

CRYO CELL INTERNATIONAL INC  
Form 10KSB  
February 28, 2006  
Table of Contents

---

## 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, 2005

.. 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  
(State or other jurisdiction of

incorporation or organization)

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

(Address of principal executive offices) (Zip Code)

Issuer s telephone number: (813) 749-2100

---

22-3023093  
(I.R.S. Employer

Identification No.)

Edgar Filing: CRYO CELL INTERNATIONAL INC - Form 10KSB

**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  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

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

Issuer's revenues for its most recent fiscal year: \$14,451,331.

As of February 15, 2006 the aggregate market value of the voting stock held by non-affiliates of the Issuer was approximately \$40,357,184. 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, 2006: 11,624,629.

**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 2006 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, 2006.

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

---

**Table of Contents**

**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, as amended. The terms CRYO-CELL International, Inc., CRYO-CELL Company, we, our and us refer to CRYO-CELL International, Inc. The words expect, believe, goal, plan, intend, estimate and similar expressions variations thereof, if 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 unique risks posed by our international activities, including but not limited to local business laws or practices that diminish our ability to effectively compete with local businesses;
- (vi) any technological or medical breakthroughs that would render the Company's business of stem cell preservation obsolete;
- (vii) any material failure or malfunction in our storage facilities; or any natural disaster or act of terrorism that adversely affects stored specimens;

## Edgar Filing: CRYO CELL INTERNATIONAL INC - Form 10KSB

- (viii) any adverse results to our prospects, financial condition or reputation arising from any material failure or compromise of our information systems;
  
- (ix) the costs associated with defending or prosecuting litigation matters, particularly including litigation related to intellectual property, and any material adverse result from such matters;

**Table of Contents**

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

(xi) any negative effect from the filed class action shareholder lawsuits.

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. 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 Cryo-Cell files from time to time with the Securities and Exchange Commission, including its Quarterly Reports on Form 10-QSB and any Current Reports on Form 8-K.

**Table of Contents**

**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 cellular processing and cryogenic storage, with a current focus on the collection and preservation of umbilical cord (U-Cord®) blood stem cells for family use. The Company believes it is the world's largest family cord blood stem cell bank in terms of the number of specimens preserved. Its headquarters facility in Oldsmar, Florida handles all aspects of its U.S.-based 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 inform expectant parents and their prenatal care providers 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 approximately 70 diseases, a number of them life-threatening. With continued research in this area of medical technology, other therapeutic uses for cord blood stem cells are being explored. A vast majority of expectant parents are simply unaware that umbilical cord blood contains a rich supply of non-controversial 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 are a perfect match for the baby throughout its life and have at least a 1-in-4 chance 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 of the newborn or a relative. 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, and anticipates that its growth and profitability 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.

The Company believes that it provides several key advantages over its competitors, including:

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,



## **Table of Contents**

the option of participating in Upromise®, a nationally recognized 529 registered college savings plan that gives clients money back for college,

our Client for Life Program, announced in December 2005, that enables clients to lock-in today's U-Cor® service prices for the family's future newborns, and

a \$10,000 CRYO-CELL Cares payment that provides families with a lump-sum payment to assist with personal living expenses in the event that their child's CRYO-CELL processed and stored cord blood specimen is utilized for bone marrow transplant.

## **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**

Hematopoietic 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). An individual's own bone marrow may be used for a transplant if the cancer has not 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/placental blood ( cord blood stem cells ) and can be collected and stored after a baby is born. Over 6,000 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, either for the donor or for another family member. Moreover, researchers believe they may be utilized in the future for treating diseases that currently have no cure.

The Company believes that the market for cord blood stem cell preservation 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-Cor® cells can be stored as a precautionary measure. Medical technology is constantly evolving which may provide new uses for cryopreserved cord blood stem cells.

## **Plureon®**

In October 2005, the Company announced an exclusive Strategic Relationship Agreement with Plureon Corporation, a private biotechnology company, to provide collection and preservation of Plureon's proprietary stem cells in the United States of America. Under the terms of the agreement, the Company will develop the proprietary methodology to collect, process and cryogenically preserve Plureon® Stem Cells ( PSCs ) collected from placental tissue at the time of birth. The agreement establishes exclusive license rights for the Company to market this service in the United States, and first right-of-refusal for other global markets. The agreement stipulates that the Company must meet certain sales thresholds in order to retain its exclusivity.



