

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): August 8, 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 August 8, 2013 Cytori Therapeutics, Inc. (Company) issued a press release announcing its financial results for the second quarter ended June 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 August 8, 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: August 8, 2013

CYTORI THERAPEUTICS, INC.

By: /s/ Mark E. Saad

Mark E. Saad
Chief Financial Officer



August 8, 2013

Cytori Reports First Half and 2nd Quarter 2013 Business and Financial Results

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

Total revenue for the six months and quarter ended June 30, 2013 were \$6.0 million and \$2.3 million, respectively. Net loss for the six months and quarter ended June 30, 2013 were \$10.9 million and \$3.2 million, respectively.

Milestone Highlights

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

- Received FDA approval to expand the ATHENA trial of Cytori's cell therapy for chronic ischemic heart failure
- Completed first BARDA objective; substantial progress toward the second objective; final objective underway and is on schedule
- Entered \$15 million agreement to divest Puregraft®; Out-licensed Celution® for Alopecia
- Restructured term loan resulting in net proceeds of approximately \$8 million and deferral of principal payments through June 2014
- Establishing a nationwide Japanese distribution network for Class 1 Celution® System sales
- Received approval for the Celution® System in Australia for processing and delivering adipose-derived regenerative cells as well as commercial registration in New Zealand
- Entered into an agreement to acquire the remaining interest in the Olympus-Cytori Joint Venture, including all manufacturing rights for the Celution® System
- Awarded three 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
- Successfully recruited Dr. Steven Kesten as Executive Vice President and Chief Medical Officer

"During the first six months we have made progress across all of our core business objectives and further sharpened our corporate focus," said Christopher J. Calhoun, Cytori's Chief Executive Officer. "We continued patient enrollment in the ATHENA trial and received FDA approval to expand the scope of the ATHENA clinical program, with the initial data to be available in the first half of 2014. We remain on track to qualify for the next phase of our BARDA contract worth up to \$56 million in development funding. Our commercial team continued to broaden market access, most recently reflected by the Australian approval and commercial registration in New Zealand, with an initial goal of selling to centers performing investigator-sponsored translational research."

Financial Performance

Total revenues for the first six months of 2013 were \$6.0 million compared to \$5.9 million for the first six months of 2012. Total revenue for the first six months of 2013 included \$2.8 million in product sales and \$1.4 million in BARDA contract revenue. Total product and BARDA contract revenues for the second quarter of 2013 were \$2.3 million, compared to \$1.9 million in the second quarter of 2012. Total revenue in the second quarter of 2012 included \$2.4 million in non cash development revenues.

Gross profit for the first six months and quarter ended June 30, 2013 were \$1.4 million and \$0.8 million respectively compared to \$1.5 million and \$0.9 million respectively for the first six months and quarter ended June 30, 2012. Gross margins are expected to increase in the second half of 2013 as increased revenues are realized.

Research and development expenses for the first six months and quarter ended June 30, 2013 were \$7.9 million and \$4.2 million respectively compared to \$6.1 million and \$3.2 million respectively for the first six months and quarter ended June 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 six months and quarter ended June 30, 2013 were \$12.6 million and \$6.5 million respectively compared to \$12.7 million and \$6.4 million respectively for the first six months and quarter ended June 30, 2012. During the second quarter of 2013, as a result of Cytori acquiring Olympus Corporation's 50% interest in the Olympus-Cytori Joint Venture, Cytori realized a non-cash gain of \$4.9 million due to the independently assessed valuation of its previously held equity interest. Also, as a result of the acquisition, Cytori recorded a \$2.5 million non-cash gain resulting from the elimination of the option liability between Olympus Corporation and Cytori.

Net loss for the first six months of 2013 was \$10.9 million, or (\$0.16) per share, compared to \$17.2 million, or (\$0.30) per share, in the first six months of 2012. Net loss for the second quarter of 2013 was \$3.2 million, or (\$0.05) per share, compared to \$7.9 million, or (\$0.13) per share, in the second quarter of 2012.

Cytori ended the second quarter of 2013 with \$13.6 million of cash and cash equivalents and \$2.9 million in accounts receivable. Subsequent to the end of the quarter Cytori received \$5 million from the upfront payment associated with the divestiture of the Puregraft® product line.

“For the first half of 2013, we increased R&D expenses, as planned, to support ATHENA and perform reimbursed services under the BARDA contract and contained SG&A expenses,” said Mark E. Saad, Chief Financial Officer of Cytori. “As previously guided, we anticipate product sales to be weighted to the second half of 2013 as we realize the impact from recent regulatory approvals in Japan, Europe and now Australia. As a result of the divestiture of Puregraft®, we are adjusting our 2013 revenue target to \$14 million in combined product and cash contract revenue.”

