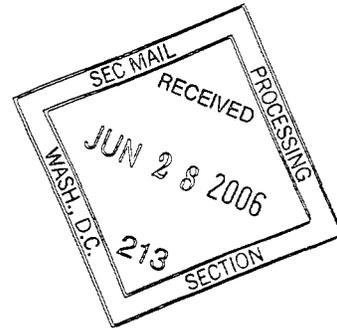




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# Cytori Therapeutics

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## Annual Report

For the year ended December 31, 2005

PROCESSED  
JUL 06 2006  
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FINANCIAL

# SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

## FORM 10-K

(Mark One)

ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended December 31, 2005

OR

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from \_\_\_\_\_ to \_\_\_\_\_

Commission file number 0-32501



### CYTORI THERAPEUTICS, INC.

(Exact name of Registrant as Specified in Its Charter)

DELAWARE  
(State or Other Jurisdiction  
of Incorporation or Organization)

33-0827593  
(I.R.S. Employer  
Identification No.)

3020 CALLAN ROAD, SAN DIEGO, CALIFORNIA  
(Address of principal executive offices)

92121  
(Zip Code)

Registrant's telephone number, including area code: (858) 458-0900

Securities registered pursuant to Section 12(b) of the Act:  
None

Securities registered pursuant to Section 12(g) of the Act:  
Common stock, par value \$0.001

Indicate by check mark if the registrant is a well-known seasoned issuer as defined in Rule 405 of the Securities Act. Yes  No

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Exchange Act. Yes  No

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes  No

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of the registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K.

Indicate by check mark whether the registrant is an accelerated filer or a non-accelerated filer as defined in Rule 12b-2 of the Exchange Act. Large Accelerated filer  Accelerated filer  Non-accelerated filer

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes  No

The aggregate market value of the common stock of the registrant held by non-affiliates of the registrant on June 30, 2005, the last business day of the registrant's most recently completed second fiscal quarter, was \$29,991,417 based on the average of the reported high and low sales price of the registrant's common stock on June 30, 2005 as reported on the Frankfurt Stock Exchange, of 2.53 Euros, or \$3.05 per share, based on the exchange rate in effect as of such date.

As of January 31, 2006, there were 15,401,865 shares of the registrant's common stock outstanding.

## DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive proxy statement for the 2006 Annual Meeting of Stockholders, which will be filed with the Securities and Exchange Commission within 120 days after the end of the year ended December 31, 2005, are incorporated by reference in Part III, Items 10, 11, 12, 13 and 14 of this Form 10-K.

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**Item 1. Business**

**General**

Cytori Therapeutics, Inc., is a biotechnology company that specializes in the discovery and development of cell based regenerative medicine therapies. Our goal is to advance adipose stem cell therapies into and through clinical trials and commercialize these therapies through an innovative cell processing system. The therapeutic indications we are focused on currently include cardiovascular disease, gastrointestinal disorders, spine and orthopedic repair, and aesthetic and reconstructive surgery. To facilitate the processing and delivery of adipose stem and regenerative cells, we have designed the proprietary point-of-care Celution™ system, to isolate and concentrate a patient's own regenerative cells in real-time in approximately one hour.

To broaden and accelerate our development efforts, we are seeking co-development partnerships with pharmaceutical, medical device or biotechnology companies. Moreover, we are searching for partners who can help identify drugs, proteins or genes that when combined with adipose stem and regenerative cells, enhance or stimulate certain select properties. For example, we may seek to identify a drug that when mixed with adipose stem and regenerative cells, directs specific cells to turn more quickly and efficiently into blood vessels.

We also have a business unit that operates under the name MacroPore Biosurgery. This business consists of two product families. The HYDROSORB™ family of bioresorbable spine and orthopedic implants is distributed worldwide exclusively by Medtronic, Inc. ("Medtronic") who owned 1.0 million shares in Cytori, or 6.5% of our total shares outstanding as of December 31, 2005. Our Thin Film product line will be marketed exclusively in Japan by Senko Medical Trading Co. ("Senko") following approval of the product in Japan. The potential revenues and profits from the MacroPore Biosurgery division would be used by Cytori to support the research and development of Cytori's cell-based therapeutics.

**Adipose Stem Cell Technology**

Adipose, also known as fat tissue, is considered the richest and most accessible known source of stem and regenerative cells. Peer reviewed research demonstrates that the mechanisms by which adipose stem and regenerative cells act are through the release of growth factors as well as other healing and repair mechanisms that occur naturally in the body. Additionally, isolated stem cells in adipose tissue have been shown to differentiate into multiple cell types, including muscle, bone, fat, cartilage, and nerve. The major advantages of adipose tissue as a source of regenerative cells, which distinguishes it from alternative cell sources, include:

- Yield: A meaningful dose of regenerative cells can be isolated in approximately one hour without cell culture (repeated cell replications)
- Safety: Patients receive their own cells (autologous-use) so there is no risk of immune rejection or disease transmission
- Versatility: Stem cells from adipose tissue impart benefit through multiple mechanisms-of-action

The Celution™ System was designed to automate our proprietary process and methods for separating, isolating and concentrating a high yield of stem and regenerative cells from adipose. Our goal is to introduce the first system that can enable real-time cellular therapy at the bedside. In 2005, we completed the development of the engineering and design for the Celution™ Clinical, which is the version of Celution™ System that will be used to conduct clinical trials in Europe and Japan to investigate clinical applications for adipose stem and regenerative cells. We received European regulatory clearance for the Celution™ Clinical through the receipt of a CE Mark in January 2006.

**Regenerative Medicine Technology Collaboration**

In November 2005, we formed a 50:50 joint venture, Olympus-Cytori, Inc. (the "Joint Venture"), with Olympus Corporation ("Olympus") to develop and manufacture future generation devices based on our Celution™ System. Olympus, a worldwide leader in the development of innovative medical products, will contribute its expertise in engineering, manufacturing and servicing of sophisticated Celution™ System associated and disposable products, enabling us to increase our focus on the development of therapeutic applications for adipose stem and regenerative cells. Key provisions of the agreement include:

- Olympus paid \$30 million to the Joint Venture for its 50% interest therein;
- We licensed our tissue processing device technology, including the Celution™ System and certain related intellectual property, to the Joint Venture and received an initial \$11 million payment and our 50% interest in the Joint Venture;
- Upon our receipt of a CE Mark for the first generation Celution™ System in January 2006, we became entitled to and

subsequently received an additional \$11 million milestone payment from the Joint Venture; and

- The Joint Venture obtained exclusive rights to develop, manufacture, and supply the devices for all therapeutic applications solely to Cytori at a formula-based transfer price and Cytori will maintain marketing rights to the devices for all therapeutic applications of adipose stem and regenerative cells.

## **Bioresorbable Technology**

Cytori's MacroPore Biosurgery unit develops and manufactures innovative bioresorbable surgical implants. Any cash flows that we may realize from MacroPore Biosurgery would be used to support the development of our adipose stem and regenerative cell therapies.

The unit's product lines include:

1. HYDROSORB™ bioresorbable spine and orthopedic surgical implants, which are marketed worldwide by Medtronic; and
2. Thin Film bioresorbable surgical implants (includes SurgiWrap™ bioresorbable products), which are used for soft tissue indications; we have disposed of our rights to these products other than in Japan. In Japan, the products will be distributed exclusively by Senko once the products receive Japanese regulatory approval.

Both bioresorbable product lines are made from a polylactide copolymer composed of lactic acid similar to that which occurs naturally in the human body. The polymer implant maintains its strength during the healing process, while slowly breaking down in the body through hydrolysis. The polymer fragments into single lactic acid molecules and the lactic acid molecules are then metabolized into carbon dioxide and water, and released from the body through the lungs and kidney. By polymerizing lactic acid and taking advantage of thermoplastic properties, we can create bioresorbable products that can be easily shaped, sized and applied to varying anatomical structures.

### *HYDROSORB™ Bioresorbable Implants*

Our HYDROSORB™ bioresorbable family of surgical implant revenues were \$5,634,000, \$3,803,000, and \$9,882,000 for the years ended December 31, 2005, 2004, and 2003, respectively. The HYDROSORB™ product line accounted for 100% of our product revenues in 2005, mostly derived from stocking orders placed for the recently launched product-line extension, Mystique™, a cervical graft containment plate. Our quarterly sales of these implants have been irregular and we currently do not observe seasonal trends for demand of the HYDROSORB™ products from Medtronic.

The HYDROSORB™ Boomerang®, HYDROSORB™ Cornerstone™ HSR, HYDROSORB™ Mesh and HYDROSORB™ Telamon® products have received FDA clearance in the United States for certain graft containment applications, and have received the CE Mark in Europe for spinal interbody fusion procedures. The HYDROSORB™ Mystique™ has received FDA clearance in the United States for use in spinal fusion procedures, in conjunction with traditional rigid fixation, as a means to maintain the relative position of weak bony tissue such as autografts. The HYDROSORB™ Shield has received FDA clearance in the United States for minimizing the attachment of soft tissue, and has received the CE Mark in Europe for the control of post-operative adhesions in spine surgery.

### *Thin Film Bioresorbable Implants*

We entered into a distribution and supply agreement in the third quarter of 2004 with Senko to market Thin Film bioresorbable implant products in Japan. The terms of the agreement include us receiving a \$1,500,000 upfront license fee, which was received in July 2004, a \$1,250,000 milestone payment related to a regulatory submission, which was received in the third quarter of 2004, a \$250,000 milestone payment for a regulatory clearance, plus manufacturing revenues and royalties for a three year-period following initiation of commercialization. We are preparing to sell Thin Film implants to Senko for distribution in Japan following our receipt of a regulatory clearance for Thin Films from the Japanese Ministry of Health, Labour and Welfare ("MHLW"). We expect regulatory clearance to be received in 2006.

We sold all worldwide rights and assets to the Thin Film product line outside of Japan to MAST Biosurgery AG and its U.S. subsidiary (MAST) in 2004 for approximately \$7,000,000. Refer to note 4 in the consolidated financial statements for further details.

## **Market and Competition**

We compete with many other pharmaceutical, biotechnology and medical device companies as well as universities, government agencies and private organizations that are involved in varying degrees in the discovery, development and commercialization of medical technologies and therapeutic products.

The field of regenerative medicine is rapidly progressing, as many organizations are initiating or expanding their research efforts in this area. Most of these organizations are involved in research using alternative cell sources to adipose tissue, including bone marrow, embryonic and fetal tissue, umbilical cord and peripheral blood, and skeletal muscle. We work exclusively with adult regenerative cells from adipose tissue.

Companies performing regenerative cell research and development include, among others, Aastrom Biosciences, Inc., Baxter International, Inc., BioHeart, Inc., Cellerix SA, Genzyme, Inc., Geron Corporation, Medtronic, MG Biotherapeutics (a joint venture between Genzyme and Medtronic), Osiris Therapeutics, Inc., Stem Cells, Inc., and ViaCell, Inc. We cannot with any accuracy forecast when or if these companies are likely to bring cell therapies to market for indications that we are also pursuing.

We are aware of two ongoing clinical studies using adipose-derived regenerative cells. One is sponsored by Cellerix, which is performing a 50 patient, Phase IIb clinical trial in Spain where adipose-derived regenerative cells are being used to treat fistulas associated with Crohn's disease. The other is sponsored by the University of Tokyo, where researchers are examining the potential of adipose-derived regenerative cells in soft tissue repair and breast tissue augmentation.

One of the most studied areas for regenerative cells is cardiovascular disease, due to its growing prevalence worldwide. According to the American Heart Association's "Heart Disease and Stroke Statistics 2005" report, heart failure affects an estimated five million Americans each year. The report added that there have been 13 million cases of coronary heart disease and of those, 865,000 have been new or recurrent cases of myocardial infarction.

Companies with advanced research and development programs for regenerative treatments of cardiovascular disease include Baxter, BioHeart, MG Biotherapeutics, Osiris, and ViaCell. Baxter supports a Phase II study at St. Elizabeth's Medical Center in Boston using stem cells extracted from peripheral blood as an investigational treatment for myocardial ischemia. BioHeart is currently conducting a Phase I clinical study in the US on the investigational product MyoCell™, an autologous, skeletal myoblast cell therapy for heart disorders as an adjunct to bypass surgery. In addition, Bioheart is conducting a Phase I trial in the US on the investigational product MyoCell™ which is delivered via a percutaneous catheter system. Osiris Therapeutics, Inc. is currently conducting a Phase I clinical trial using Provacel™, an investigational, allogeneic, adult, mesenchymal stem cell therapy for acute myocardial infarction. ViaCell, Inc. is currently in preclinical development using allogeneic cells derived from umbilical cord blood for cardiac disease and they are expected to enter clinical trials in 2006 or 2007.

The only regenerative cell product or service currently marketed by us is our cell banking service, which is being offered on a limited basis, to surgical patients undergoing liposuction procedures. We are aware of only one other company, BioMatrix, Inc., who is intending to provide a similar service. There are various companies engaged in umbilical cord blood and bone marrow stem cell preservation.

Our HYDROSORB™ product line competes primarily with titanium, allograft tissue (cadaver bone), and polyetheretherketone (PEEK) polymer products. We believe that an increasing number of other companies are developing, or are offering, bioresorbable devices. Stryker, Inc., Interpore Cross (Biomet), and Synthes are three companies that we are aware of who distribute both bioresorbable and titanium implants. Our Thin Film product line, if approved in Japan, will compete directly with Genzyme's SeptraFilm anti-adhesion barrier product.

Many of our competitors and potential competitors have substantially greater financial, technological, research and development, marketing and personnel resources than we do. These competitors may also have greater experience in developing products, conducting clinical trials, obtaining regulatory approvals, and manufacturing and marketing such products. Some of these competitors may obtain patent protection, approval or clearance by the FDA or from foreign countries, or may achieve product commercialization earlier than we can, any of which could materially and adversely affect our business or results of operations. We cannot be assured that our competitors will not succeed in developing alternative technologies and products that are more effective, easier to use or more economical than those which have been or are being developed by us or that would render our technology and products obsolete and noncompetitive in these fields. In addition, even if our products are technologically superior, it is possible that competitors' superior marketing power could limit our share of the marketplace. Furthermore, Medtronic may pursue parallel development of or acquisition of rights to other technologies or products, which may result in Medtronic developing or acquiring rights to additional products that will compete with our bioresorbable spine and orthopedic products. This would in turn induce Medtronic to further de-emphasize marketing of our products in favor of more profitable products.

## **Research and Development**

Research and development expenses, excluding stock based compensation, were \$15,271,000, \$10,352,000, and \$8,694,000 for the years ended December 31, 2005, 2004 and 2003, respectively. For 2005, \$12,930,000 was allocated toward our regenerative cell technology and \$2,341,000 was allocated toward our bioresorbable technology.

Our research and development efforts in 2005 focused predominantly on two areas:

- Completing the designing and testing of the Celution™ System and preparing international regulatory submissions; and
- Conducting preclinical studies to investigate the therapeutic potential of adipose stem and regenerative cells in primarily cardiovascular disease, as well as other select indications.

The most significant development for the Celution™ System in 2005 was that we submitted an application for a CE Mark on the system. The CE Mark, which grants regulatory approval in the European Union and other countries that recognize the CE Mark, was received in January 2006. In 2006, we will continue our efforts to seek regulatory approval for the Celution™ System in Japan and the United States.

Our preclinical research in 2005 focused predominantly on developing applications for cardiovascular disease, which include myocardial infarction and congestive heart failure. We presented data in conjunction with Tulane University, from a randomized, controlled study in October 2005. In this preclinical study, injections of either adipose stem and regenerative cells (treated) or a saline injection (control) were received via catheter into the artery at the site of the heart attack. After eight weeks, there was a statistically significant reduction in the perfusion defect, which is the area of the heart deprived of oxygen as a result of the infarct. A corresponding benefit was observed by the improvement in ejection fraction, a common measure of the heart's pumping efficiency. We reported results from additional studies, which showed that one of the primary mechanisms by which adipose stem and regenerative cells act is through the promotion of blood vessel growth, thereby improving oxygen flow to damaged tissue at risk of dying.

We also have ongoing preclinical collaborations with several other major U.S. and European academic research institutions. Our collaborators include the University of California, Los Angeles, where a team directed by W. Robb MacLellan, M.D., is working with us on a National Institutes of Health Small Business Innovation Research grant. We also have research underway both internally and with a collaborator in Europe exploring potential spine and orthopedic applications for adipose stem and regenerative cells.

In 2005, our bioresorbable technology research and development efforts resulted in multiple new spine and orthopedic products and product advancements in conjunction with existing products sold to our distributor Medtronic. This included the development and FDA clearance for a radiographically identifiable version of our HYDROSORB™ Spine System, which is the first and only resorbable spinal implant to include a radiopaque marker fabricated from a resorbable material. It will allow physicians to visualize and monitor the position and placement of plates, screws, or other implants over time without obstructing the view of the healing bone. This new product line was launched in July 2005 by Medtronic as the MYSTIQUE™ Resorbable Graft Containment Plating System.

Our bioresorbable research and development efforts also focused on gaining regulatory approval to market our Thin Film products in Japan. In September 2004, we submitted an application to the MHLW for approval to market SurgiWrap™ and CardioWrap™. We expect to receive regulatory clearance in 2006.

## **Products and Services**

Our regenerative cell related therapeutic business is currently in the development stage and we have not yet developed regenerative cell related therapies or treatments for commercial use in any region. In January 2006, we received a CE Mark for the Celution™ System, granting us regulatory approval in the European Union and all member states that recognized the CE Mark. However, at this time, we are not actively marketing the Celution™ System in Europe, and choose to do so in a very limited and controlled capacity until the completion of clinical studies to confirm the efficacy of adipose stem and regenerative cells for specific human therapeutic indications. At this time, we have not yet commercialized any regenerative cell related therapies or treatments for use in any geographical regions.

Our MacroPore Biosurgery business manufactures a line of surgical implants derived from our bioresorbable technology. The HYDROSORB™ family of products is distributed exclusively by Medtronic. HYDROSORB™ is a trademark of Medtronic. In 2005, this product line accounted for 100% of our total product revenues. The Thin Film line of products, pending regulatory approval in Japan, would be distributed exclusively through Senko. These products would be used for anti-adhesion applications, soft tissue support, and minimization of the attachment of soft tissues throughout the body.

We operate a California state-licensed tissue bank facility for the preservation of stem and regenerative cells extracted from adipose tissue. This service is being offered on a limited basis to surgical patients undergoing liposuction procedures. Typically arranged through a patient's physician, cell preservation is the process by which regenerative cells, taken from a liposuction or other procedure, are stored (cryopreserved) in a liquid nitrogen freezer at -320°F (-196°C) exclusively for the patient who preserved them. The cells can be preserved indefinitely.

## **Customers**

Medtronic is our primary distributor and our principal customer for our bioresorbable implant products, directly accounting for \$5,634,000 or 100% of our product revenues for the year ended December 31, 2005, \$4,085,000 or 64.6% of our product revenues for the year ended December 31, 2004, and \$12,893,000 or 91.6% of our product revenues for the year ended December 31, 2003.

Under our global co-development and supply agreement with Medtronic, we co-develop bioresorbable implants for spinal or reconstructive fixation, stabilization and fusion. Medtronic has exclusive worldwide rights to market and sell all of the bioresorbable products that we co-develop for this application through January 2012. Currently our only commercially available product line under this agreement is the HYDROSORB™ family of spine and orthopedic implants. Both companies own an undivided, one-half interest in any inventions we jointly develop.

In July 2004, we entered into a Distribution Agreement with Senko. Under this agreement, we granted to Senko an exclusive license to sell and distribute certain Thin Film products in Japan. The sale of products through Senko commences upon "commercialization," which requires regulatory clearance from the MHLW. We expect to gain the required regulatory clearance in 2006. Following commercialization, the Distribution Agreement has a five-year duration and is renewable for an additional five years after reaching mutually agreed minimum purchase guarantees.

## **Sales by Geographic Region**

We sell our products predominantly in the United States and to a lesser extent internationally through Medtronic. International sales may be limited or disrupted by political instability, price controls, acts of war, trade restrictions and changes in tariffs. Our existing distribution agreements all provide for payment in U.S. dollars and we intend to include similar payment provisions in future distribution agreements. Fluctuations in currency exchange rates may affect demand for our products by increasing the price of our products relative to the currency of the countries in which the products are sold.

For the year ended December 31, 2005, we recorded \$6,005,000 in product and development revenues, all of which were derived from customers based in the United States. For the year ended December 31, 2004, we recorded \$6,818,000 in product and development revenues, including \$6,602,000 of revenues in the United States and \$216,000 of revenues outside the United States. For the year ended December 31, 2003, we recorded \$14,088,000 in product and development revenues, including \$13,727,000 of revenues in the United States and \$361,000 of revenues outside the United States.

We hope that our future international product revenues will increase as a result of our Distribution Agreement with Senko.

## **Working Capital**

Based on Medtronic's volatile purchasing history, we generally build products to order. Although capital expenditures may vary significantly depending on a variety of factors, including sales, we presently intend to spend approximately \$2,500,000 on capital equipment purchases in 2006, mostly related to initial leasehold improvements at our new corporate headquarters. A portion of these may be paid with our current cash reserve.

## **Raw Materials**

We currently purchase the high molecular weight, medical grade, lactic acid copolymer used in manufacturing most of our bioresorbable products from a single qualified source, B.I. Chemicals, Inc. Although we have a contract with B.I. Chemicals, which guarantees continuation of supply through August 15, 2007, we cannot guarantee that they will elect to continue the contract beyond that date, or that they will not elect to discontinue the manufacture of the material. They have agreed that if they discontinue manufacturing they will either find a replacement supplier, or provide us with the necessary technology to self-manufacture the material, either of which could mean a substantial increase in material costs. Also, despite this agreement, they might fail to fulfill their obligations. Under the terms of the contract, B.I. Chemicals, Inc. may choose to raise their prices upon six months prior notice which may also result in a substantially increased material cost. Although we believe that we would be able to obtain the material from at least one other source in the event of a failure of supply, there can be no assurance that we will be able to obtain adequate increased commercial quantities of the necessary high quality within a reasonable period of time or at commercially reasonable rates. Lack of adequate commercial quantities or inability to develop alternative sources meeting regulatory requirements at similar prices and terms within a reasonable time or any interruptions in supply in the future could have a significant negative effect on our ability to manufacture products, and, consequently, could have a material adverse effect on the results of our operations, cash flows and financial condition.

## **Intellectual Property**

Our success depends in large part on our ability to protect our proprietary technology and information, and operate without

infringing on the proprietary rights of third parties. We rely on a combination of patent, trade secret, copyright and trademark laws, as well as confidentiality agreements, licensing agreements and other agreements, to establish and protect our proprietary rights. Our success also depends, in part, on our ability to avoid infringing patents issued to others. If we were judicially determined to be infringing any third party patent, we could be required to pay damages, alter our products or processes, obtain licenses or cease certain activities.

To protect our proprietary regenerative cell technology we have filed applications for 27 United States patents, as well as 68 corresponding international patent applications. We are also the exclusive, worldwide licensee of the Regents of the University of California's rights to one U.S. Patent (Patent No. 6,777,231) related to isolated adipose derived stem cells that can differentiate into two or more of a variety of cell types, and five related U.S. patent applications and 26 corresponding international patent applications. With respect to our bioresorbable implant products and technology, we have obtained 13 U.S. patents, three of which were sold in product line dispositions. Our three U.S. patents related to the design of our macro-porous bioresorbable sheets for skeletal repair and regeneration were issued in July 1999, August 2001 and March 2004. Our three U.S. patents for the design of our high torque bioresorbable screws were issued in August 2001, February 2002 and November 2002. Our U.S. patent related to our membrane with tissue guiding surface corrugations was issued in May 2002. Our two U.S. patents related to our bioresorbable barrier film for the control of postsurgical adhesions were issued in March 2003 and January 2004 and assigned to MAST as part of the Thin Film product line sale agreement. Our U.S. patent related to stereotaxic detachable needle extensions was issued in June 2003. Our U.S. patent related to non-scatterable radio-opaque material for imaging applications was issued in October 2003. Our U.S. patent related to a resorbable posterior spinal fusion system was issued in April 2004. Our U.S. patent for a cranial flap fixation device was issued in June 2004 and assigned to Medtronic pursuant to the September 2002 CMF product line sale agreement. We also have two Australian patents related to our bioresorbable mesh, one Australian patent for the design of our high torque bioresorbable screws and another Australian patent related to our membrane with tissue guiding surface corrugations. Our four Australian patents were issued in August 2000, January 2003 and September 2003. Each of our patents will expire 20 years from the filing date of the original patent application. In addition, we have filed applications for 15 additional U.S. patents as well as 42 corresponding international patents relating to our bioresorbable technology.

We cannot assure that any of the pending patent applications will be issued, that we will develop additional proprietary products that are patentable, that any patents issued to us will provide us with competitive advantages or will not be challenged by any third parties or that the patents of others will not prevent the commercialization of products incorporating our technology. Furthermore, we cannot assure that others will not independently develop similar products, duplicate any of our products or design around our patents. U.S. patent applications are not immediately made public, so we might be surprised by the grant to someone else of a patent on a technology we are actively using.

Patent law outside the United States is uncertain and in many countries is currently undergoing review and revisions. The laws of some countries may not protect our proprietary rights to the same extent as the laws of the U.S. Third parties may attempt to oppose the issuance of patents to us in foreign countries by initiating opposition proceedings. Opposition proceedings against any of our patent filings in a foreign country could have an adverse effect on our corresponding patents that are issued or pending in the U.S. It may be necessary or useful for us to participate in proceedings to determine the validity of our patents or our competitors' patents that have been issued in countries other than the U.S. This could result in substantial costs, divert our efforts and attention from other aspects of our business, and could have a material adverse effect on our results of operations and financial condition. We currently have pending patent applications in Europe, Australia, Japan, Canada, China, Korea, and Singapore, among others.

Patent litigation results in substantial costs to us and diversion of effort, and may be necessary from time to time to enforce or confirm the ownership of any patents issued or licensed to us or to determine the scope and validity of third party proprietary rights. If our competitors claim technology also claimed by us and prepare and file patent applications in the United States, we may have to participate in interference proceedings declared by the U.S. Patent and Trademark Office or a foreign patent office to determine priority of invention, which could result in substantial costs to and diversion of effort, even if the eventual outcome is favorable to us. For example, in the fourth quarter of 2004, the University of Pittsburgh ("U Pitt") filed a lawsuit naming all of the inventors who had not assigned their ownership interest in Patent 6,777,231 to U Pitt, seeking a determination that its assignors, rather than the University of California's assignors, are the true inventors of Patent No. 6,777,231. If U Pitt wins the lawsuit, our license rights to this patent could be nullified or rendered non-exclusive with respect to any third party that might license rights from U Pitt, and our strategy related to our regenerative cell technology could be significantly impacted. We expect to incur substantial legal costs as a result of U Pitt lawsuit, and our president, Marc Hedrick, M.D., is a named individual defendant in that lawsuit.

In addition to patent protection, we rely on unpatented trade secrets and proprietary technological expertise. We cannot assure you that others will not independently develop or otherwise acquire substantially equivalent techniques, or otherwise gain access to our trade secrets and proprietary technological expertise or disclose such trade secrets, or that we can ultimately protect our rights to such unpatented trade secrets and proprietary technological expertise. We rely, in part, on confidentiality agreements with our marketing partners, employees, advisors, vendors and consultants to protect our trade secrets and proprietary technological expertise. We cannot assure you that these agreements will not be breached, that we will have adequate remedies for any breach or that our unpatented trade secrets and proprietary technological expertise will not otherwise become known or be independently discovered by competitors.

Failure to obtain or maintain patent protection, or protect trade secrets, for any reason, third party claims against our patents, trade secrets or proprietary rights, or our involvement in disputes over our patents, trade secrets or proprietary rights, including involvement in litigation, could have a substantial negative effect on the results of our operations, cash flows and financial condition.

## Government Regulation

Most medical devices, therapies and treatments for use in humans, including our bioresorbable protective sheets, plates, and screws, are subject to stringent government regulation in the United States by the Food and Drug Administration, or "FDA," under the federal Food, Drug and Cosmetic Act, or "FDC" Act. The FDA regulates the clinical testing, manufacturing, safety, labeling, sales, distribution and promotion of medical devices and therapies. Included among these regulations are premarket clearance, premarket approval, biologic license application, new drug application, and Quality System Regulation, or "QSR," requirements. Other statutory and regulatory requirements govern, among other things, registration and inspection, medical device listing, prohibitions against misbranding and adulteration, labeling and postmarket reporting. The regulatory process may be lengthy, expensive and uncertain. Securing FDA approvals and clearances may require us to submit extensive clinical data and supporting information to the FDA. Failure to comply with applicable requirements can result in application integrity proceedings, fines, recalls or seizures of products, injunctions, civil penalties, total or partial suspensions of production, withdrawals of existing product approvals or clearances, refusal to approve or clear new applications or notifications, and criminal prosecution.

Under the FDC Act, medical devices are classified into Class I, Class II or Class III devices, based on their risks and the control necessary to reasonably ensure their safety and effectiveness. Class I devices are subject to general controls such as labeling and adherence to QSR requirements. Class II devices are subject to general controls, and may be subject to specific controls such as performance standards, postmarket surveillance and patient registries. Class II devices require premarket notification to the FDA in the form of a 510(k) application that demonstrates the new device to be "substantially equivalent" to an existing FDA 510(k) cleared device. Generally, Class III devices, which include certain life-sustaining, life-supporting and implantable devices or new devices which have been found not to be substantially equivalent to certain legally marketed devices, must receive premarket approval from the FDA. All of our bioresorbable implant products to date are Class II medical devices. Regenerative medicine devices and therapies are most likely Class III with some exceptions regarding cell processing devices that may be Class II.

Before any new Class II or III medical device may be introduced to the market, the manufacturer generally must obtain either premarket clearance through the 510(k) premarket notification process or premarket approval through the lengthier Premarket Approval Application, or "PMA," process. The FDA will grant a 510(k) premarket notification if the submitted data establishes that the proposed device is "substantially equivalent" to a legally marketed Class I or Class II medical device. The FDA may request data, including clinical studies, before it can make a determination of substantial equivalence. It generally takes from three to 12 months from submission to obtain 510(k) premarket clearance, although it may take longer. There is no assurance that clearance will be granted. We must file a PMA if one of our products is found not to be substantially equivalent to a legally marketed Class II device or if it is a Class III device for which the FDA requires PMAs. A PMA must be supported by extensive data to demonstrate the safety and effectiveness of the device, including laboratory, preclinical and clinical trial data, as well as extensive manufacturing information. Before initiating human clinical trials on devices that present a significant risk, we must first obtain an Investigational Device Exemption, or IDE, for the proposed medical device. Obtaining FDA approval of the Investigational Device Exemption allows the sponsor to begin the collection of clinical data according to a protocol that must be approved by the FDA. Several factors influence the overall time frame of the IDE process. These include: the number of patients required for statistical significance, the requirement for a pilot (safety) study in advance of initiating a pivotal study, and the duration of follow-up required before the IDE can be closed and the PMA prepared for submission to FDA. This follow-up period typically ranges from 12-24 months on the last patient to be enrolled in the study. Toward the end of the PMA review process, the FDA will generally conduct an inspection of the manufacturing facilities to ensure compliance with QSRs. Approval of a PMA could take up to one or more years from the date of submission of the application or petition; however, the entire process of IDE submission /approval, clinical data collection, patient follow-up, PMA preparation and approval typically requires 4 years or more. The PMA process can also be expensive and uncertain, and there is no guarantee of ultimate approval.

Modifications or enhancements of products that could affect the safety or effectiveness or effect a major change in the intended use of a device that was either cleared through the 510(k) process or approved through the PMA process may require further FDA review through new 510(k) or PMA submissions.

As a medical device manufacturer, we are subject to periodic inspections by the FDA to ensure that devices continue to be manufactured in accordance with QSR requirements. We are also subject to postmarket reporting requirements for deaths or serious injuries when a device may have caused or contributed to death or serious injury, and for certain device malfunctions that would be likely to cause or contribute to a death or serious injury if the malfunction were to recur. Postmarket reporting also may be required for certain corrective actions undertaken for distributed devices. If safety or effectiveness problems occur after the product reaches the market, the FDA may take steps to prevent or limit further marketing of the product. Additionally, the FDA actively enforces regulations prohibiting marketing of devices for indications or uses that have not been cleared or approved by the FDA.

Under the terms of our development and supply agreement with Medtronic, Medtronic is responsible for preparing and filing applications for, and obtaining regulatory approval of the products we co-develop for use in spinal fixation, stabilization or fusion applications.

We or our marketing partners may not be able to obtain necessary 510(k) clearances or PMA approvals to market the products we are developing in the United States for their intended use on a timely basis, if at all.

We must comply with extensive regulations from foreign jurisdictions regarding safety, manufacturing processes and quality. These regulations, including the requirements for marketing authorization, may differ from the United States FDA regulatory requirements. Specifically, in regard to our licensing agreement with Senko, marketing authorization from the Japanese Ministry of Health, Labour and Welfare is necessary for commercialization of the Thin Film product line in Japan.

We may not be able to obtain marketing authorization in all of the countries where we intend to market our products, may incur significant costs in obtaining or maintaining our foreign marketing authorizations, or may not be able to successfully commercialize our current or future products in any foreign markets. Delays in receipt of marketing authorizations for our products in foreign countries, failure to receive such marketing authorizations or the future loss of previously received marketing authorizations could have a material adverse effect on our results of operations, cash flows and financial condition.

## Staff

As of December 31, 2005, we had 137 full-time employees, comprised of 15 employees in manufacturing, 91 employees in research and development, 5 employees in sales and marketing and 26 employees in management and finance and administration. From time to time, we also employ independent contractors to support our administrative organizations. Our employees are not represented by any collective bargaining unit and we have never experienced a work stoppage. A breakout by segment is as follows:

	<u>Regenerative Cell Technology</u>	<u>MacroPore Biosurgery</u>	<u>Corporate</u>	<u>Total</u>
Manufacturing .....	0	15	0	15
Research & Development .....	86	5	0	91
Sales and Marketing .....	3	2	0	5
General & Administrative .....	0	0	26	26
Total .....	<u>89</u>	<u>22</u>	<u>26</u>	<u>137</u>

## Web Site Access to SEC Filings

We maintain an Internet website at [www.cytortix.com](http://www.cytortix.com). Through this site, we make available free of charge our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and amendments to those reports filed or furnished pursuant to Section 13(a) of the Securities Exchange Act of 1934 as soon as reasonably practicable after we electronically file such material with, or furnish it to, the U.S. Securities and Exchange Commission (SEC). In addition, we publish on our website all reports filed under Section 16(a) of the Exchange Act by our directors, officers and 10% stockholders.

These materials are accessible via the Investor Relations section of our website within the "SEC Filings" link. Some of the information is stored directly on our website, while other information can be accessed by selecting the provided link to the section on the SEC website, which contains filings for our company and its insiders.

## Item 1A. Risk Factors

*In analyzing our company, you should consider carefully the following risk factors, together with all of the other information included in this annual report on Form 10-K. Factors that could cause or contribute to differences in our actual results include those discussed in the following section, as well as those discussed below in "Management's Discussion and Analysis of Financial Condition and Results of Operations" and elsewhere throughout this annual report on Form 10-K. Each of the following risk factors, either alone or taken together, could adversely affect our business, operating results and financial condition, as well as adversely affect the value of an investment in our common stock.*

We are subject to the following significant risks, among others:

### We will need to raise more cash in the future

As of December 31, 2005, we had \$15,845,000 of cash, cash equivalents and short-term investments; we have always had negative cash flows from operations. Our regenerative cell business will continue to result in a substantial requirement for research and development expenses for several years, during which it could bring in no significant revenues. We will need to obtain additional cash, through financings or special strategic transactions, by no later than 2007. There can be no guarantee that adequate funds for our

operations from any additional debt or equity financing, our operating revenues, arrangements with distribution partners or from other sources will be available when needed or on terms attractive to us. The inability to obtain sufficient funds would require us to delay, scale back or eliminate some or all of our research or product development programs, manufacturing operations, clinical studies or regulatory activities as well as our ability to license third parties to commercialize products or technologies that we would otherwise seek to develop ourselves, thus having a substantial negative effect on the results of our operations and financial condition.

We have never been profitable on an operational basis and we will have significant operating losses for at least the next several years

We have incurred net operating losses in each year since we started doing business. These losses have resulted primarily from expenses associated with our research and development activities and general and administrative expenses. Development-stage losses related to our development of regenerative cell technology are expected to keep us in a loss position on a consolidated basis for several years. We anticipate that our recurring operating expenses will increase to high levels for the next several years, due to the continued need to fund our clinical research program as well as additional preclinical research. We expect to continue to incur operational losses in our spine and orthopedics business at least through the end of 2006, and the amount of future net losses and time necessary to reach operational profitability are somewhat uncertain.

