

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): **March 12, 2010**

CYTORI THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

Delaware

000-32501

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))
-
-

Item 2.02 Results of Operations and Financial Condition

On March 12, 2010, Cytori Therapeutics, Inc. (Company) issued a press release announcing its financial results for the fourth quarter and year ended December 31, 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 blog on the Investor Relations section of its website. A copy 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>	<u>Description</u>
99.1	Cytori Therapeutics, Inc. Press Release, dated March 12, 2010*
99.2	Cytori Therapeutics, Inc. Shareholder Letter, dated March 12, 2010*

* 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.

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 12, 2010

CYTORI THERAPEUTICS, INC.

By: /s/ Christopher J. Calhoun

Christopher J. Calhoun
Chief Executive Officer



March 12, 2010

Cytori Reports 2009 Financial Results

Cytori Therapeutics (NASDAQ:CYTX) is reporting its financial results for the year ended December 31, 2009. More information on our commercial and clinical progress is posted online in the 'March 2010 Shareholder Letter' at <http://ir.cytoritx.com/investorrelations/blog>.

During 2009, Cytori achieved the following:

- Grew system and consumable sales, predominantly into the cosmetic surgery market;
- Increased number of systems in the field that will further support consumable cartridge sales growth;
- Reported interim results from a post-marketing breast reconstruction study intended to support cosmetic and reconstructive surgery sales efforts in Europe and Asia;
- Expanded autologous fat graft product line with development of the PureGraft™ System (which received FDA clearance early 2010); and
- Completed enrollment in two cardiovascular disease safety and feasibility trials with results to be reported in May 2010.

System and Consumables

Throughout 2009, we more than doubled the cumulative number of 'revenue base' systems, which includes systems sold directly to physicians, distributors or units placed that are generating consumable sales. At the end of 2009, the cumulative number of revenue base systems was 101, compared to 85 at the end of the third quarter of 2009, and 42 at the end of 2008. In addition, a total of 337 consumables were shipped in the fourth quarter of 2009 compared to 314 consumables shipped in the third quarter of 2009 and 179 consumables shipped in the fourth quarter of 2008. Of these, 258 consumables were re-orders in the fourth quarter of 2009, compared to 185 re-orders in the third quarter of 2009. This reflects a positive trend whereby existing customers are contributing to a greater percent of consumable revenues.

System & Consumable Order Trends

	Q4 2009	Q3 2009	Q4 2008
Revenue Base Systems (Cumulative)	101	85	42
Consumables Shipped (Cumulative)	2,015	1,678	787
Consumables Shipped	337	314	179
Consumable Reorders	258	185	165

Financial Results

Total revenues for the year ending December 31, 2009 were \$14.7 million, which consisted of \$8.9 million in development revenues, related mostly to the achievement of three clinical milestones under our Olympus Corporation partnership, and \$5.8 million in product revenues. This compares to total revenues of \$6.9 million for 2008, which consisted of \$2.3 million in development revenues and \$4.5 million in product revenues in 2008. Gross profit for 2009 was \$2.4 million compared to \$2.7 million for 2008.

Total revenues for the fourth quarter of 2009 were \$2.9 million, which consisted of \$1.6 million in development revenue and \$1.3 million in product revenues. This compares to \$2.2 million in total revenues in the fourth quarter of 2008, which consisted of \$1.5 million in development revenue and \$652,000 in product revenue. Gross profit was \$513,000 in the fourth quarter of 2009, compared to \$181,000 for the same period in 2008.

Total operating expenses for 2009 were \$32.9 million compared to \$34.8 million in 2008. Approximately \$9.2 million of total expenses in 2009 were non-cash, including \$6.3 million in non-cash expenses related to the increase in fair value of warrants and stock based compensation offset by a reduction in the fair value of the option liability. In comparison, approximately \$4.8 million of total expenses were non-cash in 2008. In 2009, there was a significant reduction in operating expenses driven by \$6.5 million of reductions in research and development and general and administrative expenses offset in part by a \$2.0 increase in sales and marketing expenses. Net cash used in operating activities for the fourth quarter and full year 2009 was \$6.1 million and \$23.8 million respectively, compared to \$7.3 million and \$33.4 million, respectively in 2008.

