CRYO CELL INTERNATIONAL INC
Form 10-K
February 29, 2016

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, 2015

¨ **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	**(I.R.S. Employer**

incorporation or organization) Identification No.)

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

(Address of principal executive offices) (Zip Code)

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 $0.01 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 x

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 x

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 x 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 x No ¨

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of the Registrant s knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. Yes x No ¨

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 x
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 x

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 $15,737,020.

State the number of shares outstanding of each of the Registrant s classes of common stock, as of the latest practicable date. As of February 15, 2016, 12,260,340 shares of $0.01 par value common stock were issued and 8,960,337 were 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 . The terms Cryo-Cell International, Inc., Cryo-Cell, Company, we, our and us refer to Cryo-Cell International, Inc. The words expe believe, goal, plan, intend, estimate and similar expressions and variations thereof, if used, are intended to specif 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.

ITEM 1. BUSINESS.

Introduction

Cryo-Cell International, Inc. (the Company or Cryo-Cell) is a Delaware corporation that was incorporated in 1989. The Company is organized in two reportable segments, cellular processing and cryogenic storage, with a current focus on the collection and preservation of umbilical cord blood and tissue stem cells for family use and the manufacture of Prepacyte® CB units, the processing technology used to process umbilical cord blood stem cells. The Company, in combination with its global affiliates, currently stores over 300,000 cord blood and cord tissue specimens worldwide for the exclusive benefit of newborn babies and possibly other members of their families. Founded in 1989, the Company was the world s first private cord blood bank to separate and store stem cells in 1992. All aspects of its U.S.-based business operations, including the processing and storage of specimens, are handled from its headquarters facility in Oldsmar, Florida. The specimens are stored in commercially available cryogenic storage units at this technologically and operationally advanced facility.

In recent years, utilizing its infrastructure, experience and resources derived from its umbilical cord blood stem cell business, 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 fiscal 2011, the Company introduced the advanced new cord tissue service, which stores a section of the umbilical cord tissue. The Company offers the cord tissue service in combination with the umbilical cord blood service. This service is growing; however, the umbilical cord blood service continues to be the Company s main focus.

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 individuals the opportunity to potentially take advantage of evolving cellular therapies and other medical technologies.

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

infused into a patient. They can be returned to the individual from whom they were taken (autologous) or donated to someone else (allogeneic). An individual s own bone marrow may be used for a transplant if the cancer has not entered the marrow system (metastasized). Otherwise, a marrow donor needs to be identified to provide the needed bone marrow. The availability of a marrow donor or matched stem cell specimen allows physicians to administer larger doses of chemotherapy or radiation in an effort to eradicate the disease. Stem cell therapies and transplants are used for both cancerous and non-cancerous diseases.

Stem cells are found in umbilical cord blood (cord blood stem cells) and can be collected and stored after a baby is born. Over 30,000 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 umbilical cord blood 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 and first year of storage 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 or a lifetime 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 client services, marketing and administrative operations, is designed to accommodate a broad range of events such as client tours and open houses, as well as educational workshops for clinicians and expectant parents.

Competitive Advantages

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

- The world s first private cord blood bank, with an established client base exceeding 300,000 worldwide,

our status as a cGMP- and cGTP-compliant private cord blood bank with International Organization for Standardization (ISO) certification, AABB accreditation and FACT (the Foundation for the Accreditation for Cellular Therapy) accreditation,

a state-of-the-art laboratory processing facility,

utilization of a processing method using superior technology that yields the maximum recovery of healthy stem cells and provides superior red blood depletion over all other methods,

a safe, secure and monitored storage environment,

since inception, 100% viability rate of the Company s specimens upon thaw for therapeutic use,

a state-of the-art, insulated collection kit that protects cord blood specimens thirty times longer under extreme conditions than competitor s kits,

7 day per week processing capability,

a payment warranty under which the Company agrees to pay $50,000 (effective February 1, 2012 this payment was increased to $75,000 for new clients) to its client if the umbilical cord blood 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.

