CRYO CELL INTERNATIONAL INC
Form 10-K
March 01, 2010
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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, 2009

¨ 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)

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

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

(Address of principal executive offices)(Zip Code)

Registrant 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 þ

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 þ

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 þ No ¨

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes ¨ No ¨

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

Indicate by check mark whether the registrant is 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 ¨ (Do not check if a smaller reporting company)	Smaller reporting company þ

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 þ

The aggregate market value of the Registrant s Common Stock held by non-affiliates of the Registrant is 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 $10,697,858.

As of January 31, 2010, the Registrant had 11,752,574 shares of Common Stock, $0.01 par value, issued and outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

None.

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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 t 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 factors discussed under Item 1A Risk Factors of this Form 10-K.

ITEM 1. BUSINESS.

Introduction

Cryo-Cell International, Inc. (the Company or Cryo-Cell) operates in one reportable segment and 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, in combination with its global affiliates currently stores over 200,000 cord blood specimens worldwide for the exclusive benefit of newborn babies and possibly other members of their families. The Company is one of the world s largest and most established private family cord blood stem cell banks 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 at the Company s technologically and operationally advanced facility in Oldsmar, Florida.

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 such as fetal and maternal stem cells harvested from the placenta. During 2006, the Company discovered novel technology related to menstrual stem cells. In November 2007, the Company announced the launch of its C elle℠ 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 which is available both through a bundled offer with the Company s U-Cord service and on a stand-alone basis.

The Company was incorporated on September 11, 1989 in the State of Delaware.

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.

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Hematopoietic stem cells are the building blocks of our blood and immune systems. They form the white blood cells that fight infection, red blood cells that carry oxygen throughout the body and platelets that promote healing. Stem cells are found in bone marrow where they continue to generate cells throughout our lives. Stem cells can be stored in a cryogenic environment, and upon thawing, infused into a patient. They can be returned to the individual from whom they were taken (autologous) or donated to someone else (allogeneic). An individual s own bone marrow may be used for a transplant if the cancer has not entered the marrow system (metastasized). Otherwise, a marrow donor needs to be identified to provide the needed bone marrow. The availability of a marrow donor or matched stem cell specimen allows physicians to administer larger doses of chemotherapy or radiation in an effort to eradicate the disease. Stem cell therapies and transplants are used for both cancerous and non-cancerous diseases.

Stem cells are found in umbilical cord/placental blood (cord blood stem cells) and can be collected and stored after a baby is born. Over 12,000 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 global 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.

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.

The Company s corporate headquarters are located in a 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, effective in May 2005, requires human cellular and tissue-based products to be manufactured in compliance with good tissue practices (cGTPs). The Company s laboratory processing facility contains a Class 10,000 clean room and Class 100 environments for the processing of cord blood stem cells and other cellular tissues. In addition, the cellular products cryogenic storage area has been designed as a bunker, with enhanced provisions for security, building fortification for environmental element protection and back-up systems for operational redundancies. The Company 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 200,000 cord blood stem cell specimens worldwide for the exclusive benefit of newborn babies and possibly other members of their families. The Company believes it is one of the world s largest family cord blood stem cell banks 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 200,000 worldwide,

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Our status as the only cGMP- and cGTP-compliant private cord blood bank with both International Organization for Standardization (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 client 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 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,

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

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

C elle℠ Menstrual Stem Cell Technology

In November 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 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. The C elle service is based on Cryo-Cell s intellectual property portfolio, for which patent applications are pending, related to the procurement, processing, isolation, cryo-preservation and composition of matter of these unique menstrual stem cells. The exclusive and proprietary 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.

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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 and may potentially be pluripotent. 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 Company anticipates that C elle market penetration will expand over time as scientific research is announced and therapeutic developments emerge.

Medical and Scientific Advisory Board

The Company has an eight 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 seven other highly qualified MSAB members, each having expertise in the areas of transplant medicine, infectious disease, laboratory/transfusion medicine and/or obstetrics/gynecology.

Marketing

Marketing Approach

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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 75 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 superior quality, value-driven competitive leadership position, product differentiation, a fast-growing embedded client base, increased public awareness and accelerated market penetration.

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 2009 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.

Starting in 2007, the Company has 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 has 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 through internet marketing and print advertising 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 client support team of highly trained advisors are available by telephone 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.

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The Company continues to use its Web site, www.cryo-cell.com, to market its services and to provide resource information to expectant parents. The site, which is 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 primarily to prospective new cord blood clients through a bundled offer (Protect Baby, Protect Mom). The comprehensive website for C elle, www.celle.com, includes an e-commerce platform that enables clients to purchase annual plans or the 21-year pre-paid storage plan, which is only available with the bundled offer. The Company believes that many women in the target market may opt to participate in the C elle 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 C elle 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 C elle, 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 C elle 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 C elle 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.

The Company has executed numerous collaborative research agreements with stem cell researchers who are studying C elle menstrual stem cells in various pre-clinical models including diabetes; breast cancer; heart disease, vascular regeneration and stroke. The Company does not have funding commitments with any of the collaborative research agreements.

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, the Company believes that the competitors mentioned above, along with others, charge significantly 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 9001:2008 certification from BSI America s, Inc., a leading quality management systems registrar. ISO (International Organization for Standardization) standards are internationally recognized as an effective framework for a quality management system (QMS). This achievement positions Cryo-Cell as the industry quality leader 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.

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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 the availability of our C elle services bundled with the U-Cord services will ultimately provide a competitive advantage over competitors that offer only the storage of umbilical cord blood.

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 2010, thus meeting this compliance requirement.

The division of FDA which regulates HCT/P s is the Center for Biologics Evaluation and Research (CBER). The section of FDA Code of Federal Regulations (CFR) pertaining to cord blood is 21 CFR 1271. Since 2004, the FDA has formulated a Tissue Action Plan which consists of these three rules:

1. As of January 21, 2004, all cord blood banks are required to register with the FDA. Any cord blood bank which has a laboratory should be on the web page of FDA Registered Establishments.

2. The second rule was published May 20, 2004, and became effective May 25, 2005. It pertains to donor eligibility. This rule requires more screening of donors for communicable diseases.

3. The final rule establishes FDA standards of current Good Tissue Practice (GTP) for laboratories which process HCT/P s. This rule was published November 19, 2004, became effective May 25, 2005, and is intended to prevent contamination or cross-contamination during the handling of HCT/P s.

