

CRYO CELL INTERNATIONAL INC

Form 10-K

February 11, 2008

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## U.S. Securities and Exchange Commission

Washington, D.C. 20549

### FORM 10-K

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

For the fiscal year ended November 30, 2007

.. 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 registrant as specified in its charter)

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**DELAWARE**  
(State or other jurisdiction of

**22-3023093**  
(I.R.S. Employer

incorporation or organization)

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)

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

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

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

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

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Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, or a non-accelerated filer or a smaller reporting company. See definition of large accelerated filer, accelerated filer and smaller reporting company in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer

Accelerated filer

Non-accelerated filer

Smaller reporting company

(Do not check if a smaller reporting company)

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Securities Exchange Act of 1934). Yes  No

The aggregate market value of the Registrant's Common Stock held by non-affiliates of the Registrant (without admitting that any person whose shares are not included in such calculation is an affiliate) computed by reference to the price at which the common stock was last sold as of the last business day of the Registrant's most recently completed second fiscal quarter was \$24,662,240.

As of January 31, 2008, the Registrant had 11,672,129 shares of Common Stock, \$0.01 par value, issued and outstanding.

**DOCUMENTS INCORPORATED BY REFERENCE**

The information required by Part III of Form 10-K is incorporated by reference to the Issuer's definitive proxy statement relating to the Special Meeting of Shareholders to be held on March 4, 2008 which will be filed with Securities and Exchange Commission within 120 days.

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### **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 principally 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 units. Several other companies involved in commercial cell banking rely on shipping their specimens elsewhere for processing and storage.

In recent years, the Company has expanded its research and development (R&D) activities to develop technologies related to stem cells other than umbilical cord blood stem cells. In 2004, the Company entered into an agreement with Plureon Corporation under which the Company would provide collection and preservation of Plureon's proprietary placental fetal stem cells. During 2006 and the first part of 2007, the Company's research and development activities were focused on efforts to launch a commercial service relating to the Plureon stem cells. In April 2007, we announced that the commercial launch of this service would be postponed indefinitely due to technological commercialization considerations. During 2007, much of the Company's R&D activities focused on the development of proprietary technology related to maternal placental stem cells (MPSCs) which was subsequently postponed indefinitely due to technological commercialization findings similar to those identified with the Plureon technology.

During 2006, in parallel with its R&D associated with placental stem cells, the Company discovered novel technology related to menstrual stem cells. In November 2007, the Company announced the launch of its C-elle<sup>M</sup> service related to this patent-pending technology, and the Company continues to focus its current research and development activities principally on the C-elle service and related new menstrual stem cell technologies. The Company is actively marketing the C-elle service both through a bundled offer with the Company's U-Cord service and on a stand-alone basis.

#### **Cord Blood Stem Cell Processing and Storage Business**

##### ***Background of Business***

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.

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.

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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 8,000 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-Cord® cells can be stored as a precautionary measure. Medical technology is constantly evolving which may provide new uses for cryopreserved cord blood stem cells.

### ***Marketing Approach***

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. We intend to maximize our growth potential through our value-driven competitive leadership position; a fast-growing embedded client base; expanded consumer and professional channels; increased public awareness and accelerated market penetration.

### ***Our Cord Blood Stem Cell 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

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element protection and back-up systems for operational redundancies. The Company believes that it was the first private bank to process cord blood in a technologically and operationally advanced cGMP/cGTP-compliant facility. The Company's facility, which also currently 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.

The Company, in combination with its global affiliates, currently stores over 150,000 cord blood stem cell specimens worldwide for the exclusive benefit of newborn babies and possibly other members of their family. The Company believes it is the world's largest family cord blood stem cell bank in terms of the number of worldwide specimens preserved by the Company and its affiliates.

### ***Competitive Advantages***

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

The most established private family cord blood bank, with an established client base (including licensees) exceeding 150,000 worldwide,

Our status as the only cGMP- and cGTP-compliant private cord blood bank with both ISO certification and AABB accreditation,

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,

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-Cord® service prices for the family's future newborns,

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, and

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the availability of our C elle services bundled with the U-Cord services, which give expectant mothers the ability to store their own stem cells on a combined and value priced basis

### **C elle<sup>SM</sup> Menstrual Stem Cell Technology**

On November 1, 2007, the Company announced its discovery of novel stem cell technology and its launch of the world's first-ever commercial service allowing women to store their own menstrual stem



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cells. The new service, called C elle (pronounced C-L ), enables women to collect menstrual flow containing stem cells, which can be cryogenically preserved in a manner similar to stem cells from umbilical cord blood and may one day serve as a potential source for promising regenerative therapies to treat heart disease, diabetes, neurological disorders like spinal cord injury, Parkinson's and Alzheimer's diseases, in addition to cosmeceutical applications such as anti-aging therapies, to name a few. However, realistically, it may take several years for these menstrual stem cells to be developed into potential widely-available commercial therapies. The C elle service is based on Cryo-Cell's intellectual property, for which patent applications are pending, related to the procurement, processing, isolation and cryo-preservation of these unique menstrual stem cells. The unique C elle service is being offered following the Company's discovery of new scientific evidence that menstrual flow, which results from the shedding of the uterine lining (endometrium) during menstruation, contains millions of stem cells that have demonstrated many properties and characteristics similar to those of both bone marrow and embryonic stem cells.

The Company believes C elle menstrual stem cells will have a significant impact on regenerative medicine. C elle menstrual stem cells are easily available, compared to stem cells from bone marrow and cord blood that are commonly used in treatments today. Further, the C elle commercial service allows many more cells to be extracted and stored, compared to the limitations on the number of cells that can be extracted from bone marrow or cord blood, a factor that limits many treatments today.

Further C elle menstrual stem cells have demonstrated the capability in preliminary research to differentiate into many more types of cells. Preliminary studies have shown that these stem cells can expand their numbers in cell culture and differentiate into other cell types, such as nervous system, heart, bone, fat and cartilage cells. C elle menstrual stem cells are adult stem cells but with many properties associated with both embryonic stem cells and mesenchymal stem cells (a highly potent adult stem cell in therapeutic use today derived from connective tissue). In recent years researchers have successfully isolated stem cells from fat cells, semen, unfertilized egg cells, and other sources, but the Company believes the C elle menstrual stem cells represent the first identified adult stem cell that shows a very attractive set of features—the ability to differentiate into many types of cells, the lack of a need for invasive collection techniques, and the availability of a considerably renewable source of cells. Based on the preliminary studies, C elle menstrual stem cells may have the potential to be used to treat a broad range of diseases and conditions, including diabetes, osteoporosis, heart disease and neural disorders such as stroke, Alzheimer's and Parkinson's disease, as well as for cosmeceutical therapies such as anti-aging treatments.

