CRYO CELL INTERNATIONAL INC
Form 10KSB
February 25, 2005

U.S. Securities and Exchange Commission

Washington, D.C. 20549

FORM 10-KSB

x ANNUAL REPORT UNDER SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934.

For the fiscal year ended November 30, 2004

¨ TRANSITION REPORT UNDER SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934.

For the transition period from to

Commission File Number 000-23386

CRYO-CELL INTERNATIONAL, INC.

(Exact Name of Small Business Issuer as specified in its charter)

DELAWARE	**22-3023093**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**

700 Brooker Creek Blvd, Suite 1800, Oldsmar, FL 34677

(Address of principal executive offices) (Zip Code)

Issuer s telephone number: (813) 749-2100

Securities registered pursuant to Section 12 (b) of the Act:

Title of each class
None

Securities registered pursuant to Section 12 (g) of the Act:

Common Stock, par value $.01 per share

(Title of class)

Check whether Issuer: (1) has filed all reports required to be filed by section 13 or 15 (d) of the Securities and Exchange Act of 1934 during the past 12 months and (2) has been subject to such filing requirements for the past 90 days. Yes x No ¨

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

Issuer s Revenues for its most recent fiscal year: $12,210,273.

As of February 15, 2005 the aggregate market value of the voting stock held by non-affiliates of the Issuer was approximately $38,983,277. The market value of Common Stock of the Issuer, par value $0.01 per share, was computed by reference to the average of the closing bid and asked prices of the Issuer s Common Stock on such date.

The number of shares outstanding of the Issuer s Common Stock, par value $0.01 per share, as of February 25, 2005: 11,550,379.

DOCUMENTS INCORPORATED BY REFERENCE

The information required by Part III of Form 10-KSB is incorporated by reference to the Issuer s definitive proxy statement relating to the 2005 Annual Meeting of Shareholders or included in an amendment to this Form 10-KSB, which will be filed with Securities and Exchange Commission on or before March 30, 2005.

Transitional Small Business Disclosure Format (check one): Yes ¨; No x

FORWARD LOOKING STATEMENTS

This Form 10-KSB, press releases and certain information provided periodically in writing or orally by the Company s officers or its agents may contain statements which constitute forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended and Section 21E of the Securities Exchange Act of 1934. The terms CRYO-CELL International, Inc., CRYO-CELL Company, we, our and refer to CRYO-CELL International, Inc. The words expect, believe, goal, plan, intend, estimate and similar expressions and variations the used, are intended to specifically identify forward-looking statements. Those statements appear in a number of places in this Form 10-KSB and in other places, particularly, Management s Discussion and Analysis of Financial Condition or Plan of Operation, and include statements regarding the intent, belief or current expectations of the Company, its directors or its officers with respect to, among other things:

(i) our future performance and operating results;

(ii) our future operating plans;

(iii) our liquidity and capital resources; and

(iv) our legal proceedings;

Investors and prospective investors are cautioned that any such forward-looking statements are not guarantees of future performance and involve risks and uncertainties, and that actual results may differ materially from those projected in the forward-looking statements as a result of various factors. The factors that might cause such differences include, among others, the following:

(i) any adverse effect or limitations caused by recent increases in government regulation of stem cell storage facilities;

(ii) any increased competition in our business;

(iii) any decrease or slowdown in the number of people seeking to store umbilical cord blood stem cells or decrease in the number of people paying annual storage fees;

(iv) any adverse impacts on revenue or operating margins due to the costs associated with increased growth in our business, including the possibility of unanticipated costs relating to the operation of our new facility;

(v) any technological breakthrough that would render the Company s business of stem cell preservation obsolete;

(vi) any material failure or malfunction in our storage facilities; any natural disaster such as a tornado, other disaster (fire) or act of terrorism that adversely affects stored specimens; the costs associated with defending or prosecuting litigation matters and any material adverse result for such matters;

(vii) any decreases in asset valuations; any continued negative effect from adverse publicity in the past year regarding the Company s business operations;

(viii) any negative consequences resulting from deriving, shipping and storing specimens at a second location;

(ix) any negative effect from the filed class action shareholder lawsuits; and

(x) other risks and uncertainties.

We undertake no obligation to publicly update or revise the forward-looking statements made in this Form 10-KSB to reflect events or circumstances after the date of this Form 10-KSB or to reflect the occurrence of unanticipated events.

Readers are cautioned not to place undue reliance on these forward-looking statements, which reflect management s analysis only as of the date hereof. CRYO-CELL International, Inc. (the Company) undertakes no obligation to publicly revise these forward-looking statements to reflect events or circumstances that arise after the date hereof. Readers should carefully review the risk factors described in other documents the Company files from time to time with the Securities and Exchange Commission, including the Quarterly Reports on Form 10-QSB filed by the Company and any Current Reports on Form 8-K filed by the Company.

Part I

ITEM 1. DESCRIPTION OF BUSINESS

Introduction

CRYO-CELL International, Inc. (the Company or CRYO-CELL) was incorporated on September 11, 1989 in the state of Delaware. The Company is engaged in cryogenic cellular storage, with a focus on the processing and preservation of umbilical cord (U-Cord) blood stem cells for autologous/sibling use. The Company believes it is the world s largest private cord blood stem cell bank in terms of the number of specimens preserved. Its headquarters facility in Oldsmar, Florida handles all aspects of its business operations including the processing and storage of specimens. The specimens are stored in commercially available cryogenic storage equipment. Several other companies involved in commercial cell banking rely on shipping their specimens elsewhere for processing and storage.

It is the Company s mission to make expectant parents aware of the potential medical benefits from preserving stem cells and to provide them the means and processes for collection and storage of these cells. Today, stem cell transplants are known and accepted treatments for a number of life-threatening diseases. With continued research in this area of medical technology, other avenues for their potential use are being explored. A vast majority of expectant parents are simply unaware that umbilical cord blood contains a rich supply of stem cells and that they can be collected, processed and stored for the potential future use of the newborn and possibly related family members. A baby s stem cells will remain a perfect match for the baby throughout its life and have a 1-in-4 chance (or better) of being a perfect match for a sibling. There is no assurance, however, that a perfect match means the cells could be used to treat certain diseases. Today, it is still common for the cord blood (the blood remaining in the umbilical cord and placenta) to be discarded at the time of birth as medical waste.

Despite the potential benefits of U-Cord stem cell preservation, the number of parents of newborns participating in stem cell preservation is still relatively small compared to the number of births (four million per annum) in the United States. Some reasons for this low level of market penetration are the misperception of the high cost of stem cell storage and a general lack of awareness of the benefits of stem cell preservation programs. However, evolving medical technology could significantly increase the utilization of the U-Cord blood for transplantation and/or other types of treatments. The Company believes it offers the highest quality, highest value service targeted to a broad base of the market. The Company anticipates the growth and profitability of the Company should come from increases in stem cell specimen storage volume driven by its value-driven competitive leadership position; a fast-growing embedded client base; expanded consumer and professional channels; increased public awareness and accelerated market penetration.

Background

Nearly fifty years ago researchers discovered that cells could be cryopreserved at extremely low temperatures and all cellular activity would cease until the specimens were thawed. Historically, cryopreservation was required for organ transplants, blood banking and medical research. Today, cryopreservation of umbilical cord blood stem cells gives expectant parents the opportunity to potentially take advantage of evolving cellular therapies and other medical technologies.

Cell Banking

Hematopoeitic stem cells are the building blocks of our blood and immune systems. They form the white blood cells that fight infection, red blood cells that carry oxygen throughout the body and platelets that promote healing. Stem cells are found in bone marrow where they continue to generate cells throughout our lives. Stem cells can be stored in a cryogenic environment, and upon thawing,

infused into a patient. They can be returned to the individual from whom they were taken (autologous) or donated to someone else (allogeneic). The opportunity to use an individual s own bone marrow for a transplant is dependent upon whether the cancer has entered the marrow system (metastasized). Otherwise, a marrow donor needs to be identified to provide the needed bone marrow. The availability of a marrow donor or matched stem cell specimen allows physicians to administer larger doses of chemotherapy or radiation in an effort to eradicate the disease. Stem cell therapies and transplants are used for both cancerous and non-cancerous diseases.

Stem cells are found in umbilical cord blood and placental blood (cord blood stem cells) that can be collected and stored after a baby is born. Recent advances have provided the techniques to separate the stem cells found in these two sources. Over 3,000-cord blood stem cell transplants have been performed to date. The Company believes that parents will want to save and store these cells for potential future use by their family. These stem cells also have at least a one in four chance of being compatible for use by a sibling. Moreover, researchers believe they may be utilized in the future by parents for treating diseases that currently have no cure as a result of evolving cellular expansion technologies.

The Company believes that the market for cord blood stem cells is enhanced by the national discussion on stem cell research developments and the current focus on reducing prohibitive health care costs. With the increasing costs of bone marrow matches and transplants, a newborn s U-Cord cells are stored as a precautionary measure. Medical technology is constantly evolving which may provide new uses for cryopreserved cord blood stem cells.

Cellular Storage Services

In November 2004, the Company relocated its corporate headquarters to a newly constructed, nearly 18,000 square-foot state-of-the-art current Good Manufacturing Practice and Good Tissue Practice (cGMP/cGTP)-compliant facility. Food and Drug Administration (FDA) 21 CFR Part 1271, a new federal regulation with an anticipated effective date of May 2005, requires human cellular and tissue-based products to be manufactured in compliance with good tissue practices (cGTPs). The Company s new laboratory processing facility boasts a class 10,000 clean room and class 100 environments for the processing of cord blood stem cells and other cellular tissues. In addition, the cellular products cryogenic storage area has been designed as a bunker , with enhanced provisions for security, building fortification for environmental element protection and back-up systems for operational redundancies. CRYO-CELL is the first private bank to process cord blood in a technologically and operationally advanced cGMP/cGTP-compliant facility.

The newly constructed facility, which also houses the Company s clinical services, marketing and administrative operations, is designed and appointed to accommodate a broad range of market-facing events such as client tours and open houses, as well as clinician and expectant parent educational workshops. Building public awareness for clinicians and families on the significant benefits of umbilical cord blood stem cell preservation continues to be a major initiative for CRYO-CELL.

The Company currently stores over 75,000 cord blood stem cell specimens in Oldsmar, Florida for the exclusive use of those families who have elected to preserve them with CRYO-CELL. Approximately 25,000 of these specimens are split specimens, for which we store a duplicate specimen at a secondary storage facility in Sedona, Arizona. The Company believes it is the world s largest private cord blood stem cell bank in terms of the number of specimens preserved. The Company utilizes a strategy of offering its high quality U-Cord service at superior value to its clients. The Company provides several other key competitive advantages: a state-of-the-art laboratory processing facility, a safe, secure and monitored storage environment, demonstrated success in the transplant of processed specimens, 7 day per week processing capability, a 24 hour, 7 day per week clinical support staff to assist clients and medical caregivers, high-value pricing and beginning in December 2004, the option of participating in Upromise®, a nationally recognized 529 registered college savings plan that gives clients money back for college.