These three FDA rules only apply to cord blood processed on or after the effective date of May 25, 2005. The final rule allows the FDA to inspect cord blood laboratories to determine compliance with the provisions of 21 CFR Part 1271. In the summer of 2009, the FDA began conducting unannounced inspections of cord blood banks.

Currently, the states of California, Illinois, Maryland, New Jersey and New York 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 providers and because blood and tissue procurement and banking activities are exempt. However, the healthcare providers that collect umbilical

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cord blood for the Company s customers are subject to HIPAA. The identifiable information shared is only what is permitted by HIPAA. In 2009, a portion of the American Recovery and Reinvestment Act of 2009 modified HIPAA under the Health Information Technology for Economic and Clinical Health Act (HITECH Act). While the Company is still not subject to HIPAA for the reasons stated above the Company may incur material expenses associated with compliance efforts. In addition, compliance may require management to spend substantial time and effort on compliance measures. If the Company fails to comply with HIPAA, it could suffer criminal and civil penalties. The civil penalties could include monetary penalties ranging from $100 per violation to $1.5 million depending on the level of violation.

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), cGTPs, 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. cGTPs are laws, enforced by the 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.

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.

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 had de-emphasized certain of these activities in prior 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 recent periods, however, the Company intends to evaluate and pursue certain opportunities for global expansion, on a selective basis, in which operational synergies and economic potential align with Cryo-Cell s strategic direction.

Saneron CCEL Therapeutics, Inc. The Company owns an approximate 35% interest in Saneron CCEL Therapeutics, Inc. (Saneron) as of November 30, 2009 and 2008. Saneron is the owner and/or exclusive licensee of technology developed by and/or in collaboration with the University of South Florida (USF) and the University of Minnesota (UMN). The technology covers various patents, patent Applications and trade secrets for the therapeutic use of umbilical cord blood stem cells (U-CORD-CELL) and Sertoli cells (SERT-CELL).

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To date, Saneron has received ten 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 C elle 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.

Safti-Cell, Inc. On September 24, 2009, the Company entered into an Asset Purchase Agreement with Red Rock Investments, LLP to purchase the assets and rights related to Safti-Cell, Inc., which was mainly cryogenic storage units, to cancel the Safti-Cell contract, as well as, to assume the remaining portion of Safti-Cell s building lease. Safti-Cell had provided back-up dual cryogenic storage of umbilical cord stem cells as part of the Company s service offering. The twenty-year storage agreement required Cryo-Cell to pay fees to Safti-Cell for each specimen stored in the facility for Cryo-Cell customers. The Asset Purchase Agreement required the Company to pay $750,000 to Red Rock in installments of which $53,150 has been allocated to the purchase of the cryogenic storage units and $696,850 has been allocated to the cancellation of the contract and included in the consolidated statement of operations and comprehensive income (loss) for the year ended November 30, 2009. The first installment of $375,000 was paid on September 24, 2009. The remaining $375,000, which has a stated interest rate of 3.25% and is collateralized by the assets and the rights to the Safti-Cell cryogenic storage units, will be paid in equal quarterly installments of principal plus interest of approximately $95,000 over the next twelve months and is secured by the assets purchased by the Company. All of the specimens stored at Safti-Cell were moved to the Company s laboratory for continued storage. The twenty-year storage agreement entered into in October 2001 which required Cryo-Cell to pay fees to Safti-Cell for each specimen stored in the facility for Cryo-Cell customers was terminated as a result of the Asset Purchase Agreement. The Company s total payments to Safti-Cell for storage for the fiscal years ended November 30, 2009 and 2008 were $236,304 and $324,210, respectively. Due to the cancellation of the contract with Safti-Cell, the Company will be saving approximately $3,300,000 over the next 12 years.

Revenue Sharing Agreements

The Company entered into RSAs prior to 2002 with various third and related 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

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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 Company reflects these up-front payments as long-term liabilities on the accompanying consolidated financial statements. The Company does not intend to enter into additional RSAs.

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 quarterly payments during these periods will be treated as interest expense, which will be recognized as the payments become due. 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.

Florida. On February 9, 1999, the previous agreements with the Company s Arizona Revenue Sharing investors were modified and replaced by a revenue sharing agreement for the state of Florida for a price of $1,000,000. The revenue sharing agreement applies to net storage revenues originating from specimens from within the state of Florida. The revenue sharing agreement entitles the investors to revenues from a maximum of 33,000 storage spaces. A former member of the Board of Directors of the Company is a 50% owner of this revenue sharing agreement. The revenue sharing agreement was entered into prior to the time he became a member of the Board from which he resigned during December 2004.

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

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

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

Texas. On May 31, 2001, the Company entered into an agreement with Red Rock Partners, an Arizona general partnership, entitling them to on-going shares in a portion of the Company s net storage revenue generated by specimens originating from within the State of Texas for a price of $750,000. The investors are entitled to a 37.5% share of net storage revenues originating in the State of Texas to a maximum of 33,000 storage spaces. The same former member of the Board of Directors is a 50% owner of Red Rock.

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The revenue sharing agreement was entered into prior to the time he became a member of the Board, from which he resigned during December 2004. During fiscal 2008, Red Rock assigned 50% of their interest in the agreement to SCC Investments, Inc., an Arizona corporation. Subsequent to year end November 30, 2009, SCC Investments, Inc. assigned its interest to SCF Holdings, LLC, an Arizona limited liability company.

The Company made total payments to all RSA holders of $1,284,805 and $1,145,338 for the fiscal years ended November 30, 2009 and 2008, respectively. The Company recorded an RSA accrual of $745,127 and $602,245 as of November 30, 2009 and 2008, respectively, which are included in accrued expenses in the Company s consolidated financial statements under Item 8 of the Annual Report or Form 10-K.

International

Cryo-Cell De Mexico

In June 2001, the Company entered into an agreement with Cryo-Cell de Mexico, as amended in October 2001, February 2007 and October 2009, 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 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 also receives royalties on storage revenues based on a percentage of the amount received by Cryo-Cell de Mexico. The total royalty payments per the revised 2007 agreement are 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.

The Company recorded royalties and sub-license fees from Cryo-Cell de Mexico in the amount of approximately $699,000 and $605,000 for the years ended November 30, 2009 and 2008, respectively, and this is reflected in licensee income in the accompanying consolidated statements of operations and comprehensive income (loss). In addition, the Company processes and stores specimens sent from sub-licensees in Central America, Ecuador, and to a lesser extent Mexico (sublicensees). Under the revised agreement effective October 2009, the sublicensees terminated the rights and obligations of their agreements with Cryo-Cell de Mexico and entered into separate storage services and license agreements with the Company for the exclusive license to market the Company s U-Cord program. Processing and storage revenues from specimens originating in these territories and stored at the Company s facility in Oldsmar, Florida totaled $813,000 and $628,000 for the years ended November 30, 2009 and 2008 and are reflected in revenues in the Company s consolidated financial statements under Item 8 of this Annual Report or Form 10-K.

