# 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 9, 2009

# CYTORI THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

Delaware

(State or Other Jurisdiction of Incorporation)

000-32501 (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):

o Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

o Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

o Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

o 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 November 9, 2009, Cytori Therapeutics, Inc. (Company) issued a press release announcing its financial results for the third quarter ended September 30, 2009. 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 Investor Relations section of its website. Acopy 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

<u>Exhibit No.</u>	<b>Description</b>
99.1	Cytori Therapeutics, Inc. Press Release, dated November 9, 2009*
99.2	Cytori Therapeutics, Inc. Shareholder Letter, dated November 9, 2009*

\* 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.

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 9, 2009

By: /s/ Christopher J. Calhoun Christopher J. Calhoun Chief Executive Officer

#### Cytori Reports 3rd Quarter 2009 Financial Results

November 9, 2009 -- Cytori Therapeutics (NASDAQ:CYTX) is reporting its financial results for the quarter and nine months ended September 30, 2009. More information on commercial and clinical progress is posted online in the 'Q3 Shareholder Letter' at <u>http://ir.cytoritx.com</u>.

During the third quarter, the number of Celution and StemSource systems in the field continued to grow, as did the number of patients treated. The cumulative 'revenue base' of combined systems increased in Q3 from 70 to 85, 12 of which were sold to physician customers or distributors. In addition, a total of 314 consumables were shipped in the third quarter of 2009 and, as in previous quarters, the majority represented reorders to existing accounts. To put this in perspective, this represents more than 100% growth of the cumulative revenue base of systems and 75% growth in the number of quarterly consumables shipped since the beginning of 2009.

Product revenues were \$1.4 million and \$4.6 million for the previous three and nine months ended September 30, 2009, respectively. This compares to \$2.3 million and \$3.9 million for the same periods in 2008. Gross profit was \$0.6 million and \$1.9 million for the three and nine months ended September 30, 2009, respectively, compared to \$1.7 million and \$2.5 million for the same periods in 2008. The difference in gross profit between the third quarters of 2008 and 2009 is attributable mostly to the high margin sale of a Cell Bank in Europe in the third quarter of 2008, with no comparable sale in 2009.

Total operating expenses, less the change in fair value of warrants and option liabilities, were \$6.7 million and \$20.7 million for the three and nine months ended September 30, 2009, respectively, compared to \$8.3 million and \$26.6 million, for the same periods in 2008. Compared to 2008, operating expenses have been reduced significantly due to reductions in R&D as products have gone from development to full commercial launch and a significant reduction in G&A, offset by a modest increase in sales and marketing.

Net loss was \$6.8 million and \$13.7 million for the three and nine months ended September 30, 2009, respectively, compared to \$6.8 million and \$23.5 million for the same periods in 2008. The improvement in net loss for the first nine months of 2009 compared to 2008 is attributable mostly to increased development revenues and the reduction in research and development and general and administrative expenses.

Cytori ended the third quarter of 2009 with \$13.1 million in cash and cash equivalents plus \$1.9 million in accounts receivable, compared to \$12.6 million in cash and cash equivalents and \$1.3 million in accounts receivable as of December 31, 2008. Subsequent to the quarter ended September 30, 2009, we completed three scheduled closings with Seaside 88, LP during the period of October 1, 2009 through our filing date of November 9, 2009, raising in aggregate approximately \$2.6 million in gross proceeds from the sale of 825,000 shares of our common stock in connection with the agreement we entered into with Seaside 88, LP on June 19, 2009.

#### **Conference Call & Shareholder Letter**

Cytori's third quarter update and financial results shareholder letter are now available on the Company's Investor Relations homepage at <u>http://ir.cytoritx.com</u>. Cytori will host a conference call and question and answer session at 10:30 a.m. Eastern Time today to further discuss these results. The audio webcast of the conference call may be accessed under "Webcasts" in the Investor Relations section of Cytori's website (<u>www.cytoritx.com</u>). The webcast will be available live and by replay two hours after the call and archived for 90 days. A telephone replay will be available for one week, accessible at +1 (303) 590-3030 (PIN: 4178319).