Balance Sheet

Cytori ended the year 2009 with \$12.9 million in cash and cash equivalents plus \$1.6 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 end of the year, Cytori raised \$14.3 million from scheduled closings with Seaside 88, LP and the exercise by third parties of the warrants trading under the symbol CYTXW. Cytori believes that based on its anticipated gross profits, cash operating requirements and proceeds from Seaside 88, the Company has sufficient funds through the first half of 2011.

Conference Call & Shareholder Letter

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 the Cytori's website (www.cytori.com). 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: 4244478).

About Cytori

Cytori is an emerging leader in regenerative medicine, providing patients and physicians around the world with medical technologies that harness the potential of adult regenerative cells from adipose tissue. The Celution® System family of medical devices and instruments is being sold into the European and Asian cosmetic and reconstructive surgery markets but is not yet available in the United States. Our StemSource® product line is sold globally for cell banking and research applications. 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 statements, including, but not limited to, those regarding our forecasts for 2010 operating expenses and cash utilization rate, our sales expectations from our marketing and distribution partners which we have factored into our expected gross profit, system and consumable order trends, our ability to successfully commercialize the PureGraft™ product, 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 on Form 10-K and Form 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.

###

CONSOLIDATED BALANCE SHEETS

	As of December 31,	
	2009	2008
	(Unaudited)	
Assets		
Current assets:		
Cash and cash equivalents	\$ 12,854,000	\$ 12,611,000
Accounts receivable, net of allowance for doubtful accounts of \$751,000 and \$122,000 in 2009 and 2008, respectively	1,631,000	1,308,000
Inventories, net	2,589,000	2,143,000
Other current assets	1,024,000	1,163,000
Total current assets	18,098,000	17,225,000
Property and equipment, net	1,314,000	2,552,000
Investment in joint venture	280,000	324,000
Other assets	500,000	729,000
Intangibles, net	635,000	857,000
Goodwill	3,922,000	3,922,000
Total assets	\$ 24,749,000	\$ 25,609,000
Liabilities and Stockholders' Deficit		
Current liabilities:		
Accounts payable and accrued expenses	\$ 5,478,000	\$ 5,088,000
Current portion of long-term obligations	2,705,000	2,047,000
Total current liabilities	8,183,000	7,135,000
Deferred revenues, related party	7,634,000	16,474,000
Deferred revenues	2,388,000	2,445,000
Warrant liability	6,272,000	—
Option liability	1,140,000	2,060,000
Long-term deferred rent	—	168,000
Long-term obligations, less current portion	2,790,000	5,044,000
Total liabilities	28,407,000	33,326,000
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; 40,039,259 and 31,176,275 shares issued and 40,039,259 and 29,303,441 shares outstanding in 2009 and 2008, respectively	40,000	31,000
Additional paid-in capital	178,806,000	161,214,000
Accumulated deficit	(182,504,000)	(162,168,000)
Treasury stock, at cost	—	(6,794,000)
Total stockholders' deficit	(3,658,000)	(7,717,000)
Total liabilities and stockholders' deficit	\$ 24,749,000	\$ 25,609,000

CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

	Three		For the Years Ended December 31,	
	Months Ended December 31,		2009	
	2009	2008	2009	2008
	<u>(Unaudited)</u>	<u>(Unaudited)</u>	<u>(Unaudited)</u>	<u>(Unaudited)</u>
Product revenues				
Related party	\$ 9,000	\$ —	\$ 591,000	\$ 28,000
Third party	1,253,000	652,000	5,246,000	4,500,000
	<u>1,262,000</u>	<u>652,000</u>	<u>5,837,000</u>	<u>4,528,000</u>
Cost of product revenues				
	<u>749,000</u>	<u>471,000</u>	<u>3,394,000</u>	<u>1,854,000</u>
Gross profit (loss)	<u>513,000</u>	<u>181,000</u>	<u>2,443,000</u>	<u>2,674,000</u>
Development revenues:				
Development, related party	1,590,000	—	8,840,000	774,000
Other, related party	—	1,500,000	—	1,500,000
Research grants and other	26,000	1,000	53,000	51,000
	<u>1,616,000</u>	<u>1,501,000</u>	<u>8,893,000</u>	<u>2,325,000</u>
Operating expenses:				
Research and development	3,226,000	3,499,000	12,231,000	17,371,000
Sales and marketing	2,213,000	1,170,000	6,583,000	4,602,000
General and administrative	3,129,000	2,405,000	10,415,000	11,727,000
Change in fair value of warrants	3,016,000	—	4,574,000	—
Change in fair value of option liabilities	(360,000)	860,000	(920,000)	1,060,000
	<u>11,224,000</u>	<u>7,934,000</u>	<u>32,883,000</u>	<u>34,760,000</u>
Operating loss	<u>(9,095,000)</u>	<u>(6,252,000)</u>	<u>(21,547,000)</u>	<u>(29,761,000)</u>
Other income (expense):				
Interest income	—	67,000	20,000	230,000
Interest expense	(307,000)	(360,000)	(1,427,000)	(420,000)
Other expense, net	(79,000)	32,000	(218,000)	(40,000)
Equity loss from investment in joint venture	(9,000)	(20,000)	(44,000)	(45,000)
	<u>(395,000)</u>	<u>(281,000)</u>	<u>(1,669,000)</u>	<u>(275,000)</u>
Net loss	<u>\$ (9,490,000)</u>	<u>\$ (6,533,000)</u>	<u>\$ (23,216,000)</u>	<u>\$ (30,036,000)</u>
Basic and diluted net loss per common share	<u>\$ (0.24)</u>	<u>\$ (0.22)</u>	<u>\$ (0.65)</u>	<u>\$ (1.12)</u>
Basic and diluted weighted average common shares	<u>39,043,024</u>	<u>29,277,654</u>	<u>35,939,260</u>	<u>26,882,431</u>

CONSOLIDATED STATEMENTS OF CASH FLOWS

	For the Years Ended December 31,	
	2009	2008
	(Unaudited)	
Cash flows from operating activities:		
Net loss	\$ (23,216,000)	\$ (30,036,000)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	1,681,000	1,533,000
Amortization of deferred financing costs and debt discount	709,000	178,000
Warranty provision (reversal)	(23,000)	(44,000)
Increase (reduction) in allowance for doubtful accounts	663,000	121,000
Change in fair value of warrants	4,574,000	—
Change in fair value of option liability	(920,000)	1,060,000
Stock-based compensation	2,649,000	2,257,000
Equity loss from investment in joint venture	44,000	45,000
Increases (decreases) in cash caused by changes in operating assets and liabilities:		
Accounts receivable	(986,000)	(1,420,000)
Inventories	(446,000)	(2,143,000)
Other current assets	41,000	(147,000)
Other assets	75,000	(63,000)
Accounts payable and accrued expenses	413,000	(2,217,000)
Deferred revenues, related party	(8,840,000)	(2,274,000)
Deferred revenues	(57,000)	66,000
Long-term deferred rent	(168,000)	(305,000)
Net cash used in operating activities	<u>(23,807,000)</u>	<u>(33,389,000)</u>
Cash flows from investing activities:		
Proceeds from the sale and maturity of short-term investments	—	5,739,000
Purchases of short-term investments	—	(5,739,000)
Purchases of property and equipment	(221,000)	(393,000)
Net cash provided by (used in) investing activities	<u>(221,000)</u>	<u>(393,000)</u>
Cash flows from financing activities:		
Principal payments on long-term obligations	(2,053,000)	(958,000)
Proceeds from long-term obligations	—	7,500,000
Debt issuance costs	—	(513,000)
Proceeds from exercise of employee stock options and warrants	531,000	795,000
Proceeds from sale of common stock	23,196,000	28,954,000
Costs from sale of common stock	(1,336,000)	(850,000)
Proceeds from sale of treasury stock	3,933,000	—
Net cash provided by financing activities	<u>24,271,000</u>	<u>34,928,000</u>
Net increase in cash and cash equivalents	243,000	1,146,000
Cash and cash equivalents at beginning of year	<u>12,611,000</u>	<u>11,465,000</u>
Cash and cash equivalents at end of year	<u>\$ 12,854,000</u>	<u>\$ 12,611,000</u>

March 12, 2010

Year End 2009 Results and Commercial and Clinical Update

Dear Shareholders,

Cytori continued to build its lead in the area of cell-based regenerative medicine during 2009. The Celution® System is a product platform that is feeding both commercial opportunities in the cosmetic and reconstructive surgery (“CRS”) and translational research markets as well as a rich pipeline of clinical markets led by cardiovascular disease. The most significant areas of progress for the company during the year were the validation of our technology, growth in the installed base and usage of systems with the completion of three clinical trials, operational progress and strengthening our proprietary position (barriers-to-entry).