Cord Tissue

In August 2011, the Company introduced its advanced new cord tissue service, which stores a section of the umbilical cord tissue. Approximately six inches of the cord tissue is procured and transported to the Company s laboratory for processing, testing and cryopreservation for future potential use. Umbilical cord tissue is a rich source of mesenchymal stem cells (MSCs). Mesenchymal stem cells have many unique functions including the ability to inhibit inflammation following tissue damage, to secrete growth factors that aid in tissue repair, and to differentiate into many cell types including neural cells, bone cells, fat cells and cartilage. MSCs are increasingly being researched in regenerative medicine for a wide range of conditions including heart and kidney disease, ALS, wound healing and auto-immune diseases. Mesenchymal stem cells from several different tissues are being tested in clinical trials for efficacy. Specifically, cells derived from cord tissue are currently being used in many clinical trials; disorders being treated include cardiomyopathy, ulcerative colitis, diabetes, anemia, autism and cirrhosis of the liver.

Marketing

Marketing Approach

It is the Company s mission to inform expectant parents and their prenatal care providers of the potential medical benefits from preserving stem cells and to provide them the means and processes for collection and storage of these cells. Today, stem cell transplants are known and accepted treatments for approximately 80 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 a 1-in-4 chance of being a perfect match and a 1-in-4 chance of being an acceptable 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.

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Despite the potential benefits of umbilical cord blood 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 umbilical 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, an embedded client base, increased public awareness and accelerated market penetration.

Umbilical Cord Blood and Cord Tissue Services

The Company markets its cord blood stem cell preservation services directly to expectant parents and by distributing information through obstetricians, pediatricians, childbirth educators, certified nurse-midwives and other related healthcare professionals. The Company believes that its revenues have been facilitated by a variety of referral sources, resulting from high levels of customer satisfaction. New expectant parent referrals during fiscal 2015 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.

The Company has a national sales force to increase its marketing activities with its clinical referral sources, including physicians, midwives and hospitals. Promotional activities also include advertisements in clinical journals and telemarketing activities. In addition, the Company exhibits 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. Expectant parents have also received information via emails and internet marketing campaigns.

The Company s client support team advisors are available by telephone to enroll clients and educate both expectant parents and the medical community on the life-saving potential of cord blood stem cell preservation.

The Company continues to use its website, 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 umbilical cord blood and cord tissue service and enroll online. Viewers may read about successful transplants using Cryo-Cell stored cord blood stem cells and access other topical information. Information on our website is not incorporated into this Annual Report on Form 10-K and should not be considered part of this Annual Report on Form 10-K.

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 competitors 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 some competitors charge more for comparable (or even inferior) quality service. In

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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. During 2014, the Company was granted FACT (the Foundation for the Accreditation for Cellular Therapy) accreditation. These achievements position Cryo-Cell as an industry quality leader as a cGMP- and cGTP-compliant private cord blood bank with ISO certification, AABB and FACT accreditations.

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; 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.

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. In addition, with the purchase of the manufacturing rights to the PrepaCyte-CB Processing System on June 30, 2015, Cryo-Cell is required to register this product as a Medical Device under the Federal Food, Drug, and Cosmetic Act which is also subject to FDA inspection. At November 30, 2015, the Company was in compliance with these requirements.

The division of FDA which regulates HCT/Ps 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/Ps. 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/Ps.

These three FDA rules apply only 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. As part of this oversight authority, the FDA conducts unannounced inspections of cord blood banks.

The PrepaCyte CB (Cord Blood) Processing System is intended for use in cell processing laboratories to process and store total nucleated cells (TNC) from human umbilical cord blood, prior to banking. The device is composed of three integrally-attached processing and storage containers (or a

single processing container) with separation media. The system is 510K cleared as a Class II device. The division of the FDA which regulates this product is the Center of Biologics Evaluation and Research (CBER). Approval to market the device was determined by the Office of Cellular, Tissue and Gene Therapies. The section of FDA Code of Federal Regulations (CFR) pertaining to medical device is 21 CFR 800s. The requirements for compliance to this section include annual registration of the device, listing of devices with the FDA, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

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 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.

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.