## **Table of Contents**

PSCs are a novel type of stem cell discovered by researchers working in the Laboratory for Cell Therapy and Tissue Engineering at Children's Hospital Boston (a Harvard Medical School teaching affiliate in Boston, MA). Although, to date, PSCs have not been used in human therapies, researchers believe that PSCs may become an alternative to embryonic stem cells in the development of human cellular therapies. Researchers have already demonstrated that PSCs have the ability to cure diabetes in small animals. This finding attracted the interest of several large pharmaceutical and life sciences companies. Plureon Corporation has a research and development agreement in the field of diabetes with BD (Becton Dickinson and Company). Plureon is also researching the use of PSCs in treating a host of other diseases, disabilities, and injuries.

In the laboratory, PSCs have been differentiated into many other cell types, including bone, cardiac muscle, skeletal muscle, nerves, liver, and pancreatic cells. Even after hundreds of population doublings, PSCs appear to remain stable and retain their key characteristics. PSCs are collected without harm to an embryo or fetus, and so they do not give rise to the ethical controversy surrounding embryonic stem cells. PSCs differ from embryonic stem cells in other respects as well. For instance, embryonic stem cells have been shown to form teratomas when implanted into animals, whereas Plureon cells are non-cancer forming. In addition, PSCs have more plasticity (the ability to become multi-lineage) and can be easily cultured to multiply.

CRYO-CELL intends to launch the Plureon® service in the first half of fiscal 2006, in combination with its U-Cord® service. CRYO-CELL expects to charge a fee for cell collection, processing and storage, and pay royalties to Plureon for sub-licensing the underlying technology. The Company believes that this bundled service will provide parents with the unique opportunity to collect both cord blood and PSCs from placental tissue for their future therapeutic potential.

### **Cellular Storage Services**

The Company enters into storage agreements with its clients under which the Company charges a fee for the processing and testing of the umbilical cord blood. Thereafter, the client is charged an annual fee to store the specimen, unless the client has entered into a 21-year pre-paid storage plan.

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 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 laboratory processing facility contains 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. The Company is the first private bank to process cord blood in a technologically and operationally advanced cGMP/cGTP-compliant facility.

The Company's facility, which also houses the Company's clinical services, marketing and administrative operations, is designed and appointed to accommodate a broad range of events such as client tours and open houses, as well as educational workshops for clinicians and expectant parents. 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, in combination with its global affiliates, currently stores over 110,000 cord blood stem cell specimens worldwide for the exclusive benefit of newborn babies and possibly other members of their family. Approximately 33,000 of these specimens are split specimens, for which the Company

## **Table of Contents**

stores a duplicate specimen at a secondary storage facility in Sedona, Arizona. The Company believes it is the world's largest family cord blood stem cell bank in terms of the number of worldwide specimens preserved.

### **Medical and Scientific Advisory Board**

The Company has a seven member Medical and Scientific Advisory Board (MASB), with Stephen Noga, M.D., Ph.D. serving as its Chairman. Dr. Noga is currently the Director of Medical Oncology & Hematology at the Alvin & Lois Lapidus Cancer Institute and the Director of the Cellular Therapeutics Program, both at Sinai Hospital of Baltimore. He is an Associate Professor of Oncology and Pathology at The Johns Hopkins University School of Medicine. In addition to his expertise in cellular therapies, Dr. Noga is a noted speaker, has served on many editorial boards and has organized many conferences, advisory committees and review groups.

Dr. Noga is joined by six other highly qualified MSAB members, each having expertise in the areas of either transplant medicine, infectious disease, laboratory/transfusion medicine and/or obstetrics/gynecology.

### **Marketing**

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 believes that its growth has been facilitated by a variety of referral sources, resulting from high levels of customer satisfaction. New expectant parent referrals during 2005 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 referral base has permitted the Company to grow in past years without some of the traditional, more expensive marketing approaches.

During 2005, 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.

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 the Company has increased its internet marketing campaigns.