Although menstrual stem cells have not been used to date in human therapies, animal studies of menstrual stem cells have commenced, showing strong potential value. This research is further supported by several recent scientific publications that demonstrate the potential of menstrual stem cells for human therapies such as cardiac and bone repair. Cryo-Cell is the first and only company to launch a service, C elle, that will enable women to collect and store these stem cells. The Company has filed patent applications to protect a broad range of intellectual property (IP) associated with C elle menstrual stem cell technology, and it intends to license the exclusive service in selected global markets. The Company has executed collaborative research agreements with several leading stem cell researchers who have initiated preclinical studies in a broad range of diseases reflecting the significance of this discovery, including diabetes, cardiac, and neurological diseases and disorders such as stroke and Alzheimer's disease.

The Company estimates that over 70 million women in the U.S. alone are in the target market for the C elle service. The launch of the C elle service in November 2007 was a soft launch, prior to the commencement of full marketing efforts and before the publication of full scientific research; therefore, sales of the C elle service have only been on a preliminary basis. The Company anticipates that C elle market penetration will expand over time as scientific research is announced and therapeutic developments emerge.

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

The Company has a seven member Medical and Scientific Advisory Board (MSAB), 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 transplant medicine, infectious disease, laboratory/transfusion medicine and/or obstetrics/gynecology.

### **Marketing**

#### *U-Cord Service*

The Company markets its cord blood stem cell 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 2007 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.

During 2007, 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 and Fit Pregnancy, 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 online. Viewers may read about successful transplants using Cryo-Cell stored cord blood stem cells and access other topical information.

#### *C elle Service*

The C elle marketing strategy includes plans to leverage the new service with the Company's existing cord blood clientele and to prospective new cord blood clients through a bundled offer ( Protect Baby, Protect Yourself) ; in addition to direct-to-consumer advertising and distributor networks.

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The comprehensive website for Celle, [www.celle.com](http://www.celle.com), includes an e-commerce platform that enables clients to purchase annual; semi-annual or quarterly plans. The Company believes that many women in the target market may opt to participate in the Celle service more than one-time because of family history of disease; perimenopause; or other conditions, such as a prospective hysterectomy.

The Company also believes that its exclusive Celle service may potentially serve to enhance its competitive position in the cord blood industry as the leader of innovative stem cell solutions. As part of the initial launch of Celle, the service has been bundled with the U-Cord service and marketed to clients as a way to protect their newborn and to protect themselves. This U-Cord and Celle Combo Offer is highly differentiated and value priced in comparison to the stand-alone cord blood services of the Company's primary competitors. There are distinctive synergies between the target markets for Celle and U-Cord in that clients of both services are typically well-educated with higher discretionary incomes; are knowledgeable about the promise and potential of stem cell science; and are keenly interested in preserving stem cells for possible therapeutic applications that may emerge in the future for their families and themselves.

## **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 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, Inc., a wholly-owned subsidiary of PerkinElmer 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 was 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 Americas, 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.

The Company believes it needs to develop new products and services to stay competitive. We believe the availability of our Celle services bundled with the U-Cord services will ultimately provide a competitive advantage over competitors that offer only the storage of umbilical cord blood.

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### **Government Regulation**

The Company is required to register with the FDA under the Public Health Service Act because of its ongoing cellular storage business and is subject to FDA inspection. 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 2007, 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.

Federal and state laws govern the Company's ability to obtain and, in some cases, to use and disclose data that we may need to conduct certain activities. The Health Insurance Portability and Accountability Act of 1996 (HIPAA) requires the Department of Health and Human Services to issue a series of regulations establishing standards for the electronic transmission of certain health information. The Company is not subject to HIPAA because the Company does not engage in certain electronic transactions related to the reimbursement of healthcare and because blood and tissue procurement and banking activities are exempt. However, the healthcare providers that collect umbilical cord blood for the Company's customers are subject to HIPAA. The identifiable information shared is only what is permitted by HIPAA.

The Company is also subject to local, state and federal laws and regulations relating to safe working conditions, laboratory and manufacturing practices and the use and disposal of hazardous or potentially hazardous substances. These laws include the Occupational Safety and Health Act (OSHA), current Good Tissue Practices (cGTPs), current Good Manufacturing Practices (cGMPs), Environmental Protection Agency (EPA), and those of the local Department of Health.

Enacted in 1970, OSHA requires all employers to assure safe and healthful working conditions for working men and women through development and implementation of work standards, education, and training. OSHA enforces the standards developed under the Act, applicable to all employers in the U.S. and its territories. Current Good Tissue Practices (cGTPs) are laws, enforced by the Food and Drug Administration (FDA), that define and govern methods used in the manufacture of Human Cells, Tissues, and cellular and tissue-based Products (HCT/Ps). Current Good Manufacturing Practices (cGMPs) are laws, enforced by the FDA, that define and govern methods used in the manufacture of drugs and finished pharmaceuticals. Both of the latter federal practices, or laws, govern the Company's products.

The Environmental Protection Agency (EPA) governs the management and proper disposal of products and by-products or waste. These products must be disposed in a manner that does not adversely affect the environment from which it came or where disposed of. The Department of Health on the local level primarily regulates systems and associated equipment employed in recovery activities such as back-up generators; therefore, governing specific internal processes.

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 such technology and a verbal confirmation from the FDA, the Company believes it is no longer a medical device manufacturer.

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In addition, as the organization grows and evolves, other legislation and regulations are expected to impact the Company. One such evolution involves activities that may be designated as or involve medical research or cooperative agreements associated with medical research. These types of activities are also governed by the FDA, specifying oversight by an Institutional Review Board (IRB). The IRB is a board or committee that approves the initiation of, and conducts periodic review of, biomedical research involving human subjects. The primary purpose of such review is to assure the protection of the rights and welfare of the human subjects. Governance of biomedical research is codified as laws by Title 21 of the Code of Federal Regulations (CFR) Part 56, and enforced by the FDA.

Hence, as the Company continues to evolve, other impacting governance is expected and planned for.

## **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 36% and 38% interest in Saneron CCEL Therapeutics, Inc. ( Saneron ) as of November 30, 2007 and 2006, 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.

To date, Saneron has received nine SBIR/STTR grants, has been the industry sponsor on eight Florida High Tech Corridor grants, and has participated in several other corporate and non-profit R&D projects to continue their efforts towards the development of cellular therapies for neurological and cardiac disorders. In November 2005, Saneron received a grant from the Johnnie B. Byrd, Sr. Alzheimer's Center and Research Institute, Inc. for the study of the Saneron U-CORD-CELL as a treatment for Alzheimer's. During 2006, Saneron and GE Healthcare completed two phases of a joint research project intended to optimize GE Healthcare's Ficoll-Paque for isolating stem cells from umbilical cord blood. The preliminary results from that study were presented at the International Society for Cellular Therapy meeting in Berlin, Germany. Validation studies needed for the submission of a Drug Master File of Saneron's U-CORD-CELL have been underway at Cryo-Cell International's GMP facility and the University of South Florida. Saneron is currently finishing the preclinical studies needed for the completion of an IND application for the use of the U-CORD-CELL as a potential therapy for ALS.