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In addition, as the organization grows and evolves, other legislation and regulations are expected to impact the Company. One such evolution involves activities that may be designated as or involve medical research or cooperative agreements associated with medical research. These types of activities are also governed by the FDA, specifying oversight by an Institutional Review Board (IRB). The IRB is a board or committee that approves the initiation of, and conducts periodic review of, biomedical research involving human subjects. The primary purpose of such review is to assure the protection of the rights and welfare of the human subjects. Governance of biomedical research is codified as laws by Title 21 of the Code of Federal Regulations (CFR) Part 56, and enforced by the FDA. Other medical research associated with clinical trials may require an Investigational New Drug Application (IND). Current Federal law requires that a drug be the subject of an approved marketing application before it is transported or distributed across state lines. Because a sponsor will likely want to ship the investigational drug to clinical investigators in many states, it must seek an exemption from that legal requirement. The IND is the means through which the sponsor technically obtains this exemption from the FDA. This approval would be required in the case of a clinical trial.

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 has evaluated and pursued, and intends to continue 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 33% and 33% interest in Saneron CCEL Therapeutics, Inc. (Saneron) as of November 30, 2015 and 2014, respectively. As of November 30, 2015 and November 30, 2014, the net Saneron investment, which represents underlying goodwill, is reflected on the consolidated balance sheets at $0 and $684,000, respectively. Saneron is the owner and/or exclusive licensee of certain 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).

To date, Saneron has received thirteen SBIR/STTR grants, has been the industry sponsor on twelve Florida High Tech Corridor grants, one James and Esther King Biomedical Research Grant, 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 2005 and 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 drafting Investigational New Drug (IND) applications for the use of the U-CORD-CELL® as a potential therapy for Alzheimer s, ALS and stroke. As Pre-IND meeting with the FDA was held in February 2014.

In March 2013, Saneron received a second Phase I STTR grant for a joint project with Henry Ford Health System on the use of the U-CORD-CELL® as a potential therapy for stroke. In June 2010, Saneron received a James and Esther King Biomedical Grant, which was matched with a Florida High

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Tech Corridor Industry Seed Grant, to study the potential of Cryo-Cell s menstrual stem cell technology as a possible treatment for stroke. Finally in September 2010, Saneron received a 2½ year Phase II STTR grant to further translate the research underway on the use of the U-CORD-CELL as a potential therapy for Alzheimer s. This $2.6 million Phase II STTR grant has also been matched with three Florida High Tech Corridor Industry Seed Grants. In 2014, Saneron contributed to four peer-reviewed scientific publications. Saneron was accepted into the 2014-2015 NIH SBIR/STTR Commercialization Assistance Program (CAP) and the USF Seed Capital Accelerator Programs.

In October 2013, the Company entered into a Convertible Promissory Note Purchase Agreement with Saneron. Cryo-Cell could loan Saneron in quarterly payments an aggregate amount up to $300,000, subject to certain conditions. The initial loan amount was $150,000 to be paid in four quarterly installments of $37,500 per quarter. If after the initial loan amount, Saneron has made best efforts, satisfactory to Cryo-Cell in its sole discretion, to have started independently or via serving as a sponsor of a clinical trial related to its U-CORD-CELL program, then Cryo-Cell will agree to lend Saneron an additional $150,000 through a series of four additional quarterly payments of $37,500. Upon receipt of each quarterly payment, Saneron will deliver a convertible promissory note (Note) that matures five years from the date of the Note. Upon maturity of any Note, Saneron will have the option to repay all or a portion of the loan in cash or convert the outstanding principal and accrued interest under the applicable Note(s) into shares of Saneron common stock. The Company made five payments of $37,500 through November 30, 2014. The Company made no additional payments during fiscal 2015.

During the third quarter of fiscal 2014, the Company repurchased 93,800 common shares that were held by Saneron for $2.60 per share. During that quarter the Company was made aware that the remaining 56,300 common shares of Cryo-Cell common stock owned by Saneron were sold in prior periods. While the Company should have increased the investment in Saneron, the investment amount would have then been reduced each quarter for the Company s portion of the losses in Saneron. The correction was made during the third quarter of fiscal 2014 to reclassify approximately $400,000 from treasury stock to accumulated deficit on the accompanying consolidated balance sheets.