Asia Cryo-Cell Private Limited

On July 14, 2004, the Company entered into a definitive License and Royalty Agreement with Asia Cryo-Cell Private Limited (ACCPL), as amended on January 22, 2007, to establish and market its U-Cord® program in India. The up-front license fee of $750,000 was payable by ACCPL in installments through 2007. In consideration for the up-front license fee, the Company licensed its technology, know-how and quality systems to ACCPL in 2004. The Company also 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. The Company also receives royalties on storage revenues of 10%. The total royalty payments per the agreement are 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 $405,000 and $227,000, which principally consisted of $277,808 and $197,965 in royalty income earned on the processing and storage of cord blood stem cell specimens for the years ended November 30, 2009 and, 2008, respectively and this is reflected in licensee income in the Company s consolidated financial statements under Item 8 of this Annual Report or Form 10-K.

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On March 17, 2008, the Company entered into a definitive License and Royalty Agreement with LifeCell International Private Ltd. to establish and market its C elleSM preservation program in India and optionally, into the countries of Bangladesh, Nepal, Pakistan and Sri Lanka. The non-refundable up-front license fee of $250,000, before taxes, is payable by ACCPL in installments. The first installment of approximately $89,000, net of foreign income taxes of approximately $11,000, was paid during the second quarter of fiscal 2008. The final payments of approximately $127,000, net of foreign income taxes of approximately $23,000, were paid during the second and third quarters of 2009. In consideration for the up-front license fee, the Company licensed its technology, know-how and quality systems to ACCPL. In addition, the Company will receive royalty fees of 8% of the C elle collection and processing revenues generated by ACCPL up to 10,000 specimens. The Company will also receive royalty fees of 8% on storage revenues up to 10,000 specimens. Once ACCPL has processed 10,000 specimens, the parties have agreed to renegotiate the royalty fee on collection, processing and storage revenues.

On June 27, 2009, the Company amended the original definitive License and Royalty agreement with ACCPL dated July 14, 2004 and further amended the agreement on January 7, 2010. The amendments expand the licensed territory to include Bangladesh, Nepal, Sri Lanka, Bhutan, Maldives, Oman, Saudi Arabia and the United Arab Emirates. There are no incremental license fees associated with the expanded licensed territory.

Venezuela

On February 20, 2008, the Company entered into an agreement with Cryo-Cell de Venezuela for storage services and the exclusive license to market the Company s U-Cord program. The agreement was amended on August 29, 2008. The license allows Cryo-Cell de Venezuela to directly market the U-Cord program throughout Venezuela and to collect and ship the specimens to the Company s facility in Oldsmar, Florida for which the Company receives a fee for processing and storage of the specimens. The initial up-front storage services and license fee is $200,000 and is non-refundable. The Company received the first installment payment of $100,000 during the first quarter of fiscal 2008 and the second installment payment of $100,000 during the first quarter of fiscal 2009. The installment payments are reflected in licensee income in the accompanying consolidated statements of operations and comprehensive income (loss). Processing and storage revenue totaled approximately $245,000 and $109,000 for the years ended November 30, 2009 and 2008, respectively, and is reflected in revenues in the Company s consolidated financial statements under Item 8 of this Annual Report or Form 10-K.

On February 22, 2010, the agreement was amended extending the territory to include Peru, Chile and Colombia to directly market the U-Cord program throughout Peru, Chile and Colombia and to collect and ship the specimens to the Company s facility in Oldsmar, Florida for which the Company will receive a fee for processing and storage of the specimens. The initial up-front storage and license fee is $450,000 and is non-refundable. The Company received the first installment of $125,000 during the first quarter of 2010 and the second installment of $150,000 is due 18 months from the effective date of the amendment and the final installment of $175,000 is due 30 months from the effective date.

China

On July 8, 2009, the Company entered into a license agreement with S-Evans Biosciences, Inc. (SEB) to establish and market its C elle™ preservation program in mainland China. The agreement also allows SEB to conduct research studies using Cryo-Cell s proprietary C elle menstrual stem technology to identify future potential therapeutic applications. The Company will receive royalty fees of 15% of the C elle collection and processing revenues generated by SEB. The Company will also receive royalty fees of 15% on storage revenues. In consideration for the royalties, the Company licensed its technology, know-how and quality systems to SEB. The Company did not record royalties in fiscal 2009.

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Germany

On October 1, 2009, the Company entered into a License Agreement with Innovative Medical Solutions SRL (IMS) to establish and market the Company s U-Cord business in Germany with the option to expand the licensed territory to include Italy, Spain and France. IMS is to pay the Company an annual fee of $20,000 per year on the anniversary of the effective date for the term of the contract. The initial term of the agreement is ten years and may be extended in five year increments by mutual agreement of the parties. The Company will receive royalties of 12% of the U-Cord collection and processing revenues generated by IMS. The Company will also receive royalty fees of 14% - 18% on storage revenues. In consideration for the annual fee, the Company licensed its technology, know-how and quality systems to IMS. The Company did not record license fees or royalties in fiscal 2009.

On October 1, 2009, the Company entered into a license agreement with Innovative Medical Solutions SRL (IMS) to establish and market the Company s C elle preservation program in Germany with an option to expand the licensed territory to include Italy, Spain and France. IMS is to pay the Company an annual fee of $30,000 per year on the anniversary of the effective date for the term of the contract. The initial term of the agreement is ten years and may be extended in five year increments by mutual agreement of the parties. The Company will receive royalties of 18% - 22% of the C elle collection and processing revenues generated by IMS. The Company will also receive royalty fees of 20% - 24% on storage revenues. In consideration for the annual fee, the Company licensed its technology, know-how and quality systems to IMS. The Company did not record license fees or royalties in fiscal 2009.

Nicaragua

On January 11, 2010, the Company entered into a storage services and license agreement with Innovagen, S.A. (Innovagen) for storage services and the exclusive license to market the Company s U-Cord program. The license allows Innovagen to directly market the U-Cord program throughout Nicaragua and to collect and ship the specimens to the Company s facility in Oldsmar, Florida for which the Company receives a fee for processing and storage of the specimens. The initial up-front storage services and license fee is $60,000 which is to be paid in three installments over the next two years. The license fee is non-refundable.