In January 2008, the Company announced that it has formalized a research and development agreement with Saneron to develop regenerative therapies utilizing Cryo-Cell's Cellular menstrual stem cell technology. Cryo-Cell and Saneron will collaborate on research in pre-clinical models for certain neurological diseases and disorders. Under terms of the agreement, the Company will provide Saneron with menstrual stem cells along with proprietary methodology associated with the technology. Saneron will provide study materials and develop research methodology for potential therapeutic applications associated with designated pre-clinical applications. Intellectual property resulting from this research collaboration will be jointly owned by the parties.

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**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. 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 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.

**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 \$1,069,639 in fiscal 2007 and \$901,744 in fiscal 2006. Such payments are recorded as interest expense in the accompanying consolidated statements of operations and comprehensive loss.

In the future, the Company could reverse the liability relating to the RSAs over an appropriate period of time, based on the Company's expectations of the total amount of payments it expects to pay to the other party under the particular revenue sharing agreement. However, the RSAs do not establish a finite term or time frame over which to estimate the total payments, and the Company had not previously estimated and has concluded that it is not currently practicable to estimate the projected cash flows under the RSAs. At present, the Company intends to defer the reversal of the liability, until such time as these amounts can be determined. During the periods when the Company defers the reversal of the liability, the payments during these periods will be treated in full as interest expense, which will be recognized as payments under the RSAs become due following the accrual method of accounting. In future periods, if a portion of the liability can be de-recognized based on the effective interest method, the payments will be allocated between interest and amortization of the liability. As cash is paid out to the other party during any period, the liability would be de-recognized based on the portion of the total anticipated payouts made during the period, using the effective interest method. That is, a portion of the payment would be recorded as interest expense, and the remainder would be treated as repayment of principal, which would reduce the liability.

Summary descriptions of the Company's current RSAs are found below, grouped by the geographic location to which they relate.

**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.

**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.

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**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, entitling them to on-going shares in a portion of the Company's net storage revenue generated by specimens originating from 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

## **International**

In fiscal 2000 the Company began entering into licensing and royalty 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. The license allows Cryo-Cell de Mexico to directly market and sub-license the U-Cord® program throughout Mexico, Central America and Ecuador. The Company received an initial up-front license fee payment of \$600,000 and, until the amendment described below effective January 1, 2007, was entitled to receive ongoing royalties of 15% of adjusted cord blood processing fees and 25% of storage revenues generated by Cryo-Cell de Mexico's laboratory operations. The Company recorded royalties and sub-license fees from Cryo-Cell de Mexico in the amount of approximately \$567,000 and \$608,000 for the years ended November 30, 2007 and 2006, respectively, and this is reflected in licensee income in the accompanying consolidated statements of operations and comprehensive loss. In addition, the Company processes and stores specimens sent from sub-licensees in Central America, Ecuador, and to a lesser extent Mexico. Processing revenues from specimens originating in these territories totaled \$511,940 and \$410,785 for the years ended November 30, 2007 and 2006 and is reflected in revenues in the accompanying consolidated statements of operations and comprehensive loss.

On February 7, 2007, the Company and Cryo-Cell de Mexico executed an amendment to their definitive License and Royalty Agreement which is effective January 1, 2007. The amendment changes the royalties payable to the Company for all U-Cord® collection, processing and storage revenues generated effective January 1, 2007. Following the amendment, the Company receives royalty fees ranging from \$35 to \$75 per specimen, depending on the then current pricing structure in effect for U-Cord® collection, processing and testing fees in Mexico. The Company's royalties on storage revenues are now at a level of 10%, compared to 25% prior to the amendment. The total royalty payments per the revised agreement are now capped at \$1 million annually and \$10 million cumulatively dating back to October 15, 2001. The Company does not anticipate reaching the cumulative maximum royalty payments for a number of years.

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**India/Malaysia/Singapore.** On July 14, 2004, the Company 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 up-front license fee of \$750,000 is payable by ACCPL in installments, with \$275,000, net of taxes, paid in 2004, a second payment of \$175,000, net of taxes, paid in 2006, and the final \$300,000, net of taxes, was paid in 2007 as described below. In consideration for the up-front license fee, the Company transferred its technology, know-how and quality systems to ACCPL in 2004. During fiscal 2007, two payments totaling approximately \$255,000 net of tax were received in February and May, respectively by the Company. This income is included in licensee income in the consolidated statement of operations and comprehensive loss.

On January 22, 2007, the Company and ACCPL executed an amendment to the definitive License and Royalty Agreement. The amendment changes the royalties payable to the Company for all cord blood collection, processing and storage revenues generated after September 1, 2006. Following the amendment, the Company receives royalty fees ranging from \$35 to \$75 per specimen, depending on the then current pricing structure in effect for cord blood collection, processing and testing fees in India rather than the previous royalty rate of 8.5-10%. The Company will now receive royalties on storage revenues of 10%, compared to 10-15%, based on volume, prior to the amendment. All revenues generated prior to the effective date are subject to the original agreement. The total royalty payments per the agreement are now capped at \$1 million annually and \$10 million cumulatively dating back to July 14, 2004. The Company does not anticipate reaching the cumulative maximum royalty payments for a number of years.

The Company recorded royalties and sub-license fees from ACCPL in the amount of approximately \$129,000 and \$170,000 for the years ended November 30, 2007 and, 2006, respectively and this is reflected in licensee income in the accompanying consolidated statements of operations and comprehensive loss.

**Employees**

At November 30, 2007, there are 57 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.

**ITEM 1A. RISK FACTORS.**

Not applicable, as the Company is a smaller reporting company. For a description of risk factors relating to the Company's business, see Management's Discussion and Analysis of Financial Condition and Results of Operations Forward-Looking Information .

**ITEM 1B. UNRESOLVED STAFF COMMENTS.**

None.



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**ITEM 2. PROPERTIES.**

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.

On June 7, 2006, the Company entered into a lease amendment, which amends the Company's lease for its principal offices in Oldsmar, Florida. The original lease covered approximately 17,600 square feet of space. Under the amendment, the Company leased an additional 9,600 square feet of space at same location, beginning on August 1, 2006 and ending with the termination of the lease in 2015. The Company's rent for the additional space is \$10,712 per month through July 31, 2008, with annual increases thereafter through the entire lease term to a maximum of \$13,176 per month for the additional space.

**ITEM 3. LEGAL PROCEEDINGS.**

The Company is involved in the following legal proceedings:

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 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.

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.

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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.

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 Delaware court 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. During the first half of 2007, the Patent Office issued reexamination certificates confirming the claims of the PharmaStem patents.