During the fourth quarter of fiscal 2015, the Company reviewed the investment in Saneron and believes that there is evidence of a loss in value that is other than temporary and that goodwill was impaired as of November 30, 2015. The main factors that lead to this decision include a decline in grant funding, reduction in employees, and the inability to sustain research activities due to lack of funding. Without the ability to perform current and future research activities, management believes the carrying amount of the investment as of November 30, 2015 is impaired and not recoverable.

Revenue Sharing Agreements (RSAs)

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 RSA a percentage of its future revenue derived from the annual storage fees 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 collected for all specified specimens in the area covered by the RSA up to the number covered in the RSA. When the number of specimens is filled, any additional specimens stored in that area are not subject to the RSA. 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 up-front payments 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 RSA. However, the RSAs do not establish a finite term or time frame over which to estimate the total payments and the Company had not

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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 made during these periods are treated as interest expense, which is 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 RSA for the state of Florida for a price of $1,000,000. The RSA applies to net storage revenues originating from specimens from within the state of Florida less a deduction for billing and collection fees. The RSA entitles the investors to revenues of up to 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 RSA 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 of the Company s 75% share of the annual storage fees (net storage revenues) less a deduction for 50% of billing and collection expenses generated by specimens stored in the Illinois Masonic Medical Center for a price of $1,000,000. The agreements were modified in 1998 to broaden the covered specimens to those originating in Illinois and its contiguous states and stored in Oldsmar, Florida for a maximum of up to 33,000 storage 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 less a deduction for billing and collection fees for specimens 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. The RSA 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 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 $796,759 and $1,926,980 for the fiscal years ended November 30, 2015 and 2014, respectively. The Company recorded an RSA accrual of $820,436 and $403,975 as of November 30, 2015 and 2014, respectively, related to interest owed to the RSA holders, which is included in accrued expenses in the Company s consolidated financial statements under Item 8 of this Annual Report on Form 10-K. The Company also recorded interest expense of $1,277,815 and $1,151,459 for the fiscal years ended November 30, 2015 and 2014, respectively, which is reflected in interest expense on the accompanying consolidated statements of comprehensive income.

International

The Company enters into two types of licensing agreements and in both types, the Company earns revenue on the initial license fees. Under the technology agreements, the Company earns processing and storage royalties from the affiliates that process in their own facility. Under the marketing agreements, the Company earns processing and storage revenues from affiliates that store specimens in the Company s facility in Oldsmar, Florida.

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Technology Agreements

The Company has entered into a definitive License and Royalty Agreement with LifeCell International Private Limited, formerly Asia Cryo-Cell Private Limited, (LifeCell) to establish and market its umbilical cord blood and menstrual stem cell programs in India.

Per the License and Royalty Agreement with Lifecell, there is a $1 million cap on the amount of royalty due to the Company per year and a $10 million cap on the amount of royalties due to the Company for the term of the License and Royalty Agreement. As of November 30, 2015, Lifecell has paid the Company $4.1 million for royalties due under the terms of the License and Royalty Agreement.

The Company previously had a License and Royalty Agreement with Cryo-Cell de Mexico (Mexico) and on August 19, 2011, the Company received notification from Mexico that they were terminating the license agreement effective immediately due to an alleged breach of the license agreement. On October 17, 2011, the Company and Mexico entered into an amendment to the license agreement whereby the termination was revoked and Mexico would pay the Company $1,863,000 in 37 monthly installments of $50,000 beginning on October 17, 2011 with a final payment of $13,000. Mexico would have no other continuing obligations to the Company for royalties or other license payments and the agreement would be effectively terminated once the entire $1,863,000 was received. In December 2013, Mexico paid the balance due of $563,000 in full. The Company recognized the balance paid as licensee and interest income during the fiscal year ended November 30, 2014 in the accompanying consolidated statements of comprehensive income. Mexico has no other continuing obligations to the Company for royalties or other license payments and the agreement is terminated. The amendment has and is expected to result in a reduction of licensee and royalty income in future periods.