Looking ahead, the company is well positioned for several major advances including revenue growth in our entry CRS market, establishing a new substantive partnership, and maturing our rich product pipeline.

Key Accomplishments of 2009***Clinical Validation***

A major accomplishment for Cytori in 2009 was the completion of enrollment in three sponsored clinical trials. The largest of these studies is RESTORE 2, which treated 71 patients. Preliminary results from the RESTORE 2 breast reconstruction study demonstrated a high degree of patient and physician satisfaction at six months in the first 32 patients who underwent just a single procedure. This is consistent with the findings in the RESTORE 1 study as well as our pre-clinical data and understanding of the core mechanisms of action of these stem and regenerative cells.

Not surprisingly, the RESTORE 2 study gained significant attention amongst potential customers in Europe and Asia who are viewing the outcomes achieved in patients with severely damaged and ischemic tissue as a proxy for other applications for the technology in cosmetic surgery procedures such as breast augmentation in patients with healthy tissue.

Additionally, enrollment was completed in our two cardiovascular disease trials. Both studies met key end-points of safety and feasibility. The two studies combined enrolled 41 patients. The APOLLO trial (n=14) treated patients with acute myocardial infarction or heart attack. The PRECISE trial (n=27) included patients suffering from chronic myocardial ischemia. Importantly, the trials demonstrated that physicians were able to safely extract a meaningful volume of adipose tissue, separate and concentrate the stem and regenerative cells using the Celution® System and deliver these cells into the heart during the same interventional procedure. Outcomes from both of these studies will be reported on May 7 of this year at the Seventh International Symposium on Stem Cell Therapy and Cardiovascular Innovations in Madrid, Spain.

Commercially, Celution® System use is becoming commonplace. In 2008, its use was as much curiosity as a medical treatment. However, by the end of 2009, that is changing. In fact, in many physicians’ practices around the world it is becoming an indispensable part of their practice. Today, we believe over 1,000 patients have been treated worldwide and each weekday, on average, several patients are treated with the system.

Operational Progress

During the past year, the company demonstrated strong progress with several key operational goals. The first was to increase our installed base of Celution® Systems. The company more than doubled the cumulative number of ‘revenue base’ systems year over year, which includes systems sold directly to physicians, distributors or units placed that are generating consumable sales. At the end of 2009, the cumulative number of revenue base systems was 101. This compares favorably to 85 at the end of the third quarter of 2009, and 42 at the end of 2008.

A related goal was to increase the utilization of those systems, wherein the consumable sales annuity is the long-run key value driver for the company. We saw substantial year over year growth in customer reorders of consumables, a primary metric of system utilization. A total of 337 consumables were shipped in the fourth quarter of 2009, compared to 314 consumables shipped in the third quarter of 2009 and 179 consumables shipped in the fourth quarter of 2008. Of these, 258 consumables were re-orders, compared to 185 re-orders in the third quarter. The 258 consumable re-orders in the fourth quarter of 2009 nearly reached the 281 re-orders for the full prior year (2008).

Furthermore, we made significant progress improving on several critical variables that will drive faster adoption and make cell enriched fat grafting disruptive to existing markets. Specifically, we reduced processing times which improved efficiency within the practice and increased the volume capability of the system to more broadly meet the market demand. Additionally, we were able to make significant manufacturing improvements that will reduce the cost of goods as these changes are adopted during 2010.

Ultimately, the goal is to achieve tissue augmentation volumes, tissue processing times and pricing to enable our products to achieve a dominant market position. Progress was achieved in each of these three variables. Our development team dramatically improved the system and processing software such that we were able to increase maximum tissue volumes to 140% of 2008 levels while simultaneously decreasing overall processing time by 25%. Beyond economies of scale advantages with higher production lots, we validated and instituted numerous manufacturing improvements and efficiencies which will reduce our internal cost of goods by more than 20% on the consumable set and we will continue to drive these costs down as we drive products into the mainstream market.

Barriers to Entry

From a competitive standpoint, we created further separation from potential competitors and further strengthened our proprietary position. By the end of 2009, the company more than doubled its issued patents adding 12, ending the year with 21 issued patents and more than 100 patent applications pending.