PharmaStem filed an appeal to the United States Court of Appeals for the Federal Circuit from the final judgment entered by the District Court in the original litigation, and the defendants, including Cryo-Cell, filed a cross-appeal. On July 9, 2007, the Court entered its decision, upholding the lower court's determination to grant judgment as a matter of law in favor of the defendants, including Cryo-Cell, on the ground that the plaintiff failed to prove infringement of either the 681 or 553 patents, and reversing the lower court's ruling with respect to validity of the patents. The Court of Appeals held both patents invalid on the ground of obviousness. PharmaStem's request for rehearing was denied.

On January 2, 2008, PharmaStem filed a request that the case be heard by the United States Supreme Court, solely on issue of the validity of the patents. Any such review is subject to the discretion of the Supreme Court, which is not required to entertain this appeal.

The decision that PharmaStem failed to prove infringement of its patents in the prior action is now final and unreviewable, and the original damages judgment on the 2003 jury verdict cannot be reinstated.

The decision of the Court of Appeals will likely have a substantial impact on this second round of litigation involving related PharmaStem patents which, as noted above, has been stayed in the District Court for the District of Delaware pending final decision on the appeal.

In August 2007, Mr. David Portnoy brought an action against the Company and its directors in Delaware Chancery Court in New Castle County. The plaintiff alleged breaches of fiduciary duties in connection with the Company's 2007 Annual Meeting and requested declaratory and injunctive relief relating to the election of directors at that meeting. Among the other forms of relief Mr. Portnoy sought

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a declaration that the dissident slate was entitled to be installed as members of the Company's board of directors. Mr. Portnoy also sought reimbursement by the Company of his costs in connection with the 2007 Annual Meeting. On January 22, 2008, the Court issued an order under which the Company is required to hold a special meeting of shareholders for the election of directors on March 4, 2008; and the directors who sat on the Company's Board of Directors prior to the 2007 Annual Meeting will continue in office until the special meeting. The order provides that the members of the management slate shall pay their own proxy solicitation costs in connection with the special meeting; any costs to the Company of holding the special meeting; and the costs of a special master to preside over the special meeting. The order did not require the Company to reimburse any of Mr. Portnoy's costs in connection with the 2007 Annual Meeting.

**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 ISSUER PURCHASES OF EQUITY SECURITIES.**

The Company's common stock traded on the Over-The-Counter market beginning on 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 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
<b>2007</b>		
February 28, 2007	2.20	2.28
May 31, 2007	2.14	2.18
August 31, 2007	1.44	1.48
November 30, 2007	1.27	1.35
<b>2006</b>		
February 28, 2006	3.26	3.85
May 31, 2006	2.55	3.40
August 31, 2006	2.19	2.80
November 30, 2006	2.25	2.80

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, 2007, the Company had 291 shareholders of record, and management believes there are approximately 5,000 additional beneficial holders of the Company's common stock.

**Table of Contents****Equity Compensation Plan Information as of November 30, 2007**

<b>Equity Compensation plans approved by stockholders</b>	<b>Number of securities to be issued upon exercise of outstanding options, warrants and rights</b>	<b>Weighted-average exercise price of outstanding options, warrants and rights</b>	<b>Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in the first column)</b>
Cryo-Cell International 2000 Stock Incentive Plan	1,611,429	\$ 2.62	7,995
Cryo-Cell International, Inc. 2006 Stock Incentive Plan			1,000,000
<b>Total</b>	<b>1,611,429</b>	<b>\$ 2.62</b>	<b>1,007,995</b>

**ITEM 6. SELECTED FINANCIAL DATA****Not Applicable.****ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS.**

The following discussion and analysis of the financial condition and results of operations of the Company for the two years ended November 30, 2007, 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-K.

**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.

In recent years, the Company has expanded its research and development activities to develop technologies related to stem cells other than umbilical cord blood stem cells. In 2005, the Company entered into an agreement with Plureon Corporation under which the Company would provide collection and preservation of Plureon's proprietary placental fetal stem cells. During 2006 and the first

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part of 2007, the Company's research and development activities were focused on launching a commercial service relating to the Plureon stem cells. In April 2007, the Company announced that the commercial launch of this service would be postponed indefinitely due to technological commercialization considerations. During 2007, much of the Company's research and development activities focused on the development of proprietary technology related to maternal placental stem cells (MPSCs). Also during 2007, the Company discovered technology related to menstrual stem cells. In November 2007, the Company announced the launch of its C<sup>ell</sup>E<sup>m</sup> service related to this technology, and the Company continues to focus its current research and development activities principally on the C<sup>ell</sup>E<sup>m</sup> service and related new menstrual stem cell technologies.

During the year ended November 30, 2007, the Company increased its revenues by 2% over the level in fiscal 2006 and incurred a net loss of approximately \$5,005,000, compared to a net loss of approximately \$2,811,000 for fiscal 2006. Net storage revenues increased primarily because of a 2006 price increase for newly enrolling clients, as well as the overall increase in customer base over the prior year. The Company reported a net loss in fiscal 2007 of approximately (\$5.0 million), or (\$0.43) per basic common share, compared to a net loss of approximately (\$2.8) million, or (\$0.24) per basic common share, in fiscal 2006. The net loss in fiscal 2007 is in part the result of a 9% increase in cost of sales and a 12% increase in marketing, general and administrative expenses, with the latter increase due mainly to increases in professional and consumer advertising, increased salaries and wages and professional fees associated with a proxy contest initiated by a dissident shareholder group. In addition, the net loss was increased by certain other expenses in the 2007 period, including increased research and development expenses relating to the planned new products and services and increases in stock option compensation resulting from adoption of FASB Statement No. 123(R).

At November 30, 2007, the Company had cash and cash equivalents of \$3,364,711 and marketable securities and other investments of \$1,046,010. The Company's cash decreased by approximately \$4,049,000 during fiscal 2007, as a result of the decline in cash flow from operations and the purchase of property and equipment. The decline in operating cash flow was partially the result of the implementation of the in-house financing plans during the year and increased research and development expenses relating to the MPSC and C<sup>ell</sup>E<sup>m</sup>. The Company discontinued offering in-house financing plans during the second quarter of 2007. As of February 8, 2008, the Company maintains no indebtedness.

**Results of Operations**

**Revenues.** For the fiscal year ended November 30, 2007, the Company had revenues of \$17,460,196 compared to \$17,180,383 in fiscal 2006 representing a 2% increase. The increase is primarily attributable to the effects of a successfully implemented price increase during fiscal 2006 for newly enrolling clients, as well as the overall increase in customer base over the prior year, which led to a significant increase in storage revenues.

**Cost of Sales.** For the fiscal year ended November 30, 2007, cost of sales was \$6,592,145, as compared to \$6,067,671 in 2006 representing a 9% increase. Costs of sales were 38% of revenues in fiscal 2007 compared to 35% in fiscal 2006. The increase in cost of sales was due in part to the expenses associated with the Company's introduction of service enhancements in connection with the 2006 price increase. The enhancements include return shipping by a medical courier to all new U.S. customers, which accounted for approximately \$152,000 of the increase. Other contributing factors were increases in lab salaries and wages of approximately \$163,000 and cord blood collection reimbursements of approximately \$108,000.

