million in committed capital before the end of the year from the partnering agreement. The cash is expected to enable the Company to meet potential 2014 milestones such as achieving options under the BARDA contract and presentation of initial ATHENA data.

Strategic Partnership

Emerging Markets

Cytori entered a partnership with Lorem Vascular subsequent to the end of the quarter to commercialize Cytori Cell Therapy in China, Hong Kong, Malaysia, Singapore and Australia. Under the agreement, Cytori and Lorem Vascular entered into a long term supply agreement for a 30-year exclusive license to Cytori Cell Therapy for cardiovascular disease, renal failure, diabetes, and all other indications, except alopecia and aesthetics, in the licensed territories. Pursuant to our agreement, Lorem Vascular will pay up to \$500 million in commercial milestones and will initially commit to order \$7 million in Celution® devices and consumables. Lorem Vascular will place its first order for \$2 million of Cytori Cell Therapy products immediately, followed by a \$5 million order to be placed upon regulatory approval in China, anticipated to be received in 2014. In a related transaction, Cytori will receive \$24 million in exchange for the sale of 8 million shares of Cytori common stock at \$3.00 per share. Equity purchased will be closed in two installments; a \$12 million payment has been received and a second \$12 million payment that will be made by the end of 2013. In addition, one board seat will be granted to Mr. K.T. Lim, Chairman of Lorem Vascular.

Cardiovascular Disease Pipeline

Heart Failure: ATHENA I & II Trials

ATHENA I is a prospective, multi-center, double-blind, randomized and placebo-controlled clinical trial investigating Cytori Cell Therapy for heart failure due to ischemic heart disease. ATHENA I will enroll 45 patients at a dose of 0.4MM cells/kg at eight centers. During the first quarter of 2014, the Company expects to initiate ATHENA II enrollment of 45 patients at a higher dose of 0.8MM cells/kg at up to ten trial centers. During the recent quarter, Cytori took action to modify the ATHENA protocols to enhance enrollment and safety, streamline the screening process, better align ATHENA I and II trials and facilitate the process of obtaining approval of an anticipated U.S. pivotal trial. Enrollment, which was deferred during the IRB approval process, has now resumed at seven of eight centers. Our updated projection is that ATHENA I should be fully enrolled by April 2014 and the first patient in ATHENA II may be enrolled in January 2014. Presentation of ATHENA I top-line six-month data is expected to be announced in the second half of 2014, full enrollment of ATHENA II is anticipated in the second half of 2014 and initiation of the U.S. pivotal trial in 2015.

Acute Myocardial Infarction: ADVANCE Trial

ADVANCE is the Company's European clinical trial for acute myocardial infarction (heart attacks). Cytori previously announced plans to discontinue ADVANCE following a review of the Company's global cardiovascular strategy, resource utilization and development priorities. The trial has enrolled 23 patients who will continue to be followed according to the trial protocol.

BARDA Contract

Cytori's contract with BARDA, a division of the U.S. Department of Health and Human Services, may 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 thermal burn injuries. The initial phase of the contract includes approximately \$5 million in research funding to achieve three principal objectives. Attaining all three objectives qualifies Cytori to seek a second phase of the contract worth up to \$56 million in additional funding toward product development and clinical trials.

Cytori has submitted a final report demonstrating completion of the first objective, which was validation of the performance of the next-generation Celution® System. During the third quarter, Cytori submitted data to BARDA demonstrating substantial progress on the second and third objectives. On the basis of this progress the Company is in the process of accelerating the scheduling of an In-Process Review (IPR) meeting with BARDA early in the first quarter of 2014. Favorable review at this meeting may lead to funding of up to \$32.6 million over three years for Option 1. This would fund a pilot stage clinical trial program in thermal burn injury, ongoing development of the next generation Celution® System, and any FDA-required preclinical studies. Cytori anticipates a second IPR meeting on schedule for Option 3. Option 3 is valued at up to \$23.4 million over approximately four years.

Commercial Sales Efforts

Cytori's sales efforts continue to focus primarily on researchers performing investigator-initiated and sponsored studies. This supports the Company's strategy of facilitating the development of additional therapeutic applications for its cell therapy. For the fourth quarter of 2013 and into 2014, product revenue growth will be driven by expanded research and general clinical use based on recent regulatory approvals in Japan, Europe, and Asia Pacific, planned international registration studies, and the aforementioned strategic partnership.

Specifically, during the third quarter, Cytori received notice from the Australian Therapeutic Goods Administration (TGA) that the Celution® System was approved for commercial use through inclusion on the Australian Registry of Therapeutic Goods. Additionally, the Celution® System was approved subsequent to the end of the quarter in Singapore and Cytori has registered the Celution® System for commercial sale in New Zealand.