Pakistan

On January 27, 2010, the Company entered into a storage services and license agreement with Cryo-Cell Pakistan (Pvt.) Limited (Pakistan), for storage services and the exclusive license to market the Company s U-Cord program. The license allows Pakistan to directly market the U-Cord program throughout Pakistan and to collect and ship the specimens to the Company s facility in Oldsmar, Florida for which the Company receives a fee for processing and storage of the specimens. The initial up-front storage services and license fee is $100,000 and is non-refundable. The Company received the first installment payment of $20,000 during the first quarter of fiscal 2010. The second and third installments are payable during Q1 of fiscal 2011 and 2012, respectively.

Employees

At November 30, 2009, there are 48 full-time employees and 1 part-time employee 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. None of our employees are members of any labor union, and we are not a party to any collective bargaining agreement.

ITEM 1A. RISK FACTORS.

You should carefully consider the risks described below before making an investment decision in our securities. These risk factors are effective as of the date of this Form 10-K and shall be deemed to be modified or superseded to the extent that a statement contained in our future filings modifies or replaces such statement. The forward-looking statements in this Form 10-K involve risks and uncertainties and actual results may differ materially from the results we discuss in the forward-looking statements. If any of the following risks actually occur, our business, financial condition or results of operations could be materially adversely affected. In that case, the trading price of our stock could decline, and you may lose all or part of your investment.

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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. Further sales 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.

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, none 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 the efforts of joint venture partners, researchers and others for such development. There is no assurance that such therapies and products can be successfully developed.

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

We have not yet commercially launched services relating to fetal placental stem cells, MPSCs or other new types of stem cells other than the C elle service. 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. 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, fetal placental 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 new types of cells, this may adversely affect our future sales, if any, of these services.

Our stem cell storage business is susceptible to deteriorations in economic conditions and consumer confidence.

Our stem cell storage business is subject to the impact of deteriorating economic conditions, including rising unemployment, lower consumer confidence and restricted access to credit. Any of these conditions in the U.S. economy may adversely affect customers decisions to use our preservation and storage services or to continue making payments on existing storage contracts. These factors may adversely affect our revenues and cash flows in future periods. Because consumer spending for the processing and storage of umbilical cord blood stem cells and menstrual stem cells can generally be considered a discretionary purchase, we may experience a more negative impact on our business due to these conditions than other companies that don t depend on discretionary spending. We have experienced an increase in bad debt expense which we believe is primarily a result of the economy and we have also increased our use of discounts promotions to attract returning and new clients in light of economic conditions. Deteriorating global economic conditions may affect our revenues from our foreign licensees and distributors and may make it more difficult to sign additional license and distribution agreements in foreign countries. If these factors adversely affect our revenues, this could have a material adverse effect on our results of operations and financial condition.

Changes in the cord blood storage technologies could render our services less desirable or obsolete.

Our storage facilities could be rendered less desirable or obsolete in the future by technological advances in cryopreservation technologies. Other cord blood banks may have better technologies than ours for preserving the cord blood units collected to facilitate future harvest of stem cells contained in the cord blood. To effectively compete in the future, we may need to invest significant financial resources to keep pace with technological advances in cord blood storage technologies. If we fail to respond rapidly to changing technologies it could have a material and adverse impact on our business and cause our revenues to decline. Any significant capital requirements could adversely affect our profitability because we may not be able to pass the costs onto our clients.

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

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2004. We voluntarily registered with the FDA in January 2003 and successfully updated that registration, thus meeting the compliance requirement. The FDA in 2005 adopted rules that regulate current Good Tissues Practices (cGTP). 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 portion of our income, and the continued success of our involvement in those arrangements involves unique risks.

Our licensing activities in Mexico/Central America, India and Venezuela accounted for $1,331,553 and $1,036,965 of licensee income for the years ended November 30, 2009 and 2008, respectively. We also have new licensing activities in China, Germany, Nicaragua and Pakistan. 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.

To the extent our license agreements are exclusive we are dependent solely on the success of the particular licensee.

If we are unable to meet and overcome these challenges, our international growth may slow, be limited, or be altogether unsuccessful.

Further, the Company 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.

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.

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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.

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

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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 affect 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. We are currently in the process of switching over to a new and improved platform but there can be no assurance that it will be successful. Any of these events could have a materially adverse effect on our business and financial condition.

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 122,000 specimens in Oldsmar, Florida and Florida is susceptible to hurricanes. 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 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, hurricanes, 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 time, money and effort to comply with legislative and regulatory initiatives relating to patient privacy.

There are government regulations addressing patient information privacy and security concerns that impact our business. In particular, regulations issued under the Health Insurance Portability and Accountability Act of 1996, or HIPAA, and the Health Information Technology for Economic and Clinical Health Act, or HITECH, contain provisions that require us to adopt business procedures designed to protect the privacy of each of our patients individual health information. We may be required to spend substantial time, money and effort on compliance measures. The HIPAA regulations expose us to increased regulatory risk if we fail to comply. If we fail to comply with the HIPAA regulations, we could suffer civil and civil penalties. The civil penalties could include monetary penalties ranging from $100 per violation to $1.5 million depending on the level of violation.

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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.

We are exposed to potential risks resulting from new internal control requirements under Section 404 of the Sarbanes-Oxley Act of 2002.

While we have evaluated our internal controls in order to allow management to report on our internal controls, as required by Section 404 of the Sarbanes-Oxley Act of 2002, our independent registered public accounting firm has not issued its attestation report on our internal controls due to temporary rules of the SEC. There can be no assurances that when our independent registered public accounting firm performs its attestation work that it will concur with management s assessment. Any failure to obtain the attestation report from our independent registered public accounting firm or the identification of material weaknesses by them could result in unexpected delays in further implementing the requirements relating to internal controls; remediation actions or the impact that these activities will have on our operations. We also expect to incur additional expenses and diversion of management s time as a result of performing the system and process evaluation, testing and any remediation required when our auditors perform their attestation work in order to comply with the auditor attestation requirements. We are a small company with limited resources that could make it difficult for us to comply with the auditor attestation requirements of Section 404 in a timely fashion. If we are not able to comply with the requirements set forth in Section 404, we might be subject to sanctions or investigation by regulatory authorities. Any such action could adversely affect our business and financial results.

We depend on the services of our senior management for our success and must retain and attract other highly skilled personnel to maintain and grow our business.