Our business is high-risk

We are focusing all of our resources and efforts primarily on our regenerative cell technology and its development-stage cash needs. This is a high-risk strategy because there can be no assurance that our regenerative cell technology will ever be developed into commercially viable products (commercial risk), that we will be able to preclude other companies from depriving us of market share and profit margins by selling products based on our inventions and developments (legal risk), that we will be able to successfully manage a company in a different business than we have operated in the past (operational risk), that we will be able to deliver regenerative cells into the body to achieve the desired therapeutic results (scientific risk), or that our cash resources will be adequate to develop the regenerative cell technology until it becomes profitable, if ever (financial risk). We are using our cash in one of the riskiest industries in the economy (strategic risk). This may make our stock an unsuitable investment for some investors.

The financial risk in this strategy is significant, particularly since our bioresorbable products are not currently independently cash-flow-positive. Although we eliminated the negative cash flow of the early commercialization stage of the (non-Japan) Thin Film business by selling that business to MAST in May 2004, even our core spine and orthopedics implants business fell back into a negative cash flow position in 2004 due to the sharp reduction in orders from and sales to Medtronic. This trend continued in 2005 despite stocking orders for the new MYSTIQUE™ line and the overall biomaterials cash flow remained negative.

We must keep our joint venture with Olympus operating smoothly

Our regenerative cell business cannot succeed on the current timelines unless our joint venture collaboration with Olympus goes well. We have given Olympus-Cytori, Inc. an exclusive license to our regenerative cell therapeutic device technology for use in future generation devices. If Olympus-Cytori, Inc. does not successfully develop and manufacture future generation devices for sale to us, we may not be able to commercialize any device successfully into the market. In addition, any future disruption in or breakup of our relationship with Olympus would be extremely costly to our reputation, in addition to causing many serious practical problems.

We and Olympus must overcome contractual and cultural barriers as we work together. Our relationship is formally measured by a set of complex contracts, which have not yet been tested in practice. In addition, many aspects of the relationship will be essentially non-contractual and must be worked out between the parties and the responsible individuals over time. The joint venture is intended to have a long life, and it is difficult to maintain cooperative relationships over a long period of time in the face of various kinds of change, especially when the parties are separated by a great distance and (to some degree) language difficulties and cultural differences.

Olympus-Cytori, Inc. is 50% owned by us and 50% owned by Olympus. By contract, each side must consent before any of a wide variety of important business actions can occur. This situation possesses a risk of potential time-consuming and difficult negotiations which could at some point delay the joint venture from pursuing its business strategies.

Olympus is entitled to designate the joint venture's chief executive officer and a majority of its board of directors, which means that day-to-day decisions which are not subject to a contractual veto will essentially be controlled by Olympus. In addition, Olympus-Cytori, Inc. is likely to need more money than its initial capitalization in order to finalize development of and production of the future generation devices. If we are unable to help provide future financing for Olympus-Cytori, Inc., our relative equity interest in Olympus-Cytori, Inc. may decrease.

Furthermore, under a License/Joint Development Agreement among Olympus-Cytori, Inc., Olympus, and us, Olympus will have a primary role in the development of Olympus-Cytori, Inc.'s future generation devices. Although Olympus has extensive experience in developing medical devices, this arrangement will result in a reduction of our control over the development and manufacturing of the future generation devices.

We rely on Medtronic to distribute a majority of our current biomaterials products, but Medtronic's level of commitment to our products is doubtful

We have limited control over sales, marketing and distribution of our biomaterials products. Our strategy for sales and marketing of our bioresorbable products included entering into an agreement with Medtronic, a company with a large distribution network, to market many of our current and certain future products incorporating our technology. The sale of hard-tissue-fixation bioresorbable implant products to our distribution partner, Medtronic, has constituted the majority of our revenues.

We remain significantly dependent on Medtronic to generate sales revenues for all of our spine and orthopedics bioresorbable products. The amount and timing of resources which may be devoted to the performance of Medtronic's contractual responsibilities are not within our control. There can be no guarantee that Medtronic will perform its obligations as expected or pay us any additional option or license fees. There is also no guarantee that it will market any new products under the distribution agreements or that we will derive any significant revenue from such arrangements. Medtronic's sale of our products to end customers in 2004 and 2005, and its rate of product orders placed with us in the same period, disappointed our expectations with the exception of stocking orders for the new MYSTIQUE™ line. 2004 and 2005 results were exceptionally weak, and we are significantly disappointed with the marketing efforts of Medtronic for our non-MYSTIQUE™ products at this time. We recorded an inventory provision for slow-moving non-MYSTIQUE™ inventory in the second, third and fourth quarters of 2005.

Our dependence upon Medtronic to market and sell our bioresorbable products places us in a position where we cannot accurately predict the extent to which our products will be actively and effectively marketed, depriving us of some of the reliable data we need to make optimal operational and strategic decisions. The consequent lack of visibility is evidenced by the withdrawal of our announced financial guidance for 2004, and our results falling within the lowest range of our guidance for 2005.

The prices which Medtronic pays us are fixed (pending biannual price reviews), based on a percentage of Medtronic's historic selling price to its customers. If our costs increase but our selling prices remain fixed, our profit margin will suffer.

Medtronic owns 6.5% of our stock, which may limit our ability to negotiate commercial arrangements optimally with Medtronic. Although Medtronic has exclusive distribution rights to our co-developed spinal implants, it also distributes other products that are competitive to ours. Medtronic might choose to develop and distribute existing or alternative technologies in preference to our technology in the spine, or preferentially market competitive products that can achieve higher profit margins. We suspect that this has in fact been happening.

There can be no assurance that our interests will continue to coincide with those of Medtronic or that disagreement over rights or technology or other proprietary interests will not occur. The loss of the marketing services provided by Medtronic (or the failure of Medtronic to satisfactorily perform these marketing services), or the loss of revenues generated by Medtronic, could have a substantial negative effect on our ability or willingness to continue our spine and orthopedics biomaterials business.

Senko has not yet begun to distribute our Thin Film products in Japan; but if and when they do, we may experience similar risk with them as we have experienced in our Medtronic relationship.

We have a limited operating history; our operating results can be volatile

Our prospects must be evaluated in light of the risks and difficulties frequently encountered by emerging companies and particularly by such companies in rapidly evolving and technologically advanced fields such as the biotechnology and medical device fields. Due to our limited operating history, and the development stage status of our regenerative cell business, comparisons of our year-to-year operating results are not necessarily meaningful and the results for any periods should not necessarily be relied upon as an indication for future performance. Since our limited operating history makes the prediction of future results difficult or impossible, our recent revenue results should not be taken as an indication of any future growth or of a sustainable level of revenue. Operating results will also be affected by our transition away from our revenue generating medical device business and the focus of the vast majority of our resources into the development-stage regenerative cell business.

Moreover, our operating results can vary substantially from our previously published financial guidance (such as occurred in the second quarter of 2004), from analyst expectations and from previous periodic results for many reasons, including the timing of product introductions and distributor purchase orders. Also, the 2002 sale of our CMF bone fixation implant and accessory product line, which had represented a large portion of our revenues, plus the 2004 sale of our (non-Japan) Thin Film surgical implants for separation of soft tissues, will distort quarterly and annual earning comparisons through 2004, 2005 and 2006. Earnings surprises can have a disproportionate effect on the stock prices of emerging companies such as ours. Also, our stock price is likely to be disproportionately affected by changes which generally affect the economy, the stock market or the medical device and biotechnology industries.

From time to time, we have tried to influence our investors' expectations as to our operating results by periodically announcing financial guidance. However, we have in the past been forced to revise or withdraw such guidance due to lack of visibility and predictability of product demand. This lack of visibility and predictability of product demand for our bioresorbable implant products is likely to occur in the future as well.

#### We are vulnerable to competition and technological change, and also to physicians' inertia

We compete with many domestic and foreign companies in developing our technology and products, including biotechnical, medical device, pharmaceutical and biopharmaceutical companies. Many of our competitors and potential competitors have substantially greater financial, technological, research and development, marketing and personnel resources than we do. There can be no assurance that our competitors will not succeed in developing alternative technologies and products that are more effective, easier to use or more economical than those which we have developed or are in the process of developing or that would render our technology and products obsolete and non-competitive in these fields. In general, we may not be able to preclude other companies from developing and marketing competitive regenerative cell therapies or bioresorbable products that are similar to ours or perform similar functions.

These competitors may also have greater experience in developing therapeutic treatments, conducting clinical trials, obtaining regulatory clearances or approvals, manufacturing and commercializing therapeutic or biomaterials products. It is possible that certain of these competitors may obtain patent protection, approval or clearance by the U.S. Food and Drug Administration "FDA" or achieve commercialization earlier than we, any of which could have a substantial negative effect on our business. Finally, Olympus, Medtronic and our other partners might pursue parallel development of other technologies or products, which may result in a partner developing additional products that will compete with our products.

We also compete with other types of regenerative cell therapies such as bone marrow derived cell therapies, and potentially embryonic derived therapies. Our biomaterials business competes with manufacturers of traditional non-bioresorbable implants, such as titanium implants. Doctors have historically been slow to adopt new technologies such as ours, whatever the merits, when older technologies continue to be supported by established providers. Overcoming such inertia often requires very significant marketing expenditures or definitive product superiority.

We expect physicians' inertia and skepticism to also be a significant barrier as we attempt to gain market penetration with our future regenerative cell products. We believe we will need to finance lengthy time-consuming clinical studies (so as to provide convincing evidence of the medical benefit) in order to overcome this inertia and skepticism.

#### We depend on recently introduced products and anticipated new products, which subject us to development and marketing risks

We are in a relatively early stage of commercialization with many of our products. We believe that our long-term viability and growth will depend in large part on our ability to develop commercial quality cell processing devices and to establish the safety and efficacy of our therapies through clinical trials and studies. We are presently pursuing regenerative cell opportunities in cardiovascular disease, spine and orthopedic conditions, gastrointestinal disorders and new approaches for aesthetic and reconstructive surgery that may require extensive additional capital investment, research, development, clinical testing and regulatory clearances or approvals prior to commercialization. There can be no assurance that our development programs will be successfully completed or that required regulatory clearances or approvals will be obtained on a timely basis, if at all.

The path to commercial profit from our regenerative cell technology is unclear even if we demonstrate the medical benefit of our regenerative cell technology in various applications. There is no proven path for commercializing the technology in a way to earn a durable profit commensurate with the medical benefit. Most of our cell-related products and/or services are at least three to five years away.

Moreover, the successful development and market acceptance of our technologies and products are subject to inherent developmental risks, including ineffectiveness or lack of safety, unreliability, failure to receive necessary regulatory clearances or approvals, high commercial cost and preclusion or obsolescence resulting from third parties' proprietary rights or superior or equivalent products, as well as general economic conditions affecting purchasing patterns. There can be no assurance that we or our partners will be able to successfully develop and commercialize our technologies or products, or that our competitors will not develop competing technologies that are less expensive or otherwise superior to ours. The failure to successfully develop and market our new regenerative cell technologies would have a substantial negative effect on the results of our operations and financial condition.

#### We have limited manufacturing experience

We have no experience in manufacturing the Celution™ system at a commercial level, and although Olympus is a highly capable and experienced manufacturer of medical devices, there can be no guarantee that the Olympus-Cytori joint venture will be able to successfully develop and manufacture the Celution™ system in a manner that is cost-effective or commercially viable, or that development and manufacturing capabilities might not take much longer than currently anticipated to be ready for the market.

In the event that the Olympus-Cytori joint venture is not successful, Cytori may not have the required level of technical ability or other resources to self-manufacture commercially viable devices, and in any event this failure would substantially extend the time it would take for us to bring a commercial device to market. This makes us significantly dependent on the continued dedication and skill of Olympus for the successful development of the Celution™ system.

In addition, the future of our biomaterials business success is significantly dependent on our ability to manufacture our bioresorbable implants in commercial quantities, in compliance with regulatory requirements and in a cost-effective manner. Production of some of our products in commercial-scale quantities may involve unforeseen technical challenges and may require significant scale-up expenses for additions to facilities and personnel. There can be no guarantee that we will be able to achieve large-scale manufacturing capabilities for some of our biomaterials products or that we will be able to manufacture these products in a cost-effective manner or in quantities necessary to allow us to achieve profitability. Our 2002 sale of CMF production assets to Medtronic and our 2004 sale of the (non-Japan) Thin Film product line deprived us of some economies of scale in manufacturing. Current demand for spine and orthopedics products from Medtronic is so low that economies of scale are in some instances lacking in regard to that product line as well.

If we are unable to sufficiently meet Medtronic's requirements for certain products as set forth under its agreement, Medtronic itself may then manufacture and sell such product and only pay us royalties on the sales. The resulting loss of payments from Medtronic for the purchase of these products may have a substantial negative effect on the results of our operations and financial condition.

#### We have to maintain quality assurance certification and manufacturing approvals

The manufacture of our bioresorbable products is, and the manufacture of the Celution™ system for regenerative cells will be, subject to periodic inspection by regulatory authorities and distribution partners. The manufacture of devices and products for human use is subject to regulation and inspection from time to time by the FDA for compliance with the FDA's Quality System Regulation "QSR" requirements, as well as equivalent requirements and inspections by state and non-U.S. regulatory authorities. There can be no guarantee that the FDA or other authorities will not, during the course of an inspection of existing or new facilities, identify what they consider to be deficiencies in our compliance with QSRs or other requirements and request, or seek, remedial action.

Failure to comply with such regulations or a potential delay in attaining compliance may adversely affect our manufacturing activities and could result in, among other things, injunctions, civil penalties, FDA refusal to grant pre-market approvals or clearances of future or pending product submissions, fines, recalls or seizures of products, total or partial suspensions of production and criminal prosecution. There can be no assurance that we will be able to obtain additional necessary regulatory approvals or clearances on a timely basis, if at all. Delays in receipt of or failure to receive such approvals or clearances or the loss of previously received approvals or clearances could have a substantial negative effect on the results of our operations and financial condition.

#### We depend on a sole source supplier for our crucial raw material for our bioresorbable products

We currently purchase the high molecular weight, medical grade, lactic acid copolymer used in manufacturing most of our bioresorbable products, from a single qualified source. Although we have a contract with B.I. Chemicals, Inc., which guarantees continuation of supply through August 15, 2007, we cannot guarantee that they will elect to continue the contract beyond that date, or that they will not elect to discontinue the manufacture of the material. They have agreed that if they discontinue manufacturing they will either find a replacement supplier, or provide us with the necessary technology to self-manufacture the material, either of which could mean a substantial increase in material costs. Also, despite this agreement they might fail to do these things for us. Under the terms of the contract, B.I. Chemicals, Inc. may choose to raise their prices upon six months' prior notice which may also result in a substantially increased material cost. Although we believe that we would be able to obtain the material from at least one other source in the event of a failure of supply, there can be no assurance that we will be able to obtain adequate increased commercial quantities of the necessary high quality within a reasonable period of time or at commercially reasonable rates. Lack of adequate commercial quantities or the inability to develop alternative sources meeting regulatory requirements at similar prices and terms within a reasonable time or any interruptions in supply in the future could have a significant negative effect on our ability to manufacture products, and, consequently, could have a material adverse effect on the results of our operations and financial condition.

#### We may not be able to protect our proprietary rights

Our success depends in part on whether we can obtain additional patents, maintain trade secret protection and operate without infringing on the proprietary rights of third parties.

Our regenerative cell technology license agreement with the Regents of the University of California contains certain developmental milestones, which if not achieved could result in the loss of exclusivity or loss of the license rights. The loss of such rights could significantly impact our ability to continue the development of the regenerative cell technology and commercialize related products. Also, our power as licensee to successfully use these rights to exclude competitors from the market is untested. In addition,

further legal risk arises from a lawsuit, recently filed by U Pitt naming all of the inventors who had not assigned their ownership interest in Patent 6,777,231 to U Pitt, seeking a determination that its assignors, rather than the University of California's assignors, are the true inventors of U.S. Patent No. 6,777,231. We are the exclusive, worldwide licensee of the University of California's rights under this patent, which relates to adult stem cells isolated from adipose tissue that can differentiate into two or more of a variety of cell types. If U Pitt wins the lawsuit, our license rights to this patent could be nullified or rendered non-exclusive with respect to any third party that might license rights from U Pitt, and our regenerative cell strategy could be impacted.

We have various U.S. patents for the design of our bioresorbable plates and high torque screws and devices and we have filed applications for numerous additional U.S. patents, as well as certain corresponding patent applications outside the United States, relating to our technology. However, we believe we cannot patent the use of our lactic acid copolymer for surgical implants, nor are many of our particular implants generally patentable.

There can be no assurance that any of the pending patent applications will be approved or that we will develop additional proprietary products that are patentable. There is also no assurance that any patents issued to us will provide us with competitive advantages, will not be challenged by any third parties or that the patents of others will not prevent the commercialization of products incorporating our technology. Furthermore, there can be no guarantee that others will not independently develop similar products, duplicate any of our products or design around our patents.

Our commercial success will also depend, in part, on our ability to avoid infringing on patents issued to others. If we were judicially determined to be infringing on any third party patent, we could be required to pay damages, alter our products or processes, obtain licenses or cease certain activities. If we are required in the future to obtain any licenses from third parties for some of our products, there can be no guarantee that we would be able to do so on commercially favorable terms, if at all. U.S. patent applications are not immediately made public, so we might be surprised by the grant to someone else of a patent on a technology we are actively using. As noted above as to U Pitt lawsuit, even patents issued to us or our licensors might be judicially determined to belong in full or in part to third parties.

Litigation, which would result in substantial costs to us and diversion of effort on our part, may be necessary to enforce or confirm the ownership of any patents issued or licensed to us or to determine the scope and validity of third party proprietary rights. If our competitors claim technology also claimed by us and prepare and file patent applications in the United States, we may have to participate in interference proceedings declared by the U.S. Patent and Trademark Office or a foreign patent office to determine priority of invention, which could result in substantial costs to and diversion of effort, even if the eventual outcome is favorable to us.

Any such litigation or interference proceeding, regardless of outcome, could be expensive and time consuming. We may incur substantial legal costs as a result of the University of Pittsburgh lawsuit, and our president Marc Hedrick is a named individual defendant in that lawsuit because he is one of the inventors identified on the patent.

In addition to patents, which alone may not be able to protect the fundamentals of our regenerative cell and bioresorbable businesses, we also rely on unpatented trade secrets and proprietary technological expertise. We rely, in part, on confidentiality agreements with our partners, employees, advisors, vendors and consultants to protect our trade secrets and proprietary technological expertise. There can be no guarantee that these agreements will not be breached, or that we will have adequate remedies for any breach, or that our unpatented trade secrets and proprietary technological expertise will not otherwise become known or be independently discovered by competitors.

Failure to obtain or maintain patent protection, or protect trade secrets, for any reason (third party claims against our patents, trade secrets or proprietary rights, or our involvement in disputes over our patents, trade secrets or proprietary rights, including involvement in litigation), could have a substantial negative effect on the results of our operations and financial condition.

#### We may not be able to protect our intellectual property in countries outside the United States

Intellectual property law outside the United States is uncertain and in many countries is currently undergoing review and revisions. The laws of some countries do not protect our patent and other intellectual property rights to the same extent as United States laws. We currently have pending patent applications in Europe, Australia, Japan, Canada, China, Korea, and Singapore, among others.

#### We are, and Olympus-Cytori, Inc. will be, subject to intensive FDA regulation

As newly developed medical devices, ours as well as Olympus-Cytori's regenerative cell harvesting, isolation and delivery devices and our bioresorbable implants must receive regulatory clearances or approvals from the FDA and, in many instances, from non-U.S. and state governments, prior to their sale. Ours as well as Olympus-Cytori's current and future regenerative cell harvesting, isolation and delivery devices and bioresorbable implants are subject to stringent government regulation in the United States by the FDA under the Federal Food, Drug and Cosmetic Act. The FDA regulates the design/development process, clinical testing, manufacture, safety, labeling, sale, distribution and promotion of medical devices and drugs. Included among these regulations are

pre-market clearance and pre-market approval requirements, design control requirements, and the Quality System Regulations / Good Manufacturing Practices. Other statutory and regulatory requirements govern, among other things, establishment registration and inspection, medical device listing, prohibitions against misbranding and adulteration, labeling and post market reporting.

The regulatory process can be lengthy, expensive and uncertain. Before any new medical device may be introduced to the United States market, the manufacturer generally must obtain FDA clearance or approval through either the 510(k) pre-market notification process or the lengthier pre-market approval application "PMA" process. It generally takes from three to 12 months from submission to obtain 510(k) pre-market clearance, although it may take longer. Approval of a PMA could take four or more years from the time the process is initiated. The 510(k) and PMA processes can be expensive, uncertain and lengthy, and there is no guarantee of ultimate clearance or approval. We expect that some of our future products under development as well as Olympus-Cytori's will be subject to the lengthier PMA process. Securing FDA clearances and approvals may require the submission of extensive clinical data and supporting information to the FDA, and there can be no guarantee of ultimate clearance or approval. Failure to comply with applicable requirements can result in application integrity proceedings, fines, recalls or seizures of products, injunctions, civil penalties, total or partial suspensions of production, withdrawals of existing product approvals or clearances, refusals to approve or clear new applications or notifications and criminal prosecution.

Medical devices are also subject to post-market reporting requirements for deaths or serious injuries when the device may have caused or contributed to the death or serious injury, and for certain device malfunctions that would be likely to cause or contribute to a death or serious injury if the malfunction were to recur. If safety or effectiveness problems occur after the product reaches the market, the FDA may take steps to prevent or limit further marketing of the product. Additionally, the FDA actively enforces regulations prohibiting marketing and promotion of devices for indications or uses that have not been cleared or approved by the FDA.

Our current medical implants are at different stages of FDA review. We currently have 510(k) clearances for a wide variety of bioresorbable surgical implant products and we are constantly engaged in the process of obtaining additional clearances for new and existing products. There can be no guarantee that we will be able to obtain the necessary 510(k) clearances or PMA approvals to market and manufacture our other products in the United States for their intended use on a timely basis, if at all. The FDA approval process may be particularly problematic for ours as well as Olympus-Cytori's regenerative cell technology products in view of the novel nature of the technology. Delays in receipt of or failure to receive such clearances or approvals, the loss of previously received clearances or approvals, or failure to comply with existing or future regulatory requirements could have a substantial negative effect on the results of our operations and financial condition.

#### To sell in international markets, we will be subject to intensive regulation in foreign countries

In cooperation with our distribution partners, we intend to market our current and future products both domestically and in many foreign markets. A number of risks are inherent in international transactions. In order for us to market our products in Europe, Canada, Japan and certain other non-U.S. jurisdictions, we need to obtain and maintain required regulatory approvals or clearances and must comply with extensive regulations regarding safety, manufacturing processes and quality. For example, we still have not obtained regulatory approval for our Thin Film products in Japan. These regulations, including the requirements for approvals or clearances to market, may differ from the FDA regulatory scheme. International sales also may be limited or disrupted by political instability, price controls, trade restrictions and changes in tariffs. Additionally, fluctuations in currency exchange rates may adversely affect demand for our products by increasing the price of our products in the currency of the countries in which the products are sold.

There can be no assurance that we will obtain regulatory approvals or clearances in all of the countries where we intend to market our products, or that we will not incur significant costs in obtaining or maintaining foreign regulatory approvals or clearances, or that we will be able to successfully commercialize current or future products in various foreign markets. Delays in receipt of approvals or clearances to market our products in foreign countries, failure to receive such approvals or clearances or the future loss of previously received approvals or clearances could have a substantial negative effect on the results of our operations and financial condition.

#### We depend on a few key officers

Our performance is substantially dependent on the performance of our executive officers and other key scientific staff, including Christopher J. Calhoun, our Chief Executive Officer, and Marc Hedrick, MD, our President. We rely upon them for strategic business decisions and guidance. We believe that our future success in developing marketable products and achieving a competitive position will depend in large part upon whether we can attract and retain additional qualified management and scientific personnel. Competition for such personnel is intense, and there can be no assurance that we will be able to continue to attract and retain such personnel. The loss of the services of one or more of our executive officers or key scientific staff or the inability to attract and retain additional personnel and develop expertise as needed could have a substantial negative effect on our results of operations and financial condition.

## We may not have enough product liability insurance

The testing, manufacturing, marketing and sale of our regenerative cell and bioresorbable implant products involve an inherent risk that product liability claims will be asserted against us, our distribution partners or licensees. There can be no guarantee that our clinical trial and commercial product liability insurance is adequate or will continue to be available in sufficient amounts or at an acceptable cost, if at all. A product liability claim, product recall or other claim, as well as any claims for uninsured liabilities or in excess of insured liabilities, could have a substantial negative effect on the results of our operations and financial condition. Also, well-publicized claims could cause our stock to fall sharply, even before the merits of the claims are decided by a court.

## Our charter documents contain anti-takeover provisions and we have adopted a Stockholder Rights Plan to prevent hostile takeovers

Our Amended and Restated Certificate of Incorporation and Bylaws contain certain provisions that could prevent or delay the acquisition of the Company by means of a tender offer, proxy contest or otherwise. It could discourage a third party from attempting to acquire control of the Company, even if such events would be beneficial to the interests of our stockholders. Such provisions may have the effect of delaying, deferring or preventing a change of control of the Company and consequently could adversely affect the market price of our shares. Also, in 2003 we adopted a Stockholder Rights Plan, of the kind often referred to as a poison pill. The purpose of the Stockholder Rights Plan is to prevent coercive takeover tactics that may otherwise be utilized in takeover attempts. The existence of such a rights plan may also prevent or delay the change in control of the Company which could adversely affect the market price of our shares.

## We pay no dividends

We currently do not intend to pay any cash dividends for the foreseeable future.

## **Item 1B. Unresolved Staff Comments**

Not applicable.

## **Item 2. Property**

On May 24, 2005, we entered into a new lease for 91,000 square feet located at 3020 and 3030 Callan Road, San Diego, California. We intend to continue to move the majority of our operations to this new facility by the second quarter of 2006. The agreement bears rent at a rate of \$1.15 per square foot, with annual increases of 3%. The lease term is 57 months, commencing on October 1, 2005 and expiring on June 30, 2010. In addition, we are committed to providing a minimum of \$837,000 in improvements to the facility. As of December 31, 2005, we have made \$1,386,000 in improvements to the facility.

We also have a facility located at 6740 Top Gun Street, San Diego, California. We currently lease approximately 27,000 square feet of space at this location of which approximately 6,000 square feet is laboratory space, 12,000 square feet is office space and 9,000 square feet is manufacturing space. Our lease has a five-year term, expiring in 2008. We also lease:

- 14,000 square feet, of which approximately 4,000 square feet is for research and development and 10,000 square feet is office space, at 6749 Top Gun Street, San Diego, California for a five-year term expiring in April 2006. We currently sublease 6,000 square feet of this office and warehouse space at the rate charged per square foot in our current lease agreement. We sublease approximate 5,000 square feet to MAST and the remainder to another unrelated party.
- 16,000 additional square feet for research and development activities located at 6749 Top Gun Street, San Diego, California for a five-year term expiring 2008.
- 4,027 square feet of office space located at 9-3 Otsuka 2-chome, Bunkyo-ku, Tokyo, Japan. The agreement bears rent at a rate of \$3.66 per square foot, for a term of two years expiring on November 30, 2007.

On the properties stated above, we paid an aggregate of approximately \$75,000 in rent per month in 2005. The aggregate sublease amount is \$6,000 per month. Lease payments on the Callan Rd. location do not commence until June 2006.

## **Item 3. Legal Matters**

From time to time, we have been involved in routine litigation incidental to the conduct of our business. As of December 31, 2005, we were not a party to any material legal proceeding.

## **Item 4. Submission of Matters to a Vote of Security Holders**

None

## PART II

### Item 5. Market for Registrant's Common Equity and Related Stockholder Matters

#### Market Prices

Since our initial public offering in Germany in August 2000, our common stock has been quoted on the Frankfurt Stock Exchange under the symbol "XMPA" (formerly XMP). Until December 19, 2005, the Frankfurt Stock Exchange had served as the primary market for our securities. Effective December 19, 2005, we began trading on the NASDAQ Capital Market under the symbol "CYTX," and we have since transferred to the NASDAQ Global Market effective February 14, 2006. The following table shows the high and low sales prices for our common stock for the periods indicated, as reported by the Frankfurt Stock Exchange and the NASDAQ Capital Markets. These prices do not include retail markups, markdowns or commissions.

#### Frankfurt Stock Exchange (XETRA)

	<u>High Euro</u>	<u>High U.S.</u>	<u>Low Euro</u>	<u>Low U.S.</u>
<b>2004</b>				
Quarter ended March 31, 2004.....	€ 3.45	\$ 4.30	€ 2.00	\$ 2.58
Quarter ended June 30, 2004.....	€ 3.80	\$ 4.61	€ 3.02	\$ 3.67
Quarter ended September 30, 2004.....	€ 3.60	\$ 4.40	€ 1.93	\$ 2.38
Quarter ended December 31, 2004.....	€ 2.73	\$ 3.37	€ 1.77	\$ 2.43
<b>2005</b>				
Quarter ended March 31, 2005.....	€ 2.13	\$ 2.78	€ 2.00	\$ 2.61
Quarter ended June 30, 2005.....	€ 2.55	\$ 3.08	€ 2.50	\$ 3.02
Quarter ended September 30, 2005.....	€ 4.49	\$ 5.41	€ 4.21	\$ 5.07
Quarter ended December 31, 2005.....	€ 6.85	\$ 8.13	€ 6.47	\$ 7.68

#### NASDAQ Stock Exchange

	<u>High U.S.</u>	<u>Low U.S.</u>
<b>2005</b>		
Quarter ended December 31, 2005.....	\$ 8.30	\$ 7.60

In preparation for our NASDAQ listing, we changed depository agents from Clearstream Banking AG, Frankfurt, Germany, to the Depository Trust & Clearing Corporation, U.S ("DTCC"). All of our outstanding shares have been deposited with DTCC since December 9, 2005.

#### Dividends

We have never declared or paid any dividends and do not currently anticipate paying any cash dividends on our outstanding shares of common stock in the foreseeable future.

#### German Securities Laws

As a United States company with securities trading on a German stock exchange, we are subject to various laws and regulations in both jurisdictions. Some of these laws and regulations, in turn, can affect the ability of holders of some of our securities to transfer or sell those securities.

There are no limitations imposed by German law or our certificate of incorporation or bylaws on the right of owners to hold or vote the shares.

#### Recent Sales of Unregistered Securities

None

## Equity Compensation Plan Information

Plan Category	Number of securities to be issued upon exercise of outstanding options, warrants and rights (a)	Weighted-average exercise price of outstanding options, warrants and rights (b)	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a)) (c)
Equity compensation plans approved by security holders.....	4,792,000	\$ 4.06	444,000
Equity compensation plans not approved by security holders(1).....	993,000	\$ 4.44	2,266,000
<b>Total</b>	<b>5,785,000</b>	<b>\$ 4.12</b>	<b>2,710,000</b>

(1) The maximum number of shares shall be cumulatively increased on the first January 1 after the Effective Date, August 24, 2004, and each January 1 thereafter for 9 more years, by a number of shares equal to the lesser of (a) 2% of the number of shares issued and outstanding on the immediately preceding December 31, and (b) a number of shares set by the Board.

## Item 6. Selected Consolidated Financial Data

The selected data presented below under the captions "Statements of Operations Data," "Statements of Cash Flows Data" and "Balance Sheet Data" for, and as of the end of, each of the years in the five-year period ended December 31, 2005, are derived from our audited financial statements. The consolidated balance sheets as of December 31, 2005 and 2004, and the related consolidated statements of operations and comprehensive loss, stockholders' equity (deficit), and cash flows for each of the years in the three-year period ended December 31, 2005, which have been audited by KPMG LLP, an independent registered public accounting firm, and their report thereon, are included elsewhere in this annual report. The consolidated balance sheets as of December 31, 2003 and 2002, and the related consolidated statements of operations and comprehensive loss, stockholders' equity (deficit), and cash flows for the year ended December 31, 2002, which were also audited by KPMG LLP, are included with our annual report previously filed. The balance sheet as of December 31, 2001 and the related statement of operations and comprehensive loss, stockholders' equity and cash flow for the year ended December 31, 2001, which have been audited by Arthur Andersen LLP, independent auditors, are included with our annual report previously filed with the Securities and Exchange Commission.

The information contained in this table should be read in conjunction with "Management's Discussion and Analysis of Financial Condition and Results of Operations" and the financial statements and related notes thereto included elsewhere in this report (in thousands except share and per share data):

	2005	2004	2003	2002	2001
<b>Statements of Operations Data:</b>					
Product revenues:					
Sales to related party.....	\$ 5,634	\$ 4,085	\$ 12,893	\$ 8,605	\$ 5,547
Sales to third parties.....	—	2,237	1,186	561	101
	<u>5,634</u>	<u>6,322</u>	<u>14,079</u>	<u>9,166</u>	<u>5,648</u>
Cost of product revenues.....	3,154	3,384	4,244	4,564	4,151
Gross profit.....	<u>2,480</u>	<u>2,938</u>	<u>9,835</u>	<u>4,602</u>	<u>1,497</u>
Development revenues:					
Research grants.....	312	328	—	—	—
Development and other.....	59	168	9	—	—
	<u>371</u>	<u>496</u>	<u>9</u>	<u>—</u>	<u>—</u>
Operating expenses:					
Research and development.....	15,271	10,352	8,694	5,378	5,338
Sales and marketing.....	1,434	2,391	4,417	3,987	4,493
General and administrative.....	10,096	6,480	4,958	4,179	3,727
Stock based compensation.....	404	125	985	1,287	1,123
Change in fair value of option liabilities.....	3,645	—	—	—	—
Restructuring charge.....	—	107	451	—	—
Equipment impairment charge.....	—	42	—	370	—
In-process research and development.....	—	—	—	2,296	—
Total operating expenses.....	<u>30,850</u>	<u>19,497</u>	<u>19,505</u>	<u>17,497</u>	<u>14,681</u>
Other income (expense):					
Gain on sale of assets.....	5,526	—	—	—	—
Gain on the sale of assets, related party.....	—	13,883	—	—	—
Interest income.....	299	252	417	1,037	2,249

Interest expense .....	(137)	(177)	(126)	(241)	(100)
Other income (expense) .....	(55)	15	87	(22)	(68)
Equity loss in investments .....	(4,172)	—	—	(882)	(104)
Net loss .....	<u>\$ (26,538)</u>	<u>\$ (2,090)</u>	<u>\$ (9,283)</u>	<u>\$ (13,003)</u>	<u>\$ (11,207)</u>
Basic and diluted net loss per share .....	<u>\$ (1.80)</u>	<u>\$ (0.15)</u>	<u>\$ (0.64)</u>	<u>\$ (0.91)</u>	<u>\$ (0.75)</u>
Basic and diluted weighted average common shares.....	<u>14,704,281</u>	<u>13,932,390</u>	<u>14,555,047</u>	<u>14,274,254</u>	<u>14,926,107</u>

**Statements of Cash Flows Data:**

Net cash used in operating activities.....	\$ (1,101)	\$ (12,574)	\$ (7,245)	\$ (6,886)	\$ (8,322)
Net cash provided by investing activities.....	911	13,425	5,954	17,265	2,263
Net cash provided by (used in) financing activities .....	<u>5,357</u>	<u>(831)</u>	<u>(997)</u>	<u>(7,971)</u>	<u>1,283</u>
Net increase (decrease) in cash .....	5,167	20	(2,288)	2,408	(4,776)
Cash and cash equivalents at beginning of year.....	2,840	2,820	5,108	2,700	7,476
Cash and cash equivalents at end of year.....	<u>\$ 8,007</u>	<u>\$ 2,840</u>	<u>\$ 2,820</u>	<u>\$ 5,108</u>	<u>\$ 2,700</u>

**Balance Sheet Data:**

Cash, cash equivalents and short-term investments.....	\$ 15,845	\$ 13,419	\$ 14,268	\$ 24,983	\$ 33,951
Working capital .....	10,459	12,458	12,432	25,283	35,119
Total assets .....	28,166	25,470	28,089	39,319	43,143
Deferred revenues, related party .....	17,311	—	—	—	—
Option liabilities .....	5,331	—	—	—	—
Deferred revenues .....	2,541	2,592	—	—	—
Deferred gain on sale of assets.....	—	5,650	—	—	—
Deferred gain on sale of assets, related party.....	—	—	7,539	9,623	—
Long-term deferred rent.....	573	80	—	—	—
Long-term obligations, less current portion...	1,558	1,128	1,157	770	1,791
Total stockholders' equity (deficit).....	\$ (6,229)	\$ 12,833	\$ 14,909	\$ 25,995	\$ 38,486

**Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations**

**CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING STATEMENTS**

*This report contains certain statements that may be deemed "forward-looking statements" within the meaning of United States securities laws. All statements, other than statements of historical fact, that address activities, events or developments that we intend, expect, project, believe or anticipate will or may occur in the future are forward-looking statements. Such statements are based upon certain assumptions and assessments made by our management in light of their experience and their perception of historical trends, current conditions, expected future developments and other factors they believe to be appropriate. The forward-looking statements included in this report are also subject to a number of material risks and uncertainties, including but not limited to the risks described under the "Risk Factors" section in this Management's Discussion and Analysis of Financial Conditions and Results of Operations. We encourage you to read those descriptions carefully. We caution you not to place undue reliance on the forward-looking statements contained in this report. These statements, like all statements in this report, speak only as of the date of this report (unless an earlier date is indicated) and we undertake no obligation to update or revise the statements except as required by law. Such forward-looking statements are not guarantees of future performance and actual results will likely differ, perhaps materially, from those suggested by such forward-looking statements.*

**Overview**

In 2005, we continued to invest in the preclinical development of our adipose stem and regenerative cell therapies, with the aim of advancing them into and through clinical trials. The indications we are focused on include cardiovascular disease, gastrointestinal disorders, spine and orthopedic repair, and aesthetic and reconstructive surgery.