Upcoming Milestones

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

- Complete enrollment in the ATHENA I and II trials
- Report six-month outcomes from the ATHENA trial
- Achieve proof-of-concept milestones in the BARDA contract and qualify Cytori for up to \$56 million in additional development funding
- Obtain product registration for the Celution® System in China
- Achieve product and contract revenue objectives
- Publish the long term outcomes from the PRECISE European chronic ischemic heart failure trial

Management Conference Call Webcast

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: 95080960.

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 the end of the first quarter of 2014 with six month results in the second half of 2014, full enrollment in ATHENA II in 2014 and initiation of a pivotal trial in 2015, our ability to meet the BARDA proof-of-concept milestones by the first quarter of 2014 and conduct a successful In-Process Review meeting, our expectation of continuing demand from investigator-initiated trial customers, our expectation of product revenue growth based on recent regulatory approvals including Class I registration in Japan, expanded Celution® System CE Mark clearance in Europe for intravascular delivery and tissue ischemia, and approvals and country registrations in other regions throughout the world, our ability to meet our product and contract revenue objectives, our acceleration and expansion of our international cardiovascular business, and our publication of 18-month trial outcomes from the PRECISE trial. 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

Investor Relations Media

Tom Baker Megan McCormick

tbaker@cytori.com mmccormick@cytori.com

+1.858.875.5258 +1.858.875.5279

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

| | As of September 30, 2013 | As of December 31, 2012 |
|---|---|--|
| Assets | | |
| Current assets: | | |
| Cash and cash equivalents | \$ 10,205,000 | \$ 25,717,000 |
| Accounts receivable, net of reserves of \$1,218,000 and of \$278,000 in 2013 and 2012, respectively | 2,622,000 | 3,926,000 |
| Inventories, net | 4,138,000 | 3,175,000 |
| Other current assets | 1,128,000 | 1,161,000 |
| Total current assets | 18,093,000 | 33,979,000 |
| Property and equipment, net of accumulated depreciation of \$9,131,000 and of \$8,609,000 in 2013 and 2012, respectively | 1,550,000 | 2,174,000 |
| Restricted cash and cash equivalents | 350,000 | 350,000 |
| Investment in joint venture | — | 85,000 |
| Other assets | 1,962,000 | 2,740,000 |
| Intangibles, net | 9,345,000 | — |
| Goodwill | 3,922,000 | 3,922,000 |
| Total assets | \$ 35,222,000 | \$ 43,250,000 |
| Liabilities and Stockholders' Equity | | |
| Current liabilities: | | |
| Accounts payable and accrued expenses | \$ 5,471,000 | \$ 7,411,000 |
| Current portion of long-term obligations, net of discount | 1,193,000 | 9,784,000 |
| Termination fee obligation | 600,000 | — |
| Puregraft divestiture obligation | 608,000 | — |
| Joint Venture purchase obligation | 4,772,000 | — |
| Warrant liability | — | 418,000 |
| Total current liabilities | 12,644,000 | 17,613,000 |
| Deferred revenues, related party | — | 638,000 |
| Deferred revenues | 190,000 | 2,635,000 |
| Option liability | — | 2,250,000 |
| Long-term deferred rent and other | 754,000 | 756,000 |
| Long-term obligations, net of discount, less current portion | 24,822,000 | 12,903,000 |
| Total liabilities | 38,410,000 | 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; 67,270,466 and 65,914,050 shares issued and outstanding in 2013 and 2012, respectively | 67,000 | 66,000 |
| Additional paid-in capital | 287,752,000 | 281,117,000 |
| Accumulated other comprehensive loss | (142,000) | — |
| Accumulated deficit | (290,865,000) | (274,728,000) |
| Total stockholders' (deficit) equity | (3,188,000) | 6,455,000 |
| Total liabilities and stockholders' equity | \$ 35,222,000 | \$ 43,250,000 |