The Company has a seven member Medical and Scientific Advisory Board, with Michael Trigg, M.D. as its Chairman. Dr. Trigg is Chief, Division of Blood & Bone Marrow Transplantation, Alfred I. duPont Hospital for Children (Wilmington, DE) and Professor of Pediatrics, Jefferson Medical College of Thomas Jefferson University. Dr. Trigg is an internationally renowned pediatric marrow transplant surgeon, distinguished for his ability to treat very high-risk patients. He also chairs the Acute Lymphoblastic Leukemia (ALL) Open Trials Committee, a sub-group of the ALL Strategy Group, for the Children s Oncology Group, the largest worldwide cooperative group for the treatment of children with cancer and leukemia. The Company believes that Dr. Trigg s expertise and leadership in pediatric bone marrow transplantation serves to strengthen public awareness and education related to cord blood preservation and contributes to the Company s expansion of client and professional channels as well the Company s establishment of new strategic alliances.

Marketing

The Company enters into storage agreements with its customers under which the Company charges a fee for the initial blood collection kit sent to the expectant parents, the processing of the umbilical cord blood and the extraction of the stem cells for storage, and the first year s storage of the stem cells. Thereafter, the client is charged an annual fee to store the specimen.

The Company markets its preservation services directly to expectant parents and by distributing information through obstetricians, pediatricians, Lamaze instructors and other childbirth educators, certified nurse-midwives and other related healthcare professionals. The Company s clinical support team of specially trained R.N.s and L.P.Ns. are available 24 hours, 7 days a week to enroll clients and educate both expectant parents and the medical community on the life-saving potential of cord blood stem cell preservation.

The Company s growth has been facilitated by a variety of referral sources, resulting from a high degree of customer satisfaction. Sources of new expectant parent referrals during 2004 were provided by physicians, midwives and childbirth educators, and by client-to-client referrals and repeat clients storing the stem cells of their additional children. This strong referral base has permitted the Company to grow without some of the traditional, more expensive marketing approaches such as a dedicated field sales force. The Company invests in marketing strategies that serve to increase the awareness of its services with expectant parents and to other groups who provide advice to expectant parents such as medical caregivers and hospital personnel.

During 2004, the Company increased its marketing activities with its clinical referral sources, including physicians, midwives and hospitals. Promotional activities were launched that included advertisements in several clinical journals and telemarketing activities. In addition, the Company exhibited at conferences, trade shows and other meetings attended by medical professionals. Significant portions of client referrals to the Company are from medical caregiver professionals.

The Company continues to use its Web site, www.cryo-cell.com, to market its services and to provide resource information to expectant parents. The site, which is continually being updated and improved, is divided into areas of interest, including sections for expectant parents, medical caregivers and investors. Expectant parents may request and receive information about the U-Cord service and download enrollment forms. Viewers may also tour CRYO-CELL facilities, read about CRYO-CELL s successful transplants, and access other topical information.

To increase awareness among expectant parent audiences, the Company continues to promote its service in several national targeted prenatal magazines including American Baby, Fit Pregnancy, and ePregnancy, as well as several magazines distributed during childbirth classes. Expectant parents have also received information via emails and newsletter links through BabyCenter.com, an important on-line educational resource for expectant mothers and fathers.

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Competition

Growth in the number of families banking their newborn s cord blood stem cells has been accompanied by an increasing landscape of competitors. The Company competes against numerous local, regional and national companies. Some of these companies, such as Corcell, California Cryo-Bank, Cord Blood Registry, Inc. and Viacord are competitors who as privately owned entities, can leverage considerable resources to market and sell their services. These companies, along with other competitors, charge substantially more for comparable quality service. In addition to the Company s industry recognized American Association of Blood Banks (AABB) accreditation, the Company believes that it is the first private cord blood bank to process in a cGMP and cGTP-compliant facility which positions the Company well in the market, and ahead of emerging regulation. The Company believes it offers the most superior value of highest quality cryo-preservation processing and storage in the industry.

The Company also competes with various public cord blood banks that encourage parents to donate their newborn s cord blood rather than privately bank it. Although this option is generally no-cost to the parents, there is no assurance that the newborn s cells would be available to the family, if they were needed. The Company believes that the distinctive benefits of private cord blood banking clearly differentiate its service offer from that of public cord banks.

The Company believes that its longevity and experience; value-based pricing strategy; superior customer service supported by a 24/7 professional nurse staff; premier technical and operational expertise; state-of-the-art facilities; innovative marketing programs and its expansive client base will continue to provide a competitive advantage.

Research, Development and Related Engineering

The Company has incurred costs of $82,509 during fiscal 2004, compared to $234,374 during fiscal 2003, on research, development and related engineering expenses.

Government Regulation

The Company is required to register with the FDA under the Public Health Service Act because of its ongoing cellular storage business. This requirement applies to all establishments engaged in the recovery, processing, storage, labeling, packaging, or distribution of any Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps) or the screening or testing of a cell or tissue donor. The Company voluntarily registered with the FDA in January 2003 and has successfully updated that registration for 2005, thus meeting this compliance requirement.

In June 1998, the Company was granted a license to operate in the state of New York. The New York Department of Health approved the Company s application to operate as a comprehensive tissue procurement service, processing and storage facility. This license allows the Company to offer its cord blood stem cell storage services to the residents of New York.

In September 1999, the Company was granted a Blood Bank license to collect cord blood in the State of New Jersey. The Company has applied for a license in the State of Maryland. If the Company identifies other states with licensing requirements or if other states adopt such requirements, the Company would have to obtain licenses or registration to continue providing cord blood services in those states.

Evolving legislation and regulations governing private cord blood banking in various jurisdictions throughout the world may impact the Company s international licensees.

The Company believed until February 2004 that it was subject to regulation as a medical device manufacturer because of its development and manufacture of its proprietary storage systems technology. As a result of the Board of Directors decision in January 2004 to discontinue further investment in and utilization of the technology, the Company does not believe it continues to be a medical device manufacturer. After this decision was made, but before the Company had notified FDA and requested a cancellation of its registration and listing the Company underwent a previously-scheduled routine inspection by the FDA in early February 2004. The Company received an FDA Form 483, a written list of inspectional observations. The formal response to the list of observations was sent to the Florida District Director, on February 23, 2004, with a complete description of corrective actions undertaken. In February 2004 the Company requested FDA to cancel its device manufacture registration and device listing. The Company received verbal confirmation from the FDA in February 2004 that it was no longer registered as a medical device manufacturer.

Subsidiaries and Joint Ventures

Since its inception, CRYO-CELL has entered into a number of business activities through subsidiaries and joint ventures, including the following activities and those described under International below. CRYO-CELL has de-emphasized certain of these activities in recent periods in connection with the Board of Directors strategic decision to focus the Company s priorities and resource on its core business of marketing cord blood stem cell preservation services. In the future, the Company will evaluate and pursue certain opportunities, on a selective basis, in which operational synergies and economic potential align with CRYO-CELL s strategic direction.

Saneron CCEL Therapeutics, Inc. The Company owns an approximate 42% interest in Saneron CCEL Therapeutics, Inc. (Saneron). Saneron has exclusively licensed from the University of South Florida at Tampa (the University) various patents and patent applications for the therapeutic use of Sertoli cells. The Company received its interest in Saneron in October 2001 through the merger of a subsidiary of the Company into Saneron and the Company s contribution of various assets in exchange for the Saneron shares.

In September 2002, Saneron and the University were awarded a Florida High Tech Corridor grant in the amount of $131,000 to conduct research on the use of Sertoli cells and collagen matrices to treat peripheral nerve injury. Also in September 2002, Saneron, StemCo Biomedical, Inc. and the University were awarded a Florida High Tech Corridor grant to conduct research on the use of a subset population of umbilical cord to treat Lou Gehrig s disease. In September 2003, Saneron was awarded two grants, Sertoli Cell-Treated Umbilical Cord Blood for Stroke and Spinal Cord Repair with Human Umbilical Cord Blood Cells. The two grants total approximately $285,000. During December 2004, Saneron and the University were awarded a Small Business Innovation Research (SBIR) grant from the National Institutes of Health (NIH) to develop Sertoli cells combined with stem cells from cord blood for possible treatment of spinal cord injury. The $150,000 grant is the latest in a series of six SBIR/STTR grants in which Saneron and USF have collaborated on their efforts to create cellular therapies for neurological disorders.

Safti-Cell, Inc. In October 2001, the Company sold 90% of Safti-Cell, Inc. (Safti-Cell), a then-inactive subsidiary of the Company, to Red Rock Partners, an Arizona general partnership. Mr. Charles Nyberg, a former member of the Board of Directors of the Company, owns a significant interest in Red Rock Partners; however, the sale took place prior to the time that Mr. Nyberg became a member of the Company s Board of Directors. Subsequent to the end of fiscal 2004, Mr. Nyberg resigned from the Company s Board of Directors. In October 2001, the Company and Safti-Cell entered into a twenty-year storage agreement under which the Company pays an annual fee to Safti-Cell for each specimen stored by Safti-Cell in its Arizona facility for the Company s customers. In October 2002, Safti-Cell brought the facility into service, and the Company began providing dual storage service to its customers. The Company currently stores approximately 25,000 split specimens at the Safti-Cell facility. In 2005, the

Company expects to implement a new processing methodology in accordance with emerging requirements of the American Association of Blood Banks (AABB). The new process will utilize closed-system bags rather than vial storage. In view of this anticipated transition to a new processing methodology, as well as, the enhanced level of security designed in the Company s new facility, the Company expects that sometime in 2005, it will discontinue offering the dual storage service to new customers.

Stem Cell Preservation Technologies, Inc. Stem Cell Preservation Technologies, Inc. (SCPT), a subsidiary of the Company, was a development stage company, which was to be involved in the development of marketing programs for the collection and preservation of adult stem cells.

On January 29, 2004, CRYO-CELL announced the decision to close SCPT, following the resignation of SCPT s Board of Directors and management, and advised the CRYO-CELL shareholders that the spin-off would not be completed. CRYO-CELL rejected restructuring proposals made by SCPT s management. SCPT s management proposed to repurchase the SCPT stock held by CRYO-CELL, so that SCPT would not longer be a subsidiary of CRYO-CELL. CRYO-CELL s Board of Directors formed a special sub-committee to consider the restructuring proposals presented by SCPT s management. CRYO-CELL concluded that SCPT required significant additional funding to complete the repurchase and to remain in operation, and SCPT s proposals all would have required CRYO-CELL to make significant cash expenditures. In rejecting the SCPT proposals, CRYO-CELL s investment to date in SCPT, the failure of SCPT management to submit acceptable business plans, and the need for CRYO-CELL to conserve its capital for its core business were all considered. CRYO-CELL had no assurance that SCPT had concrete credible operational, marketing, or financing plans. CRYO-CELL owned 11,500,000 (86.6%) shares of SCPT. In accordance with SFAS No. 144, Accounting for the Impairment or Disposal of Long-Lived Assets, (SFAS No. 144) the closing of SCPT represents a discontinued operation as reflected in the November 30, 2004 consolidated financial statements. For comparative purposes, the earnings of SCPT has been reclassified in the Company s statements of operations and comprehensive income (loss) as discontinued operations for the twelve months ended November 30, 2003. The net assets of SCPT are immaterial to the consolidated financial statements.