#### **About Cytori**

Cytori is committed to providing patients and physicians around the world with medical technologies, which harness the potential of adult stem and regenerative cells from adipose tissue. With the introduction of a family of medical devices, we have made a patient's own clinical grade stem and regenerative cells available to them at the point-of-care. The Celution<sup>®</sup> System family of medical devices and instruments is being sold into the European and Asian cosmetic and reconstructive surgery markets, while we seek regulatory clearance for it in the United States. Our StemSource<sup>®</sup> product line is sold globally for cell banking and research applications. <u>www.cytoritx.com</u>

### **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 statements, including, but not limited to, those regarding our forecasts for 2009 product revenues, anticipated continued reduction in operating expenses for 2009 and the timing of that reduction, our sales expectations from our marketing and distribution partners, customer consumable reorder trends, anticipated StemSource<sup>®</sup> Cell Bank orders, our ability to introduce complementary cosmetic and reconstructive surgery products in 2009, 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 intellectual property rights, regulatory uncertainties regarding the collection and results of, clinical data, dependence on third party performance, as well as 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.

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

		As of eptember 30, 2009	As of December 31, 2008		
Assets					
Current assets:					
Cash and cash equivalents	\$	13,140,000	\$	12,611,000	
Accounts receivable, net of allowance for doubtful accounts of \$573,000 and					
\$122,000 in 2009 and 2008, respectively		1,855,000		1,308,000	
Inventories, net		1,894,000		2,143,000	
Other current assets		1,116,000		1,163,000	
Total current assets		18,005,000		17,225,000	
Droparty and aquipment not		1,547,000		2,552,000	
Property and equipment, net Investment in joint venture		289,000		324,000	
Other assets		548,000		729,000	
Intangibles, net		690,000		857,000	
Goodwill		3,922,000		3,922,000	
		5,522,000		3,322,000	
Total assets	\$	25,001,000	\$	25,609,000	
Liabilities and Stockholders' Deficit					
Current liabilities:					
Accounts payable and accrued expenses	\$	3,999,000	\$	5,088,000	
Current portion of long-term obligations		2,634,000		2,047,000	
Total current liabilities		6,633,000		7,135,000	
Deferred revenues, related party		9,224,000		16,474,000	
Deferred revenues		2,412,000		2,445,000	
Warrant liability		3,256,000			
Option liability		1,500,000		2,060,000	
Long-term deferred rent		—		168,000	
Long-term obligations, less current portion		3,399,000		5,044,000	
Total liabilities		26,424,000		33,326,000	
				55,520,000	
Commitments and contingencies					
Stockholders' deficit:					
Preferred stock, \$0.001 par value; 5,000,000 shares authorized; -0- shares issued and outstanding in 2009 and 2008		_			
Common stock, \$0.001 par value; 95,000,000 shares authorized; 38,203,569 and 31,176,275 shares issued and 38,203,569 and 29,303,441 shares					
outstanding in 2009 and 2008, respectively		38,000		31,000	
Additional paid-in capital		171,554,000		161,214,000	
Accumulated deficit		(173,015,000)		(162,168,000)	
Treasury stock, at cost				(6,794,000)	
Total stockholders' deficit		(1,423,000)		(7,717,000)	

## 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,				
		2009		2008		2009		2008
Product revenues:								
Related party	\$	9.000	\$		\$	582,000	\$	28,000
Third party		1,377,000	-	2,319,000		3,994,000		3,848,000
		1,386,000		2,319,000		4,576,000		3,876,000
Cost of product revenues		782,000		648,000		2,645,000		1,383,000
Gross profit		604,000		1,671,000	1	1,931,000		2,493,000
Development revenues:								
Development, related party						7,250,000		774,000
Research grant and other		5,000		1,000		27,000		50,000
		5,000	_	1,000		7,277,000	_	824,000
Operating expenses:								
Research and development		2,618,000		3,875,000		9,006,000		13,873,000
Sales and marketing		1,621,000		1,357,000		4,369,000		3,431,000
General and administrative		2,483,000		3,049,000		7,287,000		9,322,000
Change in fair value of warrants		446,000				1,558,000		
Change in fair value of option liabilities	_	(140,000)		200,000		(560,000)		200,000
Total operating expenses	_	7,028,000		8,481,000		21,660,000		26,826,000
Operating loss		(6,419,000)		(6,809,000)		(12,452,000)		(23,509,000)
Other income (expense):								
Interest income		2,000		49,000		19,000		163,000
Interest expense		(346,000)		(19,000)		(1,120,000)		(60,000)
Other expense, net		(31,000)		(30,000)		(139,000)		(72,000)
Equity loss from investment in joint venture		(8,000)		(8,000)	_	(35,000)	_	(26,000)
Total other income (expense)	_	(383,000)		(8,000)	_	(1,275,000)	_	5,000
Net loss	\$	(6,802,000)	\$	(6,817,000)	\$	(13,727,000)	\$	(23,504,000)
Basic and diluted net loss per common share	\$	(0.18)	\$	(0.24)	\$	(0.39)	\$	(0.90)
Basic and diluted weighted average common shares		37,176,165		27,951,369		34,893,303		26,078,196
						<u> </u>		

3

Dear Shareholders,

There are two key areas to highlight in the third quarter 2009 commercial and clinical update.