Marketing Agreements

The Company has definitive license agreements to market the Company s umbilical cord blood stem cell programs in Costa Rica, El Salvador, Guatemala, Honduras, Nicaragua, Panama and Pakistan. In October 2012, the Company sent a notice of termination to the Company s Venezuelan affiliate for failure to meet its payment obligation in accordance with the contract. Subsequent to the notice of termination, payment was received for outstanding processing and storage fees due from Venezuela. The Company is in the process of discussing a new agreement. The Company continues to accept umbilical cord blood stem cell specimens to be processed and stored during the negotiations. In December 2012, the Company sent a notice of termination to the Company s affiliate in Ecuador for failure to meet its payment obligation in accordance with the contract. Subsequent to the notice of termination, payment was received for outstanding processing and storage fees due from Ecuador. In August 2013, the Company was notified that its affiliate in Ecuador was closed by the National Institute of Organic Donation (INDOT). As a result, the Company recorded an allowance for uncollectible receivables for the $150,000 processing and storage fee receivable due from Ecuador in the third quarter of fiscal 2013. During the fourth quarter of fiscal 2013, the Company began to bill the Ecuadorian clients directly for cord blood specimens that are stored at the Company s facility in Oldsmar, Florida.

Processing and storage revenues from specimens originating in foreign territories that store at the Company s facility in Oldsmar, Florida total approximately $868,000 and $1,874,000 for fiscal years 2015 and 2014 and are reflected in processing and storage fees in the accompanying consolidated statements of comprehensive income.

The following table details the initial license fees for the technology and marketing agreements and processing and storage royalties earned for the technology agreements for fiscal years 2015 and 2014. The initial license fees and processing and storage royalties are reflected in licensee income in the accompanying consolidated statements of comprehensive income.

	For the fiscal years ended November 30,					
	2015			2014		
	License Fee	Process and Storage Royalties	Total	License Fee	Process and Storage Royalties	Total
India	$	$ 1,000,000	$ 1,000,000	$	$ 677,647	$ 677,647
Mexico					793,839	793,839
Total	$	$ 1,000,000	$ 1,000,000	$	$ 1,471,486	$ 1,471,486

Employees

At November 30, 2015, the Company had 70 full-time employees and 3 part-time employees on the staff of the Company. Additional employees and staff will be hired on an as needed basis. The Company believes its relationship with its employees is good. 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.
Not applicable.

ITEM 1B. UNRESOLVED STAFF COMMENTS.
None.

ITEM 2. PROPERTIES.
The Company entered into a ten-year lease in April 2004 for its 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.

On June 7, 2006, the Company entered into a lease amendment, which amended 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 the same location, beginning on August 1, 2006 and ending with the termination of the lease in 2013. The Company s rent for the additional space was $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.

In June 2013, the Company signed an amendment to terminate the building lease on the additional 9,600 square feet that was entered into during June 2006. The termination fee was $150,000 and is reflected, net of rent paid for May and June 2013, in selling, general, and administrative expenses. The lease amendment will result in rent savings of approximately $280,000 over the 18 months following the termination for a net savings of approximately $130,000. The Company also extended the main lease through December 31, 2015 for the 17,600 square foot space.

In January 2016, the Company extended the main lease through December 31, 2018 for the 17,600 square foot space.

Rent charged to operations was $260,272 and $256,546 for the fiscal years ended November 30, 2015 and 2014, respectively, and is included in cost of sales and selling, general and administrative expenses in the consolidated statements of comprehensive income.

The future minimum rental payments under the operating lease are as follows:

Fiscal Year Ending November 30,	Rent
2016	$ 223,490
2017	$ 196,165
2018	$ 193,600
2019	$ 16,133

The Company entered into a one-year lease in November 2013 for an additional 800 square feet of office space in Miami, Florida for annual rent of approximately $27,120. The lease commenced during December 2013. In December 2015, the Company extended the lease through December 31, 2016.

7ITEM 3. LEGAL PROCEEDINGS.