Cardiovascular Disease Pipeline

ATHENA

ATHENA is a prospective, multi-center, double-blind, randomized and placebo-controlled clinical trial investigating Cytori’s cell therapy in 45 patients with chronic ischemic heart failure. At present, 16 patients have been treated. The majority of patients have been treated at two trial centers which began treating patients in late 2012. Two new trial centers began enrolling in the second quarter and a third began enrolling in July. Three additional trial centers are expected to begin enrolling patients in September. In July, the FDA approved expanding the ATHENA trial from six trial centers to a total of eight centers. Based on the average enrollment rates of the active centers to date, the anticipated average enrollment rate going forward is one patient per-month per-center. At this rate, full enrollment should be achieved in the fourth quarter of 2013. Top-line 6-month data remains on schedule for the first half of 2014.

Cytori has also received approval from the FDA to expand the ATHENA program to include a higher cell dose (0.8MM cells/kg vs. 0.4MM cells/kg). This trial, ATHENA II, which will run in parallel to ATHENA, is a prospective, multi-center double-blind 45-patient trial with 2:1 randomization of cells to placebo. We expect the trial to begin enrolling in the fourth quarter at up to 10 centers, immediately following the full enrollment of ATHENA. Athena II is important to determining the optimal cell dose for heart failure. In addition to strengthening the clinical data on the utility of ADRCs for heart failure, Cytori believes having this additional data on a second dose will maximize the chance of a successful pivotal trial. Full enrollment of ATHENA II is anticipated during the first half of 2014 and is not expected to delay the initiation of the U.S. pivotal trial planned for 2015.

Cytori will meet with the FDA to receive input and guidance on the pivotal trial requirements including the target patient population, target clinical indication and defining the primary and secondary trial end-points. This is an important next step in completing the Company’s cardiovascular roadmap toward achieving market access, which includes FDA approval for cardiovascular indications, reimbursement and will support establishing a strategic partnership.

“Based on our current rate of enrollment with five active centers and the prospect of all eight trial centers recruiting and treating patients within the next month, we are confident we will meet our goal for completing enrollment during the fourth quarter,” said Steven Kesten, M.D., Chief Medical Officer for Cytori. “Our plan to have top-line six-month data from the ATHENA trial available in the first half of 2014 remains unchanged. The addition of a higher dose cohort will result in more comprehensive data while not slowing the timeline to initiate a U.S. pivotal trial.”

ADVANCE

ADVANCE is the Company’s European clinical trial for acute myocardial infarction (heart attack). To date, the trial has enrolled 23 patients. As part of a comprehensive evaluation of the Company’s global cardiovascular strategy, resource utilization and development priorities, Cytori has decided to discontinue enrollment in the ADVANCE trial once it has achieved the 2013 target enrollment goal of 25 patients or on September 30, 2013. All evidence to date supports a strong safety profile and the patients enrolled in the trial will continue to be followed according to the protocol. The outcomes will be fully analyzed in conjunction with the existing safety and feasibility data from the APOLLO acute myocardial infarction trial.

The decision to conclude ADVANCE is based on several considerations. Each country in Europe interprets and implements GMP requirements in a unique fashion. Satisfying these disparate and evolving requirements is proving to be more challenging and costly than anticipated. Furthermore, certain European regulatory authorities and institutional review boards have rendered mixed opinions on approving the trial with a placebo control arm, a key factor in showing scientifically valid efficacy in this trial. In short, the overall fluidity and lack of standardization in the regulatory environment in Europe around device-based cell therapy in clinical trials will continue to make it increasingly difficult to forecast and manage associated costs and resources. Management will focus internal and financial resources on the highest clinical development priority, which is the expanded U.S. ATHENA trial.

BARDA Contract

Cytori’s contract awarded by 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 targeted soft tissue 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 for 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 a next-generation, miniaturized Celution® System. During the second quarter, Cytori shared data with BARDA demonstrating substantial progress on the second objective, which is confirmation that a therapeutic cell population may be obtained from patients with severe full thickness burn injuries. Cytori plans to submit a report demonstrating achievement of this objective this quarter. Lastly, the Company is making significant progress and remains on schedule toward the third objective, which is to demonstrate efficacy in a preclinical study, which is underway.

Cytori is on schedule to hold an In-Process Review meeting with BARDA and other stakeholders (the key step to progressing to the second phase of the contract) detailing the fulfillment of the three objectives in the first quarter of 2014.