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 continues to use its Web site, [www.cryo-cell.com](http://www.cryo-cell.com), to market its services and to provide resource information to expectant parents. The site, which is frequently 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 enroll in online. Viewers may read about successful transplants using Cryo-Cell stored cord blood stem cells and access other topical information.

## **Table of Contents**

### **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 approximately 25 other national private cord blood banks. Some of these companies, such as Corcell and Cord Blood Registry, Inc. are competitors who, as privately owned entities, can leverage considerable resources to market and sell their services. Other competitors such as ViaCord, a division of ViaCell, and LifeBankUSA, a division of Celgene, are both publicly traded corporations.

The competitors mentioned above, and others, may have access to greater financial resources. Nevertheless, the Company believes it is currently well positioned to compete in the industry. Importantly, these competitors mentioned above, along with others, charge more for comparable quality service. In addition, the Company possesses an industry-recognized AABB accreditation, and believes that it is the first private cord blood bank to process in a cGMP- and cGTP-compliant facility exceeding current FDA requirements. In November 2005, the Company was granted ISO 9001:2000 certification from BSI America's, Inc., a leading quality management systems registrar. ISO (International Organization for Standardization) standards are internationally recognized as an effective framework for a quality management system (QMS). This achievement positions CRYO-CELL as the only cGMP and cGTP-compliant private cord blood bank with both ISO certification and AABB accreditation. The Company believes it offers the most superior value of highest quality cryopreservation processing and storage in the industry.

The Company also operates in an environment where various public cord blood banks are encouraging parents to donate their newborn's cord blood rather than privately banking 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 services 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 incurred costs of \$26,148 during fiscal 2005, compared to \$82,509 during fiscal 2004, 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.

Currently, the states of New York, New Jersey and Maryland require cord blood banks to be registered or licensed. The Company is currently registered or licensed to operate in these states. 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.

## **Table of Contents**

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 such technology and a verbal confirmation from the FDA, the Company believes it is no longer 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 resources on its core business of marketing cord blood stem cell preservation services. In the future, the Company expects to 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 owned an approximate 38% and 42% interest in Saneron CCEL Therapeutics, Inc. ( Saneron ) as of November 30, 2005 and 2004, respectively. Saneron has exclusively licensed from both the University of South Florida ( USF ) and the University of Minnesota ( UMN ) various patents and patent applications for the therapeutic use of umbilical cord blood stem cells and 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 Saneron shares.

In May 2005, Saneron and USF received both a NIH Small Business Technology Transfer ( STTR ) grant and a Florida High Tech Corridor grant totaling over \$250,000 to conduct research on the use of Saneron's U-CORD-CEL<sup>EM</sup> (a proprietary suspension of mononuclear cells, including stem cells, isolated from umbilical cord blood) in a large animal for the treatment of acute myocardial infarction. Also, in September 2005, Saneron and UMN received a NIH STTR grant of nearly \$160,000 to conduct research on a proprietary umbilical cord blood stem cell line developed at UMN for the treatment of hemorrhagic brain injury. To date, Saneron has received eight SBIR/STTR grants and has been the industry sponsor on seven Florida High Tech Corridor grants to continue 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. In December 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 33,000 split specimens at the Safti-Cell facility. In May 2005, the Company implemented a new processing methodology in accordance with emerging requirements of the American Association of Blood Banks (AABB). The new process utilizes closed-system bags rather than vial storage. In view of this transition to a new processing methodology, as well as the enhanced level of security designed in the Company's new facility, the Company discontinued 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 formed to be involved in the development of marketing programs for the collection and preservation of adult stem cells. During 2004, SCPT shut down its operations, paid all outstanding liabilities to employees and other creditors and completed a liquidating distribution of the remaining assets of SCPT to the holders of SCPT common stock.

## Table of Contents

### 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 the parties that have entered in to the RSAs totaled \$798,199 in fiscal 2005 and \$693,226 in fiscal 2004. Such payments are recorded as interest expense in the accompanying consolidated statements of income and comprehensive income.

Summary descriptions of the Company s current RSAs are found below, grouped by the geographic location to which they relate. As described below, SCPT also entered into revenue sharing agreements, including one with the Company.