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

| | For the Three Months Ended September 30, | | For the Nine Months Ended September 30, | |
|--|---|-----------------|--|-----------------|
| | 2013 | 2012 | 2013 | 2012 |
| Product revenues | \$ 1,616,000 | \$ 1,314,000 | \$ 4,416,000 | \$ 4,741,000 |
| Cost of product revenues | 931,000 | 703,000 | 2,296,000 | 2,588,000 |
| Gross profit | 685,000 | 611,000 | 2,120,000 | 2,153,000 |
| Development revenues: | | | | |
| Development, related party | — | — | 638,000 | 2,413,000 |
| Development revenue | — | — | 1,179,000 | — |
| Government contracts and other | 1,095,000 | 2,000 | 2,503,000 | 21,000 |
| | 1,095,000 | 2,000 | 4,320,000 | 2,434,000 |
| Operating expenses: | | | | |
| Research and development | 4,123,000 | 3,555,000 | 11,992,000 | 9,615,000 |
| Sales and marketing | 1,786,000 | 2,450,000 | 6,453,000 | 7,406,000 |
| General and administrative | 4,332,000 | 3,777,000 | 12,225,000 | 11,489,000 |
| Change in fair value of warrant liability | — | 863,000 | (418,000) | 1,244,000 |
| Change in fair value of option liability | — | 300,000 | (2,250,000) | 490,000 |
| Total operating expenses | 10,241,000 | 10,945,000 | 28,002,000 | 30,244,000 |
| Operating loss | (8,461,000) | (10,332,000) | (21,562,000) | (25,657,000) |
| Other income (expense): | | | | |
| Loss on asset disposal | — | — | (257,000) | — |
| Loss on debt extinguishment | — | — | (708,000) | — |
| Interest income | 1,000 | — | 2,000 | 3,000 |
| Interest expense | (1,094,000) | (857,000) | (2,456,000) | (2,582,000) |
| Other income (expense), net | (96,000) | (17,000) | (392,000) | (91,000) |
| Gain on Puregraft divestiture | 4,392,000 | — | 4,392,000 | — |
| Gain on previously held equity interest in Joint Venture | — | — | 4,892,000 | — |
| Equity loss from investment in joint venture | — | (42,000) | (48,000) | (128,000) |
| Total other income (expense) | 3,203,000 | (916,000) | 5,425,000 | (2,798,000) |
| Net loss | \$ (5,258,000) | \$ (11,248,000) | \$ (16,137,000) | \$ (28,455,000) |
| Other comprehensive income (loss) – foreign currency translation adjustments | (108,000) | — | (142,000) | — |
| Net comprehensive loss | \$ (5,366,000) | \$ (11,248,000) | \$ (16,279,000) | \$ (28,455,000) |
| Basic and diluted net loss per common share | \$ (0.08) | \$ (0.19) | \$ (0.24) | \$ (0.49) |
| Basic and diluted weighted average common shares | 67,248,384 | 58,713,036 | 67,147,584 | 58,292,911 |

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

**For the Nine Months Ended
September 30,**

| | 2013 | 2012 |
|---|----------------------|----------------------|
| Cash flows from operating activities: | | |
| Net loss | \$ (16,137,000) | \$ (28,455,000) |
| Adjustments to reconcile net loss to net cash used in operating activities: | | |
| Depreciation and amortization | 1,169,000 | 712,000 |
| Amortization of deferred financing costs and debt discount | 605,000 | 706,000 |
| Joint Venture acquisition obligation accretion | 204,000 | — |
| Provision for doubtful accounts | 938,000 | 99,000 |
| Change in fair value of warrants | (418,000) | 1,244,000 |
| Change in fair value of option liabilities | (2,250,000) | 490,000 |
| Share-based compensation expense | 2,723,000 | 2,907,000 |
| Equity loss from investment in joint venture | 48,000 | 128,000 |
| Loss on asset disposal | 257,000 | — |
| Gain on previously held equity interest in Joint Venture | (4,892,000) | — |
| Gain on sale of assets | (4,392,000) | — |
| Loss on debt extinguishment | 708,000 | — |
| Increases (decreases) in cash caused by changes in operating assets and liabilities: | | |
| Accounts receivable | 361,000 | 698,000 |
| Inventories | (975,000) | (93,000) |
| Other current assets | 69,000 | (253,000) |
| Other assets | (117,000) | 16,000 |
| Accounts payable and accrued expenses | (1,080,000) | 254,000 |
| Deferred revenues, related party | (638,000) | (2,413,000) |
| Deferred revenues | (1,245,000) | (97,000) |
| Long-term deferred rent | (2,000) | 180,000 |
| Net cash used in operating activities | <u>(25,064,000)</u> | <u>(23,877,000)</u> |
| Cash flows from investing activities: | | |
| Purchases of property and equipment | (536,000) | (1,077,000) |
| Proceeds from Puregraft divestiture | 5,000,000 | — |
| License agreement termination fee | (600,000) | — |
| Cash acquired in purchase of Joint Venture | 5,000 | — |
| Net cash provided by (used in) investing activities | <u>3,869,000</u> | <u>(1,077,000)</u> |
| Cash flows from financing activities: | | |
| Principal payments on long-term obligations | (22,292,000) | (210,000) |
| Proceeds from long-term obligations | 27,000,000 | — |
| Debt issuance costs and loan fees | (1,744,000) | — |
| Payments toward purchase of Joint Venture | (141,000) | — |
| Proceeds from exercise of employee stock options and warrants and stock purchase plan | 147,000 | 988,000 |
| Proceeds from sale of common stock | 3,001,000 | 4,946,000 |
| Costs from sale of common stock | (184,000) | (64,000) |
| Net cash provided by financing activities | <u>5,787,000</u> | <u>5,660,000</u> |
| Effect of exchange rate changes on cash and cash equivalents | <u>(104,000)</u> | <u>—</u> |
| Net decrease in cash and cash equivalents | <u>(15,512,000)</u> | <u>(19,294,000)</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>\$ 10,205,000</u> | <u>\$ 17,628,000</u> |