During 2004, SCPT paid all outstanding liabilities to employees and other creditors including the loan in the amount of $195,000 plus accrued interest to the shareholder of SCPT. In April 2004, the Board of Directors of SCPT approved a liquidating distribution of the remaining assets of SCPT to the holders of SCPT common stock. After payment of SCPT s remaining debts, SCPT s remaining assets consisted solely of shares of common stock of CRYO-CELL. In order to facilitate the liquidating distribution, CRYO-CELL agreed to repurchase the CRYO-CELL shares from SCPT for a cash price of $.75 per share, the average price per share for CRYO-CELL common stock reported on the OTC Bulletin Board for the twenty trading days prior to April 30, 2004. After the repurchase of CRYO-CELL common stock, SCPT s remaining assets consisted of $138,035 in cash, which was equal to approximately $.01 per share of SCPT common stock. This cash was distributed to SCPT s shareholders, including CRYO-CELL, in May 2004.

Revenue Sharing Agreements

The Company has entered into Revenue Sharing Agreements (RSAs) with various third parties. The Company s RSAs provide that in exchange for a non-refundable up-front payment, the Company would share for the duration of the contract a percentage of its future revenue derived from the annual storage fees charged related to a certain number of specimens that originated from specific geographical areas. The RSAs have no definitive term or termination provisions. The sharing applies to the storage fees for all specified specimens in the area up to the number covered in the contract. When the number of specimens is filled, any additional specimens stored in that area are not subject to revenue sharing. As there are empty spaces resulting from attrition, the Company agrees to fill them as soon as possible. The parties typically pay the Company an up-front fee for the rights to these future payments. The Company reflects these up-front payments as long-term liabilities on the accompanying consolidated financial statements. Payments by the Company to other parties to the RSAs totaled $693,226 in fiscal 2004 and

$570,292 in fiscal 2003. Such payments are recorded as interest expense in the accompanying consolidated statements of operations and comprehensive income (loss). As described below, SCPT also entered into revenue sharing agreements, including one with the Company.

Florida. On February 9, 1999, the previous agreements with the Company s Arizona Revenue Sharing investors were modified and replaced by a revenue sharing agreement for the state of Florida for a price of $1,000,000. Under the terms of this agreement the Company credited the $450,000 investors had previously paid toward the purchase of the revenue sharing agreement. The balance of $550,000 was recorded as a receivable and the receivable will be reduced through revenue sharing entitlements to their share of net storage revenues. As of November 30, 2004 and 2003, the balance of the receivable is $0 and $100,525, respectively. The revenue sharing agreement applies to net storage revenues originating from specimens from within the state of Florida. The revenue sharing agreement entitles the investors to net revenues from a maximum of 33,000 storage spaces. Mr. Charles Nyberg, who was a member of the Board of Directors of the Company as of November 30, 2004, is a 50% owner of this revenue sharing agreement. Mr. Nyberg purchased this revenue sharing agreement prior to the time he became a member of the Board. Mr. Nyberg resigned from the Board of Directors during December 2004.

Illinois. In 1996, the Company signed agreements with a group of investors entitling them to an on-going 50% share in the Company s portion of net storage revenues generated by specimens stored in the Illinois Masonic Medical Center for a price of $1,000,000. The agreements were modified in 1998 to entitle the investors to a 50% share of the Company s portion of net revenues relating to specimens originating in Illinois and its contiguous states and stored in Oldsmar, Florida for a maximum of up to 33,000 storage spaces.

Tenet Health System Hospitals, Inc. On November 30, 1996, the Company signed agreements with OrNda HealthCorp. Two one-third revenue sharing agreements were purchased in which OrNda paid the Company a total of $666,666. OrNda was acquired by Tenet Healthcare Corporation (Tenet), which agreed to be bound by the terms of the OrNda agreements. The agreements were renegotiated and the Company could store all Tenet originated specimens at its laboratory in Oldsmar, Florida while paying Tenet a revenue sharing entitlement. In September 2003, a signed agreement was received from Tenet acknowledging the rescission of the two revenue sharing agreements with Tenet affiliates. This allowed the Company to eliminate the long-term liability related to the Tenet agreements, in the aggregate amount of $666,666 and record this amount in other income as extinguishment of revenue sharing agreements in fiscal 2003.

New York. On February 26, 1999, the Company entered into a modified revenue sharing agreement with Bio-Stor International, Inc. (Bio-Stor) for the state of New York. The Company will credit the $900,000 Bio-Stor had previously paid toward the purchase of 90% of the Company s 50% portion of net storage revenues generated from the specimens originating from the Company s clients in the state of New York for up to 33,000 shared storage spaces. This agreement supersedes all other agreements between Bio-Stor and the Company.

On November 5, 1998 an agreement previously entered into by the Company with a private investor was revised. Per the terms of the original agreement, the investor had purchased 10% of a revenue sharing agreement in the state of New Jersey. The new agreement has transferred the $100,000 investment to the state of New York. Under the revised agreement the investor will receive 10% of the 50% share in the Company s portion of net storage revenues generated by the specimens originating from the Company s clients in the state of New York for up to 33,000 spaces.

New Jersey. On November 30, 1999, the Company entered into agreements with two parties entitling them to on-going shares in a portion of CRYO-CELL s net storage revenue generated by specimens originating from within the state of New Jersey for a price of $500,000. Deposits totaling $50,000 were received upon signing of the agreements and the remaining $450,000 was originally due in May 2000. As

of August 31, 2002, the Company received $130,000. The agreement originally required the notes to be paid in full by May 31, 2000. The Company had extended the payment terms of these notes to August 31, 2002. The Company did not receive the final payment due. In conversations with the two investors, the Company was informed that they were unable to pay the notes. The Company foreclosed on the notes and deemed the $370,000 receivable to be uncollectible. The original liability of $500,000 was reversed and the payments made under the contract were recognized as revenue in fiscal 2002. In May 2003, the two parties requested that the Company return the $130,000 that had previously been paid to the Company. In June 2003, the Company agreed to settle the dispute and return $86,000 to the two parties.

Texas. On May 31, 2001, the Company entered into an agreement with two investors one of whom is an affiliate with the Company entitling them to on-going shares in a portion of CRYO-CELL s net storage revenue generated by specimens originating from within the State of Texas for a price of $750,000. An initial deposit of $50,000 was received upon signing of the agreement and the remaining balance of $700,000 was paid in August 2001. The investors are entitled to a 37.5% share of net storage revenues originating in the State of Texas to a maximum of 33,000 storage spaces. Mr. Charles Nyberg is a 50% owner of this revenue sharing agreement. Mr. Nyberg purchased this revenue sharing agreement prior to the time he became a member of the Board. Mr. Nyberg resigned from the Board of Directors during December 2004.

SCPT Revenue Sharing Agreements. On August 9, 2002, the Company agreed to enter into RSAs with SCPT. The Company paid an up-front one-time fee of $3,000,000 to SCPT for the RSAs, including $600,000 paid in cash and the balance paid in 645,161 shares of the Company s common stock whose fair market value at the date of sale was $2,400,000 as determined by the average of the Company s stock bid and ask prices. This transaction eliminates upon consolidation on the accompanying consolidated balance sheets. The Company does not expect to realize any value from these RSAs, as SCPT s business has been discontinued.

In May 2003, SCPT, entered into a Revenue Sharing Agreement (RSA) with an independent limited liability company (LLC). The RSA provided that the LLC would pay a total of $2,000,000 to SCPT in varying installments through March 2007. As a result of the execution of the RSA, the Company recorded a state income tax provision of $140,000 in the quarter ended May 2003. The LLC defaulted under the RSA during the second quarter of fiscal 2003, due to non-payment of three required installment payments totaling $450,000. In September 2003, a representative of the LLC advised CRYO-CELL that it did not intend to honor its obligations under the agreement. As a result, the Company has reversed all prior entries associated with the RSA during 2003. This resulted in a reversal of the $140,000 tax provision and the recognition of the $50,000 non-refundable initial payment as other income in fiscal 2003.

International

In fiscal 2000 the Company began entering into licensing agreements with certain parties in various international areas in an attempt to capitalize on the Company s technology. The Company has discontinued two of these relationships in an effort to focus on its core business. In the future, the Company will evaluate and pursue certain opportunities, on a selective basis, in which operational synergies and economic potential align with CRYO-CELL s strategic direction. The following details the background and current status of the significant agreements.

Mexico. On June 13, 2001, the Company entered into an agreement, as amended in October 2001, for the exclusive license to market the Company s U-Cord program in Mexico. The license allows CRYO-CELL de Mexico to directly market and operate the U-Cord program throughout Mexico, Central America and Ecuador. The initial up-front cost of the license was $600,000 and the Company receives licensing fees of 15% and 25% of the adjusted U-Cord processing and storage revenues, respectively, generated in Mexico and Central America. The Company recorded royalties and sub-license fees from CRYO-CELL de Mexico in the amount of $317,205 and $211,494 for the years ended November 30, 2004 and 2003, respectively, and this is reflected in other income in the accompanying consolidated statements of operations and comprehensive income (loss).

India/Malaysia/Singapore. On October 6, 2004, the Company announced that it has entered into a definitive License and Royalty Agreement with Asia CRYO-CELL Private Limited (ACCPL) to establish and market its U-Cord program in India. The Agreement, which was signed on July 14, 2004, was contingent on India government approval. ACCPL has an option to expand into Singapore and Malaysia for one year after the program is first offered for sale to the general public in India, as defined in the agreement, or at the latest March 31, 2005. ACCPL is to pay an up-front license fee of $750,000 and in return the Company has transferred its technology, know-how and quality systems to ACCPL. The up-front license fee is payable by ACCPL in installments over a term extending for three years after the earlier of the date the services are first offered for sale to the general public in India, as defined in the agreement, or at the latest March 31, 2005. In addition, the Company will receive royalty fees of 8.5% of the U-Cord collection and processing revenues generated in India and 10% of those generated in Singapore and Malaysia if the option is elected. The Company will also receive royalties on storage revenues ranging from 10% to 15%, depending on the number of units stored by ACCPL. Per the Agreement, ACCPL paid a non-refundable deposit of $275,000, representing the first installment of the up-front license fee, into an escrow account pending approval of the Agreement by the India government. These approvals were received in November 2004 as all up-front services were completed. The Company recognized the first payment of $275,000 during fiscal 2004 and it is included in other income in the consolidated statement of operations and comprehensive income (loss). The remaining balance due of $475,000 will be recognized under the installment basis of accounting, recognizing each payment, as it becomes due.

Europe. The Company previously had an agreement with CRYO-CELL Europe, N.V., now known as Life-Sciences Group, NV (CCEU) to engage in the cryogenic cellular storage business under the agreement in Europe. In September 2002, the Company sent a letter to CCEU advising that CCEU was in default under the terms of the license agreement between the companies. In October 2002, the Company received a letter from CCEU stating that the Company had not fulfilled its obligations under the licensing agreement, which the Company disputed. In April 2003, the Company commenced legal proceedings against CCEU and an affiliated corporation. In February 2004, the Company settled the litigation with CCEU and its affiliate. See Item 3 Legal Proceedings .