**Florida.** In 1999, the Company signed a revenue sharing agreement, which applies to net storage revenues originating from specimens from within the State of Florida for \$1,000,000, and entitles the investors to net revenues from a maximum of 33,000 storage spaces. Mr. Charles Nyberg, a former member of the Board of Directors of the Company, currently has a 50% interest in the shared revenue under this 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 a maximum of 33,000 storage spaces for specimens originating in Illinois and its contiguous states and stored in Oldsmar, Florida.

**New York.** In 1999, the Company entered into a modified revenue sharing agreement with Bio-Stor International, Inc. ( Bio-Stor ) for 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.

In 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 applicable to revenue associated with specimens from 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 receives 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 storage spaces.

**Texas.** In 2001, the Company entered into an agreement with two investors, one of whom was an affiliate of the Company, entitling them to on-going shares in a portion of the Company s net storage revenue generated by specimens originating from within the State of Texas for a price of \$750,000. 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 owns a 50% interest in the shared revenue under 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.

## **Table of Contents**

### **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 expects to 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 with CRYO-CELL de Mexico, 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 Company received an initial up-front license fee payment of \$600,000 and is entitled to receive ongoing 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 \$597,013 and \$317,205 for the years ended November 30, 2005 and 2004, respectively, and this is reflected in licensee income in the accompanying consolidated statements of income and comprehensive income.

**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 Indian government approval. 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. ACCPL has an option to expand into Singapore and Malaysia for one year after the licensed services are first offered for sale to the general public in India, as defined in the agreement, which is March 5, 2006. 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. 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 therefore is exercised. The Company will also receive royalties on storage revenues ranging from 10% to 15%, depending on the number of units stored by ACCPL.

Under the terms of 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 Indian 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 licensee income in the consolidated statement of income and comprehensive income. The remaining balance due of \$475,000 will be recognized under the installment basis of accounting, recognizing each payment when received. The next installment of \$175,000 becomes due on March 1, 2006. The Company recorded royalties and sub-license fees from ACCPL in the amount of \$16,302 and \$0 for the years ended November 30, 2005 and 2004, respectively, and this is reflected in licensee income in the accompanying consolidated statements of income and comprehensive income.

### **Employees**

At November 30, 2005, there are 46 full-time and 8 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.

---

**Table of Contents**

**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 Manufacturing 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 foregoing, the Company is currently involved in the following:

***PharmaStem Litigation.*** 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), 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 use of stem cells derived from umbilical cord blood. PharmaStem, a Delaware corporation, originally named as defendants 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.

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. The defendants, including the Company, filed motions for post-trial relief, and execution of the judgment was stayed pending disposition of those motions. In December 2003, the Company transferred \$957,722 into an escrow account to secure the judgment. The plaintiff also filed motions seeking an award of approximately \$2,800,000 for enhanced damages, counsel fees and interest, and 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. 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 preserving of cord blood for families. With regard to PharmaStem's 681 patent, the court granted CRYO-CELL and its co-defendants a new trial on the issues of infringement, finding that the jury's earlier verdict of infringement was against the great weight of the evidence.

## Table of Contents

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 income and comprehensive income for fiscal 2004. Litigation accrual reversal represents the litigation expense recognized through fiscal 2003. The Company was 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 its customers 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.

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, *In re: PharmaStem Therapeutics, Inc. Patent Litigation*, MDL No. 1660. The Company intends to vigorously defend the suit. The Delaware court has stayed all proceedings in these cases, including discovery, pending the outcome of the Federal Circuit appeal and reexamination proceedings in the U.S. Patent and Trademark Office. The reexamination proceedings involve all four of the patents on which PharmaStem has sued. 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.

***Life-Sciences Litigation.*** 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 an 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.



**Table of Contents**

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 income and comprehensive income in fiscal 2004.

***Securities Class Action Litigation.*** 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. On February 25, 2005, the court issued an order approving the previously reported formal stipulation of settlement for the litigation. The settlement, which totals \$7 million, includes a payment of \$4 million paid by the insurance carrier of the Company's former auditors. In addition, the Company's insurance carrier paid \$3 million on the Company's behalf under its directors' and officers' insurance policy. The Company previously satisfied the \$175,000 deductible under its directors' and officers' insurance policy, and believes it will have no further financial obligations under the settlement.

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.