To facilitate the processing and delivery of adipose stem and regenerative cells, we developed a proprietary point-of-care system, Celution™, to isolate and concentrate a patient's own stem and regenerative cells in real-time. Our goal is that the Celution™ System will be the commercial vehicle for our investigational cell therapies across multiple therapeutic applications. The commercialization model will be based on the sale of Celution™ devices and related single-use consumables.

On November 4, 2005, we entered into a strategic development and manufacturing joint venture agreement and among other agreements ("JV Agreements") with Olympus Corporation ("Olympus"). As part of the terms of the JV Agreements, we formed a joint venture, Olympus-Cytori, Inc. (the "Joint Venture"), to develop and manufacture future generation devices based on our Celution™ System.

The key provisions of the JV Agreements are as follows:

- Olympus licensed its device-related technology to the Joint Venture and paid \$30 million to the Joint Venture for its 50% interest therein;
- We exclusively licensed our cell processing device technology, including the Celution™ System and certain related intellectual property, to the Joint Venture and received an initial \$11 million payment and a 50% interest in the Joint Venture. We also agreed to perform various pre-clinical, clinical, regulatory, and product development activities on behalf of the joint venture;
- Upon our receipt of a CE mark for the first generation Celution™ System in January 2006, we became entitled to and subsequently received a second \$11 million development milestone payment from the Joint Venture;
- The Joint Venture obtained exclusive rights to develop, manufacture, and supply the devices for all therapeutic applications solely to us at a formula-based transfer price and we will maintain marketing rights to the devices for all therapeutic applications of adipose stem and regenerative cells.

In a separate agreement entered into on February 22, 2006, we granted Olympus an exclusive right to negotiate a commercialization collaboration for the use of adipose stem and regenerative cells for a specific therapeutic area outside of cardiovascular disease. In exchange for this right, we will receive a \$1.5 million payment from Olympus, which is non-refundable but may be applied towards any definitive commercial collaboration in the future. As part of this agreement, Olympus will conduct market research and pilot clinical studies in collaboration with us over a 12 to 18 month period for the therapeutic area.

In addition to forming the Joint Venture and entering into the negotiating rights agreement, we executed a definitive Common Stock Purchase Agreement with Olympus in May 2005. As part of that agreement, under which Olympus paid us \$11 million at the time of signing, Olympus purchased 1.1 million shares, representing 7.2% of our outstanding common stock as of December 31, 2005, and received an option to purchase up to 2.2 million additional shares at \$10.00 per share through December 2006. If Olympus chooses to exercise that option, it would hold up to a 19% ownership interest in our outstanding common stock. Additionally, Olympus has a right, which it has not yet exercised, to designate a director to serve on our Board of Directors.

In August 2005, we announced the completion of the development of the first generation Celution™ system. We have since submitted and received the CE Mark granting us regulatory clearance for the system in Europe. We expect to continue submitting regulatory applications for this system in Japan and in the United States in 2006.

Before we begin to realize appreciable product revenues from the Celution™ system, and ultimately achieve consistent profitability on a quarterly and annual basis, we believe we will first need to successfully conduct controlled, randomized clinical trials in specific therapeutic areas to demonstrate the benefits of using adipose stem and regenerative cells. In 2006, we intend to initiate clinical safety studies for our investigational adipose stem and regenerative cell therapies for treatment of ischemic heart disease in Europe, which may include myocardial infarction and/or congestive heart failure, as well as for applications in reconstructive surgery in Japan. Additionally, we continue to support preclinical research in indications both within and outside these areas.

Beyond our existing arrangements with Olympus, we are seeking additional co-development partnerships with pharmaceutical, medical device or biotechnology companies. Moreover, we are searching for partners who can help identify drugs, proteins or genes that when combined with adipose stem and regenerative cells, enhance or stimulate certain select properties. For example, we may seek to identify a drug that when mixed with adipose stem and regenerative cells, directs specific cells to turn more quickly and efficiently into blood vessels.

We currently derive the majority of our revenue from our MacroPore Biosurgery unit, which develops and manufactures innovative bioresorbable surgical implants. Potential cash flows, if any, from MacroPore Biosurgery may be used to support our development of adipose stem and regenerative cell therapies.

MacroPore Biosurgery manufactures the HYDROSORB™ family of FDA-cleared bioresorbable spine and orthopedic implants, which are distributed worldwide exclusively through Medtronic, Inc. ("Medtronic"). This product line generated \$5,634,000 in revenue in 2005. The vast majority of these revenues were related to initial stocking orders that Medtronic placed for the most recent addition to this product line, the MYSTIQUE™ radiographically identifiable cervical graft containment plate, which Medtronic began to market in the third quarter of 2005. We continued to fill MYSTIQUE™ stocking orders through the fourth quarter of 2005. At present, we do not have sufficient visibility of potential orders by Medtronic in 2006 for the HYDROSORB™ product line, including MYSTIQUE™, to provide an accurate range of revenue projections for 2006. Due primarily to Medtronic's reduced orders for non-MYSTIQUE™ products in the HYDROSORB™ family, we recorded an inventory provision of \$280,000 for the year ended December 31, 2005. The prospects for this business are uncertain and rest largely upon Medtronic's efforts and intentions.

Additionally, MacroPore Biosurgery is developing Thin Film bioresorbable implants exclusively for Senko Medical Trading Co. ("Senko"), which owns distribution rights exclusively for Japan. In 2004, we disposed of all our Thin Film rights for all territories except Japan. This product line is currently under regulatory review by the Japanese Ministry of Health, Labour and Welfare. Accordingly, there have not been any sales of Thin Film product to Senko as yet.

The research and development of our adipose stem and regenerative cell therapies has been and will continue to be very costly. We anticipate expanding our research and development expenses to fund clinical trials costs (which we will be initiating for the first time in 2006), preclinical research, and general and administrative activities. As a result, we expect to continue incurring losses for the foreseeable future.

Our research and development expenses, excluding stock based compensation expense, of \$15,271,000 in 2005 consisted primarily of salaries and payroll-related expenses for research and development personnel, contract research organizations, research supplies and materials, laboratory equipment, consultants and licensing fees. The majority of these expenses were related to our research and development of applications of adipose stem and regenerative cells for cardiovascular disease. Also included in research and development are costs incurred to support research grant reimbursement and costs incurred in connection with our development arrangements with Senko and Olympus.

We believe our research and development expenses will continue to increase should we advance more products into and through clinical trials. We plan to fund this anticipated research and development from the following:

- Existing cash reserves;
- Cash from the November 2005 joint venture transaction with Olympus;
- Potential issuances of our equity, including Olympus' option to purchase up to 2.2 million shares of our common stock at \$10.00 per share;
- Potential cash flows from MacroPore Biosurgery product sales;
- Potential research grants; and
- Payments, if any, related to potential partnerships or product line divestitures.

As of December 31, 2005, we have an accumulated deficit of \$78,013,000.

### **Transactions with Olympus**

During the 2005 year, we entered into a variety of strategic and collaboration arrangements with Olympus.

For instance, in the second quarter of 2005, Olympus purchased 1,100,000 shares of our common stock. In addition, we granted Olympus an option to purchase up to 2,200,000 additional shares of common stock at \$10.00 per share; this option expires December 31, 2006. Olympus was also given a right to nominate one of our Directors, but has not yet exercised this right. We received \$11 million from Olympus upon signing this agreement.

On November 4, 2005, we formed a joint venture with Olympus called Olympus-Cytori, Inc. The joint venture will develop and manufacture future generation devices (based on our existing Celution™ System) that will process and purify adult stem and regenerative cells residing in adipose tissue, also known as fat.

This joint venture alliance creates synergies between two companies that share the same vision for regenerative medicine. Olympus, as a worldwide leader in the development of innovative medical products, will contribute its expertise in engineering, manufacturing and servicing of sophisticated devices. In parallel, Cytori will increase its focus on the development of therapeutic applications for adipose stem and regenerative cells for multiple large markets. Together, this alignment enables the creation of a premier brand of devices for regenerative medicine to be sold by Cytori.

As a result of the various arrangements with Olympus, we received \$22,000,000 in cash during 2005. We also received an additional \$11,000,000 milestone payment in January 2006 after obtaining a CE Mark for the first generation Celution™ System. We may possibly receive even more cash proceeds if Olympus decides to exercise its option to purchase 2,200,000 shares of our common stock at a fixed price of \$10.00 per share.

We plan to use this cash to fund the development activities that are necessary to support the commercialization of future generation devices based on our Celution™ System. These development activities include performing preclinical and clinical trials, seeking regulatory approval, and performing product development related to therapeutic applications for adipose stem and regenerative cells for multiple large markets.

The joint venture arrangement with Olympus provides Cytori with a source of revenue in near- and medium- term. As of November 4, 2005, \$17,311,000 in cash proceeds has been recorded on the consolidated balance sheet as deferred revenues, related party, a liability account. As noted above, we also received an additional \$11,000,000 in January 2006, which will be reported as

deferred revenues, related party in the first quarter of 2006.

We determined that the \$17,311,000 received to date was designed to compensate us for future services that we have agreed to perform on behalf of the joint venture. As and when we complete each of our future service obligations, we will recognize the relative fair value of each service provided as income (and reduce the deferred revenues, related party account). Specifically, we expect to recognize the \$17,311,000 of deferred revenues, related party account in income from 2006 through 2009. The exact timing of when amounts will be reported in income will depend on internal factors (for instance, our ability to complete the service obligations we have agreed to perform) as well as external considerations, including obtaining the necessary regulatory approvals for various therapeutic applications related to our Celution™ System.

As part of the various agreements with Olympus, we will be required, following commercialization of the Celution™ System, to provide monthly forecasts to the Joint Venture specifying the quantities of each category of devices that we intend to purchase over a rolling six-month period. Although we are not subject to any minimum purchase requirements, we are obliged to buy a minimum percentage of the products forecasted by us in such reports. Since we can effectively control the number of devices we will agree to purchase and because no commercial devices have yet been developed to trigger the forecast requirement, we estimate that the fair value of this guarantee will be de minimis as of December 31, 2005 and therefore no amounts related to this guarantee are reflected on the statement of financial position.

In certain specified circumstances of insolvency or if we experience a change in control, Olympus will have the rights to (i) repurchase our interests in the joint venture at the fair value of such interests or (ii) sell its own interests in the joint venture to Cytori at the higher of (a) \$22,000,000 or (b) their fair value (the "Put"). These put and call rights are contingent on events that are unlikely to occur. Nonetheless, accepted valuation techniques suggest that the put right has a value of approximately \$1,600,000 at December 31, 2005. This value has been recorded as a component of Option liabilities in our balance sheet. Note that the put right is perpetual and, thus, has no expiration date. Accordingly, we will continue to recognize a liability for the Put and mark it to market each quarter until it is exercised or until the arrangements with Olympus are amended.

We determined that the joint venture is a variable interest entity ("VIE") under FASB Interpretation No. 46 (revised 2003), "Consolidation of Variable Interest Entities - An Interpretation of ARB No. 51" ("FIN 46R"), but that we are not the joint venture's primary beneficiary. Accordingly, we have accounted for our interests in the joint venture using the equity method of accounting, since we can exert significant influence over the joint venture's operations.

## **Disposition of Product Lines and Related Agreements**

### Sale of Thin Film Product Line

In May 2004, we sold most, but not all, of our intellectual property rights and tangible assets related to our Thin Film product line to MAST and one of its subsidiaries for approximately \$7,000,000 in cash. We retained the rights for the territory of Japan.

As part of the Thin Film disposition agreement, and for a period of up to one year, we were required to provide training to MAST representatives in all aspects of the manufacturing process related to the transferred Thin Film product line, and to act in the capacity of a back-up supplier to MAST. Under the back-up supply agreement, we agreed in nearly all cases to supply product ordered by MAST at our manufacturing cost.

Because of these and other additional performance requirements, we did not initially recognize any gain on sale of the Thin Film assets in our statement of operations. Instead, we initially recorded approximately \$6,450,000 as deferred gain on sale in the balance sheet.

However, in 2004 we did recognize \$772,000 of the deferred gain as revenues related to the sale of Thin Film products to MAST under the back-up supply agreement at cost. The recognition of the deferred gain was necessary in 2004 in order to state revenues at fair value of products sold, based on historical selling prices of similar products, over our manufacturing cost. No deferred gain was recognized as revenue in 2005 based on the back-up supply agreement because there were no shipments of product to MAST.

Under the Thin Film sale agreement, we were potentially entitled to the following additional consideration (beyond the \$7,000,000 cash payment received at closing), none of which was recognized in our financial statements:

- \$200,000, payable only upon receipt of 510(k) clearance from the U.S. Food and Drug Administration ("FDA") for a hernia wrap product (thin film combined product); and
- \$2,000,000 on or before the earlier of (i) May 31, 2005, known as the "Settlement Date," or (ii) 15 days after the date upon which MAST has hired a Chief Executive Officer ("CEO"), provided the CEO held that position for at least four months and met other requirements specified in the sale agreement. Note that clause (ii) effectively means that we would not have received payment of \$2,000,000 before May 31, 2005 unless MAST had hired a CEO on or before January 31, 2005 (four months prior to the Settlement Date). Moreover, in the event that MAST had not hired a CEO c

or before January 31, 2005, MAST may have (at its sole option and subject to the requirements of the sale agreement), alternatively provided us with a 19% equity interest in the MAST business that is managing the Thin Film assets at May 31, 2005 in lieu of making the \$2,000,000 cash payment.

MAST did not remit to us the contingent \$2,000,000 payment noted above.

Accordingly, on June 14, 2005, we initiated arbitration proceedings against MAST, asserting that MAST was in breach of the Asset Purchase Agreement by failing to pay the final \$2,000,000 in purchase price (among other issues). MAST responded asserting its own claims in the arbitration, including but not limited to allegations that we: (i) inadequately transferred know-how to MAST, (ii) misrepresented the state of the distribution network, (iii) provided inadequate product instructions to users, and (iv) failed to adequately train various distributors. In August 2005, the parties settled the arbitration proceedings and gave mutual releases of all claims, excepting those related to the territory of Japan, and agreed to contractual compromises. These contractual compromises, the most significant of which is that we have waived the obligation for MAST to either pay the final cash purchase installment of \$2,000,000 or to deliver 19% of its shares, include the following: If MAST exercises its Purchase Right (described in the section below) and Thin Film products are ultimately marketed in Japan, MAST would no longer be obliged to share gross profits and royalties with us, as originally contemplated in the MAST agreements.

In exchange, MAST agreed to supply, at no cost to us, all required product for any necessary clinical study for the territory of Japan and would cooperate in the planning of such study. However, if MAST exercises the Purchase Right or we enter into a supply agreement with MAST related to the territory of Japan, we would be obligated to reimburse MAST for any Thin Film product supplied in connection with the Japan study at a cost of \$50 per sheet.

As a result of the settlement agreement described above, we recognized the remaining deferred gain as gain on sale of assets of \$5,650,000, less \$124,000 of related deferred costs in 2005.

#### Sale of Craniomaxillofacial (“CMF”) Product Line

In September 2002, we entered into an Asset Purchase Agreement (the “Agreement”) to sell assets related to our CMF implant and accessory product line to Medtronic for what resulted in total net consideration of \$15,500,000. In accordance with the terms of the Agreement, we received an initial payment of \$13,000,000 from Medtronic and a first milestone payment of \$1,000,000 in the fourth quarter of 2002. A final milestone payment of \$1,500,000 was received in 2004.

The Agreement requires us not to market in the craniomaxillofacial field, for five years, any products that compete with the acquired product line. Additionally, during the technology transfer transition period, we agreed to be a back-up supplier of CMF products to Medtronic at a price equal to our cost of manufacture.

The Agreement also allowed us to receive up to \$5,000,000 if and when we completed successful clinical evaluations for a new faster-resorbing polymer product, as defined in the Agreement. In January 2004, after we completed the successful clinical evaluations, we received a \$5,000,000 milestone payment from Medtronic and it was recognized as gain on sale of assets, related party, in the statement of operations.

In a separate, but simultaneous, 2002 transaction, we paid Medtronic \$4,000,000 in cash to amend an existing Development and Supply Agreement (the “Amended Development Agreement”, and collectively with the Asset Purchase Agreement, the “Agreements”) to remove a preexisting contractual right of first offer for distributorship by Medtronic of our bioresorbable Thin Film products for use in various types of soft tissue surgical applications. Medtronic will retain its right of first offer for distributorship of our other bioresorbable products in all fields, as well as to our bioresorbable thin film products for use in the spinal application field. In addition, the term of the Amended Development Agreement with Medtronic was extended to September 30, 2012.

We accounted for the net proceeds of the Agreements as deferred gain on sale of assets, related party. This gain was recognized only as certain events occurred. For instance, we recognized a portion of the deferred gain upon the sale of the CMF products to Medtronic under our back-up supply arrangement, which provided for sales of the CMF products to Medtronic at cost. The amount of the deferred gain recognized was equal to the excess of the fair value of products sold, based on historical selling prices of similar products, over our manufacturing cost. The remainder of the deferred gain was recognized in 2004 when the technology and know-how transfer was completed pursuant to the contract terms.

#### **Thin Film Japan Distribution Agreement**

Even after consummation of the 2004 Thin Film asset sale to MAST, we retained all rights to Thin Film business in Japan (subject to a purchase option of MAST, as described later below), and we received back from MAST a license of all rights to Thin Film technologies in the:

- Spinal field, exclusive at least until 2012, and

- Field of regenerative medicine, non-exclusive on a perpetual basis.

In the third quarter of 2004, we entered into a Distribution Agreement with Senko. Under this agreement, we granted to Senko an exclusive license to sell and distribute certain Thin Film products in Japan. Specifically, the license covers Thin Film products with the following indications:

- Anti-adhesion,
- Soft tissue support, and
- Minimization of the attachment of soft tissues throughout the body.

The Distribution Agreement with Senko commences upon “commercialization.” In simplest terms, commercialization occurs when one or more Thin Film product registrations are completed with the Japanese Ministry of Health, Labour and Welfare (“MHLW”).

Following commercialization, the Distribution Agreement has a duration of five years and is renewable for an additional five years after reaching mutually agreed minimum purchase guarantees.

We received a \$1,500,000 upfront license fee from Senko. We have recorded the \$1,500,000 received as a component of deferred revenues in the accompanying balance sheet. Half of the license fee is refundable if the parties agree commercialization is not achievable and a proportional amount is refundable if we terminate the arrangement, other than for material breach by Senko, before three years post-commercialization.

Under the Distribution Agreement, we will also be entitled to earn additional payments from Senko based on achieving defined milestones. On September 28, 2004, we notified Senko of completion of the initial regulatory application to the MHLW for the Thin Film product. As a result, we became entitled to a nonrefundable payment of \$1,250,000, which we received in October 2004 and recorded as a component of deferred revenues.

Of the amounts deferred, we have recognized a total of \$209,000 (\$51,000 and \$158,000 in 2005 and 2004, respectively) as development revenues. Refer to the *Critical Accounting Policies and Significant Estimates* section of this discussion for further details regarding our revenue recognition policies related to the Senko Distribution Agreement.

The previously described sale agreement granted MAST a “Purchase Right” to acquire at any time before May 31, 2007 our Thin Film-related interests and rights for Japan. If MAST chooses to exercise the Purchase Right between now and May 31, 2007, the exercise price of the Purchase Right will be equal to the fair market value of the Japanese business, but in no event will be less than \$3,000,000. Moreover, until May 31, 2007, MAST has a right of first refusal to match the terms of any outside offer to buy our Japanese Thin Film business.

If MAST exercises the Purchase Right, we both may become obligated to reimburse each other for certain costs we have respectively incurred or will incur related to product development and protection of intellectual property rights in Japan.

## Results of Operations

*Years ended December 31, 2005 and 2004 compared to years ended December 31, 2004 and 2003, respectively.*

### Product revenues

Product revenues relate to our MacroPore Biosurgery segment and include revenues from our spine and orthopedic products, thin film products and CMF products. The following table summarizes the components for the years ended December 31, 2005, 2004, and 2003:

	<u>Years ended</u>			<u>\$ Differences</u>		<u>% Differences</u>	
	<u>2005</u>	<u>2004</u>	<u>2003</u>	<u>2005 to 2004</u>	<u>2004 to 2003</u>	<u>2005 to 2004</u>	<u>2004 to 2003</u>
Spine and orthopedics products .....	5,634,000	3,803,000	9,882,000	1,831,000	(6,079,000)	48.1%	(61.5)%
Thin film products:							
Product sales (non-MAST related) ..	—	559,000	1,186,000	(559,000)	(627,000)	—	(52.9)%
Product sales to MAST .....	—	906,000	—	(906,000)	906,000	—	—
Amortization of gain on sale (MAST)	—	772,000	—	(772,000)	772,000	—	—
	—	2,237,000	1,186,000	(2,237,000)	1,051,000	—	88.6%
CMF products:							
Product sales .....	—	126,000	964,000	(126,000)	(838,000)	—	(86.9)%
Amortization of gain on sale .....	—	156,000	2,047,000	(156,000)	(1,891,000)	—	(92.4)%
	—	282,000	3,011,000	(282,000)	(2,729,000)	—	(90.6)%
Total product revenues .....	5,634,000	6,322,000	14,079,000	(688,000)	(7,757,000)	(10.9)%	(55.1)%
% attributable to Medtronic	100%	64.6%	91.6%				

- Spine and orthopedic product revenues represent sales of bioresorbable implants used in spine and orthopedic surgical procedures. These revenues were dominated by stocking orders during the year ended December 31, 2005 for our radiographically identifiable Spine System products, marketed under the name MYSTIQUE™, which Medtronic, our sole distributor of spine and orthopedic products, launched in the third quarter of 2005. This product represents the latest design addition to our family of HYDROSORB™ products.

In the second half of 2003 and first quarter of 2004, Medtronic placed initial stocking orders for other newly developed HYDROSORB™ products. We had anticipated that demand for these products from Medtronic's customers would draw down these inventories sufficiently to require Medtronic to buy substantial additional amounts. However, subsequent sales of these products to Medtronic have been well below our expectations. Medtronic also markets competing products, some of which generate a higher profit margin for Medtronic.

Refer to "The future" discussion below for our expectations regarding the outlook for spine and orthopedic revenues. Note that Medtronic owns approximately 6.5% of our outstanding common stock as of December 31, 2005.

- Thin Film product revenues in 2004 represent sales of SurgiWrap™ bioresorbable Thin Film. We sold most, but not all, of our intellectual property rights and tangible assets related to our Thin Film product line to MAST in the second quarter of 2004. We were obliged by contract to act as a back-up supplier for these products and to sell them to MAST at our manufacturing costs. However, as MAST assumed the manufacturing process, domestic revenue from Thin Film products ended in 2004. No revenues from the Thin Film product line were recognized during the year ended December 31, 2005.
- The CMF product revenues represent sales of the CMF product line used for trauma and reconstructive procedures in the mid-face and craniofacial skeleton (the head and skull). We sold this product line to Medtronic in 2002. As with the Thin Film products, we sold CMF products at cost in 2004 under a contractual back-up supply agreement with Medtronic. A portion of the deferred gain on sale of assets, related party was recognized as revenue in order to reflect the fair value of products sold, based on historical selling prices of similar products, over our manufacturing cost. During the third quarter of 2004, we completed all remaining performance obligations related to the 2002 sale of the CMF product line to Medtronic. Therefore, we did not earn any CMF product revenues during the year ended December 31, 2005 and will not generate revenue from this product line in the future.

*The future:* We sell our spine and orthopedic products exclusively to Medtronic at fixed selling prices that are subject to adjustment biannually (based on Medtronic's selling prices to its customers). Our revenue from this product line is dependent upon the market's adoption of our technology, which is largely dependent upon Medtronic's marketing efforts and pricing strategies. To increase our revenues from spine and orthopedic products, we depend largely on Medtronic's ability and commitment to build and expand HYDROSORB™ market share. We currently anticipate additional orders for the MYSTIQUE™ portion of the HYDROSORB™ product line in 2006. We have, however, been disappointed in the past by Medtronic's level of effort in marketing our HYDROSORB™ products with the exception of the MYSTIQUE™ line. It is unlikely that we will see significant sales of the current non-MYSTIQUE™ products in the future (indeed we recorded reserves of \$280,000 against non-MYSTIQUE™ HYDROSORB™ products on hand during 2005), and our visibility of the size and timing of any further MYSTIQUE™ orders is limited.

We expect the currently high percentage of product revenues attributable to Medtronic to remain high now that domestic Thin Film revenues have ceased, although this may change when commercialization of the Thin Film products in Japan occurs and we begin Thin Film shipments to Senko.

#### Cost of product revenues

Cost of product revenues relates to our MacroPore Biosurgery segment and includes material, manufacturing labor, overhead costs and an inventory provision. The following table summarizes the components of our cost of revenues for the years ended December 31, 2005, 2004, and 2003:

	<u>Years ended</u>			<u>\$ and % Differences</u>		<u>% Differences</u>	
	<u>2005</u>	<u>2004</u>	<u>2003</u>	<u>2005 to 2004</u>	<u>2004 to 2003</u>	<u>2005 to 2004</u>	<u>2004 to 2003</u>
Cost of product revenues:							
Cost of product revenues .....	\$ 2,874,000	\$ 3,142,000	\$ 4,244,000	\$ (268,000)	\$ (1,102,000)	(8.5)%	(26.0)%
% of product revenues.....	51.0%	49.7%	30.1%	1.3%	19.6%	2.6%	65.1%
Inventory provision.....	280,000	242,000	—	38,000	242,000	15.7%	—
% of product revenues.....	5.0%	3.8%	—	1.2%	3.8%	31.6%	—
Total cost of product revenues.....	<u>\$ 3,154,000</u>	<u>\$ 3,384,000</u>	<u>\$ 4,244,000</u>	<u>\$ (230,000)</u>	<u>\$ (860,000)</u>	<u>(6.8)%</u>	<u>(20.3)%</u>
Total cost of product revenues as % of Product revenues .....	<u>56.0%</u>	<u>53.5%</u>	<u>30.1%</u>				

*MacroPore Biosurgery:*

- As our product revenues are currently generated only through sales of bioresorbable products, cost of revenues is related only to our MacroPore Biosurgery segment.
- Cost of revenues, as a percent of revenues (excluding inventory provision amounts), increased by 2.6% and 65.1% for the years ended December 31, 2005 and 2004, respectively. The changes for the year ended December 31, 2005 as compared to the same period in 2004 as well as between 2004 and 2003 were due primarily to amounts of fixed labor and overhead costs as applied to product revenues in each period. As MacroPore revenues have declined, gross margins have been negatively affected by fixed costs.
- Excess manufacturing costs – that is, costs resulting from lower than “normal” production levels - expensed during the year ended December 31, 2005 were \$934,000 as compared to \$1,119,000 in the same period in 2004.
- During the fourth quarter ended December 31, 2005, we recorded a provision of \$102,000, primarily for excess and slow-moving inventory. The inventory was produced in anticipation of stocking orders from Medtronic which have not materialized. We have determined it is probable that the inventory will not be recovered. The provision has been charged to cost of sales in the fourth quarter. Similar provisions for \$132,000 and \$46,000 were recorded in the third and second quarters of 2005, respectively, for a total inventory provision of \$280,000 for the year ended December 31, 2005.

The \$242,000 inventory provision during 2004 related to excess inventory produced in consideration of our responsibility to be a back-up supplier for the CMF product line. We sold the assets related to this product line to a subsidiary of Medtronic in September 2002. In April of 2004, Medtronic indicated that it would no longer purchase CMF inventory from us under the back-up supply arrangement, leading to our determination that the remaining CMF inventory on hand would not be recoverable.

*The future.* Ceasing to manufacture the CMF product line and the non-Japan bioresorbable Thin Film product line, combined with the deterioration of Medtronic orders for HYDROSORB™ products other than MYSTIQUE™, deprives us of economies of scale and will negatively impact our margins until other sources of revenue grow large enough to compensate for the lost revenue. If demand for our MYSTIQUE™ products does not increase substantially in 2006, we will continue to incur excess manufacturing costs similar to amounts we have recorded in 2005 and this product line will remain unprofitable.

Because we have recorded provisions for most of our finished goods inventory on-hand at December 31, 2005, and we currently build to order rather than to stock, we do not anticipate any additional inventory provisions in 2006.

Development revenues

The following table summarizes the components of our development revenues for the years ended December 31, 2005, 2004, and 2003:

	<u>Years ended</u>			<u>\$ Differences</u>		<u>% Differences</u>	
	<u>2005</u>	<u>2004</u>	<u>2003</u>	<u>2005 to 2004</u>	<u>2004 to 2003</u>	<u>2005 to 2004</u>	<u>2004 to 2003</u>
<b>Regenerative cell technology:</b>							
Research grant (NIH) .....	\$ 312,000	\$ 328,000	\$ —	\$ (16,000)	\$ 328,000	(4.9)%	—
Regenerative cell storage services .....	8,000	10,000	9,000	(2,000)	1,000	(20.0)%	11.1%
Total regenerative cell technology .....	<u>320,000</u>	<u>338,000</u>	<u>9,000</u>	<u>(18,000)</u>	<u>329,000</u>	<u>(5.3)%</u>	<u>3,655.6%</u>
<b>MacroPore Biosurgery:</b>							
Development (Senko) .....	51,000	158,000	—	(107,000)	158,000	(67.7)%	—
Total development revenues .....	<u>\$ 371,000</u>	<u>\$ 496,000</u>	<u>\$ 9,000</u>	<u>\$ (125,000)</u>	<u>\$ 487,000</u>	<u>(25.2)%</u>	<u>5,411.1%</u>

*Regenerative cell technology:*

- Although our primary focus is on discovery and development of new therapies for diseases and conditions using regenerative cell technologies, many of our development activities are still in a preclinical (or earlier) stage. Consequently, most of our revenue is currently generated by sales of bioresorbable products, as discussed in product revenues above. Also see “the future” section below for expected trends associated with revenues from our regenerative cell technology segment.
- The research grant revenue relates to our agreement with the National Institutes of Health (“NIH”). Under this arrangement the NIH reimburses us for “qualifying expenditures” related to research on Adipose-Derived Cell Therapy for Myocardial Infarction. To receive funds under the grant arrangement, we are required to (i) demonstrate that we incurred “qualifying

expenses," as defined in the grant agreement between the NIH and us, (ii) maintain a system of controls, whereby we can accurately track and report all expenditures related solely to research on Adipose-Derived Cell Therapy for Myocardial Infarction, and (iii) file appropriate forms and follow appropriate protocols established by the NIH.

Our policy is to recognize revenues under the NIH grant arrangement as the lesser of (i) qualifying costs incurred (and not previously recognized), plus our allowable grant fees for which we are entitled to funding or (ii) the amount determined by comparing the outputs generated to date versus the total outputs expected to be achieved under the research arrangement.

During the year ended December 31, 2005, we incurred \$306,000 in qualifying expenditures. During the year ended December 31, 2004, we incurred \$339,000 of costs, of which only \$322,000 were qualified expenditures. We recorded a total of \$312,000 and \$328,000 in revenues for the years ended December 31, 2005 and 2004, respectively, which include allowable grant fees as well as cost reimbursements. There were no comparable revenues or expenditures in 2003.

#### *MacroPore Biosurgery:*

Under a Distribution Agreement with Senko we are entitled to earn payments based on achieving the following defined milestones:

- Upon notifying Senko of completion of the initial regulatory application to the MHLW for the Thin Film product, we were entitled to a nonrefundable payment of \$1,250,000. We so notified Senko on September 28, 2004, received payment in October of 2004, and recorded deferred revenues. Of the amount deferred, we have recognized development revenues of \$209,000 (\$51,000 for the year ended December 31, 2005 and \$158,000 for the year ended December 31, 2004);
- Under this agreement, we also received a \$1,500,000 license fee that was recorded as a component of deferred revenues in the accompanying balance sheet. We are also entitled to a nonrefundable payment of \$250,000 once we achieve commercialization. Because the \$1,500,000 in license fees are potentially refundable, such amounts will not be recognized as revenues until the refund rights expire. Half of the license fee is refundable if the parties agree commercialization is not achievable and a proportional amount is refundable if we terminate the arrangement, other than for material breach by Senko, before three years post-commercialization.

*The future:* We expect that revenues from our regenerative cell technology segment will increase significantly in 2006. This is because in 2006, we expect to be able to recognize some portion of the deferred revenues, related party account associated with our arrangements with Olympus. Specifically, we anticipate completing four pre-clinical studies and certain phases of our product development performance obligations during 2006. If we are successful in completing these activities, we will recognize approximately \$2,633,000 in revenues in 2006. The exact timing of when amounts will be reported in revenue will depend on internal factors (for instance, our ability to complete the service obligations we have agreed to perform) as well as external considerations, including obtaining the necessary regulatory approvals for various therapeutic applications related to our Celution™ System.

We are entitled to receive up to \$850,000 in grants related to Adipose-Derived Cell Therapy for Myocardial Infarction as defined by the NIH grant agreement for Phase II research. To date, we have received and recognized \$540,000 of such funding. We expect to incur additional "qualifying expenses" of \$310,000 during 2006. Subject to satisfactory progress toward meeting the goals and objectives of our grant application, we expect to recognize any remaining grant revenues during 2006.

We will continue to recognize revenue from the development work we are performing on behalf of Senko, based on the relative fair value of the milestones completed to the total efforts expected to be necessary to obtain regulatory clearance with the MHLW. Obtaining regulatory clearance with the MHLW for initial commercialization is expected in 2006. Accordingly, we expect to recognize approximately \$1,291,000 (consisting of \$1,041,000 in deferred revenues plus a non-refundable payment of \$250,000 to be received upon commercialization) in revenues associated with this milestone arrangement in 2006. Moreover, we expect to recognize \$500,000 per annum associated with deferred Senko license fees over a three-year period following commercialization as the refund rights associated with the license payment expire.