In fiscal 2003 the Company evaluated its investment in CCEU taking into consideration declines in CCEU s financial results through December 31, 2002, independent valuations performed on CCEU through May 2003, and verbal representations from CCEU management to Company management regarding the current value of the Company s investment in CCEU and CCEU s requirements for additional financing to meet obligations in the normal course of business in 2004. As a result, the Company recorded a $739,670 charge, in 2003, included in impairment of assets, to write-off its cash investment in CCEU due to a decrease in the fair value.

Israel/Middle East. In October 2001 the Company finalized a renewable three-year contract with CRYO-CELL Middle East, Inc. (CCEL ME) for the exclusive license to market the Company s U-Cord program in Israel, the Middle East and Turkey.

In February 2004, the Company sent a letter to CCEL ME advising that CCEL ME was in default under the terms of the license agreement. During September 2004, both parties agreed to a mutual release of the original license agreement, whereby CCEL ME retained the right to the Hebrew translation of CRYO-CELL ISRAEL and may only use this for the territory of Israel for the remaining period of the original agreement. The Company did not receive any past due royalties as part of this settlement.

Discontinued Proprietary Storage Systems

The Company previously developed technologies for the processing and cryogenic storage of

specimens. During the fourth quarter of fiscal 2003, the Company made the strategic decision to terminate further utilization of the proprietary storage system and abandon further construction of the units. The Board of Directors formally approved this decision in January 2004. This decision was based on the conclusion that the Company s resources are best utilized for market development and expansion of services. The decision to terminate utilization of the technology resulted in a $771,000 impairment charge in fiscal 2003 in order to reflect the CCEL Cellular Storage System at fair value. This impairment charge is included in impairment of assets in the accompanying consolidated statements of operations and comprehensive income (loss) as of November 30, 2003. The Company was unable to sell the equipment during fiscal 2004, and therefore determined that the remaining balance of $145,000 should be written down to its salvage value of $15,000. The $130,000 write-down has been included in impairment of assets as of November 30, 2004 in the accompanying consolidated financial statements of operations and comprehensive income (loss). In February 2004 the Company requested FDA to cancel its device manufacture registration and device listing. The Company received verbal confirmation from the FDA in February 2004 that it was no longer registered as a medical device manufacturer. The Company currently stores all specimens in commercially available cryogenic equipment.

Employees

At November 30, 2004, there are 35 full-time and 13 part-time employees on the staff of the Company. Additional employees and staff will be hired on an as needed basis. The Company believes its relationship with its employees is good.

ITEM 2. DESCRIPTION OF PROPERTY

The Company entered into a ten-year lease in April 2004 for its new 17,600 square foot current Good Manuafacturing and Good Tissue Practice (cGMP/cGTP) compliant corporate headquarters in Oldsmar, Florida for rent of approximately $141,000 per year for each of the first two years and escalating thereafter. The lease effectively commenced during October 2004, and the Company moved into this facility in November 2004. This facility contains the Company s executive offices, its conference and training center, its laboratory processing and cryogenic storage facility and its scientific offices. The lease on the Company s previous headquarters in Clearwater, Florida expired on December 31, 2004.

ITEM 3. LEGAL PROCEEDINGS

The Company is periodically involved in litigation and regulatory proceedings incidental to the conduct of business and the Company expects that it will be involved in such litigation and regulatory proceedings from time to time. While the Company believes that any adverse outcome of such pending matters will not materially affect our business or financial condition, there can be no assurance that this will be the case. In addition to the forgoing, the Company is currently involved in the following:

On February 22, 2002 the Company was named as a defendant in a complaint filed by Pharmastem Therapeutics, Inc. in the United States District Court of Delaware (Wilmington) (the Court), Case No. 02-148-GMS, alleging patent infringement of U.S Patents Nos. 5.004,681 (681 patent) which relates to the collection processing, and storage of stem cells derived from umbilical cord blood and 5,192.553 (553 patent) which relates to the therapeutic uses of stem cells derived from umbilical cord blood. Pharmastem, a Delaware corporation, named eight companies (three of which are now out of business) involved in cord blood banking. The suit sought an injunction against the companies, an unspecified amount of damages or royalties, treble damages and attorney s fees. The trial was held in October 2003 and pursuant to a jury verdict entered on October 30, 2003, a judgment was entered against the Company in the amount of $957,722 for damages relating to royalties resulting from revenues generated from specimens processed and stored from April 11, 2000 through August 31, 2003. The Company recognized a liability for the year ended November 30, 2003 in the amount of the judgment and an additional accrual in the amount of $145,000 for estimated damages relating to royalties resulting from revenues generated from specimens processed and stored for the three months ended November 30, 2003.

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During fiscal 2004 the Company accrued an additional $523,000 for estimated damages relating to royalties resulting from revenues generated from specimens processed and stored during the first, second and third quarters of fiscal 2004 recognizing that it was probable that the damages would continue to accrue at that rate should the judgment remain in effect related to the 681 patent. In December 2003, the Company transferred $957,722 into an escrow account. The defendants, including the Company, filed motions for post-trial relief, and execution of the judgment was stayed pending disposition of those motions. The plaintiff also filed motions seeking an award of approximately $2,800,000 for enhanced damages, counsel fees and interest, as well as for a permanent injunction against future infringement. The Company did not accrue the $2,800,000, as the Company felt the likelihood of such an award was remote.

On September 15, 2004, the Court ruled on the post trial motions. The Court vacated its judgment, overturning the jury s verdict for patent infringement and damages previously entered against the Company, and denied Pharmastem s request for an injunction and enhanced damages against the defendants. Reversing the jury s verdict, the Court entered a new judgment in favor of the Company and the other defendant blood banks with regard to PharmaStem s 553 patent, holding that the cord blood banks are not, and cannot be, liable for contributory infringement of the patent because they do not sell, or offer for sale, umbilical cord blood. Rather, the private blood banks provide a service of processing and preservation of cord blood for families. With regard to PharmaStem s original patent the 681 patent, the Court granted CRYO-CELL and its co-defendants a new trial on the issues of infringement and damages, finding that the jury s earlier verdict of infringement was against the great weight of the evidence .

As a result of the September 15, 2004 ruling, the Company reversed all prior accruals related to the 681 patent totaling $1,102,968 and has reflected this reduction, as litigation accrual Pharmastem in the accompanying consolidated statements of operations and comprehensive income (loss) for fiscal 2004. Litigation accrual reversal represents the litigation expense recognized through fiscal 2003. The Company is no longer obligated to hold the $957,722 in an escrow account and the funds were returned to the Company in October 2004.

On October 4, 2004, PharmaStem filed in the Delaware action a motion for preliminary injunction against the Company (and its co-defendants) regarding the 681 patent. PharmaStem sought an injunction limiting the ability of the Company to refer to the use of umbilical cord blood in the treatment of adults in the marketing of the Company s services, to advise customers for its services that cord blood stored hereafter is for pediatric use only, and to enjoin the Company from storing cord blood units that have sufficient stem cells to effect the hematopoietic reconstitution of an adult. The Company and other defendants filed a motion asking the court to reconsider the denial of the judgment as a matter of law on the 681 patent. On December 14, 2004, the Court ruled in favor of the Company and other defendants. The effect of this order is that final judgment has now been entered in favor of CRYO-CELL and the other defendants on PharmaStem s charges of infringement of both patents that were asserted in that case, marking a final disposition of the case in CRYO-CELL s favor, and denying PharmaStem s motion for preliminary injunction. PharmaStem has filed an appeal of the decision to the United States Court of Appeals for the Federal Circuit. CRYO-CELL and the other defendants have filed a cross-appeal on the issues of the validity and enforceability of the 681 and 553 patents.

Moreover, in a separate action, the U.S. Patent and Trademark Office has recently decided to reexamine the validity of both of the PharmaStem patents that were the subject of the litigation in Delaware, the 553 patent and the 681 patent. In January 2005, a Patent Office examiner entered an office action rejecting all claims of the 553 patent. This action is not final, and Pharmastem has the opportunity to present further argument to the examiner.

On July 28, 2004, the Company was named as a defendant in a complaint filed by PharmaStem Therapeutics, Inc. in the United States District Court for the Middle District of Florida, Tampa Division,

Case No. 8:04-cv-1740-T-30TGW alleging infringement of U.S. Patents Nos. 6,461,645 and 6,569,427. These patents are closely related to the 681 and 553 patents that were the subject of PharmaStem s Delaware litigation. PharmaStem also named as a defendant Dr. Bruce Zafran, a member of the Company s scientific and medical advisory board. The suit seeks an injunction, an unspecified amount of damages or royalties, treble damages and attorney s fees. The Company has filed an answer and counterclaims against PharmaStem and its Chief Executive Officer, Nicholas Didier. PharmaStem and Didier have filed motions to dismiss those counterclaims. The Judicial Panel on Multidistrict Litigation transferred this action to the District of Delaware for coordinated pretrial proceedings with other cases brought by PharmaStem alleging infringement of these same two patents by other defendants. The Company intends to vigorously defend the suit. Discovery in the action has not yet commenced.

In March 2003, CRYO-CELL Europe, N.V., now known as Life-Sciences Group, N.V. (CCEU) was served with a letter terminating the Company s license agreement with a CCEU affiliate. On April 15, 2003, the Company commenced legal proceedings against CCEU and an affiliated corporation in the Hague, Netherlands, for a preliminary injunction restraining CCEU from using the CRYO-CELL name. On or about May 30, 2003, the Company voluntarily withdrew its preliminary injunction application. In July 2003, the Company commenced legal proceedings against CCEU and a affiliated corporation in the Hague, Netherlands, for a preliminary injunction restraining CCEU from using the CRYO-CELL name. In September 2003, the Company and CCEU reached a settlement of the issues in the Dutch proceedings, whereby CCEU agreed to stop using CRYO-CELL in its name and the names of its affiliates, and to transfer its related Internet domain names to the Company.

The Company has settled its lawsuit against CCEU, and its affiliate CRYO-CELL Switzerland AG, now known as Life Sciences AG (collectively, Life Sciences), which was pending in the Circuit Court of the Sixth Judicial District in the State of Florida. In the lawsuit, the Company had sought to recover money damages, unpaid royalty payments due under a license agreement with the Company, and other relief. The license agreement granted COLTEC, Ltd. and its affiliates an exclusive license to market the Company s U-Cord program in Europe and allowed them to directly market the U-Cord program, sell revenue sharing agreements or further sub-license the marketing rights throughout Europe. Life Sciences assumed COLTEC s rights and obligations under the license agreement. The Company had previously advised Life Sciences that, by the Company s calculation, it owed the Company $323,562 in unpaid royalties. Life Sciences denied liability and asserted a counterclaim for damages and rescission of the license agreement. The Company recognized as an expense in fiscal 2002, a provision for doubtful accounts of approximately $129,000 as an estimate of that portion of the royalty that may not be paid. On February 17, 2004, the Company settled the litigation with Life Sciences. The terms of the settlement are confidential. As a result of the settlement, the claims and counterclaim in the lawsuit have been dismissed with prejudice. Amounts paid to the Company due to the settlement were recorded in marketing, general and administrative expenses as a reduction of bad debt expense and legal fees in the accompanying consolidated statements of operations and comprehensive income (loss) in fiscal 2004.