Our performance and success is substantially dependent on the continued services and on the performance of our senior management. Our performance and success also depends on our ability to retain and motivate our other key employees. The services of our Chairman and Chief Executive Officer, Mercedes Walton, our Vice President, Finance and Chief Financial Officer, Jill Taymans, our Vice President of Laboratory Operations and R&D, Julie Allickson, Ph.D are important to our ability to implement our business strategy and a loss of their services could harm our business. We have entered into employment agreements with Ms. Walton, Taymans and Allickson. The Company does not carry key-man life insurance on these individuals. Our future performance and success also depends on our ability to identify, attract, hire, train, retain and motivate highly skilled personnel. If we fail to attract, integrate and retain the necessary personnel, our ability to successfully maintain and build our business could suffer significantly.

Our warranty program could subject us to claims in the future that could have a material impact on our financial results

In December 2005, we began providing clients enrolled under the new pricing structure with a payment warranty under which we agree to pay $50,000 to the 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 we will pay $10,000 to the client to offset personal expenses if the U-Cord® product is used for bone marrow reconstitution in a myeloblative transplant procedure. While we have not experienced any claims under the warranty

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program nor have we incurred costs related to these warranties, we could be subject to a significant number of claims in the future that could require us to pay out substantial sums that could have a material adverse impact on our financial results. We do not maintain insurance for this warranty program but we do maintain reserves to cover our estimated potential liabilities. However, we cannot provide assurances that the reserves are adequate.

Risks Related to Our Common Stock

Our common stock price may be volatile and our trading volume low and as a result 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. Also, the daily trading volume of our common stock has historically been relatively low. Over the past two years, the price of our common stock has fluctuated from a high of $2.32 to a low of $0.40. 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

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sold at a given price, but also through delays in the timing of transactions and reduction in securities 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. In addition, if at any time our the trading price of our stock is below $5.00 per share it is subject to the SEC s penny stock rules. Because the penny stock rules impose certain requirements on brokers, they may be less willing to execute transactions in our securities. Furthermore, because of the limited market and generally low volume of trading in our common stock, our common stock is more likely to be affected by broad market fluctuations, general market conditions, fluctuations in our operating results, changes in the market s perception of our business, and announcements made by us, our competitors or parties with whom we have business relationships. Our ability to issue additional securities for financing or other purposes, or to otherwise arrange for any financing we may need in the future, may also be materially and adversely affected by the fact that our securities are not traded on a national securities exchange.

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

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

We could issue additional common stock which could negatively impact the price of our stock.

Our board of directors has authority, without action or vote of our stockholders, to issue all or a part of our authorized but unissued shares. Such stock issuances could be made at a price that reflects a discount or a premium from the then-current trading price of our common stock. In addition, if we need to raise capital, we may need to issue securities that are convertible into or exchangeable for a significant amount of our common stock. These issuances would dilute your percentage ownership interest, which would have the effect of reducing your influence on matters on which our shareholders vote, and might dilute the book value of our common stock. You may incur additional dilution if holders of stock options, whether currently outstanding or subsequently granted, exercise their options to purchase 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 1B. UNRESOLVED STAFF COMMENTS.

Not applicable.

ITEM 2. PROPERTIES.

The Company entered into a ten-year lease in April 2004 for its new 17,600 square foot 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.

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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 $11,032 per month through July 31, 2009, 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.

None.

ITEM 4. RESERVED.

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 is traded 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.

Quarter Ended	Low Closing Bid	High Closing Bid
February 28, 2009	0.42	0.74
May 31, 2009	0.46	1.48
August 31, 2009	1.12	2.32
November 30, 2009	1.66	2.31
February 29, 2008	0.67	1.22
May 31, 2008	0.65	0.93
August 31, 2008	0.62	0.85
November 30, 2008	0.40	0.80

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, 2009, the Company had 300 shareholders of record, and management believes there are approximately 5,000 additional beneficial holders of the Company s common stock.

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Equity Compensation Plan Information as of November 30, 2009

Equity Compensation plans approved by stockholders	Number of securities to be issued upon exercise of outstanding options, warrants and rights	Weighted-average exercise price of outstanding options, warrants and rights	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in the first column)
Cryo-Cell International 2000 Stock Incentive Plan	958,752	$ 2.88	0(1)
Cryo-Cell International, Inc. 2006 Stock Incentive Plan	237,728	1.64	762,272
Total	1,196,480	$ 2.66	762,272

(1) No further stock options or other awards will be granted under the 2000 Stock Incentive Plan.

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, 2009, 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. This section of the Form 10-K contains forward-looking statements that involve substantial risks and uncertainties, such as statements about our plans, objectives, expectations and intentions. We use words such as expect , anticipate , plan , believe seek , estimate , intend , future and similar expressions to identify forward-looking statements. Our actual results could differ materially from those anticipated in these forward-looking statements for many reasons, including as a result of some of the factors described below and in the section titled Risk Factors . You are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date of this 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

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contracts with such customers. The Company also offers a one-time payment plan, where the client is charged $3,495 with discounts in the case of multiple children from the same family and in other circumstances. The one-time plan includes the collection kit, processing and testing, return medical courier service and 21 years of pre-paid storage fees. 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 harvested from sources beyond umbilical cord blood stem cells. 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 in 2006, the Company discovered novel technology related to menstrual stem cells. In November 2007, the Company announced the commercial launch of C elle℠ service related to this patent-pending technology. The Company continues to focus independently-funded research and development activities through a vast network of research collaboration partners.

During the year ended November 30, 2009, the Company s revenues decreased 6% as compared to the same period in 2008. The Company reported net income of approximately $1,425,000, or $.12 per basic common share for fiscal 2009 compared to a net loss of approximately ($726,000) or ($.06) per basic common share for fiscal 2008. The increase in net income in fiscal 2009 principally resulted from a 17% decrease in marketing, general and administrative expenses, due mainly to the decrease in operational expenses that resulted from improved operating efficiencies, as well as, a 26% decrease in cost of sales primarily due to a decline in the number of specimens processed and operational efficiencies in the processing and storage process. In addition, research and development expenses were approximately $102,000 for fiscal 2009, a decrease of approximately 47% in comparison to fiscal 2008. Research and development expenses in 2008 were primarily comprised of expenses related to the initial commercialization of the Company s new stem cell technology, C elle, which was launched in November 2007. These decreases were offset by a one-time charge of approximately $697,000 for the Safti-Cell contract cancellation. Due to the cancellation of the contract with Safti-Cell, and moving all of the specimens previously stored by Safti-Cell to the Company s storage facility in Oldsmar, Florida, the Company expects to save approximately $3,300,000 in storage expense over the next twelve years.