#### Research and development expenses

Research and development expenses include costs associated with the design, development, testing and enhancement of our products, regulatory fees, the purchase of laboratory supplies, pre-clinical studies and costs associated with initiating clinical studies. It excludes related stock-based compensation expense. The following table summarizes the components of our research and development expenses for the years ended December 31, 2005, 2004 and 2003:

	Years ended			\$ Differences		% Differences	
	2005	2004	2003	2005 to 2004	2004 to 2003	2005 to 2004	2004 to 2003
<b>Regenerative cell technology:</b>							
Regenerative cell technology .....	\$ 11,448,000	\$ 6,910,000	\$ 4,205,000	\$ 4,538,000	\$ 2,705,000	65.7%	64.3%
Development milestone-Joint Venture..	1,176,000	—	—	1,176,000	—	—	—
Research grants (NIH) .....	306,000	339,000	—	(33,000)	339,000	(9.7)%	—
Total regenerative cell technology .....	<u>12,930,000</u>	<u>7,249,000</u>	<u>4,205,000</u>	<u>5,681,000</u>	<u>3,044,000</u>	78.4%	72.4%
<b>MacroPore Biosurgery:</b>							
Bioresorbable polymer implants .....	2,212,000	2,933,000	4,489,000	(721,000)	(1,556,000)	(24.6)%	(34.7)%
Development milestone-Senko .....	129,000	170,000	—	(41,000)	170,000	(24.1)%	—
Total MacroPore Biosurgery .....	<u>2,341,000</u>	<u>3,103,000</u>	<u>4,489,000</u>	<u>(762,000)</u>	<u>(1,386,000)</u>	(24.6)%	(30.9)%
Total research and development expenses	<u>\$ 15,271,000</u>	<u>\$ 10,352,000</u>	<u>\$ 8,694,000</u>	<u>\$ 4,919,000</u>	<u>\$ 1,658,000</u>	47.5%	19.1%

*Regenerative cell technology:*

- Regenerative cell technology expenses relate to the development of a technology platform that involves using adipose (fat) tissue as a source for autologous regenerative cells for therapeutic applications. The increases in regenerative cell technology expenses from 2004 to 2005 resulted primarily from the hiring of additional researchers, engineers and support staff. We incurred an additional \$2,209,000 in labor-related expenses, including benefits, during the year ended December 31, 2005 as compared with the same period in 2004. Preclinical studies expenses increased by \$1,315,000 for the year ended December 31, 2005 as compared to the same period in 2004. Rent expense increased \$736,000 in the year 2005 as compared to 2004, due to the addition of our new facility. The majority of the remainder of the increases as compared with 2004 related to increases in professional services, other supplies expense and miscellaneous expenses of \$1,421,000 during the year ended December 31, 2005. The increase in regenerative cell technology expenses from 2003 to 2004 was also due to increased labor costs, legal expenses, research supplies, consulting fees and facility expenses.
- Expenditures related to the Joint Venture with Olympus include costs that are necessary to support the commercialization of future generation devices based on our Celution™ System. These development activities include performing pre-clinical and clinical studies, seeking regulatory approval, and performing product development related to therapeutic applications for adipose stem and regenerative cells for multiple large markets. For the year ended December 31, 2005, costs associated with the development of the device were \$1,176,000. There were no comparable expenditures in 2004.
- In 2004, we entered into an agreement with the NIH to reimburse us for up to \$950,000 (Phase I \$100,000 and Phase II \$850,000) in “qualifying expenditures” related to research on Adipose-Derived Cell Therapy for Myocardial Infarction. For the year ended December 31, 2005, we incurred \$306,000 of direct qualifying expenses relating entirely to Phase II. For the year ended December 31, 2004, we incurred \$339,000 of direct expenses (\$17,000 of which were not reimbursed) relating to both Phases I and II of the agreement. The decrease in expense from 2005 to 2004 was due to the fact that 2005 expenses related to only Phase II while 2004 expenses related to both Phases I and II.

*MacroPore Biosurgery:*

- Our bioresorbable polymer surgical implants platform technology is used for development of spine and orthopedic products. The decrease in research and development costs associated with bioresorbable polymer implants in 2005 as compared with 2004 and 2003 was a result of a strategic decision to strongly focus our research and development efforts on our regenerative cell technology. For example, labor and related benefits expense decreased by \$282,000 (including \$74,000 related to Senko labor and benefit costs) for the year ended December 31, 2005 as compared to the same period in 2004. This was due to a redistribution of labor resources from one segment to the other.
- Under a Distribution Agreement with Senko we are responsible for the completion of the initial regulatory application to the MHLW and commercialization of the Thin Film product line in Japan. Commercialization occurs when one or more Thin Film product registrations are completed with the MHLW. During the year ended December 31, 2005, we incurred \$129,000 of expenses related to this regulatory and registration process. We had incurred \$170,000 of expense in this regulatory and registration process for the year ended December 31, 2004.

*The future.* Our strategy is to continue to increase our research and development efforts in the regenerative cell field and we anticipate expenditures in this area of research to be approximately \$20,000,000 to \$22,000,000 for the year 2006. We are also researching therapies for spine and orthopedic conditions, gastrointestinal disorders and new approaches for aesthetic and reconstructive surgery. The expenditures will primarily relate to developing therapeutic applications and conducting preclinical and clinical studies on adipose-derived stem and regenerative cells.

We were successful with Phase I of the NIH research on Adipose-Derived Cell Therapy for Myocardial Infarction. Therefore, we were awarded Phase II of the NIH research grant. We expect approximately \$310,000 of additional research expenses to be incurred related to Phase II of this project during 2006.

We expect that our current research and development expenditures in the bioresorbable platform technology will continue to be significantly less than our regenerative cell business expenditures. However, we will continue to invest in product development for biomaterial/polymer products to develop our pipeline of new and next generation spine and orthopedic products. We anticipate expenditures in this area of research to be approximately \$1,000,000 for the year 2006.

Also, we expect to incur substantial additional legal expenses in connection with the University of Pittsburgh's 2004 lawsuit. Although we are not litigants and are not responsible for any settlement costs, if the University of Pittsburgh wins the lawsuit, our license rights to the patent in question could be nullified or rendered non-exclusive and our regenerative cell strategy could be significantly affected.

### Sales and marketing expenses

Sales and marketing expenses include costs of marketing personnel, tradeshows, and promotional activities and materials. It excludes related stock based compensation expenses. Medtronic is responsible for the distribution, marketing and sales support of our spine and orthopedic devices. Our bioresorbable Thin Film product line (before the sale of the non-Japan Thin Film business to MAST in May 2004) was distributed domestically through a dedicated sales force, independent sales representatives and internationally through independent distributors. The following table summarizes the components of our sales and marketing expenses for the years ended December 31, 2005, 2004, and 2003:

	Years ended			\$ Differences		% Differences	
	2005	2004	2003	2005 to 2004	2004 to 2003	2005 to 2004	2004 to 2003
<b>Regenerative cell technology:</b>							
International sales and marketing .....	\$ 494,000	\$ —	\$ —	\$ 494,000	\$ —	—	—
Total regenerative cell technology .....	494,000	—	—	494,000	—	—	—
<b>MacroPore Biosurgery:</b>							
General corporate marketing .....	388,000	769,000	313,000	(381,000)	456,000	(49.5)%	145.7%
Domestic sales and marketing .....	—	846,000	3,145,000	(846,000)	(2,299,000)	—	(73.1)%
International sales and marketing .....	552,000	776,000	959,000	(224,000)	(183,000)	(28.9)%	(19.1)%
Total MacroPore Biosurgery .....	940,000	2,391,000	4,417,000	(1,451,000)	(2,026,000)	(60.7)%	(45.9)%
Total sales and marketing .....	\$ 1,434,000	\$ 2,391,000	\$ 4,417,000	\$ (957,000)	\$ (2,026,000)	(40.0)%	(45.9)%

#### *Regenerative Cell Technology:*

- International sales and marketing expenditures for the year ended December 31, 2005, relate primarily to salaries expense for employees involved in business development. The main emphasis of these newly-formed functions is to seek strategic alliances and/or co-development partners for our regenerative cell technology, which we began to focus on in the third quarter of 2005.

#### *MacroPore Biosurgery:*

- General corporate marketing expenditures relate to expenditures for maintaining our corporate image and reputation within the research and surgical communities. The decrease in 2005 as compared to 2004 was due to one-time costs incurred for an educational program we created in 2004 to inform end-users and distributors of the benefits and surgical applications for our biomaterials products. Conversely, the increase in costs in 2004 as compared to 2003 was a result of costs related to the same program. Additionally, in 2005 we allocated fewer personnel resources to general corporate marketing.
- Domestic sales and marketing expenditures relate to expenses associated with managing our domestic bioresorbable Thin Film product distribution, which included independent sales representatives and our domestic Thin Film sales consultants and marketing staff. The elimination of such expenses in 2005 and the sharp decrease in 2004 as compared to 2003 was due to the transfer of our sales force and marketing staff to MAST upon the sale of the Thin Film product line to MAST in May 2004.
- International sales and marketing expenditures relate to costs associated with developing an international bioresorbable Thin Film distributor and supporting a bioresorbable Thin Film sales office in Japan. The decreased spending in 2005 as compared to 2004 relates to a decrease in personnel resources currently dedicated to this marketing group. The decreased spending in 2004 as compared to 2003 related to the closure of our United Kingdom sales office.

*The future.* We project that general corporate marketing as well as our MacroPore Biosurgery international sales and marketing expenditures will remain reasonably stable in 2006. We also expect sales and marketing expenditures related to the regenerative cell technology to increase as we continue to expand this business segment in support of our pursuit of strategic alliances and co-development partners.

### General and administrative expenses

General and administrative expenses include costs for administrative personnel, legal and other professional expenses and general corporate expenses. Such expenses exclude related stock based compensation expenses. The following table summarizes the general and administrative expenses for the years ended December 31, 2005, 2004 and 2003:

	<u>Years ended</u>			<u>\$ Differences</u>		<u>% Differences</u>	
	<u>2005</u>	<u>2004</u>	<u>2003</u>	<u>2005 to 2004</u>	<u>2004 to 2003</u>	<u>2005 to 2004</u>	<u>2004 to 2003</u>
General and administrative expenses	\$ 10,096,000	\$ 6,480,000	\$ 4,958,000	\$ 3,616,000	\$ 1,522,000	55.8%	30.7%

- Salary and related benefit expense increased by \$981,000 during the year ended December 31, 2005, with respect to the same period in 2004. This increase was primarily caused by the addition of seven managerial employees. Legal expenses increased by \$1,444,000 for the year ended December 31, 2005, as compared with 2004, primarily due to legal expenses incurred in connection with the University of Pittsburgh's lawsuit challenging inventorship of our licensor's U.S. patent relating to adult stem cells isolated from adipose tissue. Additional professional services costs of \$460,000 as well as larger travel expenditures of \$229,000 for the year ended December 31, 2005, also contributed to the increase in general and administrative expense. The remaining increase of \$502,000 for the same period resulted from increased rent expense and various other miscellaneous expenses.
- The primary reason for the increase in 2004 as compared to 2003 was the result of salary, administrative and professional services expenses rising due to the hiring and retaining of a qualified management team to implement and manage our strategic plan. In particular, the increase in 2004 as compared to 2003 resulted primarily from salary and bonus increases of \$1,004,000 and professional services and other general overall corporate expenditure increases of \$518,000.

*The future.* We expect general and administrative expenses to increase slightly as we expand our business activities and require more support systems for those activities. We anticipate expenditures related to general and administrative costs to be approximately \$9,000,000 to \$10,000,000 in 2006.

### Stock based compensation expenses

Stock based compensation expenses include charges related to options issued to employees, directors and non-employees. The stock based compensation expenditures connected to options granted to employees and directors (in their capacity as board members) is the difference between the exercise price of the stock based awards and the market value of our underlying common stock on the date of the grant. Unearned employee stock based compensation is amortized over the remaining vesting periods of the options, which generally vest over a four-year period from the date of grant. The stock based compensation expenditures connected to options granted to non-employees initially is the fair value of the underlying common stock on the initial date of grant, but such amount is updated over the vesting period until the non-employee has met the performance commitment. Stock based compensation expense related to common stock granted to non-employees is the fair value of the stock on the date of grant, even if such stock contains sales restrictions. The following table summarizes the components of our stock based compensation expenses (excluding cost of revenues stock based compensation), for the years ended December 31, 2005, 2003, and 2002:

	<u>Years ended</u>			<u>\$ Differences</u>		<u>% Differences</u>	
	<u>2005</u>	<u>2004</u>	<u>2003</u>	<u>2005 to 2004</u>	<u>2004 to 2003</u>	<u>2005 to 2004</u>	<u>2004 to 2003</u>
<b>Regenerative cell technology:</b>							
Research and development related .....	\$ 67,000	\$ —	\$ —	\$ 67,000	\$ —	—	—
<b>MacroPore Biosurgery:</b>							
Research and development related .....	112,000	32,000	78,000	80,000	(46,000)	250.0%	(59.0)%
Sales and marketing related .....	113,000	22,000	70,000	91,000	(48,000)	413.6%	(68.6)%
Total MacroPore Biosurgery .....	225,000	54,000	148,000	171,000	(94,000)	316.7%	(63.5)%
General and administrative related .....	112,000	71,000	837,000	41,000	(766,000)	57.7%	(91.5)%
Total stock based compensation expense	\$ 404,000	\$ 125,000	\$ 985,000	\$ 279,000	\$ (860,000)	223.2%	(87.3)%

- In the second quarter of 2005, we granted 20,000 shares of restricted common stock to a non-employee scientific advisor. Because the shares granted are not subject to additional future vesting or service requirements, the stock based compensation expense of \$63,000 recorded in the second quarter of 2005 constitutes the entire expense related to this grant, and no future period charges will be reported. The stock is restricted only in that it cannot be sold for a specified period of time. There are no vesting requirements. This scientific advisor will also be receiving cash consideration as services are performed.

*MacroPore Biosurgery:*

- In August 2005, our Chief Operating Officer (“COO”), ceased employment with us. We agreed to pay the former COO a lump sum cash severance payment of \$155,164 and extended the exercise period for two years on 253,743 vested stock options. The incremental value of the options due to the modification was \$337,000. We recorded an expense in the third quarter of 2005 to reflect the lump sum cash severance payment and the value of the vested stock options, which constitutes the entire expense related to these options, and no future period charges will be required. This \$337,000 was allocated in the table above in equal portions among three departmental categories, consistent with previous allocations of the former COO’s compensation expense.
- All unearned stock based compensation was fully expensed by the end of 2004 (prior to 2004, all such stock based compensation was granted to personnel associated with our MacroPore Biosurgery segment).
- Decreases in 2004 as compared to 2003 result from the normal amortization of the stock based compensation expenses over the remaining vesting period, except for stock based compensation relating to research and development. In the second quarter of 2004, we charged \$32,000 to research and development for 100% vested options granted to a consultant for services fully rendered.

*General and Administrative:*

- During 2003, \$234,000 of general and administrative stock based compensation expense was due to the modification of certain options granted to the former Chief Financial Officer as a result of his separation agreement. The remainder of the decrease in general and administrative related stock based compensation expense was due primarily to the normal amortization in 2003 and 2004 of such expenses over the remaining vesting periods of the underlying awards.

*The future.* In December 2004, the FASB issued SFAS No. 123 (revised 2004), “Share-based Payment” (“SFAS 123R”). As affected by Securities and Exchange Commission Release No. 33-8586, “Amendment to Rule 4-01(a) of Regulation S-X Regarding the Compliance Date for Statement of Financial Accounting Standards No. 123 (Revised 2004), Share-Based Payment,” SFAS 123R is effective for annual periods beginning after June 15, 2005 (January 1, 2006 for us). Upon adoption, SFAS 123R will require us to measure all share-based payment transactions, including those with employees, at fair value. Moreover, the fair value of share-based payment awards (including employee stock option grants) will be recognized as expense in the statements of operations over the requisite service period of each award. Employee stock options granted prior to the effective date of SFAS 123R will, to the extent they vest after December 31, 2005, result in stock-based compensation expense charges beginning in 2006. SFAS 123R also changes the manner in which deferred taxes are recognized on share-based payment awards, as well as the accounting for award modifications. Subsequent to the adoption of SFAS 123R we plan to continue to grant options (which will result in an expense) to our employees and as appropriate, to non-employee service providers. The adoption of SFAS 123R will have a material impact on our results of operations. As of December 31, 2005, we estimate that our 2006 expense related to the fair value of share-based payment transactions will approximate the amount of SFAS 123 expense that we reported for 2005, as disclosed in footnote 2 to our consolidated financial statements. The full impact of the adoption of SFAS 123R in 2006 will depend on the level and terms of share-based payment transactions in 2006 as well as changes in our stock price and the assumptions used to determine the fair value of such transactions. We plan to adopt SFAS 123R using the modified prospective method of transition.

Change in fair value of option liabilities

The following is a table summarizing the change in fair value of option liabilities for the years ended December 31, 2005, 2004, and 2003:

	Years ended			\$ Differences		% Differences	
	2005	2004	2003	2005 to 2004	2004 to 2003	2005 to 2004	2004 to 2003
Change in fair value of option liability .....	\$ 3,545,000	\$ —	\$ —	\$ 3,545,000	\$ —	—	—
Change in fair value of put option liability ...	100,000	—	—	100,000	—	—	—
Total change in fair value of option liabilities .....	<u>\$ 3,645,000</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 3,645,000</u>	<u>\$ —</u>	—	—

- We granted Olympus an option to acquire 2,200,000 shares of our common stock which expires December 31, 2006. The exercise price of the option shares is \$10 per share. We have accounted for this grant as a liability because upon the exercise of the option, we will be required to deliver listed shares of our common stock to settle the option shares. In accordance with EITF 00-19, the fair value of this option has been re-measured at the end of the fourth quarter, using the Black-Scholes option pricing model, with the movement in fair value reported in the statement of operations as a change in fair value of option liabilities. The upward movement was caused primarily by our increasing public market stock price. At December 31, 2005, the contractual term, interest rate and volatility assumptions under the Black-Scholes option pricing model were 1.0 year, 4.38% and 65.1%, respectively.
- In reference to the Joint Venture, the Shareholders' Agreement between Cytori and Olympus provides that in certain specified circumstances of insolvency or if we experience a change in control, Olympus will have the rights to (i) repurchase our interests in the Joint Venture at the fair value of such interests or (ii) sell its own interests in the Joint Venture to Cytori at the higher of (a) \$22,000,000 or (b) their fair value (the "Put"). The Put value has been classified as a liability.

The valuations of the Put were completed by an independent valuation firm using an option pricing theory based simulation analysis (i.e., a Monte Carlo simulation). The valuations are based on assumptions as of the valuation date with regard to the market value of Cytori and the estimated fair value of the Joint Venture, the expected correlation between the values of Cytori and the Joint Venture, the expected volatility of Cytori and the Joint Venture, the bankruptcy recovery rate for Cytori, the bankruptcy threshold for Cytori, the probability of a change of control event for Cytori, and the risk free rate.

The following assumptions were employed in estimating the value of the Put at December 31, 2005 (these assumptions were not materially different from those used in valuing the Put as of November 4, 2005):

- The expected volatilities of Cytori and the Joint Venture were assumed to be 63.2% and 69.1%, respectively,
- The bankruptcy recovery rate for Cytori was assumed to be 21%,
- The bankruptcy threshold for Cytori was assumed to be \$10.78 million,
- The probability of a change of control event for Cytori was assumed to be 3.04%,
- The expected correlation between the fair values of Cytori and the Joint Venture in the future was assumed to be 99%, and
- The risk free rate was assumed to be 4.39%.

*The future.* Until exercise or expiration (on December 31, 2006), the fair value of the 2,200,000 share option will continue to be re-measured at the end of each reporting period, with movements in fair value reported in the statements of operations as changes in the fair value of option liabilities. Note that if the market price of our common stock increases, the option will become more valuable, resulting in an additional charge in our statements of operations.

The Put is perpetual and, thus, has no expiration date. Accordingly, we will continue to recognize a liability for the Put until it is exercised or until the arrangements with Olympus are amended.

### Restructuring charges

The following table summarizes the restructuring charges for the years ended December 31, 2005, 2004 and 2003:

	<u>Years ended</u>			<u>\$ Differences</u>		<u>% Differences</u>	
	<u>2005</u>	<u>2004</u>	<u>2003</u>	<u>2005 to 2004</u>	<u>2004 to 2003</u>	<u>2005 to 2004</u>	<u>2004 to 2003</u>
Restructuring charge .....	\$ —	\$ 107,000	\$ 451,000	\$ (107,000)	\$ (344,000)	—	(76.3)%

- In September 2003, we closed an administrative office in Königstein, Germany in an effort to reduce costs and consolidate operations in the United States. The office was rented under an operating lease and in connection with the termination of the lease, we incurred \$169,000. We also incurred restructuring charges of \$282,000 relating to the involuntary termination of three employees, including our previous CFO.
- A restructuring charge of \$107,000 was recorded in 2004 as a result of a negotiated settlement related to our remaining lease obligation for the property.

*The future.* It is possible that we may incur a restructuring charge related to our lease obligations at our Top Gun facilities wher

the majority of our operations relocate to our main facility. However, it is not determinable if this contingency each quarter.

### Equipment impairment charges

The following table summarizes the components of equipment impairment charges for the years ended December 31, 2005, 2004, and 2003:

	Years ended			\$ Differences		% Differences	
	2005	2004	2003	2005 to 2004	2004 to 2003	2005 to 2004	2004 to 2003
Equipment impairment charge.....	\$ —	\$ 42,000	\$ —	\$ (42,000)	\$ 42,000	—	—

During the fourth quarter of 2004, as a result of our normal periodic fixed asset review, we determined that certain production assets were impaired. We recorded an impairment charge that represented the excess of the net book value over the estimated fair value of the assets; as the production assets are held for sale, fair value was based on the estimated net proceeds we expect to receive upon the sale of these assets, net of selling costs.

### Other income

The following is a table summarizing the gain on the sale of assets and the gain on the sale of assets, related party for the years ended December 31, 2005, 2004 and 2003:

	Years ended			\$ Differences		% Differences	
	2005	2004	2003	2005 to 2004	2004 to 2003	2005 to 2004	2004 to 2003
Gain on the sale of assets.....	\$ 5,526,000	\$ —	\$ —	\$ 5,526,000	\$ —	—	—
Gain on the sale of assets, related party	—	13,883,000	—	(13,883,000)	13,883,000	—	—
Total.....	\$ 5,526,000	\$ 13,883,000	\$ —	\$ (8,357,000)	\$ 13,883,000	60.2%	—

- The \$5,526,000 gain on sale of assets recorded in the third quarter of 2005 was related to the sale of the majority of our Thin Film product line in May 2004 to MAST. As part of the disposal arrangement, we agreed to complete certain performance obligations which prevented us from recognizing the gain on sale of assets when the cash was initially received. In August 2005, following the settlement of arbitration proceedings related to the sale agreement, we were able to recognize the gain on sale of assets of \$5,650,000, less \$124,000 of related deferred costs, in the statement of operations.
- The gain on sale of assets, related party related to the initial payment as well as milestone payments from Medtronic for the disposition of our CMF product line in 2002. Specifically, as part of the disposal arrangement, we agreed to complete clinical research regarding Faster Resorbable Polymer, an area that directly relates to the CMF product line we transferred to Medtronic. In January 2004, we received the \$5,000,000 payment after fulfilling the research requirements set out in the CMF sale agreement. We were also obliged to transfer certain “know-how,” including manufacturing processes, patents, and other intellectual property, to Medtronic. This obligation was fulfilled and in the third quarter of 2004 we received \$1,500,000 from Medtronic. These milestones represented the last of all remaining performance obligations and therefore, we were able to recognize the remaining deferred gain on the sale of assets, related party, of \$7,383,000, in the statement of operations.

### Financing items

The following table summarizes interest income, interest expense, and other income and expenses for the years ended December 31, 2005, 2004, and 2003:

	Years ended			\$ Differences		% Differences	
	2005	2004	2003	2005 to 2004	2004 to 2003	2005 to 2004	2004 to 2003
Interest income.....	\$ 299,000	\$ 252,000	\$ 417,000	\$ 47,000	\$ (165,000)	18.7%	(39.6)%
Interest expense.....	(137,000)	(177,000)	(126,000)	40,000	(51,000)	(22.6)%	40.5%
Other income (expense) .....	(55,000)	15,000	87,000	(70,000)	(72,000)	(466.7)%	(82.8)%
Total.....	\$ 107,000	\$ 90,000	\$ 378,000	\$ 17,000	\$ (288,000)	18.9%	(76.2)%

- Interest income increased from 2004 to 2005 due to a larger balance of funds available for investment, which was a result of the transactions with Olympus, as well as higher returns on investments. Interest expense decreased due to lower principal

balances on our long-term borrowings as compared with the preceding year. Our newest promissory note, with approximately \$1,380,000 in principal, was not executed until late in 2005.

- Interest income decreased in 2004 as compared to the same period in 2003, respectively, because of a decrease in funds available for investment as well as lower interest rates.
- The changes in other income (expense) in 2005, 2004 and 2003 resulted primarily from changes in foreign currency exchange rates.

*The future.* Interest income earned in 2006 will be dependent on our levels of funds available for investment as well as general economic conditions. Interest expense will increase in 2006 due to the additional promissory note executed late in 2005.

#### Equity loss from investment in Joint Venture

The following table summarizes equity loss from investment in joint venture for the years ended December 31, 2005, 2004, and 2003:

	<u>Years ended</u>			<u>\$ Differences</u>		<u>% Differences</u>	
	<u>2005</u>	<u>2004</u>	<u>2003</u>	<u>2005 to 2004</u>	<u>2004 to 2003</u>	<u>2005 to 2004</u>	<u>2004 to 2003</u>
Equity loss from investment in Joint Venture.....	\$ 4,172,000	\$ —	\$ —	\$ 4,172,000	\$ —	—	—

- The loss in 2005 related entirely to our 50% equity interest in the Joint Venture, which we accounted for using the equity method of accounting.
- As the carrying value of our investment in the Joint Venture is presently \$0, we do not expect to recognize significant losses from the activities of the Joint Venture in the foreseeable future. Over the next two to three years, the JV is expected to incur only modest general and administrative expenses, which we will likely (but have no obligation to) fund jointly with Olympus.

#### **Liquidity and Capital Resources**

##### Short-term and long-term liquidity

The following is a summary of our key liquidity measures at December 31, 2005, 2004, and 2003:

	<u>Years ended</u>			<u>\$ Differences</u>		<u>% Differences</u>	
	<u>2005</u>	<u>2004</u>	<u>2003</u>	<u>2005 to 2004</u>	<u>2004 to 2003</u>	<u>2005 to 2004</u>	<u>2004 to 2003</u>
Cash and cash equivalents .....	\$ 8,007,000	\$ 2,840,000	\$ 2,820,000	\$ 5,167,000	\$ 20,000	181.9%	0.7%
Short-term investments, available for sale .....	7,838,000	10,579,000	11,448,000	(2,741,000)	(869,000)	(25.9)%	(7.6)%
Total cash and cash equivalents and short-term investments, available for sale .....	\$ 15,845,000	\$ 13,419,000	\$ 14,268,000	\$ 2,426,000	\$ (849,000)	18.1%	(6.0)%
Current assets .....	\$ 17,540,000	\$ 15,645,000	\$ 16,916,000	\$ 1,895,000	\$ (1,271,000)	12.1%	(7.5)%
Current liabilities .....	7,081,000	3,187,000	4,484,000	3,894,000	(1,297,000)	122.2%	(28.9)%
Working capital .....	\$ 10,459,000	\$ 12,458,000	\$ 12,432,000	\$ (1,999,000)	\$ (26,000)	(16.0)%	(0.2)%

We believe that existing funds, cash generated by operations, and existing and accessible sources of financing are adequate to satisfy our working capital, capital expenditures, debt service and other financial commitments at least through December 31, 2006. However, in order to provide greater financial flexibility and liquidity, and in view of the substantial cash needs of our regenerative cell business during its development stage, we will need to raise additional capital (notwithstanding the proceeds received from the Olympus collaboration agreements, which were entered into in November 2005).

From inception to December 31, 2005, we have financed our operations primarily by:

- Issuing our stock,
- Generating revenues,
- Selling the CMF product line in September 2002,
- Selling the Thin Film product line (except for the territory of Japan), in May 2004,
- Entering into a Distribution Agreement for the distribution rights to Thin Film in Japan, in which we received an upfront

license fee in July 2004 and an initial development milestone payment in October 2004,

- Obtaining a modest amount of capital equipment long-term financing,
- Closing a Stock Purchase Agreement with Olympus in May 2005, and
- Entering into a collaborative arrangement with Olympus in November 2005, including the formation of a joint venture called Olympus-Cytori, Inc.

We increased our cash position by \$11,000,000 in May 2005 through a common stock purchase agreement we entered into with Olympus in April 2005. This agreement covers the sale of 1.1 million shares of our common stock to Olympus at \$10.00 per share. Also as part of the agreement, we granted Olympus an option that expires December 31, 2006 to purchase an additional 2,200,000 shares of common stock at \$10.00 per share.

Furthermore, we entered into a strategic development and manufacturing joint venture as well as other agreements with Olympus in November 2005. Under the collaborative arrangements, we formed a joint venture with Olympus, Olympus-Cytori, Inc., to develop and manufacture future generation devices based on our Celution™ System. Pursuant to the terms of the agreements, we received upon closing \$11 million in cash in the fourth quarter of 2005; this cash is incremental to the proceeds received under the Olympus equity investment described above.

In January 2006, we also received an additional \$11 million upon our receipt of a CE mark for the first generation Celution™ System and will receive an additional \$1.5 million in early 2006 in exchange for the grant to Olympus of an exclusive right to negotiate a commercialization collaboration for the use of adipose stem and regenerative cells for a specific therapeutic area outside of cardiovascular disease. We may receive more proceeds if Olympus decides to exercise its option to purchase 2,200,000 shares of our common stock at a fixed price of \$10.00 per share.

To fund 2006 expected capital expenditures of \$2,500,000, primarily related to initial leasehold improvements at our new corporate headquarters, we intend to use available working capital and if available, borrow under our Amended Master Security Agreement.

Any excess funds will be invested in short-term available-for-sale investments. We believe that it is necessary to maintain a large amount of cash and short-term available-for-sale investments on hand to ensure that we have adequate resources to fund future research and development, and to manage legal and regulatory risks and challenges to our business model.

Our capital requirements for 2006 and beyond will depend on numerous factors, including the resources we devote to developing and supporting our investigational cell therapy products, market acceptance of our developed products, regulatory approvals and other factors. We have positioned ourselves to expand our cash position through actively pursuing co-development and marketing agreements, research grants, and licensing agreements related to our technology platforms. Moreover, we are committed to increasing revenues from our bioresorbable products. The revenue generated from our non-Thin Film bioresorbable products will depend in large part on the success of Medtronic's (our sole distributor of spine and orthopedics implants) marketing efforts in the bioresorbable spine and orthopedics arena. Revenue from Thin Film products can begin when Japanese regulatory approval is obtained and thereafter will depend largely on Senko's marketing efforts.

We expect to incur research and development expenses, well beyond our current levels, in our regenerative cell platform for an extended period of time. This will occur whether or not our biomaterials business reaches profitability. We will continue to seek collaborations and new sources of financing, beyond those entered into with Olympus, in order to fund operations, satisfy financial obligations, and achieve our research and development objectives.

The following summarizes our contractual obligations and other commitments at December 31, 2005, and the effect such obligations could have on our liquidity and cash flow in future periods:

Contractual Obligations	Payments due by period				
	Total	Less than 1 year	1 – 3 years	3 – 5 years	More than 5 years
Long-term obligations .....	\$ 2,510,000	\$ 952,000	\$ 1,558,000	\$ —	\$ —
Interest commitment on long-term obligations .....	366,000	198,000	168,000	—	—
Operating lease obligations .....	7,304,000	1,572,000	5,025,000	707,000	—
Research study obligations .....	2,101,000	2,101,000	—	—	—
Total .....	<u>\$ 12,281,000</u>	<u>\$ 4,823,000</u>	<u>\$ 6,751,000</u>	<u>\$ 707,000</u>	<u>\$ —</u>

Cash provided by (used in) operating, investing and financing activities for the years ended December 31, 2005, 2004, and 2003 is summarized as follows:

	Years Ended		
	2005	2004	2003
Net cash used in operating activities .....	\$ (1,101,000)	\$ (12,574,000)	\$ (7,245,000)
Net cash provided by investing activities .....	911,000	13,425,000	5,954,000
Net cash provided by (used in) financing activities.....	5,357,000	(831,000)	(997,000)

### Operating activities

Net cash used in operating activities for the year ended December 31, 2005 resulted from our \$26,538,000 net loss, adjusted for the \$17,311,000 we have received from Olympus as noted above. Other adjustments include material non-cash activities, such as the gain on sale of assets, depreciation and amortization, changes in the fair value of the Olympus option liabilities, stock based compensation expense, equity loss from investment in Joint Venture, as well as for changes in working capital due to the timing of product shipments (accounts receivable) and payment of liabilities.

Net cash used in operating activities in the year ended 2004 resulted from our adjusted net loss (as adjusted for the \$13,883,000 gain on sale of assets, related party) and changes in working capital due to the timing of product shipments and payment of liabilities. The net cash used in operations was partially offset by the \$1,500,000 upfront license fee and \$1,250,000 development milestone payment received from Senko in 2004.

In 2003, net cash used in operating activities primarily resulted from our net loss as adjusted for \$2,046,000 of non-cash amortization of gain on the sale of CMF assets to Medtronic. Other adjustments include non-cash stock based compensation expense and changes in working capital.

Operating losses in all periods resulted largely from expenses related to our regenerative medicine research and development efforts.

### Investing activities

Net cash provided by investing activities for the year ended December 31, 2005 resulted primarily from net proceeds from the sale of short-term investments, offset in part by short-term investment purchases. The proceeds were used to fund operating and financing activities during 2005.

Net cash provided by investing activities for the year ended December 31, 2004 resulted in part from the receipt of a non-recurring payment of \$6,500,000 for the completion of the CMF Faster Resorbable Polymer clinical research and the transfer of the know-how related to the 2002 sale of the CMF Product Line to Medtronic. In addition, we received net proceeds of \$6,931,000 from the sale of our Thin Film product line (except for the territory of Japan) to MAST.

The net cash provided by investing activities in the year ended 2003 primarily related to net proceeds from the sale of short-term investments, which was offset by the purchase of fewer short-term investments (i.e.- we cashed in short-term investments to fund our operating and financing activities).

Capital spending is essential to our product innovation initiatives and to maintain our operational capabilities. For the years ended December 31, 2005, 2004 and 2003, we used cash to purchase \$1,846,000, \$789,000, and \$1,743,000, respectively, of property and equipment to support manufacturing of our bioresorbable implants and for the research and development of the regenerative cell technology platform. The increase in 2005 capital spending was caused primarily by expenditures for leasehold improvements made to our new facilities. The decrease in 2004 capital spending was caused by a decrease in the purchase of bioresorbable research and development equipment, in response to lower sales demand.

### Financing Activities

The net cash provided by financing activities for the year ended December 31, 2005 related mainly to the proceeds received from Olympus as noted above. Sale proceeds were recorded as including \$3,003,000 for the sale of common stock and \$1,686,000 for the issuance of options.

The net cash used in financing activities for the year ended December 31, 2004 related to the repurchase of 290,252 shares of our common stock for \$1,052,000 as well as the payment of \$847,000 on our long term obligations.

Net cash used in financing activities in 2004 was offset by proceeds from an Amended Master Security Agreement we entered in September 2003 to provide financing for equipment purchases. In connection with this agreement, we issued promissory notes with principal amounts totaling approximately \$1,039,000 for the year ended December 31, 2004.

## Critical Accounting Policies and Significant Estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the United States requires us to make estimates and assumptions that affect the reported amounts of our assets, liabilities, revenues and expenses, and that affect our recognition and disclosure of contingent assets and liabilities.

While our estimates are based on assumptions we consider reasonable at the time they were made, our actual results may differ from our estimates, perhaps significantly. If results differ materially from our estimates, we will make adjustments to our financial statements prospectively as we become aware of the necessity for an adjustment.

We believe it is important for you to understand our most critical accounting policies. These are our policies that require us to make our most significant judgments and, as a result, could have the greatest impact on our future financial results.

### *Revenue Recognition*

We derive our revenue from a number of different sources, including but not limited to:

- Product sales,
- Payments under license or distribution agreements, and
- Fees for achieving certain defined milestones under research and/or development arrangements.

Many of our revenue generating arrangements are relatively simple in nature, meaning that there is little judgment necessary with regard to the timing of when we recognize revenues or how such revenues are presented in the financial statements.

However, we have also entered into more complex arrangements, including but not limited to our contracts with Olympus, Senko, and the NIH. Moreover, some of our non-recurring transactions, such as our disposition of the majority of our Thin Film business to MAST or our sale of our CMF product line to Medtronic, contain elements that relate to our core revenue producing activities.

As a result, some of our most critical accounting judgments relate to the identification, timing, and presentation of revenue related activities. These critical judgments are discussed further in the paragraphs that follow.

### Multiple-elements

Some of our revenue generating arrangements contain a number of distinct revenue streams, known as “elements.” For example, our Distribution Agreement with Senko contains direct or indirect future revenue streams related to:

- A distribution license fee (which was paid at the outset of the arrangement),
- Milestone payments for achieving commercialization of the Thin Film product line in Japan,
- Training for representatives of Senko,
- Sales of Thin Film products to Senko, and
- Payments in the nature of royalties on future product sales made by Senko to its end customers.

Emerging Issues Task Force Issue 00-21, “Revenue Arrangements with Multiple Deliverables” (“EITF 00-21”), governs whether each of the above elements in the arrangement should be accounted for individually, or whether the entire contract should be treated as a single unit of accounting.

EITF 00-21 indicates that individual elements may be separately accounted for only when:

- The delivered element has stand alone value to the customer,
- There is objective evidence of the fair value of the remaining undelivered elements, and
- If the arrangement contains a general right of return related to any products delivered, delivery of the remaining goods and services is probable and within the complete control of the seller.