First, our technology continued to reach more physicians' practices and patients than ever before. During the third quarter, 15 new systems were shipped, 12 of which were sold to physician customers or distributors. By quarter's end, 85 cumulative 'revenue base' systems were in the market. This compares to 70 such systems at the end of the second quarter of 2009. By revenue base systems, we mean the aggregate of systems sold to physician customers or distributors, or units placed with physicians that are generating consumable sales.

A noteworthy third quarter trend, which is continuing into the fourth quarter, is that there has been a marked reduction in inventory at key distributors, and thus an increase in the number of systems that have been installed and are now being operated. Simultaneously, we have appointed new distributors in Thailand (General Electric) and the Middle East.

Most indicative of the long-term potential of the technology and sustained customer satisfaction are the continued favorable consumable trends. A total of 314 consumables were shipped in the third quarter. Of these, there was a record number of reorders and a quarter over quarter and year over year increase in overall consumable revenue.

A second highlight is the progress we are making to accelerate our revenue growth in the cosmetic market. Cosmetic surgery is a key revenue driver for us because it is not limited by reimbursement and there is a global movement toward the use of fat tissue in cosmetic surgery.

In the third quarter, we implemented substantial sales, marketing and technology initiatives intended to better support cosmetic physicians and their office staff. We rolled out a new campaign to educate and create awareness for cell-enriched cosmetic surgery amongst patients and physicians, starting with the launch of a new website, www.cellenrich.eu. This educational campaign is intended to help physicians communicate the key benefits of Cytori's technology to their patients and drive potential patients to our physician customers. We are already seeing the effects from this initiative and anticipate these efforts will result in acceleration of system penetration and utilization.

We are also committed to optimizing our technology with new product enhancements, which reduce the processing time and improve the workflow and economics of our customers' practices. At the same time, these product enhancements increase the maximum volume of tissue that can be processed. This expands the number of potential applications for which the Celution® System may be utilized in the cosmetic market. For example, breast augmentation procedures of two and three cup size increases as well as smaller volume procedures for the face are now possible.

Our sales team is incorporating new strategies in Western Europe. Because our direct sales force has proven to be the most effective driver of cosmetic sales, we have assumed greater control of the marketing and distribution for this market segment. We are confident that this shift will result in greater market penetration and increase our sales margins for our products. Key distribution partners such as MBA Grupo and GE Healthcare in turn can now focus on growing the current non-cosmetic markets such as those for hospital-based reconstructive surgery and clinical research.

In addition, there are other noteworthy achievements since the end of the second quarter:

- The FDA confirmed that the Celution® System will be regulated in the U.S. as a medical device;
- The 69<sup>th</sup> patient has been enrolled in the RESTORE-2 breast reconstruction clinical study and completion of enrollment is imminent;
- · Preliminary results for the RESTORE-2 trial were accepted for poster presentation at the San Antonio Breast Cancer Symposium; and
- · First successful clinical tests of our forthcoming PureGraft™ product offering have been completed

1

#### **Clinical Trial Progress**

Completion of enrollment in RESTORE-2 is imminent. To date, 69 of 70 patients have been treated. The trial could potentially enroll more than 70 patients, as eligible participants who have finished screening by completion of enrollment will be allowed to enter the study if treatment is completed within three days after the last patient is enrolled. For the first 30 patients who have reached the six-month follow-up, we will report interim data on December 12 at the San Antonio Breast Cancer Symposium. This is a highly anticipated presentation of the study results for this reconstructive surgery application.

Enrollment has been completed in both of our cardiovascular disease studies in Europe this year and both were deemed to have met their safety and feasibility objectives. For each study, we are nearing completion of the six-month evaluation. For the heart attack study (APOLLO), we expect to report results as early as the first quarter of 2010. We expect to report results from the chronic heart disease study (PRECISE) later in the first half of 2010.

In addition to our three sponsored clinical trials, we evaluate the efforts of leading physicians around the world who are applying our technology for an even broader number of medical conditions. More than ten such studies are enrolling patients or are in the planning stages. These studies include but are not limited to liver insufficiency, chronic wounds, post-operative renal insufficiency, and urinary incontinence. Encouraging preliminary results continue to be reported.