Commercial Business

Cytori's commercial business has been focused primarily on selling Celution® Systems and consumables to researchers performing investigator-initiated and sponsored studies. This supports the Company's strategy of facilitating the discovery of additional therapeutic applications for its cell therapy. For the second half of 2013, it is expected that product revenue growth will be driven by expanded research and general clinical use 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.

Subsequent to the end of the second 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. This approval will allow physicians to utilize Celution across a variety of indications for patients in Australia. Additionally, Cytori has registered the Celution® System for commercial sale in New Zealand.

Also following the end of the second quarter, Cytori entered agreements with Bimini Technologies to divest the Puregraft® line of products in a \$15 million agreement, including a \$5 million up-front cash payment and up to an additional \$10 million in commercial milestone payments. In addition, Bimini Technologies was granted a license for exclusive worldwide rights to develop and sell the Celution® System for Alopecia (hair loss) in exchange for a perpetual royalty on sales.

Upcoming Milestones

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

- Complete enrollment in the ATHENA trial
- Initiate enrollment in the higher dose ATHENA II trial
- Report six-month outcomes from the ATHENA trial
- Complete enrollment in the ATHENA II trial
- Achieve proof-of-concept milestones in the BARDA contract and qualify Cytori for up to \$56 million in additional development funding
- Achieve product and contract revenue objectives
- Publish the 18-month outcomes from the PRECISE European chronic ischemic heart failure trial
- Continue to strengthen the Company's patent position

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: 25841269.

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 fourth quarter of 2013 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, 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, 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:

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

	As of June 30, 2013	As of December 31, 2012
Assets		
Current assets:		
Cash and cash equivalents	\$ 13,621,000	\$ 25,717,000
Accounts receivable, net of reserves of \$485,000 and of \$278,000 in 2013 and 2012, respectively	2,897,000	3,926,000
Inventories, net	4,012,000	3,175,000
Other current assets	1,189,000	1,161,000
Total current assets	21,719,000	33,979,000
Property and equipment, net of accumulated depreciation of \$8,604,000 and of \$8,609,000 in 2013 and 2012, respectively	2,043,000	2,174,000
Restricted cash and cash equivalents	350,000	350,000
Investment in joint venture	—	85,000
Other assets	2,448,000	2,740,000
Intangibles, net	9,282,000	—
Goodwill	3,922,000	3,922,000
Total assets	\$ 39,764,000	\$ 43,250,000
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable and accrued expenses	\$ 6,252,000	\$ 7,411,000
Current portion of long-term obligations, net of discount	21,000	9,784,000
Termination fee obligation	800,000	—
Current portion of Joint Venture purchase obligation	769,000	—
Warrant liability	—	418,000
Total current liabilities	7,842,000	17,613,000
Deferred revenues, related party	—	638,000
Deferred revenues	235,000	2,635,000
Option liability	—	2,250,000
Long-term deferred rent and other	784,000	756,000
Joint Venture purchase obligation, less current portion	3,921,000	—
Long-term obligations, net of discount, less current portion	25,719,000	12,903,000
Total liabilities	38,501,000	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; 67,235,591 and 65,914,050 shares issued and outstanding in 2013 and 2012, respectively	67,000	66,000
Additional paid-in capital	286,835,000	281,117,000
Accumulated other comprehensive loss	(34,000)	—
Accumulated deficit	(285,605,000)	(274,728,000)
Total stockholders' equity	1,263,000	6,455,000
Total liabilities and stockholders' equity	\$ 39,764,000	\$ 43,250,000