In the case of the Senko Distribution Agreement, we determined that (a) the milestones payments for achieving commercialization and (b) the future sale of Thin Film products to Senko were “separable” elements. That is, each of these elements, upon delivery, will have stand alone value to Senko and there will be objective evidence of the fair value of any remaining undelivered elements at that time. The arrangement does not contain any general right of return, and so this point is not relevant to our analysis.

On the other hand, we concluded that (a) the upfront distribution license fee, (b) the revenues from training for representatives of

Senko, and (c) the payments in the nature of royalties on future product sales are not separable elements under EITF 00-21.

In arriving at our conclusions, we had to consider whether our customer, Senko, would receive stand alone value from each delivered element. We also, in some cases, had to look to third party evidence to support the fair value of certain undelivered elements – notably, training – since we as a company do not routinely deliver this service on a stand alone basis. Finally, we had to make assumptions about how the non-separable elements of the arrangement are earned, particularly the estimated period over which Senko will benefit from the arrangement (refer to the “Recognition” discussion below for further background).

We also agreed to perform multiple services under the November 4, 2005 agreements we signed with Olympus, including:

- Granting the Joint Venture (which Olympus controls) an exclusive and perpetual license to our therapeutic device technology, including the Celution™ System and certain related intellectual property; and
- Performing development activities in relation to certain therapeutic applications associated with our Celution™ System, including completing pre-clinical and clinical trials, seeking regulatory approval as appropriate, and assisting with product development.

Following commercialization of the Celution™ System, we will provide monthly forecasts, specifying the quantities of each category of devices that we intend to purchase from the Joint Venture, at formula-based prices, over a rolling six-month period. Although we are not subject to any minimum purchase requirements, we are obliged to buy a defined percentage of the products forecasted by us in such reports. Again, however, this guarantee will trigger only upon the development of a commercializable device by the Joint Venture. Moreover, we effectively control the number of devices we will agree to purchase, since the guaranteed quantities will be derived from monthly forecasts prepared by us.

In particular, we concluded that the license and development services must be accounted for as a single unit of accounting. In reaching this conclusion, we determined that the license would not have standalone value to the Joint Venture. This is because Cytora is the only party that could be reasonably expected to perform the development services- including pre-clinical and clinical studies, regulatory filings, and product development-necessary for the Joint Venture to derive any value from the license.

#### Recognition

Besides determining whether to account separately for components of a multiple-element arrangement, we also use judgment in determining the appropriate accounting period in which to recognize revenues that we believe (a) have been earned and (b) are realizable. The following describes some of the recognition issues we have considered during the reporting period.

- Upfront License Fees/Milestones
  - As part of the Senko Distribution Agreement, we received an upfront license fee upon execution of the arrangement, which, as noted previously, was not separable under EITF 00-21. Accordingly, the license has been combined with the development (milestones) element, which was separable, to form a single accounting unit. This single element has been allocated \$3,000,000 in fees, of which \$1,500,000 are potentially refundable. We have recognized, and will continue to recognize the non-contingent fees allocated to this combined element as revenues as we complete each of performance obligations associated with the milestones component of this combined deliverable. Note that the timing of when we have recognized revenues to date does not correspond with the cash we received upon achieving certain milestones. For example, the first such milestone payment for \$1,250,000 became payable to use when we filed a commercialization application with the Japanese regulatory authorities. However, we determined that the payment received was not commensurate with the level of effort expended, particularly compared with other steps we believe are necessary to commercialize the Thin Film product line in Japan. Accordingly, we did not recognize the entire \$1,250,000 received as revenues, but instead have recorded all but \$209,000 of this amount as deferred revenues. The \$209,000 (\$51,000 in 2005 and \$158,000 in 2004) was recognized as development revenues based on our estimates of the level of effort expended for completed milestones as compared with the total level of effort we expect to incur under the arrangement to successfully achieve regulatory approval of the Thin Film product line in Japan. These estimates were subject to judgment and there may be changes in estimates regarding the total level of effort as we continue to seek regulatory approval. In fact there can be no assurance that commercialization in Japan will ever be achieved, although our latest understanding is that regulatory approval will be received in 2006.
  - We also received upfront fees as part of the Olympus arrangements (although, unlike Senko, these fees were non-refundable). Specifically, in exchange for an upfront fee, we granted the Joint Venture an exclusive, perpetual license to certain of our intellectual property and agreed to perform additional development activities. This upfront fee has been recorded in the liability account entitled deferred revenues, related party, on our consolidated balance sheet. Similar to the Senko agreement, we have elected an accounting policy to recognize revenues from the combined license/development accounting unit as we perform the development services, as this represents our financial obligation underlying the combined accounting unit. Specifically, we plan to recognize revenues from the

license/development accounting unit using a “proportional performance” methodology, resulting in the de-recognition of amounts recorded in the deferred revenues, related party account as we complete various milestones underlying the development services. For instance, we plan to recognize some of the deferred revenues, related party as revenues, related party, when we complete a pre-clinical trial, or obtain regulatory approval in a specific jurisdiction. Determining what portion of the deferred revenues, related party balance to recognize as each milestone is completed involves substantial judgment. In allocating the balance of the deferred revenues, related party to various milestones, we had in-depth discussions with our operations personnel regarding the relative value of each milestone to the Joint Venture and Olympus. We also considered the cost of completing each milestone relative to the total costs we plan to incur in completing all of the development activities, since we believe that the relative cost of completing a milestone is a reasonable proxy for its fair value. Although we have yet to recognize any revenue from the Olympus agreement, the accounting policy described above could result in revenues being recorded in an earlier accounting period than had other judgments or assumptions been made by us.

- **Government Grants**

- We are eligible to receive grants from the NIH related to our research on adipose derived cell therapy to treat myocardial infarctions. There are no specific standards under U.S. GAAP that prescribe the recognition or classification of these grants in the statement of operations. Absent such guidance, we have established an accounting policy to recognize NIH grant revenues at the lesser of:
  - Qualifying costs incurred (and not previously recognized), plus any allowable grant fees, for which Cytori is entitled to grant funding; or,
  - The amount determined by comparing the research outputs generated to date versus the total outputs that are expected to be achieved under the entire arrangement.
- Our accounting policy could theoretically defer revenue recognition beyond the period in which we have earned the rights to such fees. However, we selected this accounting policy to counteract the possibility of recognizing revenues from the NIH arrangement too early. For instance, if our policy permitted revenues to be recognized solely as qualifying costs were incurred, we could alter the amount of revenue recognized by incurring more or less cost in a given period, irrespective of whether these costs correlate to the research outputs generated. On the other hand, if revenue recognition were based on output measures alone, it would be possible to recognize revenue in excess of costs actually incurred; this is not appropriate since qualifying costs remain the basis of our funding under the NIH grant. The application of our accounting policy, nonetheless, involves significant judgment, particularly in estimating the percentage of outputs realized to date versus the total outputs expected to be achieved under the grant arrangement.

- **Back-up Supply Arrangements**

- We agreed to serve as a back-up supplier of products in connection with our dispositions of both:
  - The CMF product line to Medtronic; and,
  - Specific Thin Film assets to MAST.

Specifically, we agreed to supply CMF or Thin Film product to Medtronic and MAST, respectively, at our cost for a defined period of time. When we actually delivered products under the back-up supply arrangements, however, we recognized revenues in the financial statements at the estimated selling price which we would receive in the marketplace. We used judgment, based on historical data and expectations about future market trends, in determining the estimated market selling price of products subject to the back-up supply arrangements. The amount of the deferred gain recognized as revenue is equal to the excess of the fair value of products sold, based on historical selling prices of similar products, over our manufacturing cost.

### Presentation

We have presented amounts earned under our NIH research arrangement as research grant revenue. We believe that the activities underlying the NIH agreement constitute a portion of our ongoing major or central operations. Moreover, the government obtains rights under the arrangement, in the same manner (but perhaps not to the same extent) as a commercial customer that similarly contracts with us to perform research activities. For instance, the government and any authorized third parties may use our federally funded research and/or inventions without payment of royalties to us.

### **Warranty Provisions**

At the time of sale, we grant customers the right to a full refund if (and only if) the purchased medical device does not meet all of

the agreed upon specifications and expectations. Accordingly, we establish a liability for the estimated cost of honoring this warranty at the same time we record revenues from the sale of the related medical device.

We believe the accounting estimate related to our warranty liability is a "critical accounting estimate" because changes in the related warranty provision can materially affect our operating results. Moreover, because of our limited history and our continual development of new products, estimating our expected warranty costs requires significant judgment.

In the past, our warranty provision was based primarily on actual history of warranty claims submitted by our customers. Before the third quarter of 2003, we had de minimis warranty claims despite recognizing approximately \$27 million in cumulative sales of medical devices. Accordingly, we had no warranty reserves before the third quarter of 2003.

In the third quarter of 2003, we determined that some of the products we sold did not meet certain customer expectations, based on criteria previously communicated to our customer (Medtronic). After detecting this matter, we elected to replace all lots of affected inventory that were on hand at the customer, and we subsequently modified our procedures to seek to prevent similar occurrences in the future.

As a result, we recorded a warranty charge of \$243,000 in the third quarter of 2003. We have incorporated this new historical warranty data into our determination of appropriate warranty reserves to record prospectively and will continue to evaluate the adequacy and accuracy of our warranty obligations on a quarterly basis. There have been no material warranty claims since the third quarter of 2003.

### ***Goodwill Impairment Testing***

In late 2002, we purchased StemSource and recognized over \$4,600,000 in goodwill associated with the acquisition, of which \$4,387,000 remains on our balance sheet as of December 31, 2005. As required by Statement of Financial Accounting Standard No. 142, "Goodwill and Other Intangible Assets" ("SFAS 142"), we must test this goodwill at least annually for impairment as well as when an event occurs or circumstances change such that it is reasonable possible that impairment may exist. Moreover, this testing must be performed at a level of the organization known as the reporting unit. A reporting unit is at least the same level as a company's operating segments, and sometimes even one level lower.

Specifically, the process for testing goodwill for impairment under SFAS 142 involves the following steps:

- Company assets and liabilities, including goodwill, are allocated to each reporting unit for purposes of completing the goodwill impairment test.
- The carrying value of each reporting unit – that is, the sum of all of the net assets allocated to the reporting unit – is then compared to its fair value.
- If the fair value of the reporting unit is lower than its carrying amount, goodwill may be impaired – additional testing is required.

When we last completed our goodwill impairment testing in 2005, the fair values of our two reporting units each exceeded their respective carrying values. Accordingly, we determined that none of our reported goodwill was impaired.

The application of the goodwill impairment test involves a substantial amount of judgment. For instance, SFAS 142 requires that assets and liabilities be assigned to a reporting unit if both of the following criteria are met:

- The asset will be employed in or the liability relates to the operations of a reporting unit.
- The asset or liability will be considered in determining the fair value of the reporting unit.

We developed mechanisms to assign company-wide assets like shared property and equipment, as well as company-wide obligations such as borrowings under our GE Loan Facility, to our two reporting units. In some cases, certain assets were not allocable to either reporting unit and were left unassigned.

The most complex and challenging asset to assign to each reporting unit was our acquired goodwill. As noted previously, all of our recorded goodwill was generated in connection with our acquisition of StemSource in 2002. All of the StemSource assets and liabilities still on hand at our 2004 testing date were allocated to our regenerative cell reporting unit. However, when we first acquire StemSource, we determined that a portion of the goodwill related to the MacroPore Biosurgery reporting unit. The amount of goodwill allocated represented our best estimate of the synergies (notably future cost savings from shared research and development activities) that the MacroPore Biosurgery reporting unit would obtain by virtue of the acquisition.

Finally, with the consultation and assistance of a third party, we estimated the fair value of our reporting units by using various estimation techniques. In particular, we estimated the fair value of our MacroPore Biosurgery reporting unit based on an equal weighting of the market values of comparable enterprises and discounted projections of estimated future cash flows. Clearly,

identifying comparable companies and estimating future cash flows as well as appropriate discount rates involves judgment. On the contrary, we estimated the fair value of our regenerative cell reporting unit solely using an income approach, as we believe there are no comparable enterprises on which to base a valuation. The assumptions underlying this valuation method involve a substantial amount of judgment, particularly since our regenerative cell business has yet to generate any revenues and does not have a commercially viable product.

Again, the manner in which we assigned assets, liabilities, and goodwill to our reporting units, as well as how we determined the fair value of such reporting units, involves significant uncertainties and estimates. The judgments employed may have an effect on whether a goodwill impairment loss is recognized.

### ***Dispositions***

In 2002, we sold our CMF (skull and face) bone fixation implant and accessory product line to Medtronic.

Moreover, in 2004, we sold most of the assets and intellectual property rights in our (non-Japan) Thin Film business to MAST.

As is common in the life sciences industry, the sale agreements contained provisions beyond the simple transfer of net assets to the acquiring enterprises for a fixed price. Specifically, as part of the arrangement, we also agreed to perform the following services:

- Provide training to Medtronic or MAST personnel on production and other aspects of the CMF and Thin Film product lines, respectively.
- Provide a back-up supply of CMF product to Medtronic and Thin Film products to MAST, at cost, for a specified period of time,
- In the case of Medtronic, perform clinical evaluations for a new faster-resorbing polymer product.

Disposing assets and product lines is not one of our core ongoing or central activities. Accordingly, determining the appropriate accounting for these transactions involved some of our most difficult, subjective and complex judgments. In particular, we made assumptions around the appropriate manner and timing in which to recognize the gain on disposal for each transaction in the statement of operations. Moreover, we considered whether the dispositions should be reflected as discontinued operations in accordance with Statement of Financial Accounting Standard No. 144, "Accounting for the Impairment or Disposal of Long-Lived Assets."

For instance, upon the closing of the CMF sale agreement on September 30, 2002, we received net cash of \$9,000,000, and transferred assets to Medtronic with a net carrying value of \$476,000. The net difference of \$8,524,000 was recorded as part of a deferred gain on sale of assets, related party on our balance sheet. We deferred recognition of the majority of this gain until Medtronic accepted the transferred net assets, which was demonstrated only when Medtronic had:

- Stopped relying on us to provide product under the back-up supply agreement,
- Integrated the acquired CMF manufacturing equipment into its operations, and
- Permitted us to deliver training to Medtronic personnel on production and other aspects of the CMF product line.

Until those events occurred, we had not believed that we had transferred all risk and rewards related to the CMF product line to Medtronic and, accordingly, recognition of the deferred gain in earnings would have been inappropriate.

The risks and rewards of ownership related to the CMF product line ultimately passed to Medtronic in August 2004. The remainder of the deferred gain was recognized in the third quarter of 2004 when the technology and know-how transfer was completed pursuant to the contract terms.

We also initially deferred recognition of the gain related to our disposition of certain Thin Film assets, which occurred in May 2004. Again, the Asset Purchase Agreement governing the Thin Film sale obligated us to perform certain actions for the benefit of the buyer – MAST – for a defined period of time, such as serving as a back-up supplier. We concluded, due to the arbitration proceedings settled in August 2005, that we have completed our remaining performance obligations during the third quarter of 2005. Accordingly, we have recognized the remaining deferred gain on sale of assets as gain on sale of assets.

We also recognized a portion of the deferred gain when we sold products to Medtronic and MAST under the respective back-up supply agreements. Refer to the "Revenue Recognition" section of this Critical Accounting Policies and Significant Estimates discussion for further details.

### ***Variable Interest Entity (Olympus-Cytori Joint Venture)***

FASB Interpretation No. 46 (revised 2003), "Consolidation of Variable Interest Entities - An Interpretation of ARB No. 51" ("FIN 46R") requires a variable interest entity ("VIE") to be consolidated by its primary beneficiary. Evaluating whether an entity is a VIE and determining its primary beneficiary involves significant judgment.

In concluding that the Joint Venture was a VIE, we considered the following factors:

- Under FIN 46R, an entity is a VIE if it has insufficient equity to finance its activities. We believe that the initial cash contributed to the Joint Venture formed by Olympus and Cytori (\$30,000,000) will be completely utilized by early 2006. Moreover, it is highly unlikely that the Joint Venture would be able to obtain the necessary financing from third party lenders without additional subordinated financial support – such as personal guarantees by one or both of the Joint Venture stockholders. Accordingly, the joint venture will require additional financial support from Olympus and Cytori to finance its ongoing operations, indicating that the Joint Venture is a VIE.
- Moreover, Olympus has a contingent put option that would, in specified circumstances, require Cytori to purchase Olympus's interests in the Joint Venture for a fixed amount of \$22,000,000. Accordingly, Olympus is protected in some circumstances from absorbing all expected losses in the Joint Venture. Under FIN 46R, this means that Olympus may not be an "at-risk" equity holder, although Olympus clearly has decision rights over the operations of the Joint Venture.

Because the Joint Venture is undercapitalized, and because one of the Joint Venture's decision makers may be protected from losses, we have determined that the joint venture is a VIE under FIN 46R. Because of the complexities in applying FIN 46R, it is reasonable to expect that others may reach a different conclusion.

As noted previously, a VIE is consolidated by its primary beneficiary. The primary beneficiary is defined in FIN 46R as the entity that would absorb the majority of the VIE's expected losses or be entitled to receive the majority of the VIE's residual returns (or both).

Significant judgment was involved in determining the primary beneficiary of the Joint Venture. Under FIN 46R, we believe that Olympus and Cytori are "de facto agents" and, together, we will absorb more than 50% of the Joint Venture's expected losses and residual returns. Ultimately, we concluded that Olympus, and not Cytori, was the party most closely related with the joint venture and, hence, its primary beneficiary. Our conclusion was based on the following factors:

- The business operations of the Joint Venture will be most closely aligned to those of Olympus (i.e., the manufacture of devices).
- Olympus controls the Board of Directors, as well as the day-to-day operations of the Joint Venture.

The application of FIN 46R involves substantial judgment, and others may arrive at a conclusion that Cytori should consolidate the Joint Venture. Had we consolidated the Joint Venture, though, there would be no effect on our net income or shareholders' equity at December 31, 2005 or for the year then ended. However, certain balance sheet and income statement captions would have been presented in a different manner. For instance, we would not have presented a single line item entitled investment in joint venture in our balance sheet but, instead, would have performed a line by line consolidation of each of the Joint Venture's accounts into our financial statements.

### **Net Operating Loss and Tax Credit Carryforwards**

We have established a valuation allowance against our net deferred tax asset due to the uncertainty surrounding the realization of such assets. We periodically evaluate the recoverability of the deferred tax asset. At such time as it is determined that it is more likely than not that deferred assets are realizable, the valuation allowance will be reduced. We have recorded a valuation allowance of \$27,830,000 as of December 31, 2005 to reflect the estimated amount of deferred tax assets that may not be realized. We increased our valuation allowance by approximately \$8,213,000 during the year ended December 31, 2005. The valuation allowance includes approximately \$579,000 related to stock option deductions, the benefit of which will eventually be credited to equity and not to income.

At December 31, 2005, we had federal and state tax loss carryforwards of approximately \$42,987,000 and \$33,681,000 respectively. The federal and state net operating loss carryforwards begin to expire in 2019 and 2007 respectively, if unused. At December 31, 2005, we had federal and state tax credit carryforwards of approximately \$1,127,000 and \$1,093,000 respectively. The federal credits will begin to expire in 2017, if unused, and the state credits will begin to expire in 2009 if unused. In addition, we have a foreign tax loss carryforward of \$1,031,000 in Japan.

The Internal Revenue Code limits the future availability of net operating loss and tax credit carryforwards that arose prior to certain cumulative changes in a corporation's ownership resulting in a change of control of Cytori. Due to prior ownership changes defined in IRC Section 382, a portion of our net operating loss and tax credit carryforwards are limited in their annual utilization. In September 1999, we experienced an ownership change for purposes of the IRC Section 382 limitation. At December 31, 2005, the remaining 1999 pre-change federal net operating loss carryforward of \$973,000 is subject to an annual limitation of approximately \$573,000. It is estimated that these pre-change net operating losses and credits will be fully available by 2007.

Additionally, in 2002 when we purchased StemSource, we acquired federal and state net operating loss carryforwards of approximately \$2,700,000 and \$2,700,000 respectively. This event triggered an ownership change for purposes of IRC Section 382. As of December 31, 2005, the remaining pre-change federal and state net operating loss carryforward of \$960,000 is subject to an annual limitation of approximately \$460,000. It is estimated that the pre-change net operating losses and credits will be fully available by 2008.

We have not updated our analysis for the tax year ended December 31, 2005. The extent of any additional limitation, if any, on the availability to use net operating losses and credits, is not known at this time.

### **Unearned Compensation**

We record unearned compensation for options granted to employees as the difference between the exercise price of options granted and the fair market value of our common stock on the date of grant. Unearned compensation is amortized to stock based compensation expense and reflected as such in the Statements of Operations and Comprehensive Loss. As of December 31, 2005 there was no outstanding amount related to unearned compensation.

### **Recent Accounting Pronouncements**

In November 2004, the FASB issued SFAS No. 151, "Inventory Costs — An Amendment of ARB No. 43, Chapter 4" ("SFAS 151"). SFAS 151 clarifies that abnormal amounts of idle facility expense, freight, handling costs and spoilage should be expensed as incurred and not included in overhead. Further, SFAS 151 requires that allocation of fixed and production facilities overhead to conversion costs should be based on normal capacity of the production facilities. The provisions in SFAS 151 are effective for inventory costs incurred during fiscal years beginning after June 15, 2005. We do not believe that the adoption of SFAS 151 will have a significant effect on our financial statements.

In December 2004, the FASB issued SFAS No. 153, "Exchanges of Nonmonetary Assets — An Amendment of APB Opinion No. 29" ("SFAS 153"). The provisions of this statement are effective for non-monetary asset exchanges occurring in fiscal periods beginning after June 15, 2005. This statement eliminates the exception in previous generally accepted accounting principles that precluded the recognition of exchanges of similar productive assets at fair value. Instead, SFAS 153 provides for a general exception to the fair value principle for exchange transactions that do not have commercial substance — that is, transactions that are not expected to result in significant changes in the cash flows of the reporting entity. The adoption of SFAS 153 has not had a significant effect on our financial statements.

In December 2004, the FASB issued SFAS No. 123 (revised 2004), "Share-based Payment" ("SFAS 123R"). As affected by Securities and Exchange Commission Release No. 33-8568, "Amendment to Rule 4-01(a) of Regulation S-X Regarding the Compliance Date for Statement of Financial Accounting Standards No. 123 (Revised 2004), Share-Based Payment", SFAS 123R is effective on January 1, 2006 and will have a material effect on our results of operations. Upon adoption, SFAS 123R will require us to measure all share-based payment transactions, including those with employees, at fair value (most notably, this includes employee stock option grants, even where the exercise price is equal to the grant date fair market value). Moreover, the fair value of share-based payment awards will be recognized as expense in the statements of operations over the requisite service period of each award. SFAS 123R also changes the manner in which deferred taxes are recognized on share-based payment awards, as well as the accounting for award modifications. Our net loss will increase (or our net income will be reduced) each period as a result of adopting SFAS 123R. See the "Stock Based Compensation" section of this note above.

In May 2005, the FASB issued SFAS No. 154, "Accounting Changes and Error Corrections" ("SFAS 154"). This new standard replaces APB Opinion No. 20, "Accounting Changes", and SFAS No. 3, "Reporting Accounting Changes in Interim Financial Statements". Among other changes, SFAS 154 requires that a voluntary change in accounting principle be applied retrospectively with all prior period financial statements presented on the new accounting principle, unless it is impracticable to do so. SFAS 154 also provides that (1) a change in method of depreciating or amortizing a long-lived nonfinancial asset be accounted for as a change in estimate (prospectively) that was effected by a change in accounting principle, and (2) correction of errors in previously issued financial statements should be termed a "restatement." The new standard is effective for accounting changes and correction of errors made in fiscal years beginning after December 15, 2005. We do not believe that the adoption of SFAS 154 will have a significant effect on our financial statements.

In October 2005, the FASB issued Staff Position ("FSP") FAS 13-1, "Accounting for Rental Costs Incurred during a Construction Period" ("FSP 13-1"). The FASB concludes in this FSP that rental costs associated with ground or building operating leases that are incurred during a construction period should be expensed. FASB Technical Bulletin ("FTB") No. 88-1, "Issues Relating to Accounting for Leases", requires that rental costs associated with operating leases be allocated on a straight-line basis in accordance with FASB Statement No. 13, "Accounting for Leases", and FTB 85-3, "Accounting for Operating Leases with Scheduled Rent Increases", starting with the beginning of the lease term. The FASB believes there is no distinction between the right to use a leased asset during the construction period and the right to use that asset after the construction period. Companies are required to apply the guidance in FSP 13-1 to the first reporting period beginning after December 15, 2005. We do not believe that the adoption of FSP 13-

1 will have a significant effect on our financial statements.

In November 2005, the FASB issued Staff Position ("FSP") FIN 45-3, "Application of FASB Interpretation No. 45 to Minimum Revenue Guarantees Granted to a Business or Its Owners". The FSP revises FASB Interpretation No. 45 to explicitly indicate that FIN 45 applies to a guarantee granted to a business that the revenue of the business (or a specific portion of the business) for a , specified period of time will be at least a specified amount. Although we may enter into such guarantees in the future (see note 6 to the consolidated financial statements), no minimum revenue guarantees have been provided by us for any periods covered by these consolidated financial statements.

#### **Item 7A. Quantitative and Qualitative Disclosures About Market Risk**

We are exposed to market risk related to fluctuations in interest rates and in foreign currency exchange rates.

##### **Interest Rate Exposure**

We are not subject to market risk due to fluctuations in interest rates on our long-term obligations as they bear a fixed rate of interest. Our exposure relates primarily to short-term investments. These short-term investments, reported at an aggregate fair market value of \$7,838,000 as of December 31, 2005, consist primarily of investments in debt instruments of financial institutions and corporations with strong credit ratings and United States government obligations. These securities are subject to market rate risk as their fair value will fall if market interest rates increase. If market interest rates were to increase immediately and uniformly by 100 basis points from the levels prevailing at December 31, 2005, for example, and assuming average investment duration of seven months, the fair value of the portfolio would not decline by a material amount. We do not use derivative financial instruments to mitigate the risk inherent in these securities. However, we do attempt to reduce such risks by generally limiting the maturity date of such securities, diversifying our investments and limiting the amount of credit exposure with any one issuer. While we do not always have the intent, we do currently have the ability to hold these investments until maturity and, therefore, believe that reductions in the value of such securities attributable to short-term fluctuations in interest rates would not materially affect our financial position, results of operations or cash flows. Changes in interest rates would, of course, affect the interest income we earn on our cash balances after re-investment.

##### **Foreign Currency Exchange Rate Exposure**

Our exposure to market risk due to fluctuations in foreign currency exchange rates relates primarily to our cash balances in Europe and Japan. Although we transacted business in various foreign countries before the May 2004 sale of our non-Japan Thin Film business to MAST, settlements were usually based on the U.S. dollar. Transaction gains or losses resulting from cash balances and revenues have not been significant in the past and we are not engaged in any hedging activity in the Euro, the Yen or other currencies. Based on our cash balances and revenues derived from markets other than the United States for the year ended December 31, 2005, a hypothetical 10% adverse change in the Euro or Yen against the U.S. dollar would not result in a material foreign currency exchange loss. Consequently, we do not expect that reductions in the value of such sales denominated in foreign currencies resulting from even a sudden or significant fluctuation in foreign exchange rates would have a direct material impact on our financial position, results of operations or cash flows.

Notwithstanding the foregoing, the indirect effect of fluctuations in interest rates and foreign currency exchange rates could have a material adverse effect on our business, financial condition and results of operations. For example, foreign currency exchange rate fluctuations may affect international demand for our products. In addition, interest rate fluctuations may affect our customers' buying patterns. Furthermore, interest rate and currency exchange rate fluctuations may broadly influence the United States and foreign economies resulting in a material adverse effect on our business, financial condition and results of operations.

Under our Japanese Thin Film agreement with Senko, we would receive payments in the nature of royalties based on Senko's net sales, which would be Yen denominated. We expect such sales or royalties to begin in 2006.

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<b>Item 8. Consolidated Financial Statements and Supplementary Data</b>	
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Consolidated Balance Sheets as of December 31, 2005 and 2004	47
Consolidated Statements of Operations and Comprehensive Loss for the years ended December 31, 2005, 2004 and 2003	48
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The Board of Directors and Stockholders  
Cytori Therapeutics, Inc.:

We have audited the accompanying consolidated balance sheets of Cytori Therapeutics, Inc. and subsidiaries (the Company) as of December 31, 2005 and 2004, and the related consolidated statements of operations and comprehensive loss, stockholders' equity (deficit), and cash flows for each of the years in the three-year period ended December 31, 2005. In connection with our audits of the consolidated financial statements, we have also audited the financial statement schedule for each of the years in the three-year period ended December 31, 2005. These consolidated financial statements and financial statement schedule are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated financial statements and financial statement schedule based on our audits.

We conducted our audits in accordance with the auditing standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

As discussed in note 1 to the consolidated financial statements, the Company derives a substantial portion of its revenues from a related party.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of Cytori Therapeutics, Inc. and subsidiaries as of December 31, 2005 and 2004, and the results of their operations and their cash flows for each of the years in the three-year period ended December 31, 2005, in conformity with U.S. generally accepted accounting principles. Also, in our opinion, the related financial statement schedule for each of the years in the three-year period ended December 31, 2005, when considered in relation to the basic consolidated financial statements taken as a whole, presents fairly, in all material respects, the information set forth therein.

/s/ KPMG LLP

San Diego, California  
March 24, 2006

**CYTORI THERAPEUTICS, INC.  
CONSOLIDATED BALANCE SHEETS**

	As of December 31,	
	2005	2004
<b>Assets</b>		
<b>Current assets:</b>		
Cash and cash equivalents .....	\$ 8,007,000	\$ 2,840,000
Short-term investments, available-for-sale .....	7,838,000	10,579,000
Accounts receivable, net of allowance for doubtful accounts of \$9,000 and \$8,000 in 2005 and 2004, respectively .....	816,000	863,000
Inventories, net .....	258,000	379,000
Other current assets .....	621,000	984,000
Total current assets .....	17,540,000	15,645,000
Property and equipment, net .....	4,260,000	3,080,000
Other assets .....	458,000	236,000
Intangibles, net .....	1,521,000	2,122,000
Goodwill .....	4,387,000	4,387,000
Total assets .....	\$ 28,166,000	\$ 25,470,000
<b>Liabilities and Stockholders' Equity (Deficit)</b>		
<b>Current liabilities:</b>		
Accounts payable and accrued expenses .....	\$ 6,129,000	\$ 2,249,000
Current portion of long-term obligations .....	952,000	938,000
Total current liabilities .....	7,081,000	3,187,000
Deferred revenues, related party .....	17,311,000	—
Option liabilities .....	5,331,000	—
Deferred revenues .....	2,541,000	2,592,000
Deferred gain on sale of assets .....	—	5,650,000
Long-term deferred rent .....	573,000	80,000
Long-term obligations, less current portion .....	1,558,000	1,128,000
Total liabilities .....	34,395,000	12,637,000
<b>Commitments and contingencies .....</b>		
<b>Stockholders' equity (deficit):</b>		
Preferred stock, \$0.001 par value; 5,000,000 shares authorized; -0- shares issued and outstanding in 2005 and 2004 .....	—	—
Common stock, \$0.001 par value; 95,000,000 shares authorized; 18,194,283 and 16,820,018 shares issued and 15,321,449 and 13,947,184 shares outstanding in 2005 and 2004, respectively .....	18,000	17,000
Additional paid-in capital .....	82,196,000	74,737,000
Accumulated deficit .....	(78,013,000)	(51,475,000)
Treasury stock, at cost .....	(10,414,000)	(10,414,000)
Accumulated other comprehensive loss .....	(16,000)	(32,000)
Total stockholders' equity (deficit) .....	(6,229,000)	12,833,000
Total liabilities and stockholders' equity (deficit) .....	\$ 28,166,000	\$ 25,470,000

THE ACCOMPANYING NOTES ARE AN INTEGRAL PART OF THESE CONSOLIDATED FINANCIAL STATEMENTS

**CYTORI THERAPEUTICS, INC.**  
**CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS**

	<b>For the Years Ended December 31,</b>		
	<b>2005</b>	<b>2004</b>	<b>2003</b>
Product revenues:			
Sales to related party .....	\$ 5,634,000	\$ 4,085,000	\$ 12,893,000
Sales to third parties .....	—	2,237,000	1,186,000
	<u>5,634,000</u>	<u>6,322,000</u>	<u>14,079,000</u>
Cost of product revenues, including stock based compensation expense of \$0, \$3,000 and \$12,000 for the years ended December 31, 2005, 2004, and 2003, respectively .....	3,154,000	3,384,000	4,244,000
	<u>2,480,000</u>	<u>2,938,000</u>	<u>9,835,000</u>
Gross profit .....			
Development revenues:			
Research grants .....	312,000	328,000	—
Development and other .....	59,000	168,000	9,000
	<u>371,000</u>	<u>496,000</u>	<u>9,000</u>
Operating expenses:			
Research and development, excluding stock based compensation expense of \$179,000, \$32,000, and \$78,000 for the years ended December 31, 2005, 2004, and 2003, respectively .....	15,271,000	10,352,000	8,694,000
Sales and marketing, excluding stock based compensation expense of \$113,000, \$22,000, and \$70,000 for the years ended December 31, 2005, 2004, and 2003, respectively .....	1,434,000	2,391,000	4,417,000
General and administrative, excluding stock based compensation expense of \$112,000, \$71,000, and \$837,000 for the years ended December 31, 2005, 2004, and 2003, respectively .....	10,096,000	6,480,000	4,958,000
Stock based compensation (excluding cost of revenues stock based compensation) .....	404,000	125,000	985,000
Change in fair value of option liabilities .....	3,645,000	—	—
Restructuring charge .....	—	107,000	451,000
Equipment impairment charge .....	—	42,000	—
	<u>30,850,000</u>	<u>19,497,000</u>	<u>19,505,000</u>
Total operating expenses .....			
Operating loss .....	<u>(27,999,000)</u>	<u>(16,063,000)</u>	<u>(9,661,000)</u>
Other income (expense):			
Gain on sale of assets .....	5,526,000	—	—
Gain on sale of assets, related party .....	—	13,883,000	—
Interest income .....	299,000	252,000	417,000
Interest expense .....	(137,000)	(177,000)	(126,000)
Other income (expense), net .....	(55,000)	15,000	87,000
Equity loss from investment in joint venture .....	(4,172,000)	—	—
	<u>1,461,000</u>	<u>13,973,000</u>	<u>378,000</u>
Total other income (expense) .....			
Net loss .....	<u>(26,538,000)</u>	<u>(2,090,000)</u>	<u>(9,283,000)</u>
Other comprehensive income (loss) - unrealized holding income (loss) .....	16,000	(58,000)	(133,000)
	<u>\$ (26,522,000)</u>	<u>\$ (2,148,000)</u>	<u>\$ (9,416,000)</u>
Comprehensive loss .....			
Basic and diluted net loss per common share .....	<u>\$ (1.80)</u>	<u>\$ (0.15)</u>	<u>\$ (0.6)</u>
Basic and diluted weighted average common shares .....	<u>14,704,281</u>	<u>13,932,390</u>	<u>14,555,000</u>

THE ACCOMPANYING NOTES ARE AN INTEGRAL PART OF THESE CONSOLIDATED FINANCIAL STATEMENTS

**CYTORI THERAPEUTICS, INC.**  
**CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY (DEFICIT)**  
**FOR THE YEARS ENDED DECEMBER 31, 2005, 2004 AND 2003**