On November 13, 2013, Plaintiff Ki Yong Choi filed a Verified Shareholder Derivative Complaint in the Circuit Court for the Thirteenth Judicial Circuit in and for Hillsborough County, Florida. The Complaint names as defendants all of the members of the Company s current Board of Directors, as well as former director Anthony Atala. The complaint also names the Company as a nominal defendant only. The complaint alleges that, since the election of the Company s Board of Directors in August 2011, the Company s Co-CEOs have pursued their own enrichment and entrenchment at the expense of the Company and its shareholders. The complaint asserts claims against the Board of Directors for breach of fiduciary duty, abuse of control, corporate waste, and unjust enrichment and seeks, among other things, rescission of certain transactions between the Company and the Co-CEOs and damages from the Board of Directors. On February 14, 2014, all of the defendants filed motions to dismiss the complaint. The Company filed a motion to dismiss based on the plaintiff s failure to make a pre-suit demand on the Board of Directors or to establish that demand should be excused, as required by Delaware law. A hearing took place on July 9, 2014, and on July 28, 2014, the Court dismissed the case.

On December 3, 2015, a complaint styled *Gary T. Brotherson, M.D., et al. v. Cryo-Cell International, Inc.,* Case No. 15-007461-CI, Circuit Court, Sixth Judicial Circuit, Pinellas County, Florida, was served on the Company, naming it as defendant and alleging, among other things, that the Company breached certain agreements with plaintiffs and seeking damages in excess of $15,000, the jurisdictional amount of the court in which the action is pending. On January 12, 2016, the Company served its answer, affirmative defenses, and counterclaim against the plaintiffs. The Company believes the plaintiffs claims are without merit and it intends to contest the action vigorously. At this time, it is not possible for the Company to estimate the loss or the range of possible loss in the event of an unfavorable outcome, as the ultimate resolution of the complaint is uncertain at this time. No amounts have been accrued as of November 30, 2015.

On January 20, 2016 a class action complaint was filed in the Court of the Chancery of the State of Delaware against the Company and certain current officers and directors of the Company (Case No. 11915-VCG). The complaint alleges breaches of fiduciary duties and is seeking appropriate injunctive relief and a declaratory judgment against defendants that a certain provision of the Company s Amended and Restated Bylaws, as amended through September 22, 2014 is in violation of Section 141(k) of the Delaware General Corporation Law. The Company believes the litigation is without merit and intends to defend the litigation vigorously. The Company s maximum deductible under its Directors and Officers insurance policy for this claim is $500,000.

On February 24, 2016, a complaint styled *Charles D. Nyberg and Mary J. Nyberg, individually and as trustees of the CDMJNyberg Family Trust v. Cryo-Cell International, Inc.,* Case No. 8:16-cv-00408, United States District Court, Middle District of Florida, Tampa Division, was served on the Company, naming it as defendant and alleging, among

other things, that the Company breached certain agreements with plaintiffs and seeking damages in excess of $75,000, the jurisdictional amount of the court in which the action is pending. The Company believes the plaintiffs claims are without merit and it intends to contest the action vigorously. At this time, it is not possible for the Company to estimate the loss or the range of possible loss in the event of an unfavorable outcome, as the ultimate resolution of the complaint is uncertain at this time. No amounts have been accrued as of November 30, 2015.

In addition, from time to time the Company is subject to proceedings, lawsuits, contract disputes and other claims in the normal course of its business. The Company believes that the ultimate resolution of current matters should not have a material adverse effect on the Company s business, consolidated financial position or results of operations. It is possible, however, that there could be an unfavorable ultimate outcome for or resolution which could be material to the Company s results of operations for a particular quarterly reporting period. Litigation is inherently uncertain and there can be no assurance that the Company will prevail. The Company does not include an estimate of legal fees and other related defense costs in its estimate of loss contingencies.

ITEM 4. MINE SAFETY DISCLOSURES

Not Applicable

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 quoted on the Over-The-Counter Bulletin Board under the symbol CCEL . The following table shows, for the fiscal quarters indicated, the high and low closing bid quotations for the Company s common stock as reported by Yahoo Finance. 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, 2015	2.25	3.00
May 31, 2015	2.35	2.75
August 31, 2015	2.12	3.39
November 30, 2015	3.30	3.50
February 28, 2014	1.80	2.30
May 31, 2014	2.06	2.80
August 31, 2014	2.40	2.95
November 30, 2014	2.51	3.31

The Company has not declared any cash dividends on its common stock and has no plans to do so in the immediate future.