Between May and July 2003, ten putative class action complaints were filed in the United States District Court of the Middle District of Florida against the Company, certain current and former officers and directors of the Company and two accounting firms who previously audited the Company s consolidated financial statements. All ten complaints alleged violations of federal securities laws, including improper recognition of revenue in the consolidated financial statements presented in certain public reports of the Company. On October 22, 2003, all ten complaints were consolidated (Case No. 03-CV-1011). On February 17, 2004, the court appointed lead plaintiffs. On April 27, 2004, the lead plaintiffs filed an amended complaint. The amended complaint generally seeks, among other things, certification of a class of persons who purchased the Company s common stock between March 16, 1999 and May 20, 2003 and unspecified damages. The parties have signed a formal stipulation of settlement to settle the litigation. The settlement remains subject to approval by the United States District Court for the Middle District of Florida, and a fairness hearing is scheduled for February 25, 2005. The proposed settlement, which totals $7 million, includes a payment of $4 million, which would be paid by the carrier of the

Company s former auditors, subject to its applicable deductible. In addition, the Company s insurance carrier would pay $3 million on the Company s behalf under its directors and officers insurance policy, subject to its maximum deductible of $175,000. The Company believes the litigation is without merit and, in the event a settlement agreement is not consummated or approved by the court, the Company intends to defend the litigation vigorously.

From time to time, the Company is involved in other inquiries, administrative proceedings and litigation relating to matters arising in the normal course of business. While any proceeding or litigation has an element of uncertainty, management currently believes that the final outcome of these matters is not likely to have a material adverse effect on the Company s financial condition or results of operations.

ITEM 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS

None.

PART II

ITEM 5. MARKET FOR THE REGISTRANT S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND SMALL BUSINESS ISSUER PURCHASES OF EQUITY SECURITIES

The Company s common stock traded on the Over-The-Counter market since January 10, 1991, the date of the Company s initial public offering. In January 1997, the Company s stock began trading on the NASDAQ SmallCap market. Effective July 24, 2003, the Company s common stock was delisted from The Nasdaq SmallCap Market under a decision of the Nasdaq Listing Qualifications Panel. At that time, the Company s common stock began trading on the Over-the-Counter Bulletin Board under the symbol CCEL . The Company expects to re-apply for listing on the Nasdaq SmallCap market or another exchange in the next 12-18 months; however, there is no assurance the Company will meet the applicable listing requirements at that time. The following table shows, for the calendar periods indicated, the high and low closing bid quotations for the Company s common stock as reported by the Dow Jones Retrieval Service. The quotations represent inter-dealer prices without retail mark-up, markdown or commission and may not represent actual transactions.

2003	**High**	**Low**
February 28, 2003	1.94	1.00
May 31, 2003	1.64	.73
August 31, 2003	1.12	.48
November 30, 2003	.89	.60
2004		
February 29, 2004	.73	.92
May 31, 2004	.81	.60
August 31, 2004	3.00	.61
November 30, 2004	2.70	1.86

The Company has not declared any cash dividends on its common stock and does not expect to do so in the near future.

As of November 30, 2004 the Registrant had 363 shareholders of record, and management believes there are approximately 5,000 additional beneficial holders of the Company s common stock.

ITEM 6. MANAGEMENT S DISCUSSION AND ANALYSIS OR PLAN OF OPERATION

The following discussion and analysis of the financial condition and results of operations of the Company for the two years ended November 30, 2004, should be read in conjunction with the consolidated financial statements and related notes as well as other information contained in this Annual Report on Form 10-KSB.

Overview

The Company is engaged in cryogenic cellular storage, with a focus on the processing and preservation of umbilical cord (U-Cord) blood stem cells for autologous/sibling use. During its history, the Company has engaged in a number of other business activities outside of its core business area, such as development of cellular storage systems, development of new business enterprises and international investments. During the past several fiscal years, the Company incurred losses, related in large part to impairment of assets related to these non-core businesses, expenses of these non-core businesses and significant litigation expenses. During fiscal 2003, the Company announced that it would focus on its

core business of marketing the U-Cord storage program and increasing the number of customers enrolled, with an emphasis in the U.S. market. Management has been working to control costs and stabilize the Company s business by continuing to resolve the disputes facing the Company and by directing resources to the core business.

During fiscal 2004, the Company increased its revenues by 62% over the level in fiscal 2003 and achieved net income of approximately $2,800,000, compared to an approximately $7,500,000 net loss for fiscal 2003. Net storage revenues increased because of an increase in the customer base and the effects of two price increases during 2003 and one price increase during the third quarter of 2004 for newly enrolled customers. The Company was profitable mainly because of a $4.1 million increase in gross profits compared to 2003 levels and a reduction of $1.7 million, or 21% in marketing, general and administrative fees. In addition, a $1.1 million reversal of accrued expenses in connection with the Pharmastem patent litigation matter contributed to profits, while these accrued expenses increased the loss in 2003. Other items that contributed to the net loss in fiscal 2003 that are not included in the results of fiscal 2004 include asset impairment charges of approximately $2 million. The impairment charges in 2003 included the reduction in value of investments in subsidiaries and affiliates and charges related to the decision to discontinue further investment in and utilization of the Company s proprietary storage technology. In order to maintain profitability in 2005 and future years, the Company needs to continue to control operating costs while it works to continue to increase revenues from its core business. In the future, the Company will evaluate and pursue certain opportunities, on a selective basis, if operational synergies and economic potential align with CRYO-CELL s strategic direction.

At November 30, 2004, the Company had cash and cash equivalents of $4,737,368 and marketable securities and other investments of $1,266,909. The Company s cash increased by approximately $2,300,000 during fiscal 2004, as a result of its cash flows from operations. As of February 15, 2005, the Company maintains no indebtedness. Capital expenditures of approximately $686,000, for the build-out of Company s new facility were funded from cash flow from operations.

Discontinued Operations

On January 29, 2004, CRYO-CELL announced the decision to close SCPT, following the resignation of SCPT s Board of Directors and management. CRYO-CELL concluded that SCPT required significant additional funding to complete the repurchase and to remain in operation, and that SCPT management s restructuring proposals all would have required CRYO-CELL to make significant cash expenditures. CRYO-CELL owned 11,500,000 (86.6%) shares of SCPT. In accordance with SFAS No. 144, Accounting for the Impairment or Disposal of Long-Lived Assets, (SFAS No. 144) the closing of SCPT represents a discontinued operation as of November 30, 2004. For comparative purposes, the earnings of SCPT has been reclassified in the Company s statements of operations and comprehensive income (loss) as discontinued operations for the twelve months ended November 30, 2003. The net assets of SCPT are immaterial to the consolidated financial statements.

During the second quarter 2004, SCPT paid off all known amounts owed to employees and other creditors including the loan in the amount of $195,000 plus accrued interest to the shareholder of SCPT. In April 2004, the Board of Directors of SCPT approved a liquidating distribution of the remaining assets of SCPT to the holders of SCPT common stock. After payment of SCPT s remaining debts, SCPT s remaining assets consisted solely of shares of common stock of CRYO-CELL. In order to facilitate the liquidating distribution, CRYO-CELL agreed to repurchase the CRYO-CELL shares from SCPT for a cash price of $.75 per share, the average of the closing bid and ask prices per share for CRYO-CELL common stock reported on the OTC Bulletin Board for the twenty trading days prior to April 30, 2004. After the repurchase of CRYO-CELL common stock, SCPT s remaining assets consisted of $138,035 in cash, which was equal to approximately $.01 per share of SCPT common stock. This cash was distributed to SCPT s shareholders, including CRYO-CELL, in May 2004.

Through November 30, 2002, aggregate losses attributable to the minority interest exceeded the minority s interest in the equity capital of SCPT. As a result, minority interest on the balance sheet as of November 30, 2004 and November 30, 2003 is reflected at $0, and CRYO-CELL has recognized 100% of the loss of SCPT in its statements of operations and comprehensive income (loss) as discontinued operations during the twelve months ended November 30, 2004 and November 30, 2003 of approximately $93,000 and $689,000, respectively. The minority portion of the losses for the twelve months ended November 30, 2004 and November 30, 2003 was approximately $12,000 and $92,000, respectively.

Results of Operations

Revenues. For the fiscal year ended November 30, 2004, the Company had revenues of $12,210,273 compared to $7,549,536 in fiscal 2003, representing a 62% increase. The increase is primarily attributable to new clients and the effects of successfully implemented price increases for newly enrolling clients. During 2003 and 2004, the Company implemented price increases affecting its enrollment, processing and testing fees (Initial Fee). These increases began to have a positive impact on revenue and gross profit during the fiscal 2003 third and fourth quarters and continued through fiscal 2004.

Cost of Sales. For the fiscal year ended November 30, 2004, cost of sales was $3,162,957, as compared to $2,625,123 in 2003, representing a 20% increase. Costs of sales were 26% of revenues in fiscal 2004 compared to 35% in fiscal 2003. Cost of sales as a percentage of revenue decreased due to the increase in revenue, principally from the Initial Fee increases with an increase of only 20% in costs of sales compared to the 62% increase in revenues. Cost of sales includes wages, supplies and testing associated with the processing of cord blood specimens at the Company s facility and the costs associated with the dual storage of split specimens at the Safti-Cell facility (a related party as of November 30, 2004 and 2003) in Arizona, which commenced in October 2002. Included in the increase in cost of sales in fiscal 2004 was the write-off of certain assets in the amount of approximately $79,000 due to the move to the Company s new facility, approximately $151,000 in increased testing fees, and approximately $96,000 in increased fees paid to Safti-Cell due to new specimens stored at the Safti-Cell facility. The Company expects that in 2005, it will discontinue offering the dual storage service to new customers.

Marketing, General and Administrative Expenses. Marketing, general and administrative expenses during the fiscal year ended November 30, 2004, were $6,274,072 as compared to $7,966,734 in 2003, a decrease of $1,692,662 or 21%. Marketing, general and administrative expenses were 51% of revenues in fiscal 2004 compared to 106% for the same period in fiscal 2003. This decrease is primarily the result of the write-off in 2003 of a deferred consulting agreement with the founder and prior Chairman and Chief Executive Officer of the Company in the amount of approximately $1,300,000. The deferred consulting agreement was written off because during the fourth quarter 2003, the Company made the decision that the prior Chairman and CEO was no longer able to provide advisory services to the Board. As a result of this determination, the unamortized present value of the agreement recorded as a deferred consulting asset was expensed in fiscal year ended November 30, 2003. Professional fees decreased approximately $761,000 for the twelve months ended November 30, 2004. The decrease is due to a reduction in the Company s legal proceedings. The Company cannot provide assurance that legal fees will not increase in the foreseeable future. Rent expense will decrease in 2005 as a result of the lease of the new facility; however, management expects increased operating costs of the new facility to offset this decrease.