	Common Stock		Additional Paid-in Capital	Unearned Compensation	Accumulated Deficit	Treasury Stock		Treasury Stock Receivable	Accumulated Other Comprehensive Income (Loss)	Total
	Shares	Amount				Shares	Amount			
Balance at December 31, 2002 ...	16,646,664	17,000	74,730,000	(1,057,000)	(40,102,000)	2,118,983	(7,752,000)	—	159,000	25,995,000
Issuance of common stock under stock option plan ....	130,980	—	33,000	—	—	—	—	—	—	33,000
Compensatory stock options .....	—	—	49,000	948,000	—	—	—	—	—	997,000
Purchase of treasury stock .....	—	—	—	—	—	614,099	(2,266,000)	—	—	(2,266,000)
Sale of treasury stock ...	—	—	(10,000)	—	—	(150,500)	552,000	—	—	542,000
Treasury stock receivable .....	—	—	—	—	—	—	—	(976,000)	—	(976,000)
Exchange of unlisted common stock for listed common stock held in treasury	—	—	(104,000)	—	—	—	104,000	—	—	—
Unrealized loss on investments .....	—	—	—	—	—	—	—	—	(133,000)	(133,000)
Net loss for the year ended December 31, 2003 ...	—	—	—	—	(9,283,000)	—	—	—	—	(9,283,000)
Balance at December 31, 2003 ...	16,777,644	17,000	74,698,000	(109,000)	(49,385,000)	2,582,582	(9,362,000)	(976,000)	26,000	14,909,000
Issuance of common stock under stock option plan ....	42,374	—	29,000	—	—	—	—	—	—	29,000
Compensatory stock options .....	—	—	10,000	109,000	—	—	—	—	—	119,000
Purchase of treasury stock .....	—	—	—	—	—	27,650	(76,000)	—	—	(76,000)
Treasury stock receivable .....	—	—	—	—	—	262,602	(976,000)	976,000	—	—
Unrealized loss on investments .....	—	—	—	—	—	—	—	—	(58,000)	(58,000)
Net loss for the year ended December 31, 2004 ...	—	—	—	—	(2,090,000)	—	—	—	—	(2,090,000)
Balance at December 31, 2004 ...	16,820,018	\$ 17,000	\$ 74,737,000	\$ —	\$ (51,475,000)	2,872,834	\$ (10,414,000)	\$ —	\$ (32,000)	\$ 12,833,000
Issuance of common stock under stock option plan	232,042	—	174,000	—	—	—	—	—	—	174,000
Issuance of common stock under stock warrant agreement	22,223	—	50,000	—	—	—	—	—	—	50,000
Compensatory stock options	—	—	341,000	—	—	—	—	—	—	341,000
Compensatory common stock awards	20,000	—	63,000	—	—	—	—	—	—	63,000
Issuance of common stock to Olympus	1,100,000	1,000	3,002,000	—	—	—	—	—	—	3,003,000

Accretion of interests in joint venture	--	--	3,829,000	--	--	--	--	--	--	3,829,000
Unrealized gain on investments	--	--	--	--	--	--	--	--	16,000	16,000
Net loss for the year ended December 31, 2005	--	--	--	--	(26,538,000)	--	--	--	--	(26,538,000)
Balance at December 31, 2005 ...	<u>18,194,283</u>	<u>\$ 18,000</u>	<u>\$ 82,196,000</u>	<u>\$ --</u>	<u>\$ (78,013,000)</u>	<u>2,872,834</u>	<u>\$ (10,414,000)</u>	<u>\$ --</u>	<u>\$ (16,000)</u>	<u>\$ (6,229,000)</u>

THE ACCOMPANYING NOTES ARE AN INTEGRAL PART OF THESE CONSOLIDATED FINANCIAL STATEMENTS

**CYTORI THERAPEUTICS, INC.**  
**CONSOLIDATED STATEMENTS OF CASH FLOWS**

	<u>For the Years Ended December 31,</u>		
	<u>2005</u>	<u>2004</u>	<u>2003</u>
<b>Cash flows from operating activities:</b>			
Net loss.....	\$ (26,538,000)	\$ (2,090,000)	\$ (9,283,000)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization .....	1,724,000	1,752,000	1,657,000
Inventory provision .....	280,000	242,000	—
Warranty provision.....	53,000	86,000	267,000
Increase (reduction) in allowance for doubtful accounts.....	1,000	(44,000)	—
Change in fair value of option liabilities .....	3,645,000	—	—
Loss on disposal of assets.....	—	3,000	14,000
Equipment impairment charge .....	—	42,000	—
Restructuring charge .....	—	—	153,000
Amortization of gain on sale of assets.....	—	(772,000)	—
Amortization of gain on sale of assets, related party .....	—	(156,000)	(2,046,000)
Gain on sale of assets .....	(5,526,000)	—	—
Gain on sale of assets, related party .....	—	(13,883,000)	—
Stock based compensation .....	404,000	119,000	997,000
Equity loss from investment in joint venture.....	4,172,000	—	—
Increases (decreases) in cash caused by changes in operating assets and liabilities:			
Accounts receivable.....	46,000	472,000	(53,000)
Inventories .....	(159,000)	33,000	319,000
Other current assets.....	363,000	(458,000)	317,000
Other assets.....	(346,000)	8,000	76,000
Accounts payable and accrued expenses.....	3,027,000	(527,000)	264,000
Deferred revenues, related party .....	17,311,000	—	—
Deferred revenues .....	(51,000)	2,592,000	—
Long-term deferred rent.....	493,000	7,000	73,000
Net cash used in operating activities .....	<u>(1,101,000)</u>	<u>(12,574,000)</u>	<u>(7,245,000)</u>
<b>Cash flows from investing activities:</b>			
Proceeds from the sale and maturity of short-term investments .....	56,819,000	51,132,000	49,561,000
Purchases of short-term investments .....	(54,062,000)	(50,321,000)	(41,267,000)
Proceeds from the sale of assets, net.....	—	6,931,000	—
Proceeds from sale of assets, related party .....	—	6,500,000	—
Cost of sale of assets, related party .....	—	—	(38,000)
Purchases of property and equipment .....	(1,846,000)	(789,000)	(1,743,000)
Acquisition costs .....	—	(28,000)	(654,000)
Proceeds from the sale of impaired assets .....	—	—	95,000
Net cash provided by investing activities .....	<u>911,000</u>	<u>13,425,000</u>	<u>5,954,000</u>
<b>Cash flows from financing activities:</b>			
Principal payments on long-term obligations .....	(936,000)	(847,000)	(426,000)
Proceeds from long-term obligations.....	1,380,000	1,039,000	1,120,000
Proceeds from exercise of employee stock options and warrants .....	224,000	29,000	33,000
Proceeds from sale of common stock .....	3,003,000	—	—
Proceeds from issuance of options, related party.....	1,686,000	—	—
Purchase of treasury stock .....	—	(1,052,000)	(2,266,000)
Proceeds from sale of treasury stock .....	—	—	542,000
Net cash provided by (used in) financing activities.....	<u>5,357,000</u>	<u>(831,000)</u>	<u>(997,000)</u>
Net increase (decrease) in cash and cash equivalents.....	5,167,000	20,000	(2,288,000)
Cash and cash equivalents at beginning of year.....	<u>2,840,000</u>	<u>2,820,000</u>	<u>5,108,000</u>
Cash and cash equivalents at end of year.....	<u>\$ 8,007,000</u>	<u>\$ 2,840,000</u>	<u>\$ 2,820,000</u>

For the Years Ended December 31,		
2005	2004	2003

**Supplemental disclosure of cash flows information:**

Cash paid during period for:

Interest .....	\$ 135,000	\$ 176,000	\$ 127,000
Taxes.....	13,000	7,000	12,000

**Supplemental schedule of non-cash investing and financing activities:**

Transfer of intangible assets to joint venture (note 6) .....	\$ 343,000	\$ —	\$ —
Accretion of interest in joint venture (note 6) .....	3,829,000	—	—
Additions to leasehold improvements included in accounts payable and accrued expenses .....	800,000	—	—
Increase in cost of acquisition (goodwill) .....	—	—	371,000
Share repurchase payable (note 19) .....	—	—	976,000

THE ACCOMPANYING NOTES ARE AN INTEGRAL PART OF THESE CONSOLIDATED FINANCIAL STATEMENTS

**CYTORI THERAPEUTICS, INC.,  
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS  
FOR THE YEARS ENDED DECEMBER 31, 2005, 2004 AND 2003**

**1. Organization and Operations**

**The Company**

Cytori Therapeutics, Inc., is a biotechnology company that specializes in the discovery and development of regenerative medicine therapies. Our primary focus is to advance adipose stem and regenerative cell therapies into and through clinical trials and ultimately commercialize these therapies through an innovative cell processing device. The therapeutic indications we are focused on are cardiovascular disease, chronic wounds, spinal disc repair, and aesthetic and reconstructive surgery. To facilitate the processing and delivery of adipose stem and regenerative cells, we have designed the proprietary point-of-care Celution™ System, to isolate and concentrate a patient's own stem and regenerative cells in real-time.

We also have a business unit that operates under the name MacroPore Biosurgery. This business consists of two product families. Our HYDROSORB™ family of bioresorbable spine and orthopedic implants is distributed worldwide exclusively by Medtronic, Inc. ("Medtronic"). As of December 31, 2005, Medtronic owned 1.0 million shares of our outstanding common stock, or 6.5%. As discussed in note 18, Medtronic is a related party. Our Thin Film product line will be marketed exclusively in Japan by Senko Medical Trading Co. ("Senko") following approval of the product in Japan.

**Principles of Consolidation**

The consolidated financial statements include our accounts and those of our subsidiaries. All significant intercompany transactions and balances have been eliminated. Management evaluates its investments on an individual basis for purposes of determining whether or not consolidation is appropriate. In instances where we do not demonstrate control through decision-making ability and/or a greater than 50% ownership interest, we account for the related investments under the cost or equity method, depending upon management's evaluation of our ability to exercise and retain significant influence over the investee. Our investment in the Olympus-Cytori, Inc. joint venture has been accounted for under the equity method of accounting (see note 6 for further details).

**Certain Risks and Uncertainties**

We have a limited operating history and our prospects are subject to the risks and uncertainties frequently encountered by companies in the early stages of development and commercialization, especially those companies in rapidly evolving and technologically advanced industries such as the biotech/medical device field. Our future viability largely depends on the ability to complete development of new products and receive regulatory approvals for those products. No assurance can be given that our new products will be successfully developed, regulatory approvals will be granted, or acceptance of these products will be achieved. The development of medical devices for specific therapeutic applications is subject to a number of risks, including research, regulatory and marketing risks. There can be no assurance that our development stage products will overcome these hurdles and become commercially viable and/or gain commercial acceptance.

We currently purchase the high molecular weight, medical grade, lactic acid copolymer used in manufacturing most of our products, from a single qualified source, B.I. Chemicals, Inc. ("B.I. Chemicals"). Although we have a contract with B.I. Chemicals that guarantees continuation of supply through August 15, 2007, we cannot provide any assurances that B.I. Chemicals will elect to continue the contract beyond that date, or that B.I. Chemicals will not elect to discontinue the manufacture of the material. B.I. Chemicals has agreed that if they discontinue manufacturing they will either find a replacement supplier, or provide us with the necessary technology to self-manufacture the material, either of which could mean a substantial increase in material costs. Although we believe that we would be able to obtain the material from at least one other source in the event of a failure of supply, there can be no assurance that we will be able to obtain adequate quantities, at the necessary high quality, within a reasonable period of time or at commercially reasonable rates.

For the years ended December 31, 2005, 2004 and 2003, we recorded bioresorbable product revenue from Medtronic of \$5,634,000, \$4,085,000 and \$12,893,000, respectively, which represented 93.8%, 59.9% and 91.5% of total product and development revenues, respectively. Our future revenue generated from our bioresorbable products will continue to depend to a significant extent on Medtronic's (our sole distributor of spine and orthopedics implants) efforts in the bioresorbable spine and orthopedics arena.

**Capital Availability**

We have a limited operating history and recorded the first sale of our products in 1999. We incurred losses of \$26,538,000,

\$2,090,000, and \$9,283,000 for the years ended December 31, 2005, 2004 and 2003, respectively, and have an accumulated deficit of \$78,013,000 as of December 31, 2005. Additionally, we have used net cash of \$1,101,000, \$12,574,000, and \$7,245,000 to fund our operating activities for the years ended December 31, 2005, 2004 and 2003, respectively.

Management recognizes the need to generate positive cash flows in future periods and/or to acquire additional capital from various sources. We believe we currently have adequate cash, cash equivalent and short-term investment balances to fund operations at least through December 31, 2006. However, in the continued absence of positive cash flows from operations, no assurance can be given that we can generate sufficient revenue to cover operating costs or that additional financing will be available to us and, if available, on terms acceptable to us in the future.

## **2. Summary of Significant Accounting Policies**

### **Use of Estimates**

The preparation of consolidated financial statements in conformity with accounting principles generally accepted in the United States requires management to make estimates and assumptions affecting the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements, and the reported amounts of revenue and expenses during the reporting period. Actual results could differ from these estimates. Estimates and assumptions are reviewed periodically, and the effects of revisions are reflected in the consolidated financial statements in the periods they are determined to be necessary.

Our most significant estimates and critical accounting policies involve revenue recognition, establishing the warranty provision, evaluating goodwill for impairment, accounting for product line dispositions, and assessing how to report our investment in Olympus-Cytori, Inc.

### **Presentation**

Certain prior period amounts have been reclassified to conform to current period presentation.

### **Concentration of Credit Risk**

Financial instruments which potentially subject us to concentrations of credit risk consist of short-term available-for-sale investments and accounts receivable. Substantially all of our accounts receivable is due from Medtronic (see note 18).

### **Cash and Cash Equivalents**

We consider all highly liquid investments with maturities of three months or less at the time of purchase to be cash equivalents. Investments with original maturities of three months or less that were included with and classified as cash and cash equivalents totaled \$6,415,000 and \$2,010,000 as of December 31, 2005 and 2004, respectively.

### **Short-term Investments**

We invest excess cash in highly liquid debt instruments of financial institutions and corporations with strong credit ratings and in United States government obligations. We have established guidelines relative to diversification and maturities that maintain safety and liquidity. These guidelines are periodically reviewed and modified to take advantage of trends in yields and interest rates.

We evaluate our investments in accordance with the provisions of Statement of Financial Standards ("SFAS") No. 115, "Accounting for Certain Investments in Debt and Equity Securities." Based on our intent, our investment policies and our ability to liquidate debt securities, we classify short-term investment securities within current assets. Available-for-sale securities are carried at fair value, with unrealized gains and losses reported as accumulated other comprehensive income (loss) within stockholders' equity. The amortized cost basis of debt securities is periodically adjusted for amortization of premiums and accretion of discounts to maturity. Such amortization is included as a component of interest income or interest expense. The amortized cost basis of securities sold is based on the specific identification method and all such realized gains and losses are recorded as a component within other income (expense). Based on such evaluation, our management has determined that all investment securities (other than those classified as cash equivalents) are properly classified as available-for-sale.

We review the carrying values of our investments and write down such investments to estimated fair value by a charge to the statements of operations when the severity and duration of a decline in the value of an investment is considered to be other than temporary. The cost of securities sold or purchased is recorded on the settlement date.

At December 31, 2005, the excess of carrying cost over the fair value of our short-term investments is immaterial.

The carrying amounts of our cash and cash equivalents, accounts receivable, accounts payable and accrued expenses approximate their fair value due to the short-term nature of these balances. The carrying amounts of our current portion of long-term obligations and long-term obligations approximate fair value as the terms and rates of interest for these instruments approximate terms and market rates of interest currently available to us for similar instruments. The carrying amounts for our option liabilities approximate fair value based on established option pricing theory and assumptions (note 6). Our short-term investments are already reported at fair value in the financial statements.

**Inventories**

Inventories include the cost of material, labor and overhead, and are stated at the lower of average cost, determined on the first-in, first-out (FIFO) method, or market. We periodically evaluate our on-hand stock and make appropriate provisions for any stock deemed as excess or obsolete.

During the year ended December 31, 2005, we recorded a provision of \$280,000, for excess and slow-moving inventory. The inventory was produced in anticipation of stocking orders from Medtronic which have not materialized. The provision has been charged to cost of sales.

During the first quarter of 2004, we recorded a provision of approximately \$242,000 for excess inventory. Such excess inventory was produced in consideration of our responsibility to be a back-up supplier for the craniomaxillofacial ("CMF") product line. We sold the assets related to this product line to an affiliate of Medtronic on September 30, 2002. In April of 2004, Medtronic indicated that it would no longer purchase CMF inventory from us under the back-up supply arrangement, leading to the determination that the remaining CMF inventory on hand would not be recoverable.

**Property and Equipment**

Property and equipment is stated at cost, net of accumulated depreciation. Depreciation expense, which includes the amortization of assets recorded under capital leases, is provided for on a straight-line basis over the estimated useful lives of the assets, or the life of the lease, whichever is shorter, and range from three to seven years. When assets are sold or otherwise disposed of, the cost and related accumulated depreciation are removed from the accounts and the resulting gain or loss is included in operations. Leasehold improvements are amortized on a straight-line basis over the shorter of the estimated useful life of the asset or the lease term. Maintenance and repairs are charged to operations as incurred.

**Long-Lived Assets**

In accordance with SFAS No. 144, "Accounting for Impairment or Disposal of Long-Lived Assets," we assess certain of our long-lived assets, such as property and equipment and intangible assets other than goodwill, for potential impairment when there is a change in circumstances that indicates carrying values of assets may not be recoverable. Such long-lived assets are deemed to be impaired when the undiscounted cash flows expected to be generated by the asset (or asset group) are less than the asset's carrying amount. Any required impairment loss would be measured as the amount by which the asset's carrying value exceeds its fair value, and would be recorded as a reduction in the carrying value of the related asset and a charge to operating expense.

*Impairment*

During the year ended December 31, 2004, we recorded an equipment impairment charge of \$42,000 related to production assets which were used in multiple product lines. The impairment charge represented the excess of the net book value over the estimated net proceeds we expected we would receive upon sale of the assets.

*Assets held for sale*

At December 31, 2003, we classified certain assets as held for sale, including certain tangible assets related to our Thin Film product line (note 4), as well as certain tangible assets associated with a foreign facility whose lease was terminated in September 2003.

These assets were disposed of during 2004 at an amount net of estimated selling cost, which exceeded the respective carrying values.

**Goodwill and Intangibles**

SFAS No. 142, "Goodwill and Other Intangible Assets," establishes financial accounting and reporting standards for acquired goodwill and other intangible assets. Under SFAS No. 142, goodwill and indefinite-lived intangible assets are not amortized but

are reviewed at least annually for impairment. Separable intangible assets that have finite useful lives will continue to be amortized over their respective useful lives.

SFAS No. 142 requires that goodwill be tested for impairment on at least an annual basis or whenever events or changes in circumstances indicate that the carrying value of goodwill may not be recoverable. We last completed this testing as of November 30, 2005 and concluded that no impairment existed.

Intangibles, consisting of patents and core technology purchased in the acquisition of StemSource, Inc. in 2002, are being amortized on a straight-line basis over their expected lives of ten years.

In the year ended December 31, 2005 we licensed a portion of our patents and core technology to a joint venture which we formed with Olympus Corporation ("Olympus"), named Olympus-Cytori, Inc. (the "Joint Venture"). Of the \$1,735,000 previously allocated to patents and core technology, \$343,000 (net of accumulated amortization of \$136,000), was transferred to the Joint Venture (see note 6).

The changes in the carrying amounts of other indefinite and finite-life intangible assets and goodwill for the years ended December 31, 2005 and 2004 are as follows:

	December 31, 2005		
	Regenerative Cell Technology	MacroPore Biosurgery	Total
<b>Other intangibles, net:</b>			
Beginning balance .....	\$ 2,122,000	\$ —	\$ 2,122,000
Amortization .....	(258,000)	—	(258,000)
Subtotal .....	<u>1,864,000</u>	<u>—</u>	<u>1,864,000</u>
Patents and core technology transferred to Joint Venture (note 6) .....	(479,000)	—	(479,000)
Accumulated amortization related to above .....	136,000	—	136,000
Patents and core technology transferred to Joint Venture, net .....	<u>(343,000)</u>	<u>—</u>	<u>(343,000)</u>
Ending balance .....	<u>1,521,000</u>	<u>—</u>	<u>1,521,000</u>
<b>Goodwill, net:</b>			
Beginning balance .....	3,922,000	465,000	4,387,000
Disposal of assets .....	—	—	—
Ending balance .....	<u>3,922,000</u>	<u>465,000</u>	<u>4,387,000</u>
Total goodwill and other intangibles, net .....	<u>\$ 5,443,000</u>	<u>\$ 465,000</u>	<u>\$ 5,908,000</u>
Cumulative amount of amortization charged against intangible assets .....	<u>\$ 695,000</u>	<u>\$ —</u>	<u>\$ 695,000</u>
	<b>December 31, 2004</b>		
	Regenerative Cell Technology	MacroPore Biosurgery	Total
<b>Other intangibles, net:</b>			
Beginning balance .....	\$ 2,392,000	\$ —	\$ 2,392,000
Amortization .....	(270,000)	—	(270,000)
Subtotal .....	<u>2,122,000</u>	<u>—</u>	<u>2,122,000</u>
Patents and core technology transferred to Joint Venture (note 6) .....	—	—	—
Accumulated amortization related to above .....	—	—	—
Patents and core technology transferred to Joint Venture, net .....	<u>—</u>	<u>—</u>	<u>—</u>
Ending balance .....	<u>2,122,000</u>	<u>—</u>	<u>2,122,000</u>
<b>Goodwill, net:</b>			
Beginning balance .....	3,922,000	705,000	4,627,000
Disposal of assets .....	—	(240,000)	(240,000)
Ending balance .....	<u>3,922,000</u>	<u>465,000</u>	<u>4,387,000</u>
Total goodwill and other intangibles, net .....	<u>\$ 6,044,000</u>	<u>\$ 465,000</u>	<u>\$ 6,509,000</u>
Cumulative amount of amortization charged against intangible assets .....	<u>\$ 573,000</u>	<u>\$ —</u>	<u>\$ 573,000</u>

As of December 31, 2005, future estimated amortization expense for these other intangible assets is expected to be as follows:

2006 .....	\$ 222,000
2007 .....	222,000
2008 .....	222,000
2009 .....	222,000
Thereafter .....	633,000
	<u>\$ 1,521,000</u>

## Revenue Recognition

### *Product Sales*

We sell our MacroPore Biosurgery products to distributors and, prior to the sale of our Thin Film product line in May 2004 (see note 4), also sold products directly to hospitals. We recognize revenue on product sales to distributors only after both (a) the receipt of a purchase order from a distributor and (b) shipment of ordered products to that distributor, as title and risk of loss pass upon shipment. Before the sale of the Thin Film product line in May 2004, revenue from sales to hospitals was recognized upon delivery of the product.

On occasion, we offer extended payment terms to customers. We do not recognize revenues under these arrangements until the payment becomes due or is received, if that occurs earlier. Moreover, we warrant that our products are free from manufacturing defects at the time of shipment to our customers. We have recorded a reserve for the estimated costs we may incur under our warranty program (see "Warranty" section of this Summary of Significant Accounting Policies note below).

The majority of our product sales are to Medtronic, under a Distribution Agreement dated January 5, 2000 and amended December 22, 2000 and October 8, 2002, as well as a Development and Supply Agreement dated January 5, 2000 and amended December 22, 2000 and September 30, 2002. These revenues are classified as sales to related party in our statements of operations.

In September 2002, we entered into various agreements with Medtronic and a subsidiary of Medtronic for the sale of our CMF product line. Moreover, in May 2004, we sold most, but not all, of our intellectual property rights and tangible assets related to our Thin Film product line to MAST Biosurgery AG, a Swiss corporation ("MAST") and a subsidiary of MAST. In both cases, the net proceeds received initially were recorded as deferred gain on sale of assets (see notes 3 and 4).

As part of the sale agreements, we agreed to act as a back-up supplier to Medtronic and MAST until those respective parties could integrate the acquired assets into their own manufacturing operations. Specifically, the back-up supply agreements required us to sell products ordered by Medtronic and MAST at our manufacturing cost. Accordingly, we recognized a portion of the deferred gains as revenues upon the sale of products to Medtronic and MAST under the back-up supply arrangements. The amount of the deferred gain recognized as revenues was equal to the excess of (a) the fair value of products sold, based on historical selling prices of similar products, over (b) our manufacturing cost. In the case of Medtronic, we recognized \$156,000 of the deferred gain as revenues in 2004 and \$2,047,000 of the deferred gain as revenues in 2003. In the case of MAST, we recognized \$722,000 of the deferred gain as revenues in 2004.

### *License/Distribution Fees*

If separable under Emerging Issues Task Force Issue 00-21, "Revenue Arrangements with Multiple Deliverables" ("EITF 00-21"), we recognize any upfront payments received from license/distribution agreements as revenues ratably over the period in which the customer benefits from the license/distribution agreement.

To date, we have not received any upfront license payments that are separable under EITF 00-21. Accordingly, such license revenues have been combined with other elements, such as research and development activities, for purposes of revenue recognition. For instance, we account for the license fees and milestone payments under the Distribution Agreement with Senko as a single unit of accounting. Similarly, we have attributed the upfront fees received under the Olympus arrangements to a combined unit of accounting comprising a license we granted to Olympus-Cytori, Inc. as well as development services we agreed to perform for this entity.

### *Research and Development*

We earn revenue for performing tasks under research and development agreements with both commercial enterprises, such as Olympus and Senko, and governmental agencies like the National Institutes of Health ("NIH"). Revenue earned under development agreements is classified as either "research grant" or "development" revenues in our statements of operations, depending on the nature of the arrangement. The costs associated with earning these revenues are typically recorded as research and development expense.

We have received a total of \$22,000,000 from Olympus and the Joint Venture during 2005 in two separate but related transactions (see note 6). Approximately \$4,689,000 of this amount related to common stock that we issued, as well as two options we granted, to Olympus (see note 6 for further details). In addition to the \$4,689,000, we recorded upfront fees totaling \$17,311,000 as deferred revenues. In exchange for these proceeds, we agreed to (a) provide Olympus-Cytori, Inc. an exclusive and perpetual license to our therapeutic device technology, including the Celution™ System and certain related intellectual property, and (b) perform future development services related to commercializing the Celution™ System (see note 6). As noted above, the license and development services are not separable under EITF 00-21. Accordingly, we will recognize a portion of the

\$17,311,000 allocated to deferred revenues, related party, using a proportional performance methodology- that is, as we complete substantive milestones related to the development component of the combined accounting unit. During the year ended December 31, 2005, we did not complete any of our performance obligations and did not recognize any revenues associated with Olympus fees received. However, all costs are expensed as incurred.

In the third quarter of 2004, we entered into a Distribution Agreement with Senko. Under this agreement, we granted to Senko an exclusive license to sell and distribute certain Thin Film products in Japan. We have also earned or will be entitled to earn additional payments under the Distribution Agreement based on achieving the following defined research and development milestones:

- In 2004, we received a nonrefundable payment of \$1,250,000 from Senko after filing an initial regulatory application with the MHLW related to the Thin Film product line. We initially recorded this payment as deferred revenues of \$1,250,000.
- Upon the achievement of commercialization (i.e. regulatory approval by the MHLW), we will be entitled to an additional nonrefundable payment of \$250,000.

Of the amounts received and deferred, we recognized development revenues of \$51,000 in 2005 and \$158,000 in 2004, representing the fair value of the completed milestones relative to the fair value of the total efforts expected to be necessary to achieve regulatory approval by the Japanese Ministry of Health, Labor and Welfare (“MHLW”). As noted above, the license and the milestone components of the Senko Distribution Agreement are accounted for as a single unit of accounting. This single element has been allocated \$3,000,000 in fees, of which \$1,500,000 are potentially refundable. We have recognized, and will continue to recognize, the non-contingent fees allocated to this combined deliverable as we complete performance obligations under the Distribution Agreement with Senko. We will not recognize the potentially refundable portion of the fees until the right of refund expires. See note 5 for further details.

Under our agreement with the NIH, we are reimbursed for “qualifying expenditures” related to research on adipose-derived cell therapy for myocardial infarction. To receive funds under the grant arrangement, we are required to (i) demonstrate that we incurred “qualifying expenses,” as defined in the grant agreement between the NIH and us, (ii) maintain a system of controls, whereby we can accurately track and report all expenditures related solely to research on Adipose-Derived Cell Therapy for Myocardial Infarction, and (iii) file appropriate forms and follow appropriate protocols established by the NIH. When we are reimbursed for costs incurred under grant arrangements with the NIH, we recognize revenues for the lesser of:

- Qualifying costs incurred (and not previously recognized) to date, plus any allowable grant fees for which we are entitled to funding from the NIH; or,
- The outputs generated to date versus the total outputs expected to be achieved under the research arrangement.

In 2005, we recognized NIH grant revenue of \$312,000 and incurred qualifying costs of \$306,000. In 2004, we recognized NIH grant revenue of \$328,000 and incurred qualifying costs of \$339,000.

### Warranty

We provide a limited warranty under our agreements with our customers for products that fail to comply with product specifications. We have recorded a reserve for estimated costs we may incur under our warranty program.

The following summarizes the movements in our warranty reserve, which is subcategorized under accounts payable and accrued expenses, at December 31, 2005 and 2004:

	As of January 1,	Additions- charges to expenses	Claims	As of December 31,
2005:				
Warranty reserve	\$ 102,000	\$ 53,000	\$ —	\$ 155,000
2004:				
Warranty reserve	\$ 267,000	\$ 86,000	\$ (251,000)	\$ 102,000

In August 2003, as part of our ongoing product monitoring process, we determined that some of the products sold to Medtronic did not meet certain expectations, based on criteria we previously communicated to Medtronic. We agreed to a “no charge” replacement of the affected inventory in the possession of Medtronic. In the first half of 2004, we incurred claims of \$251,000 related to the replacement of this product. There were no similar claims made in 2005.

## Research and Development

Research and development expenditures, which are charged to operations in the period incurred, include costs associated with the design, development, testing and enhancement of our products, regulatory fees, the purchase of laboratory supplies, pre-clinical and future clinical studies. Also included in research and development are costs incurred to support research grant reimbursement and costs incurred in connection with our development arrangements with Senko and Olympus as discussed below.

Our agreement with the NIH entitles us to qualifying expenditures of up to \$950,000 for Phase I and Phase II related to research on Adipose-Derived Cell Therapy for Myocardial Infarction. We incurred \$306,000 and \$339,000 (\$17,000 of which were not reimbursed) of direct expenses for the years ended December 31, 2005 and 2004, respectively. There were no comparable expenditures in 2003.

Under a Distribution Agreement with Senko we are responsible for the completion of the initial regulatory application to the MHLW and commercialization of the Thin Film product line in Japan. During the years ended December 31, 2005 and 2004, we incurred \$129,000 and \$170,000, respectively, of expenses related to this regulatory and registration process. There were no comparable expenditures in 2003.

Expenditures related to the Joint Venture with Olympus include costs that are necessary to support the commercialization of future generation devices based on our Celution™ System. These development activities include performing preclinical and clinical trials, seeking regulatory approval, and performing product development related to therapeutic applications for adipose stem and regenerative cells for multiple large markets. For the year ended December 31, 2005, costs associated with the development of the device were \$1,176,000. There were no comparable expenditures in 2004 and 2003.

## Income Taxes

Income taxes are accounted for under the asset and liability method. Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases and operating loss and tax credit carry forwards. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income (loss) in the years in which those temporary differences are expected to be recovered or settled. Due to our current loss position, a full valuation allowance was recognized against deferred tax assets.

## Stock Based Compensation

We apply the intrinsic value-based method of accounting as prescribed by Accounting Principles Board (APB) Opinion No. 25, "Accounting for Stock Issued to Employees," and related interpretations including Financial Accounting Standards Board ("FASB") Interpretation No. 44, "Accounting for Certain Transactions Involving Stock Compensation-An Interpretation of APB Opinion No. 25" to account for our employee stock option plans. Under the intrinsic value method, compensation expense is recognized only if the current market price of the underlying stock exceeds the exercise price as of the measurement date (typically the date of grant). Any resulting expense is recorded on a straight-line basis over the applicable vesting period. Statement of Financial Accounting Standards ("SFAS") No. 123, "Accounting for Stock-Based Compensation," established accounting and disclosure requirements using a fair value-based method of accounting for stock-based employee compensation plans. As permitted by SFAS No. 123, we have elected to continue to apply the intrinsic value-based method of accounting described above, and have adopted the disclosure requirements of SFAS No. 123, as amended by SFAS No. 148, "Accounting for Stock-Based Compensation—Transition and Disclosure."

The fair value of the stock-options were estimated at the date of grant using the Black-Scholes option-pricing model with the following weighted-average assumptions:

	Years ended December 31,		
	2005	2004	2003
Expected term .....	8 years	6 years	7 years
Risk free interest rate .....	3.9-4.4%	3.3 - 4.4%	2.8 - 3.9%
Volatility .....	80%	85%	91%
Dividends .....	—	—	—
Resulting average grant date fair value .....	\$ 3.25	\$ 3.26	\$ 3.54

Had compensation expense been recognized for stock-based compensation plans in accordance with SFAS No. 123, we would have recorded the following net loss and net loss per share amounts:

	Years ended December 31,		
	2005	2004	2003
Net loss:			
As reported .....	\$ (26,538,000)	\$ (2,090,000)	\$ (9,283,000)
Add: Employee stock based compensation expense included in reported net loss, net of related tax effects .....	341,000	96,000	997,000
Deduct: Total employee stock based compensation expense determined under the fair value method for all awards, net of related tax effects .....	(2,675,000)	(2,586,000)	(4,367,000)
Pro forma .....	<u>\$ (28,872,000)</u>	<u>\$ (4,580,000)</u>	<u>\$ (12,653,000)</u>
Basic and diluted loss per common share:			
As reported .....	\$ (1.80)	\$ (0.15)	\$ (0.64)
Pro forma .....	<u>\$ (1.96)</u>	<u>\$ (0.33)</u>	<u>\$ (0.87)</u>

The pro forma compensation expense may not be representative of such expense in future years.

In December 2004, the FASB issued SFAS No. 123 (revised 2004), "Share-based Payment" ("SFAS 123R"). As affected by Securities and Exchange Commission Release No. 33-8568, "Amendment to Rule 4-01(a) of Regulation S-X Regarding the Compliance Date for Statement of Financial Accounting Standards No. 123 (Revised 2004), Share-Based Payment", SFAS 123R is effective for annual periods beginning after June 15, 2005 (January 1, 2006 for us). See the Recent Accounting Pronouncements section of this note below.

We will adopt SFAS 123R using the modified prospective transition method. The adoption of SFAS 123R will have a material effect on our results of operations. Based on pro forma amounts for historical periods presented earlier in this note, our reported net loss will increase (or our net income will be reduced) each quarterly period once SFAS 123R has been adopted. The full impact of the adoption of SFAS 123R in 2006 will depend on the level and terms of share-based payment transactions in 2006 as well as changes in our stock price and the assumptions used to determine the fair value of such transactions.

#### Other Comprehensive Income (Loss)

Comprehensive income (loss) is the total of net income (loss) and all other non-owner changes in equity. Other comprehensive income (loss) refers to these revenues, expenses, gains, and losses that, under generally accepted accounting principles, are included in comprehensive income (loss) but excluded from net income (loss).

During the years ended December 31, 2005, 2004 and 2003 our only element of other comprehensive income (loss) resulted from unrealized gains (losses) on available-for-sale investments, which are reflected in the statements of changes in stockholders' equity as accumulated other comprehensive loss.

#### Segment Information

On July 11, 2005, we announced the reorganization of our business based on two distinct operating segments – (a) Regenerative cell technology and (b) MacroPore Biosurgery, which manufactures bioresorbable implants. In the past, our resources were managed on a consolidated basis. However, in an effort to better reflect our focus and significant progress in the development of regenerative therapies, we are now evaluating and therefore reporting our financial results in two segments.

Our regenerative cell technology segment is focused on the discovery and development of cell-based therapies for cardiovascular disease, spine and orthopedic conditions, gastrointestinal disorders and new approaches for aesthetic and reconstructive surgery using regenerative cells from adipose tissue, also known as fat tissue. Our MacroPore Biosurgery unit manufactures and distributes the HYDROSORB™ family of FDA-cleared bioresorbable spine and orthopedic implants; it also develops the Thin Film bioresorbable implants for Senko, which has exclusive distribution rights to these products in Japan.

We measure the success of each operating segment based on operating results and, additionally, in the case of the regenerative cell technology segment, the achievement of key research objectives. In arriving at operating loss for each segment, we used the same accounting policies as those used for our consolidated company and as described throughout this note. However, segment operating results exclude allocations of company-wide general and administrative costs, changes in fair value of our option liabilities, and any restructuring charges.

Prior year results presented below have been developed on the same basis as the current year figures. For all periods presented we did not have any intersegment transactions.