As an example, results were recently reported at a medical conference on the use of the Celution® System and its cellular output for the treatment of stress urinary incontinence (SUI) as part of an independent, investigator-initiated five patient safety and feasibility study in Japan. The results suggest that the investigational treatment is thus far safe and feasible. The treatment resulted in improved sphincter muscle control and increased blood flow, through the combination of bulking generated by a cell-enriched graft and an injection of cells directly into the sphincter. As a result, the investigator is now planning a larger study to more fully evaluate the potential for the Celution® System in SUI.

Our ultimate goal is to advance select applications through clinical development. Feasibility data like this can be used to attract partners and we are in active discussions with multiple parties. While such transactions remain in the negotiating stages, if achieved, they would further enhance our ability to leverage our technology platform and bring in additional, non-dilutive capital to the company.

#### **Regulatory Update**

Our regulatory path in the European Union has been clearly defined as a medical device since we first sought marketing approval for the Celution System in Europe. The path in the United States had previously been less defined. Recently however, the FDA has determined that our Celution® 700 System will be regulated in the U.S. as a medical device.

Though we anticipate that the product will be regulated in the United States as a Class II or III device, it is unclear at this time if a clinical study will be required for an initial clearance and if so, what the scale and scope of the study design will be. We believe there is technical merit to substantiate a 510(K) application for the use of the Celution® System to support autologous fat transfers to soft tissue defects and expect to finalize and submit the application within the next few weeks. A response from the FDA could result in an initial market clearance, or allow us to further define the specific path, which may be required.

#### **Financial Results**

Product revenues were \$1.4 million and \$4.6 million for the three and nine months ended September 30, 2009, respectively, compared to \$2.3 million and \$3.9 million for the same periods in 2008. Gross profit was \$0.6 million and \$1.9 million for the three and nine months ended September 30, 2009, respectively, compared to \$1.7 million and \$2.5 million for the same periods in 2008. The difference in gross profit between the third quarters of 2008 and 2009 is attributable mostly to the sale of a Cell Bank in Europe in the third quarter of 2008, with no comparable sale in 2009.

Total operating expenses, less the change in fair value of warrants and option liabilities, were \$6.7 million and \$20.7 million for the three and nine months ended September 30, 2009, respectively, compared to \$8.3 million



and \$26.6 million, for the same periods in 2008. Compared to 2008, operating expenses have been reduced significantly due to targeted reductions in R&D, which no longer require the same level of research investment now that our products are on the market, and a modest reduction in G&A, offset by a slight increase in sales and marketing.

Net loss was \$6.8 million and \$13.7 million for the three and nine months ended September 30, 2009, respectively, compared to \$6.8 million and \$23.5 million for the same periods in 2008. The improvement in net loss for the first nine months of 2009 compared to 2008 is attributable mostly to increased development revenues and the reduction in research and development and general and administrative expenses.

We ended the third quarter of 2009 with \$13.1 million in cash and cash equivalents plus \$1.9 million in accounts receivable, compared with \$12.6 million in cash and cash equivalents and \$1.3 million in accounts receivable as of December 31, 2008. We subsequently completed three scheduled closings with Seaside 88, LP during the period of October 1, 2009 through our filing date of November 9, 2009 raising in aggregate approximately \$2.6 million in additional gross proceeds from the sale of 825,000 shares of our common stock.

#### Establishing the Market in Regenerative Medicine

Cytori Therapeutics is the first commercial-stage regenerative medicine company with a point of care device that provides a patient's own stem and regenerative cells in a single procedure. Our success to date would not have come without our substantial commitment and investment in research, which established the deepest biological understandings of regenerative cells in adipose tissue. This understanding has allowed Cytori to translate our discoveries into the only commercially viable products predicated on stem and regenerative cells from adipose tissue. The first mover advantage and market share we are establishing, along with our intellectual property, proprietary know-how, and blue chip corporate partners, position us to establish Celution® as the leading brand in cell-based regenerative medicine.

Thank you for your interest in Cytori and we look forward to keeping up updated on our growth and progress.

Warm Regards,

Christopher J. Calhoun Chief Executive Officer

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

This shareholder letter includes forward-looking statements regarding a variety of 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 forecasts for 2009 product sales and revenues, our anticipated regulatory clearances and approvals, the growth of potential clinical applications for our products, market acceptance of our products, and our ability to continue enrollment of patients in clinical trials 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 intellectual property rights, regulatory uncertainties regarding the collection and results of, clinical data, dependence on third party performance, as well as 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.

3