Litigation Accrual. During fiscal 2003 the Company accrued approximately $1,100,000 as the result of a judgment entered against the Company in October 2003 related to the Pharmastem verdict. During fiscal 2004 the Company accrued an additional $523,000 for estimated damages relating to royalties resulting from revenues generated for specimens processed and stored during the first, second and third quarters of fiscal 2004. During the third quarter 2004, the Company reversed all prior accruals totaling approximately $1,600,000 as a result of the ruling by the Court on the post trial motions with regards to the Pharmastem litigation. The litigation accrual reversal for the year ended November 30, 2004 was $1,102,968 representing litigation expense recognized during fiscal 2003.

Research, Development and Related Engineering Expenses. Research, development and related engineering expenses for the fiscal year ended November 30, 2004, were $82,509 as compared to $234,374 in 2003, a decrease of 65%.

Impairment of Assets. The Company previously developed several technologies for the processing and cryogenic storage of specimens. During the fourth quarter of fiscal 2003, the Company made the strategic decision to terminate further utilization of its proprietary storage system and abandon further construction of the units. The Board of Directors formally approved this decision in January 2004. This decision was based on the conclusion that the Company s resources are best utilized for market development and expansion of services. The decision to terminate utilization of the technology resulted in a $771,000 impairment charge in fiscal 2003 in order to reflect the storage system assets at fair value. This impairment charge is included in impairment of assets in the accompanying consolidated statements of operations and comprehensive income (loss) as of November 30, 2003. The Company was unable to dispose of this equipment during 2004. As a result, the Company recorded an impairment charge of approximately $130,000 during 2004 to write-down this equipment to its salvage value.

In fiscal 2003 the Company evaluated its investment in CCEU taking into consideration declines in CCEU s financial results through December 31, 2002, independent valuations performed on CCEU through May 2003, and verbal representations from CCEU management to Company management regarding the current value of the Company s investment in CCEU and CCEU s requirements for additional financing to meet obligations in the normal course of business in 2004. As a result, the Company recorded a $739,670 charge, in fiscal 2003, included in impairment of assets, to write-off the investment due to a decrease in the market value that is considered to be other than temporary.

For the years ended November 30, 2003 and 2004, the Company has ownership interest of approximately 43% and 42%, respectively, in Saneron, which is accounted for under the equity method of accounting, along with approximately $684,000 that represents goodwill and is reflected in the investment balance. As of November 30, 2004, and November 30, 2003, independent valuations appraised the Company s approximate 42% and 43% interest in Saneron at $2,070,000 and $900,000, respectively. As of November 30, 2003, the decline was considered other than temporary. Due to the apparent permanent decline in the value of the Company s 43% interest in 2003, the Company recorded a charge of approximately $616,000 to impairment of assets in 2003, to properly reflect the investment balance as of November 30, 2003. As of November 30, 2004 and 2003, the net Saneron investment which includes goodwill of approximately $684,000 is reflected on the consolidated balance sheets at approximately $716,500 and $799,000, respectively.

Interest Expense. Interest expense during the fiscal year ended November 30, 2004, was $750,128 compared to $654,322 in 2003. Interest expense is mainly comprised of payments made to the other parties to the Company s RSAs based on the Company s storage revenue. Prior to fiscal 2002, the Company entered into RSAs with individuals and entities for specific geographic areas. The Company s RSAs provide that in exchange for an up-front payment, the Company would share in perpetuity a percentage of its future revenue derived from the annual storage fees charged related to a certain number of specimens that originated from specific areas. The Company currently has four RSAs in effect covering the following areas: New York, Texas, Florida and Illinois (including contiguous states). During 2003 the Company s agreement with Tenet was rescinded. Also included in interest expense is the amortization of the present value of a deferred consulting agreement in the amount of $56,902 and $84,030 for the years ended November 30, 2004 and 2003, respectively. If the Company s revenues continue to increase in areas covered by RSAs, the Company s interest expense related to the RSA payments will also increase.

Other Income. Other income for the fiscal year ended November 30, 2004, was $549,084 as compared to $211,494 in 2003. Other income increased by approximately $338,000 from 2003 to 2004. Other income for fiscal 2004 was comprised of income recognized on the sale of the India license agreement of approximately $232,000 and approximately $317,000 from royalty income earned in geographical areas

where the Company has license agreements and the sale of sublicense agreements. Other income for fiscal 2003 was comprised of royalty income earned in geographical areas where the Company has license agreements and the sale of sub-license agreements. There can be no assurances that income from licenses and royalties will continue at the same rates as in the past.

Extinguishment of Revenue Sharing Agreement. In September 2003 the two revenue sharing agreements with Tenet were rescinded, which allowed the Company to eliminate the long-term liability related to the Tenet agreements. This rescission resulted in the recognition of $666,666 in other income as extinguishment of revenue sharing agreements in fiscal 2003.

Equity in Losses of Affiliates. Equity in losses of affiliates was $137,852 for the fiscal year ended November 30, 2004 compared to a loss of $344,840 in 2003. During fiscal 2003 and 2004, the Company identified certain stock and warrant awards that were granted by Saneron at below fair market value to certain employees, consultants and members of Saneron management who represent owners of Saneron and serve on the board of directors. As a result, included in equity in losses of affiliates is approximately $55,000 related to compensation expense that resulted from the stock awards in 2004 and approximately $257,000 in 2003.

Income Taxes. Income taxes were $86,001 for the fiscal year ended November 30, 2004 compared to $0 in 2003. The Company recorded an income tax provision for federal income taxes for the year ended November 30, 2004 based on the net profits of the Company.

Liquidity and Capital Resources

Through November 30, 2004, the Company s principal source of cash has been from sales of its U-Cord program to customers, the sale of license agreements and proceeds from RSAs. Currently, the Company s cash flow is derived primarily from sales relating to its storage services, including the Initial Fee and ongoing storage fees.

At November 30, 2004, the Company had cash and cash equivalents of $4,737,368 as compared to $2,452,006 in 2003. The increase in cash and cash equivalents was primarily attributable to the Company s operating activities including a price increase and an increase in recurring revenue from a growth in the client base, the maturity of certificates of deposit and reimbursement of a portion of the legal and settlement fees pertaining to settled lawsuits filed by the Company s former President and Chief Operating Officer for approximately $135,000. In August 2004, the Company purchased a certificate of deposit in connection with a letter of credit required under an agreement between the Company and a third party financing institution for approximately $200,000 and has classified this as restricted cash in the accompanying consolidated balance sheets.

Cash provided by operating activities in fiscal 2004 amounted to $4,647,542 which was primarily attributable to the Company s operating activities including a price increase and an increase in recurring revenue from the growth in the client base.

Cash used in investing activities in fiscal 2004 amounted to $2,254,853, which was primarily attributable to purchase of approximately $686,000 in leasehold improvements in the Company s new facility, $674,000 in furniture, machinery & equipment, $392,000 in laboratory equipment, and $490,000 in software.

Cash used in financing activities in fiscal 2004 amounted to $107,327, which consisted primarily of a repayment of a loan in the amount of $195,000 to a former officer, director and shareholder of SCPT as a result of the liquidation of SCPT. See SCPT s liquidity and capital resources discussion below.

The Company also has certain investments in marketable securities and certificates of deposit, totaling $1,266,909 at November 30, 2004.

The Company does not have a line of credit or other type of financing instrument. Capital expenditures for the Company s new facility were funded from cash flow from operations. The Company anticipates making capital expenditures of approximately $700,000 over the next twelve months.

The Company anticipates that its cash and cash equivalents, marketable securities and cash flows from operations will be sufficient to fund its operations for at least the next 12 to 18 months. Cash flows from operations will depend primarily upon increasing revenues from sales of its umbilical cord blood cellular storage services and controlling expenses. The Company has attempted to focus its capital resources on its core business of cellular storage services by de-emphasizing certain non-core business activities and through settlement of some of its legal disputes. In the future, the Company will evaluate and pursue certain opportunities, on a selective basis, in which operational synergies and economic potential align with the Company s strategic direction. The adequacy of the Company s cash resources will depend to some extent on its ability to further reduce legal expenses resulting from continuing legal disputes and to minimize the impact of legal settlements or judgments from these disputes.

Since inception SCPT s costs and expenses were funded by capital contributions, advances for the purchase of revenue sharing agreements sold by SCPT, the sale of a promissory note for $500,000, which was converted into SCPT s capital stock, and the sale of common stock. In August 2003, SCPT received a $100,000 interest-bearing loan from an officer, director and shareholder of SCPT (and a shareholder of CRYO-CELL) to fund its operations. The note, including 4% interest, was due on September 5, 2004. On November 20, 2003, the loan agreement was amended to allow additional loans to SCPT of $45,000. The amended loan agreement, including 4% interest, was due on September 5, 2004. SCPT pledged 345,161 shares of the CRYO-CELL common stock held by SCPT to secure this note. On December 28, 2003, SCPT entered into an additional, separate loan agreement with the officer, director and shareholder of SCPT for up to $50,000. The loan, including 5% interest, was due on demand or no later than December 31, 2004. On January 29, 2004, CRYO-CELL made the decision to close SCPT, following the resignation of SCPT s Board of Directors and management. In connection with closing SCPT, CRYO-CELL repaid the loans in May 2004, and the shares held as collateral were released.

Critical Accounting Policies

The preparation of consolidated financial statements and related disclosures in conformity with accounting principles generally accepted in the United States requires estimates and assumptions that affect the reported amounts of assets and liabilities, revenues and expenses and related disclosures of contingent assets and liabilities in the consolidated financial statements and accompanying notes. The SEC has defined a company s critical accounting policies as the ones that are most important to the portrayal of the company s financial condition and results of operations, and which require the company to make its most difficult and subjective judgments, often as a result of the need to make estimates of matters that are inherently uncertain. The Company believes that its estimates and assumptions are reasonable under the circumstances; however, actual results may vary from these estimates and assumptions. We have identified the following critical accounting policies that affect the more significant judgments and estimates used in the preparation of the consolidated financial statements. For further discussion of the Company s significant and critical accounting policies, refer to Note 1 Summary of Critical and Significant Accounting Policies to the Consolidated Financial Statements contained in Item 7 of this document.

Revenue Recognition

During the first quarter of 2003, the Company changed its method of recognizing enrollment fee revenue. Through November 30, 2002, the Company recognized enrollment fees upon completion of the enrollment into the U-Cord storage program. Beginning December 1, 2002, enrollment fees and the related direct incremental costs associated with these fees are deferred and recognized once the processing of the specimens is completed.

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The Company records revenue from processing and storage of specimens. The Company recognizes revenue from processing fees upon completion of processing and cellular storage fees ratably over the contractual storage period. The Company also records revenue from shipping and handling when earned and includes in revenue. Shipping and handling costs are expensed and included in cost of sales.