The following tables provide information regarding the performance and assets of our operating segments:

	Year ended December 31,		
	2005	2004	2003
<b>Revenues:</b>			
Regenerative cell technology	\$ 320,000	\$ 338,000	\$ 9,000
MacroPore Biosurgery	5,685,000	6,480,000	14,079,000
Total Revenues	<u>\$ 6,005,000</u>	<u>\$ 6,818,000</u>	<u>\$ 14,088,000</u>
<b>Segment losses:</b>			
Regenerative cell technology	\$(13,171,000)	\$(6,964,000)	\$(4,410,000)
MacroPore Biosurgery	(975,000)	(2,441,000)	995,000
General and administrative expenses	(10,208,000)	(6,551,000)	(5,795,000)
Changes in fair value of option liabilities	(3,645,000)	—	—
Restructuring charge	—	(107,000)	(451,000)
Total operating loss	<u>\$(27,999,000)</u>	<u>\$(16,063,000)</u>	<u>\$ (9,661,000)</u>

	As of December 31,	As of December 31,
	2005	2004
<b>Assets:</b>		
Regenerative cell technology	\$ 9,152,000	\$ 7,799,000
MacroPore Biosurgery	2,206,000	3,458,000
Corporate assets	16,808,000	14,213,000
Total assets	<u>\$ 28,166,000</u>	<u>\$ 25,470,000</u>

We derived our revenues from the following products, research grants, development and service activities:

	Years ended December 31,		
	2004	2004	2003
<b>Regenerative cell technology:</b>			
Development revenues:			
Research grant (NIH) .....	\$ 312,000	\$ 328,000	\$ —
Regenerative cell storage services .....	8,000	10,000	9,000
Total regenerative cell technology .....	<u>320,000</u>	<u>338,000</u>	<u>9,000</u>
<b>MacroPore Biosurgery:</b>			
Product revenues:			
Spine & orthopedics products .....	5,634,000	3,803,000	9,882,000
Thin Film products:			
Product sales (non-MAST-related) .....	—	559,000	1,186,000
Product sales to MAST .....	—	906,000	—
Amortization of gain on sale (MAST) .....	—	772,000	—
	—	<u>2,237,000</u>	<u>1,186,000</u>
Craniomaxillofacial (CMF) products:			
Product sales .....	—	126,000	964,000
Amortization of gain on sale .....	—	156,000	2,047,000
	—	<u>282,000</u>	<u>3,011,000</u>
Development revenues .....	51,000	158,000	—
Total MacroPore Biosurgery .....	<u>5,685,000</u>	<u>6,480,000</u>	<u>14,079,000</u>
Total Revenues .....	<u>\$ 6,005,000</u>	<u>\$ 6,818,000</u>	<u>\$ 14,088,000</u>

The following table provides geographical information regarding our sales to external customers:

For the Years Ended:	U.S. Revenues	Non-U.S. Revenues	Total Revenues
December 31, 2005 .....	\$ 6,005,000	\$ —	\$ 6,005,000
December 31, 2004 .....	\$ 6,602,000	\$ 216,000	\$ 6,818,000
December 31, 2003 .....	\$ 13,727,000	\$ 361,000	\$ 14,088,000

At December 31, 2005 and 2004, our long-lived assets, excluding goodwill and intangibles, are located in the following jurisdictions:

As of:	U.S. Domiciled	Non-U.S. Domiciled	Total
December 31, 2005 .....	\$ 4,539,000	\$ 179,000	\$ 4,718,000
December 31, 2004 .....	\$ 3,311,000	\$ 5,000	\$ 3,316,000

### Loss Per Share

We compute loss per share based on the provisions of SFAS No. 128, "Earnings Per Share." Basic per share data is computed by dividing income or loss available to common stockholders by the weighted average number of common shares outstanding during the period. Diluted per share data is computed by dividing net income or loss available to common stockholders by the weighted average number of common shares outstanding during the period increased to include, if dilutive, the number of

additional common share equivalents that would have been outstanding if potential common shares had been issued using the treasury stock method. Potential common shares were related entirely to outstanding but unexercised option awards and warrants for all periods presented.

We have excluded all potentially dilutive securities from the calculation of diluted loss per share attributable to common stockholders for the years ended December 31, 2005, 2004 and 2003, as their inclusion would be antidilutive. Potentially dilutive common shares excluded from the calculations of diluted loss per share were 4,464,722, 2,189,414 and 2,585,420 for the years ended December 31, 2005, 2004 and 2003, respectively.

Additionally, potential common shares excluded from per share calculations due to exercise prices that exceeded average market values were 3,520,019, 2,834,382 and 2,262,580 for the years ended December 31, 2005, 2004 and 2003, respectively. Potential common shares in 2005 include an option to purchase 2,200,000 shares related to the Olympus equity agreement (see note 6).

### **Recent Accounting Pronouncements**

In November 2004, the FASB issued SFAS No. 151, "Inventory Costs — An Amendment of ARB No. 43, Chapter 4" ("SFAS 151"). SFAS 151 clarifies that abnormal amounts of idle facility expense, freight, handling costs and spoilage should be expensed as incurred and not included in overhead. Further, SFAS 151 requires that allocation of fixed and production facilities overhead to conversion costs should be based on normal capacity of the production facilities. The provisions in SFAS 151 are effective for inventory costs incurred during fiscal years beginning after June 15, 2005. We do not believe that the adoption of SFAS 151 will have a significant effect on our financial statements.

In December 2004, the FASB issued SFAS No. 153, "Exchanges of Nonmonetary Assets — An Amendment of APB Opinion No. 29" ("SFAS 153"). The provisions of this statement are effective for non-monetary asset exchanges occurring in fiscal periods beginning after June 15, 2005. This statement eliminates the exception in previous generally accepted accounting principles that precluded the recognition of exchanges of similar productive assets at fair value. Instead, SFAS 153 provides for a general exception to the fair value principle for exchange transactions that do not have commercial substance — that is, transactions that are not expected to result in significant changes in the cash flows of the reporting entity. The adoption of SFAS 153 has not had a significant effect on our financial statements.

In December 2004, the FASB issued SFAS No. 123 (revised 2004), "Share-based Payment" ("SFAS 123R"). As affected by Securities and Exchange Commission Release No. 33-8568, "Amendment to Rule 4-01(a) of Regulation S-X Regarding the Compliance Date for Statement of Financial Accounting Standards No. 123 (Revised 2004), Share-Based Payment", SFAS 123R is effective on January 1, 2006 and will have a material effect on our results of operations. Upon adoption, SFAS 123R will require us to measure all share-based payment transactions, including those with employees, at fair value (most notably, this includes employee stock option grants, even where the exercise price is equal to the grant date fair market value). Moreover, the fair value of share-based payment awards will be recognized as expense in the statements of operations over the requisite service period of each award. SFAS 123R also changes the manner in which deferred taxes are recognized on share-based payment awards, as well as the accounting for award modifications. See the "Stock Based Compensation" section of this note above.

In May 2005, the FASB issued SFAS No. 154, "Accounting Changes and Error Corrections" ("SFAS 154"). This new standard replaces APB Opinion No. 20, "Accounting Changes", and SFAS No. 3, "Reporting Accounting Changes in Interim Financial Statements". Among other changes, SFAS 154 requires that a voluntary change in accounting principle be applied retrospectively with all prior period financial statements presented on the new accounting principle, unless it is impracticable to do so. SFAS 154 also provides that (1) a change in method of depreciating or amortizing a long-lived nonfinancial asset be accounted for as a change in estimate (prospectively) that was effected by a change in accounting principle, and (2) correction of errors in previously issued financial statements should be termed a "restatement." The new standard is effective for accounting changes and correction of errors made in fiscal years beginning after December 15, 2005. We do not believe that the adoption of SFAS 154 will have a significant effect on our financial statements.

In October 2005, the FASB issued Staff Position 13-1, "Accounting for Rental Costs Incurred during a Construction Period" ("FSP 13-1"). The FASB concludes in this FSP that rental costs associated with ground or building operating leases that are incurred during a construction period should be expensed. FASB Technical Bulletin ("FTB") No. 88-1, "Issues Relating to Accounting for Leases", requires that rental costs associated with operating leases be allocated on a straight-line basis in accordance with FASB Statement No. 13, "Accounting for Leases", and FTB 85-3, "Accounting for Operating Leases with Scheduled Rent Increases", starting with the beginning of the lease term. The FASB believes there is no distinction between the right to use a leased asset during the construction period and the right to use that asset after the construction period. Companies are required to apply the guidance in FSP 13-1 to the first reporting period beginning after December 15, 2005. We do not believe that the adoption of FSP 13-1 will have a significant effect on our financial statements.

In November 2005, the FASB issued Staff Position ("FSP") FIN 45-3, "Application of FASB Interpretation No. 45 to Minimum Revenue Guarantees Granted to a Business or Its Owners". The FSP revises FASB Interpretation No. 45 to explicitly indicate

that FIN 45 applies to a guarantee granted to a business that the revenue of the business (or a specific portion of the business) for a specified period of time will be at least a specified amount. Although we may enter into such guarantees in the future (see note 6), no minimum revenue guarantees have been provided by us for any periods covered by these consolidated financial statements.

### 3. Gain on Sale of Assets, Related Party

In January 2004, we received a \$5,000,000 milestone payment from Medtronic relating to the 2002 disposition of our CMF product line. As part of the disposition arrangement, we had agreed to complete clinical research regarding Faster Resorbable Polymers, an area that directly relates to the CMF product line transferred to Medtronic. We became entitled to the \$5,000,000 payment after fulfilling the research requirements set out in the CMF sale agreement. The \$5,000,000 payment was recognized during the first half of 2004 as gain on sale of assets, related party in the accompanying statement of operations.

During the third quarter of 2004, we completed all remaining performance obligations related to the 2002 sale of the CMF product line to Medtronic. Accordingly, we recorded \$7,383,000 as a component of gain on sale of assets, related party, representing the remaining balance that had theretofore been reported as deferred gain on sale of assets, related party.

Pursuant to the sale of the CMF product line, we were obliged to transfer certain "know-how," including manufacturing processes, patents, and other intellectual property, to Medtronic. If such know-how was transferred within a certain time frame defined in the CMF Asset Purchase Agreement dated September 30, 2002 (the "APA"), we would become entitled to a \$2,000,000 milestone payment.

In the second quarter of 2004, we provided notice to Medtronic that the requisite know-how associated with the transferred CMF product line had been transferred, pursuant to the terms of, and within the timeframe specified by, the APA. Medtronic did not agree that know-how transfer had been completed and asserted that, in any case, that the maximum payment due to us was \$1,000,000 rather than \$2,000,000.

To avoid the risk and expense of arbitration, in the third quarter of 2004 we agreed to accept a negotiated settlement with Medtronic in the amount of \$1,500,000 related to the know-how transfer. The \$1,500,000 payment was recognized as gain on sale of assets, related party in 2004.

As noted above, the total gain on sale of assets, related party, recognized in 2004 was \$13,883,000.

### 4. Gain on Sale of Assets, Thin Film Product Line

In May 2004, we sold most, but not all, of our intellectual property rights and tangible assets related to our Thin Film product line to MAST (see note 5). The carrying value of the assets transferred to MAST prior to disposition totaled \$634,000, and was comprised of the following:

- Finished goods inventory of \$177,000,
- Manufacturing and development equipment of \$217,000, and
- Goodwill of \$240,000.

Under this agreement we were contractually entitled to the following additional consideration (none of this consideration has been recognized in the financial statements):

- \$200,000, payable only upon receipt of 510(k) clearance from the U.S. Food and Drug Administration ("FDA") for a hernia wrap product (thin film combined product); and
- \$2,000,000 on or before the earlier of (i) May 31, 2005, known as the "Settlement Date," or (ii) 15 days after the date upon which MAST has hired a Chief Executive Officer ("CEO"), provided the CEO held that position for at least four months and met other requirements specified in the sale agreement. Note that clause (ii) effectively means that we would not have received payment of \$2,000,000 before May 31, 2005 unless MAST had hired a CEO on or before January 31, 2005 (four months prior to the Settlement Date). Moreover, in the event that MAST had not hired a CEO on or before January 31, 2005, MAST may have (at its sole option and subject to the requirements of the sale agreement) alternatively provided us with a 19% equity interest in the MAST business that is managing the Thin Film assets at May 31, 2005 in lieu of making the \$2,000,000 payment. Our contention was that MAST did in fact hire a CEO on or before January 31, 2005 and, thus, we were entitled to a \$2,000,000 cash payment on or before May 31, 2005.

MAST did not make the payments specified above. Therefore, on June 14, 2005, we initiated arbitration proceedings against MAST, asserting that MAST was in breach of the Asset Purchase Agreement by failing to pay the final \$2,000,000 in purchase price (among other issues). MAST responded asserting its own claims on or about June 23, 2005. MAST's claims included but were not limited to the following allegations: (i) we inadequately transferred know-how to MAST, (ii) we misrepresented the state of the distribution network, (iii) we provided inadequate product instructions to users, and (iv) we failed to adequately train

various distributors.

In August 2005, the parties settled the arbitration proceedings and gave mutual releases of all claims, excepting those related to the territory of Japan, and agreed to contractual compromises, the most significant of which is our waiving of the obligation for MAST to either pay the final cash purchase installment of \$2,000,000 or to deliver 19% of its shares. Moreover, if MAST exercises its Purchase Right (see note 5) and Thin Film products are marketed in Japan, MAST would no longer be obliged to share certain gross profits and royalties with us.

In exchange, MAST agreed to supply - at no cost to us- all required product for any necessary clinical study for the territory of Japan and to cooperate in the planning of such study. However, if MAST exercises its Purchase Right or if we enter into a supply agreement with MAST for the territory of Japan, we would be obliged to reimburse MAST for any Thin Film product supplied in connection with the Japanese study at a cost of \$50 per sheet.

As a result of the arbitration settlement, we recognized the remaining deferred gain on sale of assets of \$5,650,000, less \$124,000 of related deferred costs, in the statement of operations in 2005. The \$5,526,000 gain on sale of assets recorded in the third quarter of 2005 was related to the sale of the majority of our Thin Film product line in May 2004 to MAST. As part of the disposal arrangements, we agreed to complete certain performance obligations which prevented us from recognizing the gain on sale of assets when the cash was initially received.

## 5. Thin Film Japan Distribution Agreement

In the third quarter of 2004, we entered into a Distribution Agreement with Senko. Under this agreement, we granted to Senko an exclusive license to sell and distribute certain Thin Film products in Japan. Specifically, the license covers Thin Film products with the following indications:

- Anti-adhesion,
- Soft tissue support, and
- Minimization of the attachment of soft tissues throughout the body.

The Distribution Agreement with Senko commences upon “commercialization”. In simplest terms, commercialization occurs when one or more Thin Film product registrations are completed with the Japanese Ministry of Health, Labour and Welfare (“MHLW”).

Following commercialization, the Distribution Agreement has a duration of five years and is renewable for an additional five years after reaching mutually agreed minimum purchase guarantees.

The Distribution Agreement also provides for us to supply certain products to Senko at fixed prices over the life of the agreement once we have received approval to market these products in Japan. In addition to the product price, Senko will also be obligated to make royalty payments to us of 5% of the sales value of any products Senko sells to its customers during the first three years post-commercialization.

At the inception of this arrangement, we received a \$1,500,000 license fee which was recorded as deferred revenues in 2004. We have also received \$1,250,000 in milestone payments from Senko. See “Revenue Recognition” under note 2 above for our policies with regard to the timing of when these amounts will be recognized as revenues.

As part of the Thin Film sales agreement (see note 4), we granted MAST a right to acquire our Thin Film-related interest in Japan (the “Purchase Right”) during the time period and according to the following terms:

- From May 31, 2005 to May 31, 2007, the exercise price of the Purchase Right will be equal to the fair market value of the Japanese business, but in no event will be less than \$3,000,000.
- Moreover, between May 31, 2005 and May 31, 2007, MAST will have a right of first refusal to match the terms of any outside offer to buy our Japanese Thin Film business.

We have agreed to provide back-up supply of products to Senko subject to the terms of the Distribution Agreement in the event that (a) MAST exercises its Purchase Right and (b) MAST materially fails to deliver product to Senko. In this circumstance, Senko would pay any amounts due for purchases of product, as well as make royalty payments directly to us. We would be obliged to remit 5% of the gross margin to MAST on any products sold to Senko. We believe that it is unlikely in practice that this contingency will materialize. Accordingly, we estimate the fair value of this guarantee to be de minimis as of the end of the current reporting period.

## 6. Transactions with Olympus Corporation

### *Initial Investment by Olympus Corporation in Cytori*

In the second quarter of 2005, we entered into a Common Stock Purchase Agreement (the "Purchase Agreement") with Olympus Corporation ("Olympus") in which we received \$11,000,000 in cash proceeds.

Under this agreement, we distributed 1,100,000 newly issued shares of common stock to Olympus. We reflect the common stock issued to Olympus in our financial statements at the market value of our common stock at the time of the Purchase Agreement (\$2.73 per share, or \$3,003,000 in the aggregate).

In addition, we also granted Olympus an immediately exercisable option to acquire 2,200,000 shares of our common stock on or before December 31, 2006 at \$10 per share. We have accounted for this grant as a liability in accordance with Emerging Issues Task Force Issue No. 00-19, "Accounting for Derivative Financial Instruments Indexed to, and Potentially Settled in, a Company's Own Stock" because from the date of grant through the expiration, we are required to deliver listed common stock to settle the option shares upon exercise.

At the time we entered into the Purchase Agreement, we estimated the fair value of the option liability to be \$186,000 based on the following assumptions:

- Contractual term of 1.67 years,
- Risk-free interest rate of 3.46%, and
- Estimated share-price volatility of 59.7%

As of December 31, 2005, we re-estimated the fair value of the option liability to be \$3,731,000 based on the following assumptions:

- Contractual term of 1.00 year,
- Risk-free interest rate of 4.38%, and
- Estimated share-price volatility of 65.1%

The change in the fair value of \$3,545,000 from the date the option was issued to December 31, 2005 was recorded in the statements of operations as change in fair value of option liabilities.

The \$11,000,000 in total proceeds we received in the second quarter of 2005 exceeded the sum of (i) the market value of our stock as well as (ii) the fair value of the option at the time we entered into the share purchase agreement. The \$7,811,000 difference between the proceeds received and the fair values of our common stock and option liability was recorded as a component of deferred revenues, related party in the accompanying balance sheet.

As of December 31, 2005, Olympus holds approximately 7.2% of our issued and outstanding shares. If Olympus had chosen to exercise its option on December 31, 2005 to purchase all 2,200,000 shares, it would have possessed 18.8% of our outstanding common stock as of December 31, 2005. Additionally, Olympus has a right, which it has not yet exercised, to designate a director to serve on our Board of Directors.

### *Formation of the Olympus-Cytori Joint Venture*

As discussed in note 2 above, on November 4, 2005, we entered into a joint venture and other related agreements (the "Joint Venture Agreements") with Olympus. The Joint Venture is owned equally by Olympus and us.

Under the Joint Venture Agreements:

- Olympus paid \$30,000,000 for its 50% interest in the Joint Venture. Moreover, Olympus simultaneously entered into a License/Joint Development Agreement with the Joint Venture and us to develop a second generation commercial therapeutic system and manufacturing capabilities.
- We licensed our therapeutic device technology, including the Celution™ System and certain related intellectual property, to the Joint Venture for use in future generation devices. These devices will process and purify adult stem and regenerative cells residing in adipose (fat) tissue for various therapeutic clinical applications. In exchange for this license, we received a 50% interest in the Joint Venture, as well as an initial \$11,000,000 payment from the Joint Venture; the source of this payment was from the \$30,000,000 contributed to the Joint Venture by Olympus. Moreover, upon receipt of a CE mark for the first generation Celution™ System we received an additional \$11,000,000 development milestone payment from the Joint Venture in January 2006 (see note 20).

As a result of the \$30 million cash contribution to the joint venture by Olympus, we realized an immediate appreciation in the carrying value of our interests in the Joint Venture. As a result, we reported accretion of interests in the joint venture of \$3,829,000 as a credit directly to additional paid-in capital. This accounting treatment is required by Securities and Exchange Commissions Staff Accounting Bulletin No. 51, "Accounting for Sales of Stock by a Subsidiary," which prohibits gains from equity transactions (in this case, the non-cash accretion of the interests held in an investment issuing additional shares to another shareholder) when such entity is a "newly-formed, non-operating entity" or a "research and development stage company."

We have determined that the Joint Venture is a variable interest entity ("VIE") pursuant to FASB Interpretation No. 46 (revised 2003), "Consolidation of Variable Interest Entities - An Interpretation of ARB No. 51" ("FIN 46R"), but that Cytori is not the VIE's primary beneficiary. Accordingly, we have accounted for our interests in the Joint Venture using the equity method of accounting, since we can exert significant influence over the joint venture's operations. At December 31, 2005, the carrying value of our investment in the joint venture is \$0, as our share of the Joint Venture's incurred losses reduced the investment balance to \$0 (see Other Related Party Transactions section below of this footnote for further details). We are under no obligation to provide additional funding to the Joint Venture, but may choose to do so if supported by a good business case.

#### *Put/Calls and Guarantees*

The Shareholders' Agreement between Cytori and Olympus provides that in certain specified circumstances of insolvency or if we experience a change in control, Olympus will have the rights to (i) repurchase our interests in the Joint Venture at the fair value of such interests or (ii) sell its own interests in the Joint Venture to Cytori at the higher of (a) \$22,000,000 or (b) their fair value (the "Put").

As of November 4, 2005, the fair value of the Put was determined to be \$1,500,000. As of December 31, 2005, the fair value of the Put increased to \$1,600,000 and has been recorded in the caption Option liabilities in the balance sheet. The change in the Put value was recorded in the statements of operations as a component of change in fair value of option liabilities.

The valuations of the Put were completed by an independent valuation firm using an option pricing theory based simulation analysis (i.e., a Monte Carlo simulation). The valuations are based on assumptions as of the valuation date with regard to the market value of Cytori and the estimated fair value of the Joint Venture, the expected correlation between the values of Cytori and the Joint Venture, the expected volatility of Cytori and the Joint Venture, the bankruptcy recovery rate for Cytori, the bankruptcy threshold for Cytori, the probability of a change of control event for Cytori, and the risk free rate.

The following assumptions were employed in estimating the value of the Put at December 31, 2005 (these assumptions were not materially different from those used in valuing the Put as of November 4, 2005):

- The expected volatilities of Cytori and the Joint Venture were assumed to be 63.2% and 69.1%, respectively,
- The bankruptcy recovery rate for Cytori was assumed to be 21%,
- The bankruptcy threshold for Cytori was assumed to be \$10.78 million,
- The probability of a change of control event for Cytori was assumed to be 3.04%, and
- The expected correlation between fair values of Cytori and the Joint Venture in the future was assumed to be 99%
- The risk free rate was assumed to be 4.39%.

The Put is perpetual and, thus, has no expiration date. Accordingly, we will continue to recognize a liability for the Put and mark it to market each quarter until it is exercised or until the arrangements with Olympus are amended.

The Joint Venture has exclusive access to our technology for the development, manufacture, and supply of the devices (second generation and beyond) for all therapeutic applications. Once a second generation Celution™ System is developed and approved by regulatory agencies, the Joint Venture may sell such systems exclusively to us at a formula-based transfer price; we have retained marketing rights to the second generation devices for all therapeutic applications of adipose stem and regenerative cells.

As part of the various agreements with Olympus, we will be required, following commercialization of the Celution™ System, to provide monthly forecasts to the Joint Venture specifying the quantities of each category of devices that we intend to purchase over a rolling six-month period. Although we are not subject to any minimum purchase requirements, we are obliged to buy a minimum percentage of the products forecasted by us in such reports. Since we can effectively control the number of devices we will agree to purchase and because no commercial devices have yet been developed to trigger the forecast requirement, we estimate that the fair value of this guarantee will be de minimis as of December 31, 2005, and therefore no amounts related to the guarantee are reflected on the statement of financial position.

*Deferred revenues, related party*

At December 31, 2005, the deferred revenues, related party account consists of the consideration we have received in exchange for future services that we have agreed to perform on behalf of Olympus and the Joint Venture. These services include completing preclinical and clinical studies, product development and seeking regulatory approval for the treatment of various therapeutic conditions with adult stem and regenerative cells residing in adipose (fat) tissue. These services also include providing an exclusive and perpetual license to our therapeutic device technology, including the Celution™ System and certain related intellectual property.

Pursuant to Emerging Issues Task Force Issue 00-21, *Revenue Arrangements with Multiple Deliverables*, we have concluded that the license and development services must be accounted for as a single unit of accounting. Refer to note 2 for a full description of our revenue recognition policy.

*Other Related Party Transactions*

As part of the formation of the Joint Venture and as discussed above, the Joint Venture agreed to purchase development services from Olympus. In December 2005, the Joint Venture paid to Olympus \$8,000,000 as a payment for those services. The payment has been recognized in its entirety as an expense on the books and records of the Joint Venture as the expenditure represents a payment for research and development services that have no alternative future uses. Our share of this expense has been reflected within the account, Equity loss from investment in joint venture, within the consolidated statement of operations.

*Condensed financial information for the Joint Venture*

A summary of the unaudited condensed financial information for the Joint Venture as of December 31, 2005 and for the period from November 4, 2005 (inception) to December 31, 2005 is as follows:

Balance Sheet:	
Assets - cash .....	\$ 11,000,000
Stockholders' equity .....	<u>\$ 11,000,000</u>
Statement of Operations:	
Net loss - research and development expense ...	<u>\$ (19,343,000)</u>

**7. Short-term Investments**

As of December 31, 2005 and 2004, all short-term investments were classified as available-for-sale, which consisted of the following:

	December 31, 2005						
	Amortized Cost	Less than 12 months temporary impairment		Greater than 12 months temporary impairment		Total	
		Gross Unrealized Losses	Estimated Fair Value	Gross Unrealized Losses	Estimated Fair Value	Gross Unrealized Losses	Estimated Fair Value
Corporate notes and bonds .....	\$ 1,984,000	\$ (2,000)	\$ 1,882,000	\$ —	\$ 100,000	\$ (2,000)	\$ 1,982,000
Agency securities .....	5,870,000	(14,000)	5,456,000	—	400,000	(14,000)	5,856,000
Total .....	<u>\$ 7,854,000</u>	<u>\$ (16,000)</u>	<u>\$ 7,338,000</u>	<u>\$ —</u>	<u>\$ 500,000</u>	<u>\$ (16,000)</u>	<u>\$ 7,838,000</u>
	December 31, 2004						
	Amortized Cost	Less than 12 months temporary impairment		Greater than 12 months temporary impairment		Total	
		Gross Unrealized Losses	Estimated Fair Value	Gross Unrealized Losses	Estimated Fair Value	Gross Unrealized Losses	Estimated Fair Value
Corporate notes and bonds .....	\$ 1,633,000	\$ (5,000)	\$ 1,628,000	\$ —	\$ —	\$ (5,000)	\$ 1,628,000
Agency securities .....	8,978,000	(27,000)	8,951,000	—	—	(27,000)	8,951,000
Total .....	<u>\$ 10,611,000</u>	<u>\$ (32,000)</u>	<u>\$ 10,579,000</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ (32,000)</u>	<u>\$ 10,579,000</u>

As of December 31, 2005 and 2004, investments available-for-sale had the following maturities:

	December 31, 2005		December 31, 2004	
	Amortized Cost	Estimated Fair Value	Amortized Cost	Estimated Fair Value
Corporate notes and bonds:				
with maturity of less than 1 year .....	\$ 1,984,000	\$ 1,982,000	\$ 1,529,000	\$ 1,524,000
with maturity of 1 to 2 years .....	—	—	104,000	104,000
Agency securities:				
with maturity of less than 1 year .....	5,870,000	5,856,000	7,898,000	7,877,000
with maturity of 1 to 2 years .....	—	—	1,080,000	1,074,000
	<u>\$ 7,854,000</u>	<u>\$ 7,838,000</u>	<u>\$ 10,611,000</u>	<u>\$ 10,579,000</u>

Proceeds from sales and maturity of short term investments for the year ended December 31, 2005, 2004 and 2003 were \$56,819,000, \$51,132,000, \$49,561,000, respectively. Gross realized losses for such sales in 2005 were approximately \$12,000. Gross realized gains on such sales for the years ended December 31, 2004 and 2003 were approximately \$4,000, and \$38,000, respectively.

Based on our ability and intent to hold the investments for a reasonable period of time sufficient for a forecasted recovery of fair value and the low severity of impairment, we do not consider these investments to be other-than-temporarily impaired as of December 31, 2005.

## 8. Composition of Certain Financial Statement Captions

### Inventories, net

As of December 31, 2005 and 2004, inventories, net, was comprised of the following:

	As of December 31,	
	2005	2004
Raw materials .....	\$ 232,000	\$ 189,000
Finished goods .....	26,000	190,000
	<u>\$ 258,000</u>	<u>\$ 379,000</u>

### Other Current Assets

As of December 31, 2005 and 2004, other current assets was comprised of the following:

	As of December 31,	
	2005	2004
Prepaid expenses .....	\$ 506,000	\$ 809,000
Accrued interest receivable .....	77,000	121,000
Other receivables .....	38,000	54,000
	<u>\$ 621,000</u>	<u>\$ 984,000</u>

### Property and Equipment, net

As of December 31, 2005 and 2004, property and equipment, net, was comprised of the following:

	As of December 31,	
	2005	2004
Manufacturing and development equipment .....	\$ 4,681,000	\$ 3,928,000
Office and computer equipment .....	2,682,000	2,186,000
Leasehold improvements .....	3,359,000	1,963,000
	<u>10,722,000</u>	<u>8,077,000</u>
Less accumulated depreciation and amortization .....	(6,462,000)	(4,997,000)
	<u>\$ 4,260,000</u>	<u>\$ 3,080,000</u>

### Accounts Payable and Accrued Expenses

As of December 31, 2005 and 2004, accounts payable and accrued expenses was comprised of the following:

	As of December 31,	
	2005	2004
Accounts payable .....	\$ 933,000	\$ 481,000
Accrued bonus .....	981,000	472,000
Accrued legal fees .....	975,000	27,000
Leasehold improvements .....	800,000	—
Accrued studies .....	712,000	6,000
Accrued vacation .....	680,000	579,000
Accrued expenses .....	556,000	437,000
Accrued accounting fees .....	199,000	135,000
Warranty reserve (note 2) .....	155,000	102,000
Deferred rent expense .....	138,000	10,000
	<u>\$ 6,129,000</u>	<u>\$ 2,249,000</u>

## 9. Commitments and Contingencies

We have contractual obligations to make payments on leases of office and manufacturing space as follows:

Years Ending December 31,	Operating Leases
2006 .....	\$ 1,572,000
2007 .....	2,086,000
2008 .....	1,556,000
2009 .....	1,383,000
2010 .....	707,000
Total .....	<u>\$ 7,304,000</u>

Rent expense for the years ended December 31, 2005, 2004, and 2003 was \$1,632,000, \$801,000 and \$931,000, respectively.

On May 24, 2005, we entered into a lease for 91,000 square feet of space located at 3020 and 3030 Callan Road, San Diego, California. We intend to complete the move of the majority of our operations to this new facility over the next year. The agreement bears rent at a rate of \$1.15 per square foot, with annual increases of 3%. The lease term is 57 months, commencing on October 1, 2005 and expiring on June 30, 2010. In addition, we are committed to providing a minimum of \$837,000 in agreed-upon leasehold improvements to the facility, which are not reflected in the table of contractual obligations shown above. As of December 31, 2005, we have made \$1,383,000 in improvements to the facility as a part of our facility retrofits which, when completed, will total approximately \$3,000,000.

We are subject to various claims and contingencies related to legal proceedings. Due to their nature, such legal proceedings involve inherent uncertainties including, but not limited to, court rulings, negotiations between affected parties and governmental actions. Management assesses the probability of loss for such contingencies and accrues a liability and/or discloses the relevant circumstances, as appropriate. Management believes that any liability to us that may arise as a result of currently pending legal proceedings will not have a material adverse effect on our financial condition, liquidity, or results of operations as a whole.

Refer to note 5 for a discussion of our commitments and contingencies related to our arrangements with MAST and Senko.

Refer to note 6 for a discussion of our commitments and contingencies related to our transactions with Olympus, including (a) our obligation to the Joint Venture in future periods and (b) certain put and call rights embedded in the arrangements with Olympus.

Refer to note 10 for a discussion of our commitments and contingencies related to our interactions with the University of California.

## 10. License Agreement

On October 16, 2001, StemSource entered into an exclusive worldwide license agreement with the Regents of the University of California ("UC"), licensing all of UC's rights to certain pending patent applications under prosecution by UC and (in part) by the University of Pittsburgh ("U Pitt"), for the life of these patents, with the right of sublicense. The exclusive license currently relates to an issued patent and various pending applications relating to Adipose Derived Stem Cells. In November 2002, we acquired StemSource, and the license agreement was assigned to us.

The agreement calls for annual payments until such time as we begin commercial sales of any products utilizing the licensed technology. Upon achieving commercial sales we will be required to pay variable royalties based on the net sales of products sold. The royalties are further subject to minimum annual royalties increasing annually with a plateau in the fifth year. In addition, we are obligated to pay certain milestone payments upon achieving any of the following: (a) the filing of an

investigational new drug application, (b) applying for marketing approval, or (c) receiving marketing approval. We may also be subject to a substantial change of control payment within sixty days of a change of control transaction.

Additionally, we are obligated to reimburse UC for patent prosecution costs on any patents pending including foreign applications.

Although our power as licensee to successfully use these rights to exclude competitors from the market is untested, we believe that the loss of all rights to this patent could significantly impact our development of the regenerative cell technology and/or commercialization of related products.

The University of Pittsburgh filed a lawsuit in the fourth quarter of 2004, naming all of the inventors who had not assigned their ownership interest in Patent 6,777,231 to U Pitt. It was seeking a determination that its assignors, rather than the University of California's assignors, are the true inventors of U.S. Patent No. 6,777,231. This lawsuit could subject us to significant costs and, if U Pitt wins the lawsuit, our license rights to this patent could be nullified or rendered non-exclusive with respect to any third party that might license rights from U Pitt. Accordingly, if U Pitt wins the lawsuit, our regenerative cell strategy could be significantly affected.

We are not named as a party to the lawsuit but our president, Marc Hedrick, is a named individual defendant because he is one of the inventors identified on the patent. We are providing substantial financial and other assistance to the defense of the lawsuit.

In the years ended December 31, 2005, 2004 and 2003 we expensed \$1,303,000, \$190,000 and \$112,000, respectively, under this license agreement. These expenses have been classified as general and administrative expense in the accompanying consolidated financial statements. We believe that the amount expensed for December 31, 2005 is a reasonable estimate of our exposure for the probable expenses for litigation, prosecution, and other expenses related to the license agreement.

## 11. Restructuring Event

In September 2003, we closed an administrative office in Königstein, Germany in an effort to reduce costs and consolidate operations in the United States.

In connection with the facility closure, we involuntarily terminated three employees and relocated another employee to the United States. We incurred a liability of approximately \$282,000 related to severance benefits and paid all the severance benefits prior to December 31, 2003.

The Königstein, Germany office was rented under an operating lease. As of September 30, 2003, we ceased using the office space, but continued to remain liable for monthly rent payments of approximately \$12,500 per month under a lease agreement that would have expired in February 2006. We sought to sublease the entire facility for the remaining term of the lease agreement. However, due to the unique nature of the office building and the depressed rental market in and around Frankfurt, Germany, we expected that a sublease of the entire facility (if one was successfully negotiated) would yield only approximately 65% of our monthly rental obligation. Accordingly, we recorded a restructuring expense of \$169,000 in the year 2003.

During the second quarter of 2004, we re-assessed the expected range of probable sublease rates giving consideration to the current market for commercial real estate, the condition of the property, its location, and other relevant factors. It was expected that we could potentially sublease the entire facility (if one was successfully negotiated) for only 45% of our current monthly rental obligation. It was also expected to take a minimum of seven months to find such a tenant. As a result of this analysis, we recorded an additional provision of \$70,000 in the second quarter of 2004. This additional provision was recorded as restructuring expense.

During the third quarter of 2004, we negotiated a settlement of the remaining lease payments with the lessor. As a result of the settlement, we recorded an additional provision of \$37,000 in the third quarter of 2004. This additional provision was recorded as restructuring expense.

The following outlines the restructuring activity recorded to the liability account during the years ended December 31, 2004 and 2003:

	As of	January 1,	Charged to Expense*	Costs Paid	Adjustments to Liability**	As of December 31,
2004:						
Lease termination.....	\$	153,000	\$ 107,000	\$ (255,000)	\$ (5,000)	\$ —
2003:						
One-time termination benefits.....	\$	—	\$ 282,000	\$ (284,000)	\$ 2,000	\$ —
Lease termination.....		—	169,000	(28,000)	12,000	153,000
	\$	—	\$ 451,000	\$ (312,000)	\$ 14,000	\$ 153,000

- \* All amounts recorded as "Restructuring charge" in the accompanying statements of operations.  
 \*\* Revaluation of monetary liability denominated in a foreign currency, which was charged to other income (expense) during the period.

## 12. Long-term Obligations

In 2003, we entered into an Amended Master Security Agreement to provide financing for new equipment purchases. In connection with the agreement, we issued three promissory notes to our lender under the agreement in an aggregate principal amount of approximately \$1,120,000. In 2004, we issued three additional promissory notes in an aggregate principal amount of approximately \$1,039,000 and in 2005, we issued one additional promissory note for an amount of approximately \$1,380,000. All notes are secured by equipment with an aggregate cost of approximately \$3,539,000.