As of November 30, 2009, the Company had cash and cash equivalents of $6,850,765. The Company s cash increased by approximately $3,300,000 during fiscal 2009, primarily as a result of positive cash flow from operations. The increase in operating cash flow was primarily attributable to the Company s net income during fiscal 2009. As of February 28, 2010, the Company maintains no long-term indebtedness.

Results of Operations

Revenue. For the fiscal year ended November 30, 2009, the Company had revenue of $16,326,684 compared to $17,278,058 for the fiscal year ended November 30, 2008 representing a 6% decrease. The decrease is primarily attributable to a decrease in specimens processed of 8%, in addition to an increase in sales discounts of 23%, partially offset by a 10% increase in recurring annual storage fee revenue for the year ended November 30, 2009 compared to the 2008 period. Sales discounts represent discounts to returning clients and promotions offered to newly enrolled clients.

Cost of Sales**.** For the fiscal year ended November 30, 2009, cost of sales was $4,532,509, as compared to $6,113,514 for the fiscal year ended November 30, 2008 representing a 26% decrease. Costs of sales were 28% and 35% of revenues in fiscal 2009 and 2008, respectively**.** Cost of sales includes wages and supplies associated with process enhancements to the existing production procedures and quality systems in the processing of cord blood specimens at the Company s facility in Oldsmar, Florida and depreciation expense of approximately $286,000 for the year ended November 30, 2009 compared to approximately $282,000 for the 2008 period. The decrease in cost of sales is primarily attributable to the increase in operational efficiencies as well as the decrease in specimens processed during the year ended November 30, 2009 compared to the 2008 period.

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Marketing, General and Administrative Expenses. Marketing, general and administrative expenses during the fiscal year ended November 30, 2009 were $8,936,679 as compared to $10,827,326 for the fiscal year ended November 30, 2008 representing a 17% decrease. These expenses are primarily comprised of expenses for consumer advertising, salaries and wages for personnel and professional fees. The decrease was principally attributable to a 25% decrease in expenses from public relations activities and a 35% decrease in expenses from consumer advertising. The higher expenses in fiscal year 2008 were principally attributable to the implementation of the Company s strategic initiatives to increase market share and achieve unit growth by strengthening the resources allocated to sales and marketing. The Company began to reduce these expenses during the latter part of fiscal 2008.

Research, Development and Related Engineering Expenses. Research, development and related engineering expenses for the fiscal year ended November 30, 2009, were $102,414 as compared to $194,462 in 2008. The expenses for the years ended November 30, 2009 and 2008 are primarily comprised of expenses related to the continued commercialization of the Company s new stem cell technology, C elle, which was launched in November 2007.

Impairment of Assets. For the fiscal year ended November 30, 2008, the Company recorded an impairment of marketable securities of $60,736. During the quarter ended August 31, 2008, 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 were no such impairments recorded during fiscal 2009.

Depreciation and Amortization. Depreciation and amortization (not included in Cost of Sales) for the year ended November 30, 2009 was $385,978 compared to $408,766 for the 2008 period.

Safti-Cell Contract Cancellation Costs. On September 24, 2009, the Company entered into an Asset Purchase Agreement with Red Rock Investments, LLP to purchase the assets and rights related to Safti-Cell, Inc., which was mainly cryogenic storage units, to cancel the Safti-Cell contract, as well as, to assume the remaining portion of Safti-Cell s building lease. Safti-Cell had provided back-up dual cryogenic storage of umbilical cord stem cells as part of the Company s service offering. The twenty-year storage agreement required Cryo-Cell to pay fees to Safti-Cell for each specimen stored in the facility for Cryo-Cell customers. The Asset Purchase Agreement required the Company to pay $750,000 to Red Rock in installments of which $53,150 has been allocated to the purchase of the cryogenic storage units and $696,850 has been allocated to the cancellation of the contract and included in the consolidated statements of operations and comprehensive income (loss) for the year ended November 30, 2009. The first installment of $375,000 was paid on September 24, 2009. The remaining $375,000, which has a stated interest rate of 3.25% and is collateralized by the assets and the rights to the Safti-Cell cryogenic storage units, will be paid in quarterly installments of principal and interest of approximately $95,000 over the next twelve months and is secured by the assets purchased by the Company. All of the specimens stored at Safti-Cell were moved to the Company s laboratory for continued storage. The twenty-year storage agreement entered into in October 2001 which required Cryo-Cell to pay fees to Safti-Cell for each specimen stored in the facility for Cryo-Cell customers was terminated as a result of the Asset Purchase Agreement. The Company s total payments to Safti-Cell for storage for the fiscal years ended November 30, 2009 and 2008 were $236,304 and $324,210, respectively. Due to the termination of the back-up storage agreement, the Company will no longer be obligated to make the storage payments. Due to the cancellation of the contract with Safti-Cell, the Company expects to save approximately $3,300,000 over the next twelve years.

Interest Expense. Interest expense during the fiscal year ended November 30, 2009, was $1,416,160 compared to $1,321,771 in 2008. 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

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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 33,000 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). 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. Also included in interest expense is the amortization of the present value of a deferred consulting agreement in the amount of $23,759 and $30,251 for the years ended November 30, 2009 and 2008, respectively.

Licensee Income. Licensee income for the fiscal year ended November 30, 2009, was $1,331,553 as compared to $1,036,965 in 2008. Licensee income for fiscal 2009 principally consisted of $1,104,113 in royalty income earned on the processing and storage of cord blood stem cell specimens in geographic areas where the Company has license agreements as compared to $847,567 in the 2008 period. The increase is due to an increase in the customer base of the Company s international affiliates. The remaining 2009 and 2008 licensee income related to installment payments of non-refundable up-front license fees from the licensees of the Company s U-Cord program in Nicaragua and Venezuela and the Company s C elle program in India.

Equity in Losses of Affiliate. Equity in losses of affiliate was $112,769 for the fiscal year ended November 30, 2009 compared to $164,337 in 2008. Equity in losses of affiliate for the years ended November 30, 2009 and November 30, 2008 solely consists of amounts related to compensation expense for stock option awards that were granted by Saneron to certain consultants and employees.

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, 2009 and November 30, 2008, 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 provision or benefit during the fiscal years ended November 30, 2009 and 2008, as the provision for 2009 was offset by the utilization of net operating loss carry forwards and the benefit for 2008 was offset by an increase in the valuation allowance. The Company did not pay United States federal income taxes during the fiscal years ended November 30, 2009 and November 30, 2008 because the Company utilized their net operating loss carryforward.