2009 Financial Results Summary

From a financial perspective, the company accomplished several important goals during the past year. First, we achieved growth in product revenues compared with 2008 with an increasing percentage of revenues from consumable reorders. Second, we reduced cash operating loss by nearly \$10 million or approximately 30% compared to 2008. Finally, we strengthened the balance sheet through three equity transactions, which provide us with sufficient cash well into 2011 before factoring in the potential for revenue growth, strategic partnerships, or other transactions.

PART II: Primary Goals for 2010

With the advances achieved in 2009, Cytori is very well positioned for continued success in 2010. We have set three major goals for 2010 and beyond. First, we aim to expand and grow our Cosmetic and Reconstructive Surgery product revenue. Second, we will continue to drive our core cardiovascular pipeline product applications through the regulatory process toward the market. And third, we intend to establish a new substantive partnership that appropriately values the therapeutic impact of the technology.

Primary Goal for 2010

Our primary goal for 2010 is to expand and grow our cosmetic and reconstructive surgery ("CRS") product revenue on a worldwide basis. Based on the progress achieved in 2009, we believe that Cytori is well positioned for continued growth in this emerging and expansive market. Since this growth will be a critical value driver for the company, I would like to take some time and share the evolution of this opportunity and the Cytori product portfolio which is uniquely positioned to address it.

First, let's define the CRS market: natural soft tissue filling. This can be utilized for cosmetic or reconstructive indications and includes specific applications such as breast augmentation, facial filling and rejuvenation, soft tissue reconstruction after breast cancer treatment, as well as other soft tissue filling, or lipo-filling (commonly called fat grafting) procedures.

Cytori is leading the emerging global revolution in natural soft tissue filling. Cytori is the first and only company that has developed an expertise in the use of adipose tissue and a comprehensive, innovative and proprietary portfolio of products for such procedures as tissue harvest, processing, enzymatic digestion, stem and regenerative cell concentration, enriched graft preparation, delivery and cryo-preservation for future applications.

In 2001, Cytori's president Marc Hedrick, MD published the article "Multilineage cells from human adipose tissue: implications for cell-based therapies (Tissue Eng. 2001 Apr;7(2):211-28. PubMed PMID: 11304456). This foundational publication was the first that identified and proved that stem cells exist in adipose tissue. This has become the cornerstone for work now being conducted around the world using adipose-derived stem cells (pure population) and adipose-derived stem and regenerative cells (mixed population). This article is highly referenced and holds the record for being the most cited article (>2,000) in this Journal's history. Beyond establishing that adipose (fat) is the richest and most easily accessible source of stem cells with the possibility to treat many therapeutic indications, it brought to life an unanticipated consequence: the emergence of a potential global mega-trend in Plastic Surgery / Dermatology: Natural Soft Tissue Filling.

Using fat as a tissue graft for soft tissue filling has been sporadically attempted across many generations dating as far back as the late nineteenth century – with early case reports appearing circa 1880. Surgeons have always strived to use fat tissue as a graft. This is idealized in the plastic surgery mantra: 'replace like with like'. But unfortunately, the documented clinical results have been inconsistent, with unpredictable volume retention levels and the corresponding negative consequences of grafted tissue necrosis. During the past few decades, a variety of individual techniques for harvesting, processing and delivery of fat tissue have been developed by enterprising surgeons with a varying degree of success and reproducibility, but for the most part, the field remained challenged by unpredictable graft survival and highly personalized non-standardized approaches to fat grafting. The discovery of stem and regenerative cells within fat tissue has fueled the resurgence of using fat tissue for transplantation.

Correspondingly, Cytori has taken on a decade long investment and effort to scientifically understand the core aspects of adipose tissue –defining not only the variety of rich and powerful regenerative cell populations including stem cells and how to ideally process the tissue to maximize cell yield and viability, but the full experience from the tissue harvest through processing and ultimate delivery back into the patient.

Over the years, an extensive amount of work was conducted to optimize the initial tissue harvest procedure. This was essential because effectively all devices in the marketplace were designed to remove fat, not reuse it. This reality created work for us but also an opportunity. Cytori scientists evaluated multiple fat harvesting techniques and commercial devices. Each key element and feature was then assessed with the goal in mind of minimizing tissue damage and maximizing cell yield and viability, a unique paradigm in the industry. As a result, we achieved the objective of identifying 'best practices' for fat tissue harvesting but also it has laid the foundation for the Cytori Tissue Collection Instrument Set, now on sale around the world to be used with our cell processing technology.