Investments

The Company has made several significant investments in entities that operate in related businesses. The Company has made these investments in order to expand into international markets and be involved in the area of stem cell research. The Company accounts for these investments under either the cost or equity method, as applicable, and at least annually, reviews its investments for possible impairment and, if necessary, adjusts the carrying value of such investments.

Revenue Sharing Agreements

The Company has entered into Revenue Sharing Agreements (RSAs) with various parties whereby these parties contracted with the Company for a percentage of future storage revenues the Company generates from clients in specific geographical areas. The parties typically pay the Company a non-refundable up-front fee for the rights to these future payments. The Company had recognized these non-refundable fees as a long-term liability. Given the criteria under which these RSAs are established, cash receipts from these contracts can fluctuate from period to period. The Company periodically, and at least annually, reviews its RSAs receivables for collectibility. All payments made to the other parties to the RSAs are recognized as interest expense. At such time as the total payments can be determined, the Company will commence amortizing these liabilities under the effective interest method.

License and Royalty Agreements

The Company enters into licensing agreements with certain investors in various international markets in an attempt to capitalize on the Company s technology. The investors typically pay a licensing fee to receive Company marketing programs, technology and know-how in a selected area. The investor may be given a right to sell sub-license agreements as well. As part of the accounting for the up-front license revenue, revenue from the up-front license fee is recognized based on such factors as when the payment is due, collectibility and when all material services or conditions relating to the sale have been substantially performed based on the terms of the agreement.

In addition to the license fee, the Company earns royalties on subsequent processing and storage revenues by the investor in the selected area and a fee on any sub-license agreements that are sold by the investor where applicable. As part of the accounting for royalty revenue, the Company uses estimates and judgments in determining the timing and amount of royalty revenue to recognize. The Company periodically, and at least annually, reviews license and royalty receivables for collectibility and, if necessary, will record an expense for an allowance for an uncollectible account.

Marketable Securities and Other Investments

The Company has certain investments in certificates of deposit, and equity securities, which are categorized as marketable securities and other investments. The Company believes these are conservative investments with a low risk for any loss of principal. The Company regularly assesses its marketable security investments for impairments and adjusts its investment strategy, as it deems appropriate.

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Litigation

The Company is periodically involved in litigation and regulatory proceedings incidental to the conduct of our business and the Company expects that it will be involved in such litigation and regulatory proceedings from time to time. The Company regularly reviews any such litigation and regulatory proceedings for possible adverse outcomes, and provides estimates for the possible liability to the Company from such adverse outcomes, as it considers appropriate.

Deferred Consulting Fees

The Company entered into a long-term consulting agreement with the founder and prior Chairman and Chief Executive Officer to provide future consulting services to the Company. The Company initially recognized the present value of this agreement as a deferred consulting fee with a related deferred consulting obligation. During the fourth quarter 2003, the Company determined that the prior Chairman and Chief Executive Officer was no longer able to provide advisory services to the board. As a result of this determination, the unamortized present value of the deferred consulting fee assets was recognized as an expense for the year ended November 30, 2003. The unamortized present value of the deferred consulting fee was recognized as a liability for the years ended November 30, 2003 and November 30, 2004. In August 2004, the Company stopped making payments under the consulting agreement and the liability is currently being renegotiated.

Off-Balance Sheet Arrangements

The Company has no off-balance sheet arrangements that have or are reasonably likely to have a current or future effect on its financial condition, changes in financial condition, revenues or expenses, results of operations, liquidity, capital expenditures or capital resources that is material to investors.

Risk Factors That May Affect Future Results

We operate in a rapidly changing environment that involves a number of risks, some of which are beyond our control. A number of these risks are listed below. These risks could affect actual future results and could cause them to differ materially from any forward-looking statements we have made. You should carefully consider the risks described below, as well as the other information set forth in this Form 10-KSB. The risks and uncertainties described below are not the only ones we face. Any of the risks described below could significantly and adversely affect our business, prospects, financial condition or results of operations. In that case, the trading price of our common stock could fall and you may lose all or part of the money you paid to buy our common stock.

Risks Related to Our Business

Possible Need for Additional Capital

The Company currently has approximately $6,000,000 in cash, cash equivalents and liquid marketable securities and other investments. The Company believes it has sufficient capital to fund its operations for at least the next 12 to 18 months. Cash flows from operations will depend primarily upon increasing revenues from sales of its umbilical cord blood cellular storage services and controlling expenses. The Company has attempted to focus its capital resources on its core business of cellular storage services by de-emphasizing certain non-core business activities and through settlement of some of its legal disputes. The adequacy of the Company s cash resources will depend to some extent on its ability to maintain lower levels of legal expenses resulting from continuing legal disputes and to minimize the impact of legal settlements or judgments from these disputes. There can be no assurance that sales will continue to increase or even maintain current levels. There can be no assurance that such capital, if needed, will be available.

If our umbilical cord blood stem cell storage services do not achieve continued market acceptance we will not be able to generate revenue necessary to support our business.

We anticipate that service fees from the processing and storage of umbilical cord blood stem cells will comprise a substantial majority of our revenue in the future and, therefore, our future success depends on the successful and continued market acceptance of this service. Broad use and acceptance of our service requires marketing expenditures and education and awareness of consumers and medical practitioners, and the time and expense required to accomplish such education and awareness of our services and its potential benefits could adversely affect market acceptance. Successful commercialization of our services will also require that we satisfactorily address the needs of various medical practitioners that constitute a target market to reach consumers of our services and to address potential resistance to recommendations for our services.

We may not be able to achieve further growth or continue to operate our business profitably.

Our business may decline, may not grow further or may grow more slowly than expected. To the extent we are unable to achieve continued growth in our business we may incur losses. Our current and future expense levels are based on our operating plans and estimates of future revenues and are subject to increase as we implement our strategy. We may be unable to adjust spending in a timely manner to compensate for any unexpected revenue shortfall. Accordingly, any significant shortfall in revenues would likely have an immediate material adverse effect on our business, operating results and financial condition.

If we do not continue to obtain and maintain necessary domestic regulatory registrations, approvals and comply with ongoing regulations, we may not be able to market our services in the United States.

Historically, the FDA has not regulated banks that collect and store cord blood for private or family use. Recent changes, however, require establishments engaged in the recovery, processing, storage, labeling, packaging or distribution of any Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps) or the screening or testing of a cell tissue donor to register with the FDA in January 2004. We voluntarily registered with the FDA in January 2003 and have successfully updated that registration for 2004, thus meeting the compliance requirement. The FDA has proposed rules that will regulate current Good Tissues Practices (cGTP). The final rules are to become effective during 2005. Future FDA conditions or regulations could adversely impact or limit our ability to market or perform or services. Failure to comply with applicable regulatory requirements can result in, among other things, injunctions, operating restrictions, and civil fines and criminal prosecution. Delays or failure to obtain registrations could have a material adverse effect on the marketing and sales of our services and impair our ability to operate profitably in the future.

International licenses of our technology and services account for a portion or our other income and our international growth may be limited if we are unable to successfully manage our international activities.

Our licensing activities in Mexico/Central America and India, accounted for $549,084 and $211,494 of other income for the years ended November 30, 2004 and 2003 respectively. We are subject to a number of challenges that relate to our international business activities. Our growth and future license income and return on investments from these sources will be impacted by these challenges, which include:

Failure of local laws to provide the same degree of protection against infringement of our intellectual property rights;

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Certain laws and business practices that could prevent our business from operating or favor local competitors, which could slow or limit our growth in international markets;

Entering into licensing agreements with organizations capable of undertaking and sustaining operations; and

The expense of entering into licensing and investment arrangements in new foreign markets.

Currently, the majority of our international license fees are denominated in U.S. dollars. As a result, an increase in the value of the U.S. dollar relative to foreign currencies could make our services less competitive in international markets. If we are unable to meet and overcome these challenges, our international operations may not be successful and may suffer. In fiscal 2003 we wrote down the remaining investment in CCEU in the amount of $739,670. To the extent our international business activities do not significantly improve in the near future we could have further write-downs of receivables arising from our licensing agreements.

If we are unable to protect our intellectual property from use by third parties, or if third parties claim that we infringe on their intellectual property, our ability to compete in the market will be harmed.

There can be no assurance that third parties will not seek to assert that our devices, systems and services infringe their patents or seek to expand their patent claims to cover aspects of our technology. As a result, there can be no assurance that we will not become subject to future patent infringement claims or litigation in a court of law, interference proceedings, or opposition to a patent granted in a foreign jurisdiction. The defense and prosecution of such intellectual property claims are costly, time-consuming, divert the attention of management and technical personnel and could result in substantial cost and uncertainty regarding our future viability. Future litigation or regulatory proceedings, which could result in substantial cost and uncertainty, may also be necessary to enforce our patent or other intellectual property rights or to determine the scope and validity of other parties proprietary rights. Any public announcements related to such litigation or regulatory proceedings that we initiate, or that are initiated or threatened against us by our competitors, could adversely affect the price of our common stock. We rely upon patent protection trade secrets, technical know-how and continuing technological innovation to develop and maintain our competitive position, and we typically require our employees, consultants and advisors to execute confidentiality and assignment of inventions agreements in connection with their employment, consulting or advisory relationships. There can be no assurance, however, that these agreements will not be breached or that we will have adequate remedies for any breach. Failure to protect our intellectual property would limit our ability to produce and/or market our products in the future and would likely have an adverse affect on the revenues generated by the sale or license of such intellectual property.

We are involved in intellectual property litigation, which may hurt our business, may be costly to us and may prevent us from selling or licensing our products or services.

On February 22, 2002 the Company was named as a defendant in a complaint filed by Pharmastem Therapeutics, Inc. in the United States District Court of Delaware (Wilmington) (the Court), Case No. 02-148-GMS, alleging patent infringement of U.S Patents Nos. 5.004,681 (681 patent) which relates to the collection processing, and storage of stem cells derived from umbilical cord blood and 5,192.553 (553 patent) which relates to the therapeutic uses of stem cells derived from umbilical cord blood.

As a result of a favorable ruling in September 2004, the Company reversed all prior accruals related to the 681 patent totaling $1,102,968 and has reflected this reduction, as litigation accrual Pharmastem in the accompanying consolidated statements of operations and comprehensive income (loss) for fiscal 2004. Litigation accrual reversal represents the litigation expense recognized through fiscal 2003. In December 2004, the District Court issued another favorable ruling in favor of the Company and other defendants. PharmaStem has noticed an appeal of the decision to the United States Court of Appeals for the Federal Circuit. If the Court of Appeals issued an adverse ruling, this could have a material adverse effect on the Company.

A failure in the performance of our cryopreservation storage facility or systems could harm our business and reputation.