The Company records foreign income taxes withheld from installment payments of non-refundable up-front license fees and royalty income earned on the processing and storage of cord blood stem cell specimens in geographic areas where the Company has license agreements. The Company recognized approximately $122,000 and $105,000 for the years ended November 30, 2009 and 2008, respectively, of foreign income tax expense. The increase in foreign tax expense is attributable to the increase in royalties recognized during fiscal 2009.

Liquidity and Capital Resources

Through November 30, 2009, the Company s principal source of cash has been from sales of its U-Cord® program to customers, the sale of license agreements and proceeds from licensees. Currently, the Company s cash flow is derived primarily from sales relating to its storage services, including the initial fee and ongoing storage fees, as well as licensee income. The Company does not expect a change in its principal source of cash flow.

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At November 30, 2009, the Company had cash and cash equivalents of $6,850,765 as compared to $3,566,366 in 2008. The Company also has certain investments in marketable securities, which totaled $966,404 as of November 30, 2009. The increase in cash and cash equivalents in 2009 was primarily attributable to the following:

Net cash provided by operating activities in fiscal 2009 was $3,747,854, which was primarily attributable to the Company s net income, payments received on long-term storage contracts and payments from licensees, including the receipt of the second $100,000 installment payment from the sale of the Cryo-Cell de Venezuela licensee agreement and the receipt of the second and third installment payments from ACCPL totaling $127,440, net of taxes which was partially offset by the first installment paid for the cancellation of the Safti-Cell contract during the fourth quarter of fiscal 2009 in the amount of $375,000.

Net cash provided by operating activities in fiscal 2008 was $614,163, which was primarily attributable to the Company s net income and payments received on long-term storage contracts including receipt of approximately $189,000 from the sale of licensee agreements to international affiliates during fiscal 2008.

Net cash used in investing activities in fiscal 2009 was $463,455, which was primarily attributable to the purchase of property and equipment and the investment in patents.

Net cash used in investing activities in fiscal 2008 was $413,858, which was attributable to the sale of marketable securities offset by the purchase of property and equipment and the costs associated with the application and development of patents.

There was no cash provided by or used in financing activities during fiscal 2009.

Net cash provided by financing activities in fiscal 2008 was $1,350 as a result of an exercise of stock options.

The Company does not have a line of credit. The Company owes the remaining balance of $375,000 to be paid to Red Rock for the acquisition of Safti-Cell, which is secured by the assets purchased by the Company. The balance is to be paid in quarterly installments of principal and interest of $95,388 during fiscal 2010.

The Company anticipates making non-discretionary capital expenditures of approximately $500,000 over the next twelve months. The Company anticipates funding future property and equipment purchases with cash-on-hand and cash flows from future operations.

The Company anticipates that its cash and cash equivalents, marketable securities and cash flows from future operations will be sufficient to fund its known 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 the C elle service, 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 and Estimates

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

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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 Description of Business and Summary of Critical and Significant Accounting Policies to the Consolidated Financial Statements contained in Item 8 of this document.

Revenue Recognition

The Company records revenue from processing and storage of specimens. The Company recognizes revenue from processing fees upon completion of processing and cellular storage fees ratably over the contractual storage period, as well as, other income from royalties paid by licensees related to long term storage contracts which the Company has under license agreements. 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 well as royalties received from foreign licensees related to long-term storage contracts in which the Company has future obligations under the license agreement. The Company classifies deferred revenue as current if the Company expects to recognize the related revenue over the next 12 months. As of November 30, 2009 and November 30, 2008, the current portion of deferred revenue is approximately $5,400,000 and $5,000,000, respectively, and the long-term portion of deferred revenue is approximately $7,400,000 and $7,000,000, respectively. The Company also records revenue from shipping and handling billed to customers when earned. Shipping and handling costs that the Company incurs are expensed and included in cost of sales.

Accounts Receivable

Accounts receivable consist of the amounts due from clients that have enrolled and processed in the U-Cord® processing and storage program and amounts due from licensee 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. Accounts outstanding longer than the contractual payment terms are considered past due. The Company determines its allowance by considering the length of time accounts receivable are past due, the Company s previous loss history, and the customer s current ability to pay its obligations. Therefore, if the financial condition of the Company s clients were to deteriorate beyond the estimates, the Company may have to increase the allowance for doubtful accounts which could have a negative impact on earnings. 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

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, 2009 and November 30, 2008, 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 provision or benefit during the fiscal years ended November 30, 2009 and 2008, as the provision for 2009 was offset by the utilization of net operating loss carry forwards and the benefit for 2008 was offset by an increase in the valuation allowance. The Company did not pay United States federal income taxes during the fiscal years ended November 30, 2009 and November 30, 2008 because the Company utilized their net operating loss carryforward.

The Company records foreign income taxes withheld from installment payments of non-refundable up-front license fees and royalty income earned on the processing and storage of cord blood stem cell specimens in geographic areas where the Company has license agreements. The Company recognized approximately $122,000 and $105,000 for the years ended November 30, 2009 and 2008, respectively, of foreign income tax expense. The increase in foreign tax expense is attributable to the increase in royalties recognized during fiscal 2009.

The Company recognizes the financial statement benefit of a tax position only after determining that the relevant tax authority would more likely than not sustain the position following an audit. For tax positions meeting the more-likely-than-not threshold, the amount recognized in the financial statements is the largest benefit that has a greater than 50 percent likelihood of being realized upon ultimate settlement with the relevant tax authority. Increases or decreases to the unrecognized tax benefits could result from management s belief that a position can or cannot be sustained upon examination based on subsequent information or potential lapse of the applicable statute of limitation for certain tax positions.

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The Company recognizes interest and penalties related to uncertain tax positions in income tax expense. As of November 30, 2009 and 2008, the Company had no provisions for interest or penalties related to uncertain tax positions.

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 annually to determine if an other than temporary impairment exists. The Company previously recorded equity in losses of affiliate until the investment balance was zero and only goodwill remained. 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, 2009 and November 30, 2008. If actual future results are not consistent with the Company s assumptions and estimates, the Company may be required to record impairment charges in the future which could have a negative impact on earnings.

Patents

The Company incurs certain legal and related costs in connection with patent applications. If a future economic benefit is anticipated from the resulting patent or an alternate future use is available to the Company, such costs are capitalized and amortized over the expected life of the patent. The Company s assessment of future economic benefit involves considerable management judgment. A different conclusion could result in the reduction of the carrying value of these assets.