**Table of Contents****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.

	Low Closing Bid	High Closing Bid
<u>2004</u>		
February 29, 2004	.73	.92
May 31, 2004	.60	.81
August 31, 2004	.61	3.00
November 30, 2004	1.86	2.70
<u>2005</u>		
February 28, 2005	2.75	6.70
May 31, 2005	2.15	3.86
August 31, 2005	2.82	3.90
November 30, 2005	2.30	3.89

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, 2005, the Company had 334 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, 2005, 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 cellular processing and cryogenic storage, with a current focus on the collection and preservation of umbilical cord (U-Cord®) blood stem cells for family use. The Company's principal sources of revenues are service fees for cord blood processing and preservation for new customers and recurring annual storage fees. The Company currently charges fees of \$1,595 to new clients for the collection kit, processing and testing and return medical courier service, with discounts in the case of multiple children from the same family and in other circumstances. The Company currently charges an annual storage fee of \$125 for new clients; storage fees for existing customers depend on the contracts with such customers. The Company also receives other income from licensing fees and royalties from global affiliates.

## **Table of Contents**

During fiscal 2005, the Company increased its revenues by 18% over the level in fiscal 2004 and achieved net income of approximately \$1,000,000, compared to approximately \$2,800,000 of net income for fiscal 2004. Net storage revenues increased because of an increase in the customer base and the effects of one price increase during 2004 for newly enrolled customers. The Company continued to be profitable largely due to the 18% increase in revenues offset by increases in cost of sales and marketing, general, and administrative expenses, and a gain recognized on the renegotiation of a deferred consulting agreement for approximately \$498,000. Net income decreased from the prior year largely due to the reversal of a litigation accrual in 2004 and an increase in marketing, general, and administrative expenses as a percentage of revenues during 2005.

In October 2005, the Company announced an agreement with Plureon under which the Company will have the exclusive rights to market the service of collecting, processing and preserving placental stem cells as a supplement to its existing services involving U-Cord® stem cells. During the first half of 2006, the Company expects to launch this service. The Company expects to charge an initial fee for collection and processing the placental stem cells, in addition to its existing fees for collection and processing of U-Cord® stem cells. Also, the Company will charge an additional annual storage fee for storage of the placental stem cells, in addition to the storage fee for the U-Cord® stem cells. The Company will pay royalties to Plureon for sub-licensing the underlying technology.

At November 30, 2005, the Company had cash and cash equivalents of \$7,979,377 and marketable securities and other investments of \$519,713. The Company's cash increased by approximately \$3,200,000 during fiscal 2005, as a result of its cash flows from operations. As of February 25, 2006, the Company maintains no indebtedness.

## **Discontinued Operations**

In accordance with SFAS No. 144, Accounting for the Impairment or Disposal of Long-Lived Assets, ( SFAS No. 144 ) the closing of SCPT in 2004 represents a discontinued operation as of November 30, 2004. The net assets of SCPT are immaterial to the consolidated financial statements. Through November 30, 2003, 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 is reflected at \$0, and CRYO-CELL has recognized 100% of the loss of SCPT in its statement of income and comprehensive income as discontinued operations during the twelve months ended November 30, 2004 of approximately \$93,000. The minority portion of the losses for the twelve months ended November 30, 2004 was approximately \$12,000.

## **Results of Operations**

**Revenues.** For the fiscal year ended November 30, 2005, the Company had revenues of \$14,451,331 compared to \$12,210,273 in fiscal 2004, representing an 18% increase. The increase is primarily attributable to the effects of successfully implemented price increases during 2004 for newly enrolling clients, as well as the overall increase in customer base over the prior year, which led to an increase in storage revenues. These increases were partially offset by an increase in sales discounts. During 2004, the Company implemented a price increase affecting the initial fee. This price increase had a positive impact on revenue and gross profit during fiscal 2004 and continued through fiscal 2005.