To the extent our cryopreservation storage service is disrupted, discontinued or the performance is impaired, our business and operations could be adversely affected. We store approximately 75,000 specimens in Oldsmar, Florida and approximately 25,000 split specimens at a secondary storage facility in Sedona, AZ. Any failure, including network, software or hardware or equipment failure, that causes a material interruption or discontinuance in our cryopreservation storage of stem cell specimens could result in stored specimens being damaged and unable to be utilized. Specimen damage, including loss in transit to the Company or loss of bulk shipments to its secondary storage site, could result in litigation against us and reduced future revenue to us, which in turn could be harmful to our reputation. Our insurance may not adequately compensate us for any losses that may occur due to any failures in our system or interruptions in our ability to maintain proper, continued, cryopreservation storage services. Any material disruption in our ability to maintain continued uninterrupted storage systems could have a material adverse effect on our business, operating results and financial condition. Our systems and operations are vulnerable to damage or interruption from fire, flood, equipment failure, break-ins, tornadoes and similar events for which we do not have redundant systems or a formal disaster recovery plan and may not carry sufficient business interruption insurance to compensate us for losses that may occur.

Because our industry is subject to rapid technological and therapeutic changes and new developments, our future success will depend on the continued viability of the use of stem cells.

Our success will depend to a significant extent upon our ability to enhance and expand the use of and utility of our services so that they gain increased market acceptance. There can be no assurance that expectant parents will continue to use our services or that our services will provide competitive advantages with current or future technologies. Failure to achieve increased market acceptance could have a material adverse effect on our business, financial condition and results of operations. The use of stem cells in the treatment of disease is subject to potentially revolutionary technological, medical and therapeutic changes. Future technological and medical developments could render the use of stem cells and our equipment obsolete and unmarketable. We may incur significant costs in replacing or modifying equipment in which we have already made a substantial investment prior to the end of its anticipated useful life. In addition, there may be significant advances in other treatment methods, such as genetics, or in disease prevention techniques, which could significantly reduce the need for the services we provide.

We may be required to spend substantial amounts to comply with legislative and regulatory initiatives relating to patient privacy.

Regulations issued under the Health Insurance Portability and Accountability Act of 1996, or HIPAA, contain provisions that require us to adopt business procedures designed to protect the privacy of each of our patients individual health information. The Department of Health and Human Services recently issued health privacy regulations, which required compliance by April 14, 2003 for most health care organizations, including us, and we may incur additional costs associated with compliance. We cannot predict the impact of these regulations on our business. Compliance with these regulations may

require management to spend substantial time and effort on compliance measures. If we fail to comply with the new regulations, we could suffer civil penalties up to $100 per violation with a maximum penalty of $25,000 per each requirement violated per calendar year and criminal penalties with fines up to $250,000 per violation.

Our information systems are critical to our business, and a failure of those systems could materially harm us.

We depend on our ability to store, retrieve, process and manage a significant amount of information. If our information systems fail to perform as expected, or if we suffer an interruption, malfunction or loss of information processing capabilities, it could have a material adverse effect on our business.

The stem cell preservation market is increasingly competitive.

Stem cell preservation is becoming an increasingly competitive business. Our business faces competition from other operators of stem cell preservation businesses and providers of stem storage services. Certain of our competitors may have greater financial and other resources than us. Competitors with greater access to financial resources may enter our markets and compete with us. In the event that we are not able to compete successfully, our business may be adversely affected and competition may make it more difficult for us to grow our revenue and maintain our existing business on terms that are favorable to us.

Our failure to comply with laws related to hazardous materials could materially harm us.

We are subject to state and federal laws regulating the protection of employees who may be exposed to hazardous material and regulating the proper handling and disposal of that material. Although we believe we are in compliance with all applicable laws, a violation of such laws, or the future enactment of more stringent laws or regulations, could subject us to liability, or require us to incur costs that would have an adverse effect on us.

Risks Related to Our Stock

Sales of substantial amounts of our common stock, or the availability of those shares for future sale, could adversely affect our stock price and limit our ability to raise capital.

We are unable to predict the effect, if any, that future sales of common stock or the potential for such sales may have on the market price of the common stock prevailing from time to time. The market price of our common stock could decline as a result of sales of substantial amounts of our common stock in the public market or the perception that substantial sales could occur. These sales also may make it more difficult for us to sell common stock in the future to raise capital.

Our common stock price may be volatile and you may not be able to resell your shares of our common stock at or above the price you paid.

The market price for our common stock is likely to be highly volatile and is likely to experience wide fluctuations in response to factors including the following:

actual or anticipated variations in our quarterly operating results;

announcements of technological innovations or new services by us or our competitors;

changes in financial estimates by securities analysts;

conditions or trends in the stem cell preservation business;

changes in the economic performance or market valuations of other stem cell storage companies;

announcements by us or our competitors of significant acquisitions, strategic partnerships, joint ventures or capital commitments;

additions or departures of key personnel;

sales of additional shares of common stock by us;

adverse results on existing or potential new litigation;

investor perceptions of us and the stem cell preservation business;

general economic trends and market conditions;

adverse announcements by our competitors; and

adverse publicity.

Broad market and industry factors may adversely affect the market price of our common stock, regardless of our actual operating performance. Over the past two years, our stock price has fluctuated from a high of $6. 70 to a low of $.60. To the extent our stock price fluctuates, it could impair our ability to raise capital through the offering of additional equity securities. As a result, investors in our common stock may not be able to resell their stock at or above the price at which they purchase it. Our stock was delisted from the Nasdaq SmallCap market in July 2003 and now is traded on the Over-the-Counter Bulletin Board. The Company expects to re-apply for listing on the Nasdaq SmallCap market or another exchange in the next 12-18 months; however, there is no assurance the Company will meet the applicable listing requirements at that time.

Our Board of Directors has the authority to issue preferred stock, which could deter takeover bids even if those bids are in the stockholders best interests.

We have 500,000 shares of authorized and unissued preferred stock, which could be issued to third parties selected by management or used as the basis for a stockholders rights plan, which could have the effect of deterring potential acquirers. The ability of our Board of Directors to establish the terms and provisions of different series of preferred stock could discourage unsolicited takeover bids from third parties even if those bids are in the stockholders best interests.

ITEM 7. FINANCIAL STATEMENTS

The consolidated financial statements and supplementary data listed in the accompanying Index to Consolidated financial statements are attached as part of this report.

FINANCIAL STATEMENTS

The following consolidated financial statements of CRYO-CELL International, Inc. are included in Item 7:

Report of Independent Certified Public Accountant

Consolidated Balance Sheets as of November 30, 2004 and 2003

Consolidated Statements of Operations and Comprehensive Income (loss)

For the Years Ended November 30, 2004 and 2003

Consolidated Statements of Cash Flows

For the Years Ended November 30, 2004 and 2003

Consolidated Statements of Stockholders (Deficit) Equity For the Years Ended November 30, 2004 and 2003

Notes to Consolidated Financial Statements

All other schedules for which provision is made in the applicable accounting regulation of the Securities and Exchange Commission are not required under the related instructions or are inapplicable, and therefore have been omitted.

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and

Shareholders of Cryo-Cell, International, Inc.:

We have audited the accompanying consolidated balance sheets of Cryo-Cell International, Inc. and subsidiaries (a Delaware corporation) as of November 30, 2004 and 2003, and the related consolidated statements of operations and comprehensive income (loss), stockholders deficit, and cash flows for each of the two years in the period ended November 30, 2004. These financial statements are the responsibility of the Company s management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the 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. An audit also includes 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.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of Cryo-Cell International, Inc. and subsidiaries as of November 30, 2004 and 2003, and the results of its operations and its cash flows for each of the two years in the period ended November 30, 2004 in conformity with accounting principles generally accepted in the United States of America.

/s/ GRANT THORNTON LLP

Tampa, Florida

February 15, 2005

CRYO-CELL INTERNATIONAL, INC. AND SUBSIDIARIES

CONSOLIDATED BALANCE SHEETS

	November 30, 2004	November 30, 2003
ASSETS		
Current Assets		
Cash and cash equivalents	$ 4,737,368	$ 2,452,006
Restricted cash	200,000	
Marketable securities and other investments	782,419	798,077
Accounts receivable and advances (net of allowance for doubtful accounts of $379,654 and $200,010, respectively)	1,044,430	483,926
Receivable - Affiliates (net of allowance for doubtful accounts of $0 and $128,540, respectively)	231,880	195,022
Prepaid expenses and other current assets	427,629	366,579
Total current assets	7,423,726	4,295,610
Property and Equipment-net	2,822,616	1,354,619
Other Assets		
Marketable securities and other investments	484,490	468,102
Notes receivable	100,000	100,000
Receivable - Revenue sharing agreement		100,525
Investment in Saneron CCEL Therapeutics, Inc.	716,545	799,328
Deposits and other assets	93,336	99,004
Total other assets	1,394,371	1,566,959
Total assets	$ 11,640,713	$ 7,217,188

LIABILITIES AND STOCKHOLDERS DEFICIT	November 30, 2004	November 30, 2003
Current Liabilities		
Accounts payable	$ 482,703	$ 340,731
Loan payable to related party		145,000
Accrued expenses	1,337,024	1,637,540
Deferred revenue	2,771,490	2,108,292
Total current liabilities	4,591,217	4,231,563
Other Liabilities		
Deferred revenue	2,884,782	1,686,916
Long-Term Liability-Revenue sharing agreements	3,750,000	3,750,000
Deferred consulting obligation	1,250,466	1,339,718
Total other liabilities	7,885,248	6,776,634
Minority Interest		
Commitments and Contingencies (Note 10)		

Stockholders Deficit		
Preferred stock ($.01 par value, 500,000 authorized and none issued)		
Common stock ($.01 par value, 20,000,000 authorized; 11,397,379 as of November 30, 2004, and 11,352,379 as of November 30, 2003 issued and outstanding)	113,974	113,524
Additional paid-in capital	23,428,840	23,295,659
Treasury stock	(839,301)	(839,301)
Accumulated other comprehensive loss	(130,250)	(111,522)
Accumulated deficit	(23,409,015)	(26,249,369)
Total stockholders deficit	(835,752)	(3,791,009)
	$ 11,640,713	$ 7,217,188

The accompanying notes are an integral part of these consolidated financial statements.

CRYO-CELL INTERNATIONAL, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE INCOME (LOSS)

	For the years ended	
	November 30, 2004	November 30, 2003
Revenue	$ 12,210,273	$ 7,549,536
Costs and Expenses (Income):		
Cost of sales	3,162,957	2,625,123
Marketing, general & administrative expenses	6,274,072	7,966,734
Litigation Accrual (Pharmastem)	(1,102,968)	1,102,968
Research, development and related engineering	82,509	234,374
Impairment of assets	132,500	2,048,579
Depreciation and amortization	481,580	353,179
Total cost and expenses	9,030,650	14,330,957
Operating Income (Loss)	3,179,623	(6,781,421)
Other (Expense) Income:		
Interest income	47,513	48,931
Interest expense	(750,128)	(654,322)
Licensee income	549,084	211,494
Extinguishment of revenue sharing agreements		666,666
Settlement on insurance claim	135,338	
(Loss) gain on sale of fixed asset	(7,625)	41,548
Gain (Loss) on sale of marketable securities	2,958	(20,210)
Total other (expense) income	(22,860)	294,107
Income (loss) before income taxes and equity in losses of affiliates	3,156,763	(6,487,314)
Income taxes	(86,001)	
Equity in losses of affiliates	(137,852)	(344,840)
	(223,853)	(344,840)
Income (loss) from continuing operations	2,932,910	(6,832,154)