Another key link in fat grafting chain is the preparation of the fat tissue graft for transplantation. More than one hundred years of fat grafting experience has produced very little in the way of new processing technology for fat grafts and ultimately no gold standard. In fact, it's not uncommon for physicians to sterilize common kitchen tools like tea strainers and gravy bowls for use in the OR on patients. It's precisely this surprising lack of advancement in the field that has created the opportunity for Cytori's technology. Our recently released PureGraft™ product is a simple to use but important advance in the field. It can rapidly process high volumes of fat in the sterile field to produce a pure and concentrated graft.

From a technological perspective, PureGraft™ leverages technology found in hemodialysis and peritoneal dialysis procedures and uses it to ‘dialyze’ a fat graft to remove the impurities that accumulate during liposuction as well as excess water that doctors don’t want to add back to patients. Dr. Steven Cohen, a plastic surgeon here in San Diego has called it a ‘game changer’ and we agree. Early results in the field are very promising. An important strategic benefit of PureGraft™ is that it is a means to segment the market and target physicians, not yet ready for Celution®, with a useful product today. Then in the future, PureGraft™ customers can be transitioned to Celution® customers, with its proven performance over fat grafting alone. Another attractive business feature of the PureGraft™ product is that it has a low entry price, provides a high margin consumable and has U.S. FDA clearance for aesthetic body contouring indications today.

However, to create the ideal graft with the highest survival, predictability and best outcome, enriching with stem and regenerative cells is a must. The only way to make these cells clinically available is to free them from the fat tissue matrix, concentrate them and reintroduce them to the graft. The use of an enzyme is required for the process. The enzyme acts as ‘chemical scissors’ without negatively affecting the regenerative cells. This has been scientifically evaluated, optimized and developed for maximizing cell yield, cell survival and viability. Celase™, our proprietary enzyme product, has been co-developed with a large pharmaceutical company partner and is exclusive to Cytori. This reagent sets the standard for clinical grade enzymes being mammalian free, sterile filled and GMP manufactured. In all of our research, the only way to effectively release the stem and regenerative cells is to use an enzyme.

The Celution® 800/CRS System enables preparation of the cells destined to be co-transplanted with an autologous fat graft back into the patient. With improvements including faster tissue processing and higher maximum volume grafts, natural augmentation procedures are now more attractive from a physician practice point of view. Offering natural augmentation is clearly a practice differentiator and active physicians are finding that many of the patients coming in are new patients that would not have had a traditional artificial implant, effectively expanding the market for cosmetic augmentation to a new group of patients that historically has been un-served.

Delivery of the graft back to the patient is also an important last link in the chain to achieve a successful transplantation. Cytori has studied a variety of fat tissue delivery approaches and has developed novel new products to optimize the delivery of fat tissue back to the patient. The Cytori Graft Delivery Instrument Set is anchored with the proprietary Celbrush™ device. This product, optimized for both small and large volume delivery, enables the physician to accurately control the delivery of the tissue graft that again maximizes tissue viability and survival.

Clearly, Cytori, with the portfolio of products mentioned above, is no longer a niche player in the CRS market albeit with exciting new cell therapy technology. Rather, Cytori now has a compelling product portfolio targeted at this emerging new trend in the marketplace we call ‘natural soft tissue filling’. The importance of this portfolio of technology is that it enables us to meaningfully target the market as a provider of natural soft tissue filling solutions through the sale of multiple new ‘best in class’ products. Now, based on geography, here is how we intend to grow our lead and market share in the CRS market.

In Europe and Asia, we have an established base of Celution® Systems that are generating annuity revenue through the reorder of consumable products. Our strategy to expand our presence in the CRS market is to increase our sales force in key regions where demand is already growing. The underlying demand is coming predominantly from surgeons performing breast augmentation, but we’re increasingly seeing demand among customers who are performing facial rejuvenation as well as several other cosmetic applications.

In Europe we are seeking to expand our regulatory claims for Celution®, which will enable more flexibility in our marketing efforts as well as gain reimbursement based on RESTORE 2 trial data. In Japan, we recently filed a device application with MHLW for the Celution® System with similar claims to our CE Mark in Europe.