**Cost of Sales.** For the fiscal year ended November 30, 2005, cost of sales was \$4,143,002, as compared to \$3,162,957 in 2004, representing a 31% increase. Costs of sales were 29% of revenues in fiscal 2005 compared to 26% in fiscal 2004. Cost of sales as a percentage of revenue increased due to an increase in costs of lab supplies, sales promotions, and cord blood collection reimbursements. Cost of sales includes

---

**Table of Contents**

wages and supplies associated with new process enhancements to the existing production procedures and quality systems in the processing of cord blood specimens at the Company's facility in Oldsmar, Florida and the costs associated with storage of specimens at the Safti-Cell facility (a related party during portions of 2004 and 2005) in Arizona. During the second quarter of fiscal 2005, the Company implemented a new processing methodology in accordance with emerging requirements of the American Association of Blood Banks (AABB). The new process utilizes closed-system bags rather than vial storage. Due to this transition to a new processing methodology, as well as, the enhanced level of security designed in the Company's new facility, the Company discontinued offering the dual storage service to new customers during the second quarter of fiscal 2005.

**Marketing, General and Administrative Expenses.** Marketing, general and administrative expenses during the fiscal year ended November 30, 2005, were \$9,104,087 as compared to \$6,274,072 in 2004, an increase of \$2,830,015 or 45%. The increase was largely attributable to a significant increase in consumer advertising. Consulting fees related to the deployment of a new customer database, corporate rebranding, and Sarbanes-Oxley compliance also contributed to the increase. Marketing, general and administrative expenses were 63% of revenues in fiscal 2005 compared to 51% for the same period in fiscal 2004. Marketing, general and administrative expenses increased as a percentage of revenue due to the aforementioned increases.

**Litigation Accrual.** During fiscal 2003 the Company accrued approximately \$1,100,000 as the result of a judgment entered against the Company in 2003 related to the Pharmastem litigation. In 2004, the Company reversed all prior accruals as a result of a ruling by the Court on the post trial motions with regards to the Pharmastem litigation. The litigation accrual reversal for fiscal 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, 2005, were \$26,148 as compared to \$82,509 in 2004, a decrease of 68%.

**Impairment of Assets.** The Company previously developed several technologies for the processing and cryogenic storage of specimens. During 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 Company was unable to dispose of the storage system equipment during 2004. As a result, the Company recorded an impairment charge of approximately \$130,000 in 2004 to write-down this equipment to its salvage value.

**Interest Expense.** Interest expense during the fiscal year ended November 30, 2005, was \$863,713 compared to \$750,128 in 2004. 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). Also included in interest expense is the amortization of the present value of a deferred consulting agreement in the amount of \$30,779 and \$56,902 for the years ended November 30, 2005 and 2004, respectively. If the Company's storage revenues continue to increase in areas covered by RSAs, the Company's interest expense related to the RSA payments will also increase.

**Licensee Income.** Licensee income for the fiscal year ended November 30, 2005, was \$613,316 as compared to \$549,084 in 2004. Licensee income increased by approximately \$64,000 from 2004 to 2005. Licensee income for fiscal 2005 and fiscal 2004 was royalty income earned in geographical areas where the Company has license agreements and the sale of sublicense agreements. There can be no assurances that income from licenses and royalties will continue at the same rates as in the past.

## **Table of Contents**

**Renegotiation of Deferred Consulting Agreement.** For the year ended November 30, 2005, the Company recorded other income of \$498,161 due to the cancellation of a deferred consulting obligation agreement. A new deferred consulting agreement was negotiated and signed during the second quarter 2005. The terms of this settlement agreement are confidential.

**Equity in Losses of Affiliates.** Equity in losses of affiliates was \$119,762 for the fiscal year ended November 30, 2005 compared to a loss of \$137,852 in 2004. During fiscal 2005 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 \$88,000 related to compensation expense that resulted from the stock awards in 2005 and approximately \$55,000 in 2004.

**Income Taxes.** Income tax benefit was \$36,001 for the fiscal year ended November 30, 2005 compared to income tax expense of \$86,001 in 2004. The Company recorded an income tax benefit due to the reversal of a federal income tax accrual that had been recorded during the fourth quarter of fiscal 2004 for estimated tax payments, which was partially offset by the current year provision recorded for the year ended November 30, 2005 based on the net profits of the Company.

## **Liquidity and Capital Resources**

Through November 30, 2005, the Company's principal source of cash has been from sales of its U-Cor® 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, 2005, the Company had cash and cash equivalents of \$7,979,377 as compared to \$4,737,368 in 2004. The increase in cash and cash equivalents was primarily attributable to the following:

Cash provided by operating activities in fiscal 2005 amounted to \$3,218,576 which was primarily attributable to the Company's operating activities including licensing fees, a price increase, and an increase in recurring revenue from the current client base.