**Marketing, General and Administrative Expenses.** Marketing, general and administrative expenses during the fiscal year ended November 30, 2007 were \$14,462,914 as compared to \$12,957,465 for the fiscal year ended November 30, 2006 representing a 12% increase. The increase in fiscal year 2007 was principally attributable to the implementation of the Company's previously announced strategic

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initiatives to increase market share and achieve unit growth by strengthening the resources allocated to sales and marketing. This resulted in an increase of approximately \$1,505,000 in expense, principally related to expenses for professional and consumer advertising and salaries and wages. Included in the expense increase in the 2007 period was approximately \$874,000 in professional fees associated with a proxy contest initiated by a dissident shareholder group. During 2007, the Company adopted SFAS 123R, resulting in stock option compensation expense of approximately \$266,000 versus approximately \$78,000 in the 2006 period.

**Research, Development and Related Engineering Expenses.** Research, development and related engineering expenses for the fiscal year ended November 30, 2007, were \$545,489 as compared to \$486,164 in 2006. The increase was due to expenses related to the Company's expenses for new product development, principally methods, processes and systems for the procurement, isolation, processing and cryopreservation of maternal placental stem cells (MPSCs) and commercialization of the Company's new stem cell technology, Celle.

A portion of the Company's research and development expenses in fiscal year 2007 are also related to development expenses of proprietary technology developed by the Company for the collection, processing and cryogenic preservation of Plureon® fetal placental stem cells. In April 2007, the Company announced that it has decided to indefinitely postpone plans to launch the fetal placental stem cell service, primarily due to technological commercialization considerations. The Company's research and development relating to the procurement, processing and cryopreservation of stem cells from placental tissue has contributed to its independent creation of valuable proprietary technology that the Company will protect and commercialize.

**Impairment of Assets.** For the fiscal year ended November 30, 2006, the Company recorded an impairment of assets of \$147,420. During the fiscal year ended November 30, 2006, management reviewed the cost basis of certain investments in marketable securities and determined that the decline in market value was other-than temporary, resulting in these investments being written down to fair value. There was no impairment in fiscal year 2007.

**Interest Expense.** Interest expense during the fiscal year ended November 30, 2007, was \$1,390,264 compared to \$1,015,389 in 2006. 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 \$36,103 and \$41,391 for the years ended November 30, 2007 and 2006, 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, 2007, was \$950,881 as compared to \$926,824 in 2006. Licensee income for the fiscal years ended November 30, 2007 and 2006, consisted of \$254,880 and \$148,723, respectively, received as an installment payment from the non-recurring sale of the India license agreement and \$696,001 and \$778,101, respectively, of royalty income earned on the subsequent processing and storage of specimens in geographical areas where the Company has license agreements, and from the sale of sub-license agreements by licensees. In late 2006 and early 2007, the Company and its international licensees agreed to changes in the royalty fees for processing and storage in those geographical areas. The new rates are expected to have a negative impact on future royalty income.

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**Equity in Losses of Affiliates.** Equity in losses of affiliates was \$221,797 for the fiscal year ended November 30, 2007 compared to a loss of \$84,287 in 2006. During the fiscal year ended November 30, 2006, the Company ceased recording equity in losses from operations once the investment balance was written down to the total amount of goodwill, as goodwill is not amortized. Equity in losses of affiliates for the year ended November 30, 2007 solely consists of amounts related to compensation expense for stock option awards that were granted by Saneron to certain consultants and employees. Included in equity in losses of affiliates is approximately \$83,000 related to compensation expense that resulted from the stock awards in 2006. This expense was offset by income from the affiliate.

**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 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 deferred tax assets of the Company as of November 30, 2007 and November 30, 2006, has been provided as the Company does not believe it is more likely than not that the future income tax benefits will be realized. The Company did not record an income tax benefit during the fiscal years ended November 30, 2007 and 2006, as the benefit was offset by an increase in the valuation allowance.

**Liquidity and Capital Resources**

Through November 30, 2007, 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, 2007, the Company had cash and cash equivalents of \$3,364,711 as compared to \$7,414,140 in 2006. The Company also has certain investments in marketable securities, which totaled \$1,046,010 as of November 30, 2007. The decrease in cash and cash equivalents in 2007 was primarily attributable to the following:

Cash used in operating activities in fiscal 2007 amounted to \$3,404,396, which was primarily attributable to the implementation of interest-free financing plans that extended payments for services for a maximum period of 15 months and the payments of certain accrued purchases relating to laboratory equipment and outstanding invoices related to the return medical courier service. The Company discontinued offering the financing plans during the second quarter of 2007. In addition, the net loss for the year ended November 30, 2007 contributed to the use of cash.

Cash provided by operating activities in fiscal 2006 amounted to \$924,901 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. During the prior year, the Company began requiring credit cards to be used by all new clients. This resulted in an increase in operating cash flow.

Cash used in investing activities in fiscal 2007 amounted to \$670,683, which was primarily attributable to the purchase of property and equipment.

Cash used in investing activities in fiscal 2006 amounted to \$1,490,138, which was primarily attributable to the purchase of a bond investment and property and equipment, partially offset by proceeds for the redemption of marketable securities.

Cash provided by financing activities in fiscal 2007 amounted to \$25,650 which is attributable to the exercise of stock options.

There was no cash provided by financing activities in fiscal 2006.

The Company does not have a line of credit or other type of financing instrument. The Company anticipates making capital expenditures of approximately \$250,000 over the next twelve months.



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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 months. Cash flows from operations will depend primarily upon increasing revenues from sales of its umbilical cord blood cellular storage services and new service offerings, and controlling expenses. If expected increases in revenues are not realized, or if expenses are higher than anticipated, the Company may be required to reduce or defer cash expenditures or otherwise manage its cash resources during the next 12 months so that they are sufficient to meet the Company's cash needs for that period. In addition, the Company may consider seeking equity or debt financing if deemed appropriate for its plan of operations, and if such financing can be obtained on acceptable terms. There is no assurance that the reductions in expenditures, if necessary, will not have an adverse effect on the Company's business operations, including sales activities and the development of new services and technology.

## **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**

The Company records revenue from processing and storage of specimens. We recognize revenue in accordance with SEC Staff Accounting Bulletin No. 101, (SAB 101) as amended by SAB 104, and Emerging Issues Task Force (EITF) Issue No. 00-21 for all revenue transactions. The Company recognizes revenue from processing fees upon completion of processing and cellular storage fees ratably over the contractual storage period. Deferred revenue on the accompanying balance sheets includes the portion of the annual storage fee and the twenty-one year storage fee that is being recognized over the contractual storage period. As of November 30, 2007 and November 30, 2006 the current portion of deferred revenue is approximately \$4,100,000 and \$3,600,000, respectively, and the long-term portion of deferred revenue is approximately \$6,700,000 and \$5,900,000, respectively. The Company also records revenue from shipping and handling when earned. Shipping and handling costs are expensed and included in cost of sales.