As of November 30, 2015, the Company had 224 shareholders of record, and management believes there are approximately 1,500 additional beneficial holders of the Company s common stock.

The following table sets forth as of November 30, 2015, the Company s equity compensation plans approved by shareholders. At such date the Company had no equity compensation plans that had not been approved by shareholders.

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			(1)
Cryo-Cell International, Inc. 2006 Stock Incentive Plan	568,930	$ 2.49	253,679
Cryo-Cell International, Inc. 2012 Stock Incentive Plan	849,371	$ 1.81	1,650,629
Total	1,418,301	$ 2.08	1,904,308

(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, 2015, 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 , esti 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. 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 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. Effective July 2015, the Company offers two pricing models, a standard plan and premium plan. The Company charges fees of $1,400 for the standard plan and $1,950 for the premium plan to new clients for the collection kit, processing, testing and return medical courier service, with discounts in the case of multiple children from the same family and in other circumstances. The Company charges an annual storage fee of $150 for new clients that enroll in the standard and premium plans; storage fees for existing customers depend on the contracts with such customers. The Company continues to offer a one-time payment plan for 21 years of storage and a life-time payment plan, pursuant to which the client is charged $3,899 for the standard plan and $4,449 for the premium plan and $6,000 for the standard plan and $7,000 for the premium plan, respectively, less 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 life-time plan includes the collection kit, processing and testing, return medical courier service and pre-paid storage fees for the life of the client. The Company also receives other income from licensing fees and royalties from global affiliates.

On June 11, 2015, the Company entered into an Asset Purchase Agreement (the Asset Purchase Agreement) with CytoMedical Design Group LLC (CytoMedical), for the purchase of certain assets and assumption of certain liabilities and contracts that CytoMedical used in the operation of its cord blood business. The Prepacyte-CB Processing System is used in cell processing laboratories to process and store stem cells from umbilical cord blood. The purchase price was $2,400,000, plus the value of inventory, comprised of $1,553,272 in cash and assumed liabilities less any prepayment made by the Company to CytoMedical ($966,597 at closing and $586,675 on or before September 30, 2015) and a note payable to the seller in the amount of $1,300,000. The closing was effective on June 30, 2015.

During the year ended November 30, 2015, the Company s total revenue increased 5% as compared to fiscal 2014. The Company reported net income of approximately $8,100,000, or $0.85 per basic common share for fiscal 2015 compared to net income of approximately $554,000 or $0.05 per basic common share for fiscal 2014. The increase net income for the year ended November 30, 2015 resulted from a 5% increase in revenues. Also during fiscal 2015, the Company reversed approximately $7.0 million and $1.2 million of its valuation allowance for income taxes, respectively. The decision to reverse a portion of the allowance is based on the Company s historical operating performance, which includes profitability in ten of the last eleven quarters, steadily improving operations and positive expectations for future taxable income.

As of November 30, 2015, the Company had cash and cash equivalents of $4,152,162. The Company s cash increased by approximately $873,000 during fiscal 2015, primarily as a result of approximately $5,000,000 of cash provided by operations, offset by approximately $3,200,000 used for the stock repurchase plan and tender offer pursuant to which the Company repurchased 1,034,210 shares of the Company s common stock during the twelve months ended November 30, 2015 and $375,000 paid directly to CytoMedical Design Group LLC and $1,074,000 paid to third parties per the Asset Purchase Agreement for the Prepacyte® CB cord blood business (See Note 2 to the consolidated financial statements).

Consistent with its fiduciary duties, the board of directors and management has reviewed and will continue to review strategic options and opportunities for the Company, in order to maximize shareholder value. These options may include, but are not limited to, strategic mergers or acquisitions, investments in other public and/or private companies, repurchases of the Company s stock, repurchases of RSA interests, a deregistration of the Company s common stock under the Securities Exchange Act of 1934 or a going-private transaction. In order to undertake any of the aforementioned activities, the Company may take on substantial debt or equity capital which could increase the risk of investment in the Company.

Results of Operations

Revenue. For the fiscal year ended November 30, 2015, the Company had revenue of $21,091,431 compared to $20,126,546 for the fiscal year ended November 30, 2014. The increase in revenue was primarily attr