Cash used in investing activities in fiscal 2005 amounted to \$86,924, which was primarily attributable to the purchase of approximately \$709,000 of software, furniture, and equipment, offset by approximately \$596,000 of proceeds received for the redemption of marketable securities.

Cash provided by financing activities in fiscal 2005 amounted to \$110,357, which consisted primarily of proceeds provided by the exercise of stock options.

The Company also has certain investments in marketable securities and certificates of deposit, totaling \$519,713 at November 30, 2005, compared to \$1,266,909 as of 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 \$2,000,000 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 cash needs for at least the next 12 to 18 months. Cash flows

## **Table of Contents**

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 processing and cryogenic 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.

### **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**

Enrollment fee revenue and the related direct incremental costs associated with these fees are deferred and recognized once the processing of the specimens is completed.

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. Shipping and handling costs are expensed and included in cost of sales.

### **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 has entered 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.

## **Table of Contents**

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 uncollectible accounts.

## **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. The Company classifies marketable securities and other investments as current in the accompanying consolidated balance sheets based on original maturity dates of less than one year. The Company has certain investments as of November 30, 2005 and 2004 that have been below fair market value for several years. The write down associated with these investments has been recorded in other comprehensive income. Management believes that the decline in market value of these investments is temporary based on current industry reports and economic and technological trends.

## **Accounts Receivable**

Accounts receivable consist of the amounts due from clients that have enrolled in the U-Cord<sup>®</sup> processing and storage program and amounts due from license affiliates. Accounts receivable due from clients are due within 30 days and are stated at amounts due from clients net of an allowance for doubtful accounts. Accounts outstanding longer than the contractual payment terms are considered past due. The Company determines its allowance by considering the length of time accounts receivable are past due, the Company's previous loss history, and the customer's current ability to pay its obligations. The Company writes-off accounts receivable when they become uncollectible, and payments subsequently received on such receivables are credited to the allowance for doubtful accounts.

## **Investment in Saneron**

The Company made a significant investment in an entity that is involved in the area of stem cell research. The Company accounts for this investment under the equity method, and at least annually, reviews its investment for possible impairment and, if necessary, adjusts the carrying value of such investment. The Company does not believe that an impairment exists as of November 30, 2005 and November 30, 2004.

## **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 liability. In August 2004, the Company stopped making payments under the consulting agreement. This agreement was terminated and following negotiations, a new agreement was negotiated by the parties and signed on April 15, 2005. The Company commenced payments under the terms of the new agreement during the second quarter of 2005. The terms of the settlement are confidential. The present value of the 2005 agreement has been reflected as a liability on the consolidated balance sheet as of November 30, 2005 and 2004.

## **Income Taxes**

Under the asset and liability method of SFAS No. 109 Accounting for Income Taxes, deferred tax assets and liabilities are recognized for the estimated future tax consequences attributable to differences between financial statement carrying amounts of existing assets and liabilities and their

## **Table of Contents**

respective tax bases. Deferred tax assets and liabilities are measured using enacted tax rates expected to be recovered or settled. A valuation allowance covering the net deferred tax assets of the Company as of November 30, 2005 and November 30, 2004, has been provided as the Company does not believe it is more likely than not that the future income tax benefits will be realized.

### **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.

### **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 in this report. 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. Should they materialize, 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**

**We may be forced to undertake lengthy and costly efforts to build market acceptance of our umbilical cord blood stem cell storage services, the success of which is critical to our profitability.**

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 educate and build awareness of our services and its potential benefits could significantly delay market acceptance and our ultimate profitability. The successful commercialization of our services will also require that we satisfactorily address the needs of obstetricians and family medicine practitioners in order to address potential resistance to recommendations for our services and ultimately reach our potential consumers.

**Our placental stem cell storage services have not yet been offered, and there is no assurance that these services will gain market acceptance.**

We intend to launch our offering of the services of processing and storing Plureon® Stem Cells in the first six months of 2006. This represents a new and untested service offering of the Company, and there is no assurance that it wil