In the U.S., we are building our presence with the launch of the PureGraft™ System. We believe that we will see meaningful revenues in the U.S. this year based on our portfolio of products, even as the Celution® System works its way through the FDA.

The FDA provided a response on our regulatory path, for which they have requested a Pre-Market Approval application for 'soft tissue filling' claims. We have requested a pre-IDE meeting with the Agency to determine the exact scale, scope, design, timing and any other requirements of a U.S. study and to discuss the specific marketing claims. We intend to utilize data from our multi-center European RESTORE 2 trial to address safety and feasibility, and anticipate a U.S. pivotal / approval study. An advantage to the PMA process is that this will add yet another meaningful barrier to entry for potential competitors as well as provide data for marketing and reimbursement. Ultimately, the approval of Celution® will be an important addition to our current line of cosmetic and reconstructive surgery products.

We are actively expanding our sales activities into select emerging markets utilizing a combination of direct sales representatives and distributors, consistent with our current approach. We believe that there is an opportunity for these markets to meaningfully contribute to revenues in 2010.

Opportunity for Partnership

We believe that the company is well positioned to establish another substantial partnership in 2010. All of the requisite elements are converging including clinical data, business model, clear regulatory strategy for FDA, expansive barriers-to-entry, growing body of successful clinical and commercial work. We presently have numerous partnership opportunities that we are considering, but maintain the goal to achieve the balance of the right partner and the right deal. While we continue to move forward with the Japanese group with whom we have signed a letter of intent, we are also looking more expansively at a variety of meaningful partnerships. As always, these are very complex and time consuming efforts and obtaining the best possible overall transaction for the company is the core goal.

Development of Product Pipeline

As noted earlier, the company successfully completed three European clinical trials during 2009 and will have additional data available from all three trials in 2010. Most notably are the two cardiovascular trials, which move our products through the regulatory process toward large unaddressed markets. Pending analysis and presentation of the data, it is our goal to continue developing a cardiovascular product for the market. We already know from the study investigators that both trials met the primary objectives of achieving safety and feasibility. The data is currently under evaluation to determine the strength and direction of the therapeutic signal. Based on the outcome, a pivotal European trial would be undertaken. Additionally, using the same path with FDA as described above, a U.S. trial is also likely, ideally leveraging the European Cardiac trials to address safety and feasibility.

Our translational product strategy continues to provide valuable clinical experience and data for a variety of medical indications. The most compelling data from numerous studies being conducted around the world is in the area of wound healing and radiation injury. Investigators are reporting complete wound healing and closure in 12 weeks on average following a single Celution® System stem and regenerative cell-based procedure. Most of these procedures are treating extremely difficult chronic wounds. Data is now available from another academic hospital treating a small population of male incontinence patients, a complication from a radical prostatectomy procedure. Early data is suggestive of a therapeutic effect and significant improvement in continence. Additional studies are planned or underway including peripheral vascular disease, heart failure, liver insufficiency, kidney ischemia, burn scar adhesions, HIV facial wasting, wrinkle therapy, GvHD, and others.

Using the Celution® System for access to the patient's own cells at the point-of-care creates this opportunity for open-architecture cell therapy where clinical investigators effectively develop early experience in numerous indications. Based on that work, the company can better select specific applications to pursue with a strong indication of ultimate clinical success. RESTORE 1 is a good example of this process. Essentially, the translational work being conducted around the world is an invaluable engine for our clinical development pipeline.

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 our deep biological understandings of adipose tissue and its rich population of stem and regenerative cells. This understanding has allowed Cytori to translate our discoveries into commercially viable products predicated on stem and regenerative cells from adipose tissue. Additionally, we are able to leverage this knowledge and comprehensive portfolio of products into the emerging global natural soft tissue filling market. This technology not only has the capability to supplant existing paradigms of patient care but also to open new markets. The first mover advantage and market share we have established, along with our intellectual property, proprietary know-how, rich product pipeline and blue chip corporate partners, position us to establish Cytori and Celution® as the leading brand in cell-based regenerative medicine.

Thank you for your interest in Cytori and we look forward to keeping you 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 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 2010 operating expenses and cash utilization rate, our sales expectations from our marketing and distribution partners which we have factored into our expected gross profit, system and consumable order trends, our ability to successfully commercialize the PureGraft™ product, 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 on Form 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.