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

	For the Three Months		For the Six Months	
	Ended June 30,		Ended June 30,	
	2013	2012	2013	2012
Product revenues	\$ 1,408,000	\$ 1,947,000	\$ 2,800,000	\$ 3,427,000
Cost of product revenues	<u>608,000</u>	<u>1,032,000</u>	<u>1,365,000</u>	<u>1,885,000</u>
Gross profit	<u>800,000</u>	<u>915,000</u>	<u>1,435,000</u>	<u>1,542,000</u>
Development revenues:				
Development, related party	—	2,413,000	638,000	2,413,000
Development revenue	—	—	1,179,000	—
Government contracts and other	<u>859,000</u>	<u>16,000</u>	<u>1,408,000</u>	<u>19,000</u>
	<u>859,000</u>	<u>2,429,000</u>	<u>3,225,000</u>	<u>2,432,000</u>
Operating expenses:				
Research and development	4,150,000	3,224,000	7,869,000	6,060,000
Sales and marketing	2,410,000	2,581,000	4,667,000	4,956,000
General and administrative	4,046,000	3,788,000	7,892,000	7,712,000
Change in fair value of warrant liability	(84,000)	251,000	(418,000)	381,000
Change in fair value of option liability	<u>(2,500,000)</u>	<u>460,000</u>	<u>(2,250,000)</u>	<u>190,000</u>
Total operating expenses	<u>8,022,000</u>	<u>10,304,000</u>	<u>17,760,000</u>	<u>19,299,000</u>
Operating loss	<u>(6,363,000)</u>	<u>(6,960,000)</u>	<u>(13,100,000)</u>	<u>(15,325,000)</u>
Other income (expense):				
Loss on asset disposal	(257,000)	—	(257,000)	—
Loss on debt extinguishment	(708,000)	—	(708,000)	—
Interest income	1,000	1,000	1,000	2,000
Interest expense	(652,000)	(860,000)	(1,361,000)	(1,726,000)
Other income (expense), net	(124,000)	(27,000)	(296,000)	(73,000)
Gain on previously held equity interest in Joint Venture	4,892,000	—	4,892,000	—
Equity loss from investment in joint venture	<u>—</u>	<u>(37,000)</u>	<u>(48,000)</u>	<u>(86,000)</u>
Total other income (expense)	<u>3,152,000</u>	<u>(923,000)</u>	<u>2,223,000</u>	<u>(1,883,000)</u>
Net loss	<u>\$ (3,211,000)</u>	<u>\$ (7,883,000)</u>	<u>\$ (10,877,000)</u>	<u>\$ (17,208,000)</u>
Other comprehensive income (loss) – foreign currency translation adjustments	<u>76,000</u>	<u>—</u>	<u>(34,000)</u>	<u>—</u>
Net comprehensive loss	<u>\$ (3,135,000)</u>	<u>\$ (7,883,000)</u>	<u>\$ (10,911,000)</u>	<u>\$ (17,208,000)</u>
Basic and diluted net loss per common share	<u>\$ (0.05)</u>	<u>\$ (0.13)</u>	<u>\$ (0.16)</u>	<u>\$ (0.30)</u>
Basic and diluted weighted average common shares	<u>67,200,588</u>	<u>58,676,092</u>	<u>67,096,348</u>	<u>58,080,541</u>

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

**For the Six Months Ended June
30,**

	2013	2012
Cash flows from operating activities:		
Net loss	\$ (10,877,000)	\$ (17,208,000)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	660,000	453,000
Amortization of deferred financing costs and debt discount	330,000	470,000
Joint Venture acquisition obligation accretion	51,000	—
Provision for doubtful accounts	188,000	19,000
Change in fair value of warrants	(418,000)	381,000
Change in fair value of option liabilities	(2,250,000)	190,000
Share-based compensation expense	1,838,000	1,977,000
Equity loss from investment in joint venture	48,000	86,000
Loss on asset disposal	257,000	—
Gain on previously held equity interest in Joint Venture	(4,892,000)	—
Loss on debt extinguishment	708,000	—
Increases (decreases) in cash caused by changes in operating assets and liabilities:		
Accounts receivable	862,000	258,000
Inventories	(816,000)	210,000
Other current assets	(27,000)	(278,000)
Other assets	(587,000)	17,000
Accounts payable and accrued expenses	(279,000)	(268,000)
Deferred revenues, related party	(638,000)	(2,413,000)
Deferred revenues	(1,200,000)	52,000
Long-term deferred rent	28,000	96,000
Net cash used in operating activities	<u>(17,014,000)</u>	<u>(15,958,000)</u>
Cash flows from investing activities:		
Purchases of property and equipment	(432,000)	(886,000)
License agreement termination fee	(400,000)	—
Cash acquired in purchase of Joint Venture	5,000	—
Net cash used in investing activities	<u>(827,000)</u>	<u>(886,000)</u>
Cash flows from financing activities:		
Principal payments on long-term obligations	(22,292,000)	(140,000)
Proceeds from long-term obligations	27,000,000	—
Debt issuance costs and loan fees	(1,744,000)	—
Payments toward purchase of Joint Venture	(70,000)	—
Proceeds from exercise of employee stock options and warrants and stock purchase plan	115,000	951,000
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>5,826,000</u>	<u>5,693,000</u>
Effect of exchange rate changes on cash and cash equivalents	<u>(81,000)</u>	<u>—</u>
Net decrease in cash and cash equivalents	(12,096,000)	(11,151,000)
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>\$ 13,621,000</u>	<u>\$ 25,771,000</u>