## **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 and do not require collateral. 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. Also included in accounts receivable are amounts due from interest-free financing plans that extended payments for services for a maximum period of 15 months. During 2007, the Company discontinued offering these financing plans. 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

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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.

### **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 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 deferred tax assets of the Company as of November 30, 2007 and November 30, 2006, has been provided as the Company does not believe it is more likely than not that the future income tax benefits will be realized. The Company did not record an income tax benefit during the fiscal year ended November 30, 2007, as the benefit was offset by an increase in the valuation allowance.

In June 2006, the FASB issued Interpretation No. 48, *Accounting for Uncertainty in Income Taxes, an interpretation of FAS109, Accounting for Income Taxes* (FIN 48), to create a single model to address accounting for uncertainty in tax positions. FIN 48 clarifies the accounting for income taxes, by prescribing the minimum recognition threshold a tax position is required to meet before being recognized in the financial statements. FIN 48 also provides guidance on derecognition, measurement, classification, interest and penalties, accounting in interim periods, disclosure and transition. FIN 48 is effective for fiscal years beginning after December 15, 2006. The Company adopted FIN 48 as of December 1, 2007, as required. The Company is in the process of completing their initial analysis and does not believe that FIN 48 will have a material impact on the Company's financial position and results of operations.

### **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 reviews its investment for possible impairment when there are indicators of possible impairment and, if necessary, adjusts the carrying value of such investment. The Company records equity in losses of affiliates until the investment balance is zero and only goodwill is remaining. The investment is reviewed annually to determine if an other than temporary impairment exists. The Company does not believe that an impairment exists as of November 30, 2007 and November 30, 2006.

### **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 generated from clients in 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 a non-refundable up-front fee for the rights to these future payments. The Company recognized these non-refundable fees as a long-term liability. Given the criteria under which these RSAs are established, cash flows related to these contracts can fluctuate from period to period. 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. The Company does not intend to enter into additional RSAs.

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### **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, collectability and when all material services or conditions relating to the sale have been substantially performed based on the terms of the agreement. The Company has two active licensing agreements, one covering Mexico, Central America, and Ecuador, and the other one covering India.

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. The Company also processes and stores specimens sent directly from customers of sub-licensees in Mexico, Central America, and Ecuador. These fees are included in revenue on the consolidated statements of operations and comprehensive loss. 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 collectability 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, bonds 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 certain marketable securities and other investments as current in the accompanying consolidated balance sheets based on original maturity dates of less than one year. The cost basis of the other investments has been written down to fair value. The Company recorded an impairment charge of approximately \$147,000 on one of its available for sale securities during the fiscal year ended November 30, 2006 as its decline in fair market value was determined to be other-than-temporary.

### **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.

### **Product Warranty and Cryo-Cell Cares™ Program**

In December 2005, the Company began providing its customers enrolled under the new pricing structure with a payment warranty under which the Company agrees to pay \$50,000 to its client if the U-Cord® product retrieved is used for a stem cell transplant for the donor or an immediate family member and fails to engraft, subject to various restrictions. Additionally, under the Cryo-Cell Cares™ program the Company will pay \$10,000 to the client to offset personal expenses if the U-Cord® product is used for bone marrow reconstitution in a myeloblastic transplant procedure. The Company has not experienced any claims under the warranty program nor has it incurred costs related to these warranties. The Company does not maintain insurance for this warranty program and therefore maintains reserves to

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cover our estimated potential liabilities. The Company accounts for the warranty as an obligation and recognizes the obligation in accordance with SFAS No. 5, Accounting for Contingencies. The Company's reserve balance is based on the \$50,000 maximum payment and the \$10,000 maximum expense reimbursement multiplied by formulas to determine the projected number of units requiring a payout. The Company determined the estimated expected usage and engraftment failure rates based on an analysis of the historical usage and failure rates and the historical usage and failure rates in other private and public cord blood banks based on published data. The Company's estimates of expected usage and engraftment failure could change as a result of changes in actual usage rates or failure rates and such changes would require an adjustment to the established reserves. The historical usage and failure rates have been very low and a small increase in the number of transplants or engraftment failures could cause a significant increase in the estimated rates used in determining our reserve. In addition, the reserve will increase as additional U-Cord<sup>®</sup> specimens are stored which are subject to the warranty. As of November 30, 2007 and November 30, 2006 the Company recorded reserves under these programs in the amounts of \$72,633 and \$35,238, respectively, which are included in accrued expenses in the accompanying consolidated balance sheets.

## **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.

## **Forward-Looking Statements**

This Form 10-K, 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 us refer to Cryo-Cell International, Inc. The words expect, believe, goal, plan, intend, estimate and similar expressions and variations used, are intended to specifically identify forward-looking statements. Those statements appear in a number of places in this Form 10-K and in other places, and include statements regarding the intent, belief or current expectations of the Company, its directors or its officers with respect to, among other things, our future performance and operating results, our future operating plans, our liquidity and capital resources; and 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:

## **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.

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### **Market acceptance of our new C elle service will require publication of scientific studies, consumer awareness, and the development of new therapies from the C elle technology, not of which are certain.**

The launch of the C elle service in November 2007 was a soft launch , prior to the commencement of full marketing efforts and before the publication of full scientific research; therefore, sales of the C elle service have only been on a preliminary basis. Market acceptance of this service will depend on several factors, none of which are certain. First, media attention and success with new customers will depend on publication of scientific data that supports the regenerative capabilities of our menstrual stem cells. We are working with respected researchers who are endeavoring to publish data to support these claims; however, there is no assurance that multiple studies will be accepted for publication, that the content of these publications will attract media attention or customer acceptance, and the timing of any publications is not certain. Second, the success of this business will depend upon the effectiveness of our consumer marketing efforts, and the efforts of our sales force to build awareness among medical professionals who would encourage women to purchase these services. Third, the long-term growth of this business will depend on the development and commercialization of effective therapies derived from these stem cells. Such development is subject to many factors, such as development and protection of intellectual property, regulatory approvals and commercialization factors. There is no assurance that such therapies and products can be successfully developed.

### **The successful development of new therapies from the C elle technology will depend on overcoming a variety of challenges.**

The Company is protecting intellectual property relating to various medical therapies and applications relating to its proprietary C elle menstrual stem cells. Successful development of products and other applications will depend on many factors, such as development and protection of intellectual property, regulatory approvals and commercialization factors. The Company will also be reliant on efforts of joint venture partners, researchers and others for such development. There is no assurance that such therapies and products can be successfully developed.