Additional details relating to the above promissory notes are presented in the following table:

<u>Origination Date</u>	<u>Interest Rate</u>	<u>Current Monthly Payment*</u>	<u>Term</u>	<u>Remaining Principal</u>
October 2003	8.6 %	6,000	48 Months	\$ 113,000
October 2003	8.6 %	8,000	36 Months	81,000
October 2003	8.8 %	17,000	48 Months	299,000
March 2004	8.2 %	16,000	48 Months	337,000
April 2004	9.0 %	3,000	48 Months	79,000
September 2004	9.0 %	9,000	48 Months	221,000
December 2005	10.75%	41,765	35 Months	1,380,000
				<u>\$ 2,510,000</u>

\*Includes principal and interest

As of December 31, 2005, the future contractual principal payments on all of our promissory notes are as follows:

### Years Ending December 31,

2006.....	\$ 952,000
2007.....	836,000
2008.....	544,000
2009.....	178,000
Total	<u>\$ 2,510,000</u>

Our interest expense for the years ended December 31, 2005, 2004, and 2003 (all of which related to these promissory notes) was \$137,000, \$177,000 and \$126,000, respectively.

## 13. Income Taxes

Due to our net loss position for the years ended December 31, 2005, 2004 and 2003, and as we recorded a full valuation allowance against deferred tax assets, there was no provision or benefit for income taxes recorded. There were no components of current or deferred federal or state income tax provisions for the years ended December 31, 2005, 2004, and 2003.

A reconciliation of the total income tax provision tax rate to the statutory federal income tax rate of 34% for the years ended December 31, 2005, 2004 and 2003 is as follows:

	<u>2005</u>	<u>2004</u>	<u>2003</u>
Income tax expense (benefit) at federal statutory rate.....	(34.00)%	(34.00)%	(34.00)%
Stock based compensation.....	0.05%	1.54 %	3.38 %
Credits.....	(0.59)%	(3.58)%	(1.99)%
Change in federal valuation allowance.....	23.46%	31.05 %	30.00 %
Equity loss on investment in Joint Venture	5.35%	—	—
Gain on intangible property	4.74%	—	—
Other, net.....	0.99%	4.99 %	2.61 %
	<u>0.00 %</u>	<u>0.00 %</u>	<u>0.00 %</u>

The tax effects of temporary differences that give rise to significant portions of the deferred tax assets and deferred tax liabilities as of December 31, 2005 and 2004 are as follows:

	2005	2004
Deferred tax assets:		
Allowances and reserves .....	\$ 190,000	\$ 46,000
Accrued expenses .....	275,000	251,000
Deferred revenue and gain on sale of assets .....	5,784,000	3,833,000
Stock based compensation .....	1,604,000	1,509,000
Net operating loss carryforwards .....	17,917,000	13,228,000
Income tax credit carryforwards .....	2,195,000	1,517,000
Capitalized assets and other .....	435,000	434,000
	<u>28,400,000</u>	<u>20,818,000</u>
Valuation allowance .....	<u>(27,830,000)</u>	<u>(19,582,000)</u>
Total deferred tax assets, net of allowance .....	<u>570,000</u>	<u>1,236,000</u>
Deferred tax liabilities:		
Property and equipment, principally due to differences in depreciation .....	174,000	(378,000)
Intangibles .....	(738,000)	(845,000)
Other .....	<u>(6,000)</u>	<u>(13,000)</u>
Total deferred tax liability .....	<u>(570,000)</u>	<u>(1,236,000)</u>
Net deferred tax assets (liability) .....	<u>\$ —</u>	<u>\$ —</u>

We have established a valuation allowance against our net deferred tax asset due to the uncertainty surrounding the realization of such assets. Management periodically evaluates the recoverability of the deferred tax asset. At such time as it is determined that it is more likely than not that deferred assets are realizable, the valuation allowance will be reduced. We have recorded a valuation allowance of \$27,830,000 as of December 31, 2005 to reflect the estimated amount of deferred tax assets that may not be realized. We increased our valuation allowance by approximately \$8,213,000 for the year ended December 31, 2005. The valuation allowance includes approximately \$579,000 related to stock option deductions, the benefit of which will, if they are ever utilized, be credited to equity.

At December 31, 2005, we had federal and state tax net operating loss carryforwards of approximately \$42,987,000 and \$33,681,000, respectively. The federal and state net operating loss carryforwards begin to expire in 2019 and 2007, respectively, if unused. At December 31, 2005, we had federal and state tax credit carryforwards of approximately \$1,127,000 and \$1,093,000, respectively. The federal credits will begin to expire in 2017, if unused, and the state credits will begin to expire in 2009 if unused. In addition, we have a foreign tax loss carryforward of \$1,031,000 in Japan.

The Internal Revenue Code limits the future availability of net operating loss and tax credit carryforwards that arose prior to certain cumulative changes in a corporation's ownership resulting in a change of our control. Due to prior ownership changes as defined in IRC Section 382, a portion of the net operating loss and tax credit carryforwards are limited in their annual utilization. In September 1999, we experienced an ownership change for purposes of the IRC Section 382 limitation. As of December 31, 2005, the remaining 1999 pre-change federal net operating loss carryforward of \$973,000 is subject to an annual limitation of approximately \$573,000. It is estimated that the pre-change net operating losses and credits will be fully available by 2007.

Additionally, in 2002 when we purchased StemSource, we acquired federal and state net operating loss carryforwards of approximately \$2,700,000 and \$2,700,000, respectively. This event triggered an ownership change for purposes of IRC Section 382. As of December 31, 2005, this remaining pre-change federal and state net operating loss carryforward of \$960,000 is subject to an annual limitation of approximately \$460,000. It is estimated that the pre-change net operating losses and credits will be fully available by 2008.

We have not updated our analysis for the tax year ended December 31, 2005. The extent of any additional limitation, if any, on the availability to use net operating losses and credits, is not known at this time.

#### 14. Employee Benefit Plan

We implemented a 401(k) retirement savings and profit sharing plan (the "Plan") effective January 1, 1999. We may make discretionary annual contributions to the Plan, which is allocated to the profit sharing accounts based on the number of years of employee service and compensation. At the sole discretion of the Board of Directors, we may also match the participants' contributions to the Plan. We made no discretionary or matching contributions to the Plan in 2005, 2004 and 2003.

#### 15. Stockholders' Equity

##### Preferred Stock

We have authorized 5,000,000 shares of \$.001 par value preferred stock, with no shares outstanding as of December 31, 2005 and 2004. Our Board of Directors is authorized to designate the terms and conditions of any preferred stock we issue without

further action by the common stockholders.

## **Treasury Stock**

On August 11, 2003, the Board of Directors amended the April 3, 2001 authorization to purchase treasury stock and authorized the repurchase of up to 3,000,000 shares of our common stock in the open market, from time to time until August 10, 2004 at a purchase price per share not to exceed €15.00, based on the exchange rate in effect on August 11, 2003. During 2003, we repurchased 614,099 shares of our Common Stock at an average cost of \$3.69 per share for a total of \$2,266,000.

In 2003, we sold 150,500 shares of treasury stock for \$542,000 at an average price of \$3.60 per share. The basis of the treasury stock sold was the weighted average purchase price or \$3.67 per share with the difference of \$10,000 accounted for as a reduction to additional paid-in capital.

On December 6, 2003, we exchanged 1,447,755 shares of common stock (all listed on the Frankfurt Stock Exchange) held in our treasury for 1,447,755 of our unlisted outstanding common stock issued to former StemSource shareholders. \$104,000 was accounted for as a charge against additional paid-in capital relating to the difference between the weighted average purchase price and fair market value of the listed shares held in treasury at the time of the exchange.

In 2004, we repurchased 27,650 shares of our common stock for \$76,000 on the open market at a price of \$2.75 per share. Additionally in 2004, we repurchased 262,602 shares of our common stock for \$976,000 from a former director and officer of StemSource at a price of \$3.72 per share as discussed in note 19.

See also the description in note 18, Related Party Transactions, regarding the repurchase of 375,000 shares from related parties in 2003.

Our repurchase program expired on August 10, 2004. We have no plans to initiate a new repurchase program at this time.

## **16. Stockholders Rights Plan**

On May 28, 2003, the Board of Directors declared a dividend distribution of one preferred share purchase right (a "Right") for each outstanding share of our Common Stock. The dividend is payable to the stockholders of record on June 10, 2003, and with respect to shares of Common Stock issued thereafter until the Distribution Date (as defined below) and, in certain circumstances, with respect to shares of Common Stock issued after the Distribution Date. Except as set forth below, each Right, when it becomes exercisable, entitles the registered holder to purchase from us one one-thousandth (1/1000th) of a share of our Series RP Preferred Stock, \$0.001 par value per share (the "Preferred Stock"), at a price of \$25.00 per one one-thousandth (1/1000th) of a share of Preferred Stock, subject to adjustment. Each share of the Preferred Stock would entitle the holder to Common Stock with a value of twice that paid for the Preferred Stock. The description and terms of the Rights are set forth in a Rights Agreement (the "Rights Agreement") between us and Computershare Trust Company, Inc., as Rights Agent, dated as of May 29, 2003, and as amended on May 12, 2005.

The Rights attach to all certificates representing shares of our Common Stock outstanding, and are evidenced by a legend on each share certificate, incorporating the Rights Agreement by reference. The Rights trade with and only with the associated shares of the Company's Common Stock and have no impact on the way in which holders can trade the Company's shares. Unless the Rights Agreement were to be triggered, it would have no effect on the Company's balance sheet or income statement and should have no tax effect on the Company or its stockholders. The Rights Agreement is triggered upon the earlier to occur of (i) a person or group of affiliated or associated persons having acquired, without the prior approval of the Board, beneficial ownership of 15% or more of the outstanding shares of Common Stock or (ii) 10 days, or such later date as the Board may determine, following the commencement of or announcement of an intention to make, a tender offer or exchange offer the consummation of which would result in a person or group of affiliated or associated persons becoming an Acquiring Person (as defined in the Rights Agreement) except in certain circumstances (the "Distribution Date"). The Rights are not exercisable until the Distribution Date and will expire at the close of business on May 29, 2013, unless we redeem them earlier.

## **17. Stock Based Compensation**

During 2004, we adopted the 2004 Equity Incentive Plan (the "2004 Plan"), which provides our employees, directors and consultants the opportunity to purchase our common stock through non-qualified stock options, stock appreciation rights, restricted stock units, or restricted stock and cash awards. The 2004 Plan initially provides for issuance of 3,000,000 shares of our common stock, which number may be cumulatively increased (subject to Board discretion) on an annual basis beginning January 1, 2005, which increase shall not exceed 2% of our then outstanding stock.

During 1997, we adopted the 1997 Stock Option and Stock Purchase Plan (the "1997 Plan"), which provides for the direct award or sale of shares and for the grant of incentive stock options ("ISOs") and non-statutory options to employees, directors or

consultants. The 1997 Plan, as amended, provides for the issuance of up to 7,000,000 shares of our repurchase program common stock.

The exercise price of ISOs cannot be less than the fair market value of the underlying shares on the date of grant. ISOs can be granted only to employees. Option vesting is determined by the Board of Directors and is generally over a four-year period. Options expire no later than ten years from date of grant.

The following summarizes activity with respect to the options granted under the 2004 and 1997 Plans:

	Years ended December 31,					
	2005		2004		2003	
	Options	Weighted Average Exercise Price	Options	Weighted Average Exercise Price	Options	Weighted Average Exercise Price
Options outstanding at beginning of period .....	5,001,000	\$ 3.92	4,801,000	\$ 3.96	4,263,000	\$ 3.85
Granted .....	1,399,000	\$ 4.20	681,000	\$ 4.14	896,000	\$ 4.26
Exercised .....	(252,000)	\$ 0.69	(42,000)	\$ 0.69	(131,000)	\$ 0.26
Cancelled .....	(363,000)	\$ 4.06	(439,000)	\$ 5.02	(227,000)	\$ 5.13
Options outstanding at end of period .....	<u>5,785,000</u>	\$ 4.12	<u>5,001,000</u>	\$ 3.92	<u>4,801,000</u>	\$ 3.96
Options vested at end of period .....	<u>4,007,000</u>	\$ 4.03	<u>3,609,000</u>	\$ 3.87	<u>3,130,000</u>	\$ 3.78

The following table summarizes information about options outstanding under the 2004 and 1997 Plans as of December 31, 2005:

Range of Exercise Price .....	Options Outstanding	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life in Years	Options Vested	Weighted Average Exercise Price
\$ 0.05 - \$1.90 .....	403,000	\$ 0.29	3.0	403,000	\$ 0.29
\$ 2.50 - 3.00 .....	976,000	\$ 2.91	4.4	927,000	\$ 2.92
\$ 3.09 - 3.88 .....	1,402,000	\$ 3.17	7.4	762,000	\$ 3.19
\$ 4.00 - 5.00 .....	1,684,000	\$ 4.23	7.2	1,093,000	\$ 4.25
\$ 5.10 - 7.50 .....	1,218,000	\$ 6.65	6.8	720,000	\$ 6.95
\$ 8.00 - 17.26 .....	<u>102,000</u>	\$ 12.05	4.8	<u>102,000</u>	\$ 12.05
\$ 0.05 - \$17.26 .....	<u>5,785,000</u>	\$ 4.12	6.4	<u>4,007,000</u>	\$ 4.03

### Unearned Stock Based Compensation

In connection with the grant of stock options to employees and directors, we recorded unearned stock based compensation within stockholders' equity of \$0, \$(13,000), and \$49,000 during the years ended December 31, 2005, 2004 and 2003, respectively. This represents the difference between the exercise price of these stock based awards and the deemed market value of the underlying common stock on the date of grant, reduced by any forfeitures during the period. Amortization of unearned stock based compensation, net of any charges reversed during the period for the forfeiture of unvested awards, was \$0, \$96,000 and \$997,000 for the years ended December 31, 2005, 2004, and 2003, respectively.

There was no remaining unearned stock based compensation at December 31, 2005.

### Employee Stock Based Compensation

In August 2005, our Chief Operating Officer ("COO"), ceased employment with us. We paid the former COO a lump sum cash severance payment of \$155,164 and have extended the post-separation exercise period for two years on 253,743 vested stock options. In addition to the cash severance payment, we have recorded stock based compensation expense of \$337,000 in the third quarter of 2005, which represents the intrinsic value of the options held by the COO at the date of the modification.

### Non-Employee Stock Based Compensation

In the second quarter of 2005, we granted 20,000 shares of restricted common stock to a non-employee scientific advisor. Because the shares granted are not subject to additional future vesting or service requirements, the stock based compensation expense of \$63,000 recorded in the second quarter of 2005 constitutes the entire expense related to this grant, and no future period charges will be required. The stock is restricted only in that it cannot be sold for a specified period of time. There are no vesting requirements. This scientific advisor will also be receiving cash consideration as services are performed. The fair value

of the stock granted was \$3.15 per share based on the market price of our common stock on the date of grant.

We issued 10,000 stock options to a non-employee for consulting services for the year ended December 31, 2004. The fair value per share of these stock options was \$3.17. As a result, we recorded stock based compensation expense of \$32,000 for the year ended December 31, 2004. The expense recorded constitutes the entire expense related to these options, and no future period charges will be required. The fair value of the grant was estimated using the Black-Scholes option-pricing model with the following weighted average assumptions for the year ended December 31, 2004: expected dividend yield of 0.0%, risk-free interest rate of 4.3%, expected volatility factor of 87% and life of 7 years.

### **Warrants**

In connection with our convertible bridge loan financing in 1998 and 1999, we issued warrants to purchase 25,000 shares of Series C convertible preferred stock with an exercise price of \$2.25 per share. Upon conversion of our outstanding preferred stock into common stock, which occurred in August 2000, the warrants became immediately exercisable into shares of our common stock. All of the warrants were to expire in 2008 or 2009. As of December 31, 2004, 2,777 of these warrants were exercised. The remaining 22,223 warrants were exercised in 2005.

## **18. Related Party Transactions**

Refer to note 6 for a discussion of related party transactions with Olympus.

In January 2000, we entered into a five-year distribution agreement with Medtronic. Under the terms of the agreement, we granted Medtronic exclusive worldwide rights, except for certain international rights previously granted, to market, distribute and sell all of our products for use in the cranial and facial areas. In consideration for this exclusive right, Medtronic paid us a \$1,500,000 up-front license fee, which was initially to be recognized ratably over the same five-year period. We concurrently entered into a five-year development and supply agreement with Medtronic, which provided Medtronic exclusive worldwide rights for products developed as a result of the agreement. In connection with the sale of the CMF product line to Medtronic, the terms of this agreement have changed substantially. Moreover, any unrecognized amounts related to the upfront license fee received were recorded as part of gain on sale of assets, related party (see note 3).

Additionally, in January 2000, Medtronic purchased 1,000,000 shares of Series D convertible preferred stock for \$3,500,000. The terms of the sale of the Series D convertible preferred stock were equivalent to the terms and price paid by unaffiliated third parties who also purchased shares of Series D convertible preferred stock. In August 2000, the preferred stock was converted into common stock. Medtronic continues to hold at December 31, 2005, 1,000,000 shares of our common stock, which constitutes approximately 6.5% of our outstanding common stock at December 31, 2005.

For the years ended December 31, 2005, 2004 and 2003, we had sales to Medtronic of \$5,634,000, \$4,085,000 and \$12,893,000, respectively, which represented 93.8%, 59.9% and 91.5% of total product and development revenues, respectively. At December 31, 2005 and 2004, we had amounts due from Medtronic of \$721,000 and \$767,000, respectively.

On December 8, 2003, we repurchased from two of our executives (each a senior officer and a director) and from a trust for the benefit of the family of another senior officer and director, a total of 375,000 shares of common stock for \$1,393,000 in cash (this repurchase was part of the 614,099 share repurchase discussed in note 15). The repurchase price was established by the Board of Directors as 100% of the mean average of the closing sale prices of our common stock on the Frankfurt Stock Exchange over the 10 trading days before the repurchase. We are holding the 375,000 shares as treasury stock.

## **19. Treasury Stock Receivable Contra-Equity Account**

On December 17, 2003, we agreed to repurchase 262,602 shares of common stock for \$975,934 in cash from a former director and officer of StemSource, Inc., who was also a stockholder of StemSource when we acquired StemSource on November 13, 2002. We had issued our common stock to this stockholder (who never became one of our directors, officers or employees) in exchange for his StemSource shares.

All of the shares issued to acquire StemSource, including the 262,602 shares to be repurchased, were unlisted and were not registered for sale in a public market.

As part of the StemSource acquisition agreement, we agreed to list the unlisted shares on a liquid market by December 13, 2003. Although most of our outstanding shares of common stock are listed on the Frankfurt Stock Exchange and the unlisted StemSource acquisition shares would have been eligible for listing on the Frankfurt Stock Exchange, we elected not to apply to list them. At the time of the acquisition, and in late 2003, we held as treasury stock in excess of 1,500,000 listed shares of our common stock. Accordingly, in lieu of listing the shares issued in the StemSource acquisition, we simply exchanged listed treasury shares for the unlisted acquisition shares, before thirteen months following the acquisition date.

In December 2003, logistical problems prevented us from formally delivering the listed securities into all of the respective holders' brokerage accounts. The former director and officer of StemSource, Inc. purported to exercise a contractual right embedded in the StemSource acquisition agreement to put 262,602 shares that he received as part of the StemSource acquisition back to us at a calculated price (approximating market value), as we had not listed and delivered his shares nor delivered the swapped-in listed shares into his brokerage account by the December 13, 2003 deadline. The other former StemSource shareholders either received Frankfurt Stock Exchange-listed shares before the December 13, 2003 deadline or allowed their put right to lapse.

As of December 21, 2003, we had recorded our obligation to repurchase the shares of common stock from the former StemSource owner as a liability included in accounts payable and accrued expenses. We also recorded the shares to be received as Treasury stock receivable, a contra-equity account in 2003. The repurchase was effected in January 2004.

## 20. Subsequent Events

Upon receipt of a CE Mark for the Celution™ System in January 2006, we became entitled to and subsequently received an \$11 million milestone payment from the Joint Venture.

On February 22, 2006, we granted Olympus an exclusive right to negotiate a commercialization collaboration for the use of adipose stem and regenerative cells for a specific therapeutic area outside of cardiovascular disease. In exchange for this right, we will receive a \$1.5 million payment from Olympus, which is non-refundable but may be applied towards any definitive commercial collaboration in the future. As part of this agreement, Olympus will conduct market research and pilot clinical studies in collaboration with us over a 12 to 18 month period for the therapeutic area.

## 21. Quarterly Information (unaudited)

The following unaudited quarterly financial information includes, in management's opinion, all the normal and recurring adjustments necessary to fairly state the results of operations and related information for the periods presented.

	For the three months ended			
	March 31, 2005	June 30, 2005	September 30, 2005	December 31, 2005
Product revenues .....	\$ 1,755,000	\$ 1,477,000	\$ 1,544,000	\$ 858,000
Gross profit .....	1,010,000	739,000	616,000	115,000
Development revenues .....	34,000	64,000	38,000	235,000
Operating expenses, excluding stock based compensation	5,573,000	6,091,000	8,182,000	10,600,000
Stock based compensation .....	—	63,000	341,000	—
Other income .....	2,000	(8,000)	5,581,000	(4,114,000)
Net loss .....	<u>\$ (4,527,000)</u>	<u>\$ (5,359,000)</u>	<u>\$ (2,288,000)</u>	<u>\$ (14,364,000)</u>
Basic and diluted net loss per share .....	<u>\$ (0.32)</u>	<u>\$ (0.37)</u>	<u>\$ (0.15)</u>	<u>\$ (0.96)</u>

	For the three months ended			
	March 31, 2004	June 30, 2004	September 30, 2004	December 31, 2004
Product revenues .....	\$ 2,258,000	\$ 1,528,000	\$ 1,485,000	\$ 1,051,000
Gross profit .....	1,139,000	1,214,000	301,000	284,000
Development revenues .....	94,000	12,000	289,000	101,000
Operating expenses, excluding stock based compensation	4,691,000	4,967,000	4,952,000	4,762,000
Stock based compensation .....	46,000	79,000	—	—
Other income .....	4,994,000	10,000	8,908,000	61,000
Net income (loss) .....	<u>\$ 1,490,000</u>	<u>\$ (3,810,000)</u>	<u>\$ 4,546,000</u>	<u>\$ (4,316,000)</u>
Basic net income (loss) per share .....	<u>\$ 0.11</u>	<u>\$ (0.27)</u>	<u>\$ 0.33</u>	<u>\$ (0.31)</u>
Diluted net income (loss) per share .....	<u>\$ 0.10</u>	<u>\$ (0.27)</u>	<u>\$ 0.31</u>	<u>\$ (0.31)</u>

## Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure

Not applicable.

## Item 9A. Controls and Procedures

Christopher J. Calhoun, our Chief Executive Officer, and Mark E. Saad, our Chief Financial Officer, after evaluating the effectiveness of our "disclosure controls and procedures" (as defined in Securities Exchange Act Rule 13a-15(e)), have concluded that as of December 31, 2005, our disclosure controls and procedures are effective.

**Item 9B. Other Information**

None.

**PART III**

**Item 10. Directors and Executive Officers of the Registrant**

The information called for by Item 10 is incorporated herein by reference to the material under the captions "Election of Directors" and "Directors and Executive Officers of the Registrant" in our proxy statement for our 2006 annual stockholders' meeting, which will be filed with the SEC on or before May 1, 2006.

**Item 11. Executive Compensation**

The information called for by Item 11 is incorporated herein by reference to the material under the caption "Executive Compensation" in our proxy statement for our 2006 annual stockholders' meeting, which will be filed with the SEC on or before May 1, 2006.

**Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters**

The information called for by Item 12 is incorporated herein by reference to the material under the caption "Security Ownership of Certain Beneficial Owners and Management" in our proxy statement for our 2006 annual stockholders' meeting, which will be filed with the SEC on or before May 1, 2006.

**Item 13. Certain Relationships and Related Transactions**

The information called for by Item 13 is incorporated herein by reference to the material under the caption "Compensation and Other Information Concerning Directors and Executive Officers- Certain Relationships and Related Transactions" in our proxy statement for our 2006 annual stockholders' meeting, which will be filed with the SEC on or before May 1, 2006.

**Item 14. Principal Accountant Fees and Services**

The information called for by Item 14 is incorporated herein by reference to the material under the caption "Principal Accountant Fees and Services" in our proxy statement for our 2006 annual stockholders meeting, which will be filed with the SEC on or before May 1, 2006..

**PART IV**

**Item 15. Exhibits and Financial Statement Schedules**

**(a) (1) Financial Statements**

Report of KPMG LLP, Independent Registered Public Accounting Firm

Consolidated Balance Sheets as of December 31, 2005 and 2004

Consolidated Statements of Operations and Comprehensive Loss for the years ended December 31, 2005, 2004 and 2003

Consolidated Statements of Stockholders' Equity (Deficit) for the years ended December 31, 2005, 2004 and 2003

Consolidated Statements of Cash Flows for the years ended December 31, 2005, 2004 and 2003

Notes to Consolidated Financial Statements

## SCHEDULE II – VALUATION AND QUALIFYING ACCOUNTS

For the years ended December 31, 2005, 2004 and 2003  
(in thousands of dollars)

	Balance at beginning of year	Additions/(Reductions) ((charges)/ credits to expense)	Charged to Other Accounts	Deductions	Balance at end of year
<u>Allowance for doubtful accounts</u>					
Year ended December 31, 2005 .....	\$ 8	\$ 1	\$ —	\$ —	\$ 9
Year ended December 31, 2004 .....	\$ 62	\$ (44)	\$ —	\$ 10	\$ 8
Year ended December 31, 2003 .....	\$ 50	\$ 15	\$ —	\$ 3	\$ 62

## Table of Contents

## (a)(3) Exhibits

Exhibit Number	Description
3.1	Amended and Restated Certificate of Incorporation (filed as Exhibit 3.1 to our Form 10-Q Quarterly Report as filed on August 13, 2002 and incorporated by reference herein)
3.2	Amended and Restated Bylaws of Cytori Therapeutics, Inc. (filed as Exhibit 3.2 to our Form 10-Q Quarterly Report, as filed on August 14, 2003 and incorporated by reference herein)
3.3	Certificate of Ownership and Merger (effecting name change to Cytori Therapeutics, Inc.) (filed as Exhibit 3.1.1 to our Form 10-Q, as filed on November 14, 2005 and incorporated by reference herein)
4.1	Rights Agreement, dated as of May 19, 2003, between Cytori Therapeutics, Inc. and Computershare Trust Company, Inc. as Rights Agent, which includes: as Exhibit A thereto, the Form of Certificate of Designation, Preferences and Rights of Series RP Preferred Stock of Cytori Therapeutics, Inc.; as Exhibit B thereto, the Form of Right Certificate; and, as Exhibit C thereto, the Summary of Rights to Purchase Series RP Preferred Stock (filed as Exhibit 4.1 to our Form 8-A which was filed on May 30, 2003 and incorporated by reference herein)
4.2	Amendment No. 1 to Rights Agreement dated as of May 12, 2005, between Cytori Therapeutics, Inc. and Computershare Trust Company, Inc. as Rights Agent (filed as Exhibit 4.1.1 to our Form 8-K, which was filed on May 18, 2005 and incorporated by reference herein).
10.1#	Amended and Restated 1997 Stock Option and Stock Purchase Plan (filed as Exhibit 10.1 to our Form 10 registration statement, as amended, as filed on March 30, 2001 and incorporated by reference herein)
10.2+	Development and Supply Agreement, made and entered into as of January 5, 2000, by and between the Company and Medtronic (filed as Exhibit 10.4 to our Form 10 registration statement, as amended, as filed on June 1, 2001 and incorporated by reference herein)
10.3+	Amendment No. 1 to Development and Supply Agreement, effective as of December 22, 2000, by and between the Company and Medtronic (filed as Exhibit 10.5 to our Form 10 registration statement, as amended, as filed on June 1, 2001 and incorporated by reference herein)
10.4+	License Agreement, effective as of October 8, 2002, by and between the Company and Medtronic PS Medical, Inc. (filed as Exhibit 2.2 to our Current Report on Form 8-K which was filed on October 23, 2002 and incorporated by reference herein)
10.5+	Amendment No. 2 to Development and Supply Agreement, effective as of September 30, 2002, by and between the Company and Medtronic, Inc. (filed as Exhibit 2.4 to our Current Report on Form 8-K which was filed on October 23, 2002 and incorporated by reference herein)
10.6+	Exclusive License Agreement, effective October 16, 2001, by and between The Regents of the University of California and StemSource, Inc. (the Company was substituted for StemSource in the agreement effective November 8, 2002) (filed as Exhibit 10.10 to our Annual Report on Form 10-K which was filed on March

- 31, 2005 and incorporated by reference herein)
- 10.7 Amended Master Security Agreement between the Company and General Electric Corporation, September, 2003 (filed as Exhibit 10.1 to our Form 10-Q Quarterly Report, as filed on November 12, 2003 and incorporated by reference herein)
- 10.8# Asset Purchase Agreement dated May 7, 2004 between Cytori Therapeutics, Inc. and MAST Biosurgery AG (filed as Exhibit 2.1 to our Form 8-K Current Report, as filed on May 28, 2004 and incorporated by reference herein.)
- 10.8.1 Settlement Agreement dated August 9, 2005, between MAST Biosurgery AG, MAST Biosurgery, Inc. and the Company (filed as Exhibit 10.26 to our Form 10-Q, which was filed on November 14, 2005 and incorporated by reference herein)
- 10.9# Offer Letter for the Position of Chief Financial Officer dated June 2, 2004 between the Company and Mark Saad (filed as Exhibit 10.18 to our Form 10-Q Quarterly Report, as filed on August 16, 2004 and incorporated by reference herein)
- 10.10# 2004 Equity Incentive Plan of Cytori Therapeutics, Inc. (filed as Exhibit 10.1 to our Form 8-K Current Report, as filed on August 27, 2004 and incorporated by reference herein)
- 10.11 Exclusive Distribution Agreement, effective July 16, 2004 by and between the Company and Senko Medical Trading Co. (filed as Exhibit 10.25 to our Form 10-Q Quarterly Report, as filed on November 15, 2004 and incorporated by reference herein)
- 10.12# Notice and Agreement for Stock Options Grant Pursuant to Cytori Therapeutics, Inc. 1997 Stock Option and Stock Purchase Plan; (Nonstatutory) (filed as Exhibit 10.19 to our Form 10-Q Quarterly Report, as filed on November 15, 2004 and incorporated by reference herein)
- 10.13# Notice and Agreement for Stock Options Grant Pursuant to Cytori Therapeutics, Inc. 1997 Stock Option and Stock Purchase Plan; (Nonstatutory) with Cliff (filed as Exhibit 10.20 to our Form 10-Q Quarterly Report, as filed on November 15, 2004 and incorporated by reference herein)
- 10.14# Notice and Agreement for Stock Options Grant Pursuant to Cytori Therapeutics, Inc. 1997 Stock Option and Stock Purchase Plan; (Incentive) (filed as Exhibit 10.21 to our Form 10-Q Quarterly Report, as filed on November 15, 2004 and incorporated by reference herein)
- 10.15# Notice and Agreement for Stock Options Grant Pursuant to Cytori Therapeutics, Inc. 1997 Stock Option and Stock Purchase Plan; (Incentive) with Cliff (filed as Exhibit 10.22 to our Form 10-Q Quarterly Report, as filed on November 15, 2004 and incorporated by reference herein)
- 10.16# Form of Options Exercise and Stock Purchase Agreement Relating to the 2004 Equity Incentive Plan (filed as Exhibit 10.23 to our Form 10-Q Quarterly Report, as filed on November 15, 2004 and incorporated by reference herein)
- 10.17# Form of Notice of Stock Options Grant Relating to the 2004 Equity Incentive Plan (filed as Exhibit 10.24 to our Form 10-Q Quarterly Report, as filed on November 15, 2004 and incorporated by reference herein)
- 10.18# Separation Agreement and General Release dated July 15, 2005, between John K. Fraser and the Company (filed as Exhibit 10.25 to our Form 10-Q, which was filed on November 14, 2005 and incorporated by reference herein)
- 10.19# Consulting Agreement dated July 15, 2005, between John K. Fraser and the Company (filed as Exhibit 10.28 to our Form 10-Q, which was filed on November 14, 2005 and incorporated by reference herein)
- 10.20 Agreement Between Owner and Contractor dated October 10, 2005, between Rudolph and Sletten, Inc. and the Company (filed herewith)
- 10.21# Severance Agreement and General Release dated August 10, 2005, between Sharon V. Schulzki and the Company (filed as Exhibit 10.27 to our Form 10-Q, which was filed on November 14, 2005 and

incorporated by reference herein)

- 10.22 Common Stock Purchase Agreement dated April 28, 2005, between Olympus Corporation and the Company (filed as Exhibit 10.21 to our Form 10-Q, which was filed on August 15, 2005 and incorporated by reference herein)
- 10.23 Sublease Agreement dated May 24, 2005, between Biogen Idec, Inc. and the Company (filed as Exhibit 10.21 to our Form 10-Q, which was filed on August 15, 2005 and incorporated by reference herein)
- 10.24# Employment Offer Letter to Doug Arm, Vice President of Development—Biologics, dated February 1, 2005 (filed as Exhibit 10.21 to our Form 10-Q, which was filed on August 15, 2005 and incorporated by reference herein)
- 10.25# Employment Offer Letter to Alex Milstein, Vice-President of Clinical Research, dated May 1, 2005 (filed as Exhibit 10.21 to our Form 10-Q, which was filed on August 15, 2005 and incorporated by reference herein)
- 10.26# Employment Offer Letter to Vice-President of Research, dated November 15, 2005 (filed herewith)
- 10.27+ Joint Venture Agreement dated November 4, 2005, between Olympus Corporation and the Company (filed herewith)
- 10.28+ License/ Commercial Agreement dated November 4, 2005, between Olympus-Cytori, Inc. and the Company (filed herewith)
- 10.29+ License/ Joint Development Agreement dated November 4, 2005, between Olympus Corporation, Olympus-Cytori, Inc. and the Company (filed herewith)
- 10.30+ Shareholders Agreement dated November 4, 2005, between Olympus Corporation and the Company (filed herewith)
- 14.1 Code of Ethics (filed as Exhibit 14.1 to our Annual Report on Form 10-K which was filed on March 30, 2004 and incorporated by reference herein)
- 23.1 Consent of KPMG LLP, Independent Registered Public Accounting Firm (filed herewith).
- 31.1 Certification of Principal Executive Officer Pursuant to Securities Exchange Act Rule 13a-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 (filed herewith).
- 31.2 Certification of Principal Financial Officer Pursuant to Securities Exchange Act Rule 13a-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 (filed herewith).
- 32.1 Certifications Pursuant to 18 U.S.C. Section 1350/ Securities Exchange Act Rule 13a-14(b), as adopted pursuant to Section 906 of the Sarbanes – Oxley Act of 2002 (filed herewith).

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+ Portions of these exhibits have been omitted pursuant to a request for confidential treatment.

# Indicates management contract or compensatory plan or arrangement.

## SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this registration statement to be signed on its behalf by the undersigned, thereunto duly authorized.

### CYTORI THERAPEUTICS, INC.

By: /s/ Christopher J. Calhoun  
 Christopher J. Calhoun  
 Chief Executive Officer  
 March 30, 2006

Pursuant to the requirements of the Securities Exchange Act of 1934, this annual report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

SIGNATURE	TITLE	DATE
<u>/s/ Marshall G. Cox</u> Marshall G. Cox	<i>Chairman of the Board of Directors</i>	March 30, 2006
<u>/s/ Christopher J. Calhoun</u> Christopher J. Calhoun	<i>Chief Executive Officer, Director (Principal Executive Officer)</i>	March 30, 2006
<u>/s/ Marc H. Hedrick, MD</u> Marc H. Hedrick, MD	<i>President, Director</i>	March 30, 2006
<u>/s/ Mark E. Saad</u> Mark E. Saad	<i>Chief Financial Officer (Principal Financial Officer)</i>	March 30, 2006
<u>/s/ Charles E. Galetto</u> Charles E. Galetto	<i>Senior Vice President of Finance (Principal Accounting Officer)</i>	March 30, 2006
<u>/s/ David M. Rickey</u> David M. Rickey	<i>Director</i>	March 30, 2006
<u>/s/ Ronald D. Henriksen</u> Ronald D. Henriksen	<i>Director</i>	March 30, 2006
<u>/s/ E. Carmack Holmes, MD</u> E. Carmack Holmes, MD	<i>Director</i>	March 30, 2006
<u>/s/ Paul W. Hawran</u> Paul W. Hawran	<i>Director</i>	March 30, 2006