Patent costs are capitalized on the date that the utility patent was filed and are amortized over a period of 20 years. Capitalized patent costs, net of accumulated amortization, as of November 30, 2009 and November 30, 2008 are $401,206 and $243,863, respectively, and are included in deposits and other assets in the accompanying consolidated balance sheets.

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.

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

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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 fourteen active licensing agreements. The following areas each have one license agreement: Mexico, El Salvador, Guatemala, Nicaragua, Ecuador, Panama, Honduras, Venezuela, China and Pakistan. The following areas each have two license agreements: China and Germany.

In addition to the license fee, the Company earns royalties on subsequent processing and storage revenues received by the licensee in the selected area and a fee on any sub-license agreements that are sold by the licensee where applicable. The Company also processes and stores specimens sent directly from customers of sub-licensees in Mexico, Central America, Ecuador, Pakistan and Venezuela. These fees are included in revenue on the consolidated statements of operations and comprehensive income (loss). As part of the accounting for royalty revenue, the Company uses estimates and judgments based on historical processing and storage volume in determining the timing and amount of royalty revenue to recognize. The Company periodically reviews license and royalty receivables for collectability and, if necessary, will record an expense for an allowance for uncollectible accounts. If the financial condition of the Company s sub-licensees were to deteriorate beyond the estimates, the Company may have to increase the allowance for doubtful accounts which could have a negative impact on earnings. If the licensee s customer base were to decrease, it would negatively impact the Company s ongoing license income.

Recently Issued Accounting Pronouncements

Business Combinations

In December 2007, the Financial Accounting Standards Board (FASB) issued an accounting standard to improve the relevance, representational faithfulness, and comparability of the information that a reporting entity provides in its financial reports about a business combination and its effects. This standard establishes principles and requirements for how the acquirer recognizes the identifiable assets acquired, the liabilities assumed, and any noncontrolling interest in the acquiree, recognizes and measures goodwill or a gain from a bargain purchase, and identifies financial statement disclosures related to the business combination. This standard applies prospectively to business combinations for which the acquisition date is on or after the beginning of the first annual reporting period beginning on or after December 15, 2008. The Company will adopt this standard on December 1, 2009.

Equity Method Investment Accounting Considerations

In November 2008, the FASB issued an accounting standard to clarify the accounting for certain transactions and impairment considerations involving equity method investments. This accounting standard is effective in fiscal periods beginning on or after December 15, 2008. The Company is currently assessing the impact that this standard may have on its consolidated financial statements upon adoption on December 1, 2009.

Subsequent Events

In May 2009, the FASB issued an accounting standard, which established general standards of accounting for and disclosure of events that occur after the balance sheet date but before financial statements are issued. This standard is effective for interim or annual periods ending after June 15, 2009, and accordingly, the Company adopted this standard during the third quarter ended August 31, 2009.

Revenue Arrangements with Multiple Deliverables

In October 2009, the FASB issued an Accounting Standard Update (ASU), which addresses the accounting for multiple-deliverable arrangements to enable vendors to account for products or services separately rather than as a combined unit and modifies the manner in which the transaction consideration

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is allocated across the separately identified deliverables. The ASU significantly expands the disclosure requirements for multiple-deliverable revenue arrangements. The ASU will be effective for the first annual reporting period beginning on or after June 15, 2010, and may be applied retrospectively for all periods presented or prospectively to arrangements entered into or materially modified after the adoption date. Early adoption is permitted, provided that the guidance is retroactively applied to the beginning of the year of adoption. The Company has not determined if it will adopt this new update on December 1, 2010. The Company is currently evaluating the impact this update may have on its consolidated financial statements upon its required adoption on December 1, 2011.

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.

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

Not applicable.

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, 2009 and 2008

Consolidated Statements of Operations and Comprehensive Income (Loss)
For the Years Ended November 30, 2009 and 2008

Consolidated Statements of Cash Flows
For the Years Ended November 30, 2009 and 2008

Consolidated Statements of Stockholders Deficit
For the Years Ended November 30, 2009 and 2008

Notes to Consolidated Financial Statements

All other schedules for which provision is made in the applicable accounting regulations of the Securities and Exchange Commission are not required under the related instructions, are already included in the Notes to the Consolidated Financial Statements included under this Item 8 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

Shareholders of Cryo-Cell International, Inc.

We have audited the accompanying consolidated balance sheets of **Cryo-Cell International, Inc.** and subsidiaries (a Delaware corporation) as of November 30, 2009 and 2008, and the related consolidated statements of operations and comprehensive income (loss), stockholders deficit, and cash flows for the years then ended. 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, 2009 and 2008, and the results of their operations and their cash flows for the years then ended in conformity with accounting principles generally accepted in the United States of America.

/s/ GRANT THORNTON LLP

Orlando, Florida

March 1, 2010

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CRYO-CELL INTERNATIONAL, INC. AND SUBSIDIARIES

CONSOLIDATED BALANCE SHEETS

	November 30, 2009	November 30, 2008
ASSETS		
Current Assets		
Cash and cash equivalents	$ 6,850,765	$ 3,566,366
Restricted cash	200,000	200,000
Marketable securities and other investments	960,000	1,125,000
Accounts receivable and advances (net of allowance for doubtful accounts of $510,440 and $766,524, respectively) (1)	2,246,181	2,250,835
Deferred tax assets	15,000	21,000
Prepaid expenses and other current assets	682,215	521,041
Total current assets	10,954,161	7,684,242
Property and Equipment-net	2,369,888	2,570,597
Other Assets		
Marketable securities and other investments	6,404	6,404
Note receivable	91,758	89,411
Investment in Saneron CCEL Therapeutics, Inc.	684,000	684,000
Deposits and other assets	501,917	282,122
Total other assets	1,284,079	1,061,937
Total assets	$ 14,608,128	$ 11,316,776
LIABILITIES AND STOCKHOLDERS DEFICIT		
Current Liabilities		
Accounts payable	$ 750,127	$ 835,670
Accrued expenses	2,130,760	1,226,045
Deferred revenue (1)	5,449,483	4,939,653
Total current liabilities	8,330,370	7,001,368
Other Liabilities		
Deferred revenue, net of current portion (1)	7,407,287	6,996,264
Deferred tax liabilities	15,000	21,000
Long-term liability-revenue sharing agreements	3,750,000	3,750,000
Deferred consulting obligation	286,441	382,847