### **Any new services relating to MPSCs or any other new types of stem cells have not yet been offered commercially, and there is no assurance that the MPSC services or other stem cell services will be launched or will gain market acceptance.**

We have not yet commercially launched services relating to MPSCs or any other new types of stem cells. Such commercial launches are subject to certain developments, including completion of clinical validation and testing. There can be no assurance that completion of these developments will be successful or that any new services will ever be commercially launched. In addition to the MPSC services, the Company continues to work on other intellectual property, to explore new technologies related to other types of stem cells that could potentially lead to new products or services. However, further development is necessary before we can announce commercialization plans. There can be no assurance that such development will be successful or that such commercial services will ever be launched. Such service offerings will be new and untested, and there is no assurance that, if launched, they would gain market acceptance. Unlike umbilical cord blood stem cells, MSPCs and any other new stem cells that may be offered have not yet been used in human therapies. Market acceptance of such new services will depend upon the willingness of prospective parents to pay for the processing and storage of such cells based upon the possibility that such treatments will be discovered in the future. Further, if there are setbacks in medical and scientific research relating to treatment applications for MPSCs and other new types of cells, this may adversely affect our future sales, if any, of these services.

### **The commercial launch of our fetal placental stem cell storage services has been postponed indefinitely, and there is no assurance that these services will be launched commercially**

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In April 2007, we announced that the commercial launch of the fetal placental stem cell service in association with Plureon Corporation would be postponed indefinitely due to technological commercialization considerations. There is no assurance that this service will be launched commercially in the future.

### **We operate in a regulated environment, and our failure to comply with applicable regulations, registrations and approvals could materially and adversely affect our business.**

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 successfully updated that registration, thus meeting the compliance requirement. The FDA proposed rules that will regulate current Good Tissues Practices (cGTP). The final rules became effective during 2005. Future FDA regulations could adversely impact or limit our ability to market or perform our 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 material portion of our income, and the continued success of our involvement in those arrangements involves unique risks.**

Our licensing activities in Mexico/Central America and India accounted for \$950,881 and \$926,824 of licensee income for the years ended November 30, 2007 and 2006, respectively. Our international business activities present a number of challenges. Specifically, our growth and future license income and return on investments from these sources will face the following challenges, among others:

Local laws may not provide the same degree of protection against infringement of our intellectual property rights;

Local laws and business practices could prevent our business from operating or favor local competitors;

It may be difficult and time consuming to locate local organizations, with whom to partner, that are capable of undertaking and sustaining operations;

We may be forced to incur significant expenses related to entering into licensing and investment arrangements in new foreign markets; and

Because the majority of our international license fees are currently denominated in U.S. dollars, 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 growth may slow, be limited, or be altogether unsuccessful.

Further, the Company recently renegotiated its international license agreements covering these countries, which significantly reduced the ongoing revenues from these countries and provided an overall cap on the revenues. There is no assurance that further renegotiation will not be necessary.

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### **We may be unable to protect our intellectual property from infringement by third parties, and third parties may claim that we infringe on their intellectual property, either of which could materially and adversely affect the Company.**

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 such breach.

Despite our efforts to protect our intellectual property, third parties may infringe or misappropriate our intellectual property or may develop intellectual property competitive to ours. Our competitors may independently develop similar technology, duplicate our processes, products or services or design around our intellectual property rights. As a result, we may have to litigate to enforce and protect our intellectual property rights to determine their scope, validity or enforceability. Intellectual property litigation is particularly expensive, time-consuming, diverts the attention of management and technical personnel and could result in substantial cost and uncertainty regarding our future viability. The loss of intellectual property protection or the inability to secure or enforce intellectual property protection 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. Furthermore, any public announcements related to such litigation or regulatory proceedings could adversely affect the price of our common stock.

We also may be subject to costly litigation in the event our products or technology infringe upon another party's proprietary rights. Third parties may have, or may eventually be issued, patents that would be infringed by our technology. Any of these third parties could make a claim of infringement against us with respect to our technology. We may also be subject to claims by third parties for breach of copyright, trademark or license usage rights. Any such claims and any resulting litigation could subject us to significant liability for damages. An adverse determination in any litigation of this type could require us to design around a third party's patent, license alternative technology from another party or otherwise result in limitations in our ability to use the intellectual property subject to such claims.

### **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), 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. Pursuant to a jury verdict in 2003, a judgment was entered against the Company in the amount of approximately \$958,000 for estimated damages relating to royalties resulting from revenues generated from specimens processed and stored from April 11, 2000 through August 31, 2003.

In 2004, the court reversed this judgment and issued two favorable rulings in favor of the Company and other defendants. However, PharmaStem has noticed an appeal of the decision to the United States Court of Appeals. Further, there is a separate action against the Company pending in Delaware state courts. The Delaware court has stayed all proceedings pending an outcome in the federal case. If the Court of Appeals and/or the Delaware court issues an adverse ruling, this could have a material adverse effect on the Company.

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### **The cord blood stem cell preservation market has and continues to become increasingly competitive.**

Cord blood 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. Currently, the Company competes against approximately 25 other national private cord blood banks. Some of these companies, such as 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, a wholly-owned subsidiary of PerkinElmer) and LifeBankUSA (a division of Celgene) are affiliates of publicly traded corporations. These competitors may have access to greater financial resources. In addition, established companies with greater access to financial resources may enter our markets and compete with us. Finally, various public cord blood banks are encouraging parents to donate their newborn's cord blood rather than privately banking it.

In the event that we are not able to compete successfully with our current or potential competitors, it may be difficult for us to grow our revenue and maintain our existing business without incurring significant additional expenses to try and refine our technology, services or approach to our business to better compete, and even then there would be no guarantee of success.

### **Because our industry is subject to rapid technological and therapeutic changes, our future success will materially depend on the continued viability of the use of cord blood stem cells.**

Our success materially depends on the continued viability of cord blood stem cells for developing therapeutic treatments and cures for disease. The broader medical and research environment for such treatments and cures critically affects the utility of stem cells, the services we offer to the public, and our future success. 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 services and equipment obsolete and unmarketable. As a result, there can be no assurance that our services will provide competitive advantages over other technologies. If technological or medical developments arise that materially alter the commercial viability of our technology or services, we may be forced to 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. Alternatively, significant advances may be made in other treatment methods or in disease prevention techniques which could significantly reduce or entirely eliminate the need for the services we provide. The materialization of any of these risks could have a material adverse effect on our business, financial condition and results of operations.

In connection with our offering of the C-elle service and development of new therapies and products using the C-elle menstrual stem cells, there is no assurance that future developments in stem cell technology will not render these services, therapies and products obsolete. Such developments would adversely effect the future revenues we expect to derive from these services, therapies and products.

### **Our information systems are critical to our business, and a failure of those systems could have a materially adverse effect on the Company's business, financial condition and reputation.**

We depend on our ability to store, retrieve, process, and manage a significant amount of information through our computer systems. Like most computer systems, our systems are subject to the risks of failure, computer viruses, and unauthorized individuals (hackers) obtaining access to and inadvertently or purposefully damaging them. The Company believes the security systems and virus-detection controls we have implemented significantly reduce these risks. If our computer systems nonetheless fail or are compromised, sensitive information regarding our customers may become publicly available. In such an event, we may be exposed to liability from customers, may lose customers and may suffer significant damage to our business reputation. Any of these events could have a materially adverse effect on our business and financial condition.



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**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 95,000 specimens in Oldsmar, Florida and approximately 33,000 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.

**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 applicable to most health care organizations, including us, and we may incur material expenses associated with compliance efforts. In addition, compliance 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 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 such 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.

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### **Risks Related to Our Common Stock**

**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, the price of our common stock has fluctuated from a high of \$3.85 to a low of \$0.65. 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, holders of our common stock may not be able to resell their stock at or above the price at which they purchase it.

**Our common stock trades in an illiquid market, which may make it difficult for you to sell your shares at times and prices you believe to be appropriate.**

Trading of our common stock is conducted on the OTC Bulletin Board. This has an adverse effect on the liquidity of our common stock, not only in terms of the number of shares that can be bought and sold at a given price, but also through delays in the timing of transactions and reduction in security analysts' and the media's coverage of our Company and its common stock. This may result in lower prices for our common stock than might otherwise be obtained and could also result in a larger spread between the bid and asked prices for our common stock.

**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

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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. Further, the issuance of additional shares having preferential rights could adversely affect other rights appurtenant to shares of our common stock.

**We have no intention of paying dividends on our common stock.**

To date, we have not paid any cash dividends and do not anticipate the payment of cash dividends in the foreseeable future. Accordingly, the only return on an investment in shares of our common stock, if any, may occur upon a subsequent sale of such shares.

**ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK.**

Foreign Exchange Risk

The Company is not exposed to material fluctuations in currency exchange rates because the payments from the Company's international affiliates are received in U.S. dollars.

Interest Rate Risk

The Company invests its cash in a variety of financial instruments, principally securities issued by the U.S. government and its agencies, investment grade corporate and money market instruments. These investments are denominated in U.S. dollars. These bonds are subject to interest rate risk, and could decline in value if interest rates fluctuate. Due to the conservative nature of these instruments, the Company does not believe that there is a material exposure to interest rate risk.

**ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA.**

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

The following consolidated financial statements of CRYO-CELL International, Inc. are included in Item 8:

Report of Independent Registered Public Accounting Firm

Consolidated Balance Sheets as of November 30, 2007 and 2006

Consolidated Statements of Operations and Comprehensive Loss

For the Years Ended November 30, 2007 and 2006

Consolidated Statements of Cash Flows

For the Years Ended November 30, 2007 and 2006

Consolidated Statements of Stockholders' Deficit

For the Years Ended November 30, 2007 and 2006

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.



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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and

Stockholders 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, 2007 and 2006, and the related consolidated statements of operations and comprehensive loss, stockholders' deficit, and cash flows for each of the two years in the period ended November 30, 2007. 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. The Company is not required to have, nor were we engaged to perform an audit of its internal control over financial reporting. Our audit included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

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, 2007 and 2006, and the results of their operations and their cash flows for each of the two years in the period ended November 30, 2007 in conformity with accounting principles generally accepted in the United States of America.

As discussed in Note 1 to the consolidated financial statements, the Company adopted Statement of Financial Accounting Standards No. 123 (revised 2004), *Share-Based Payment* effective December 1, 2006.

/s/ GRANT THORNTON LLP

Tampa, Florida

February 8, 2008

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## CONSOLIDATED BALANCE SHEETS

	November 30, 2007	November 30, 2006
<b><u>ASSETS</u></b>		
<b><u>Current Assets</u></b>		
Cash and cash equivalents	\$ 3,364,711	\$ 7,414,140
Restricted cash	200,000	200,000
Marketable securities and other investments	1,002,810	989,581
Accounts receivable and advances (net of allowance for doubtful accounts of \$625,349 and \$905,984, respectively)	2,431,554	1,213,569
Deferred tax assets	18,000	45,000
Prepaid expenses and other current assets	570,112	649,971
<b>Total current assets</b>	<b>7,587,187</b>	<b>10,512,261</b>
<b><u>Property and Equipment-net</u></b>	<b>3,115,581</b>	<b>3,188,662</b>
<b><u>Other Assets</u></b>		
Marketable securities and other investments	43,200	50,760
Note receivable	80,088	93,238
Investment in Saneron CCEL Therapeutics, Inc.	684,000	684,000
Deposits and other assets	123,653	111,462
<b>Total other assets</b>	<b>930,941</b>	<b>939,460</b>
<b>Total assets</b>	<b>\$ 11,633,709</b>	<b>\$ 14,640,383</b>
<b><u>LIABILITIES AND STOCKHOLDERS DEFICIT</u></b>		
<b><u>Current Liabilities</u></b>		
Accounts payable	\$ 1,891,601	\$ 1,207,167
Accrued expenses	1,331,170	1,706,199
Deferred revenue	4,064,035	3,592,485
<b>Total current liabilities</b>	<b>7,286,806</b>	<b>6,505,851</b>
<b><u>Other Liabilities</u></b>		
Deferred revenue	6,696,841	5,875,107
Deferred tax liabilities	18,000	45,000
Long-term liability-revenue sharing agreements	3,750,000	3,750,000
Deferred consulting obligation	472,744	556,571
<b>Total other liabilities</b>	<b>10,937,585</b>	<b>10,226,678</b>
Commitments and Contingencies (Note 8)		
<b><u>Stockholders Deficit</u></b>		
Preferred stock (\$.01 par value, 500,000 authorized and none issued)		
Common stock (\$.01 par value, 20,000,000 authorized; 11,672,129 as of November 30, 2007 and 11,624,629 as of November 30, 2006 issued and outstanding)	116,721	116,247

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Additional paid-in capital	24,410,628	23,929,761
Treasury stock, at cost	(807,020)	(839,301)
Accumulated other comprehensive loss	(118,619)	(111,876)
Accumulated deficit	(30,192,392)	(25,186,977)
Total stockholders' deficit	(6,590,682)	(2,092,146)
Total liabilities and stockholders' deficit	\$ 11,633,709	\$ 14,640,383

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



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## CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

	For the Years Ended	
	November 30, 2007	November 30, 2006
<b>Revenue</b>	\$ 17,460,196	\$ 17,180,383
<b>Costs and Expenses:</b>		
Cost of sales	6,592,145	6,067,671
Marketing, general & administrative expenses	14,462,914	12,957,465
Research, development and related engineering	545,489	486,164
Impairment of marketable securities		147,420
Depreciation and amortization	532,311	481,727
Total costs and expenses	22,132,859	20,140,447
<b>Operating Loss</b>	(4,672,663)	(2,960,064)
<b>Other Income (Expense):</b>		
Interest income	318,009	322,369
Interest expense	(1,390,264)	(1,015,389)
Other income (expense)	10,419	(821)
Licensee income	950,881	926,824
Total other (expense) income	(110,955)	232,983
Loss before equity in losses of affiliate and income tax expense	(4,783,618)	(2,727,081)
Equity in losses of affiliate	(221,797)	(84,287)