CESCA THERAPEUTICS INC.
Form 10-K
September 21, 2016
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SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

ANNUAL REPORT PURSUANT TO SECTION 13 OR 15 (d) OF THE

SECURITIES EXCHANGE ACT OF 1934

For the Fiscal Year Ended: **June 30, 2016**

Commission File Number: 000-16375

Cesca Therapeutics Inc.

(Exact name of registrant as specified in its charter)

Delaware **94-3018487**

(State of incorporation) (I.R.S. Employer Identification No.)

2711 Citrus Road

Rancho Cordova, California 95742

(Address of principal executive offices) (Zip Code)

(916) 858-5100

(Registrant's telephone number, including area code)

Securities Registered Pursuant to Section 12(b) of the Act:

Title of each class Name of each exchange on which registered

Common Stock, $0.001 par value Nasdaq Stock Market, LLC

Securities Registered Pursuant to Section 12(g) of the Act: None

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

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

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.
[X] Yes [ ] 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 (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files.) [X] Yes [ ] No

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of “large accelerated filer” and “small reporting company” in Rule 12b-2 of the Exchange Act.

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 Exchange Act)

[ ] Yes [X] No

The aggregate market value of the common stock held by non-affiliates as of December 31, 2015 (the last business day of the most recently completed second quarter) was $5,975,000 based on the closing sale price on such day.

As of September 16, 2016, 9,790,500 shares of the registrant's Common Stock were outstanding.

Documents Incorporated By Reference: Portions of the registrant's proxy statement for its 2016 Annual Meeting of Stockholders are incorporated by reference into Part III hereof.

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PART I

All dollar amounts are presented in thousands except as otherwise noted.

CAUTIONARY STATEMENT REGARDING FORWARD LOOKING STATEMENTS

This report contains forward-looking statements within the meaning of the “safe harbor” provisions of the Private Securities Litigation Reform Act of 1995. All statements, other than statements of historical fact included in this report, are forward-looking statements. Reference is made in particular to the description of our plans and objectives for future operations, assumptions underlying such plans and objectives, and other forward-looking statements included in this report. Such statements may be identified by the use of forward-looking terminology such as “may,” “will,” “expect,” “believe,” “estimate,” “anticipate,” “intend,” “continue,” “plan,” “predict,” “seek,” “should,” “would,” “could” “ongoing,” or similar terms, variations of such terms, or the negative of such terms, and include, but are not limited to, statements regarding projected results of operations, capital expenditures, earnings, management’s future strategic plans, development of new technologies and services, litigation, regulatory matters, market acceptance and performance of our services, the success and effectiveness of our technologies and services, our ability to retain and hire key personnel, the competitive nature of and anticipated growth in our markets, market position of our services, marketing efforts and partnerships, liquidity and capital resources, our accounting estimates, and our assumptions and judgments. Such statements are based on management’s current expectations, estimates and projections about our industry, management’s beliefs, and certain assumptions made by us, all of which are subject to change.

These forward looking statements are not guarantees of future results and are subject to a number of risks, uncertainties and assumptions that are difficult to predict and that could cause actual results to differ materially and adversely from those described in the forward-looking statements, including:

- the sufficiency and source of capital required to fund our operations and in furtherance of our business plan;
- our ability to remain listed on NASDAQ and remain in compliance with its listing standards;
- the global perception of the clinical utility of banked cord blood and the amount of investment in research and development supporting clinical data for additional applications;
- delays in commencing or completing clinical testing of products;
- the success of any collaborative arrangements to commercialize our products;
- our reliance on significant distributors or end users;
- the availability and sufficiency of commercial scale manufacturing facilities and reliance on third party contract manufacturers; and
- our ability to protect our patents and trademarks in the U.S. and other countries.

These forward-looking statements speak only as of the date of this report and we expressly disclaim any obligation or undertaking to release publicly any updates or revisions to any forward-looking statements contained herein to reflect any change in the expectations with regard thereto or any change in events, conditions, or circumstances on which any such statement is based, except as otherwise required by law. Additional factors that could cause such results to differ materially from those described in the forward-looking statements are set forth in connection with the forward-looking statements.

TRADEMARKS

This report contains references to our trademarks and to trademarks belonging to other entities. Solely for convenience, trademarks and trade names referred to in this report, including logos, artwork and other visual displays, may appear without the ® or TM symbols, but such references are not intended to indicate, in any way, that their respective owners will not assert, to the fullest extent under applicable law, their rights thereto. We do not intend our use or display of other companies' trade names or trademarks to imply a relationship with, or endorsement or sponsorship of us by, any other companies.

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ITEM 1. BUSINESS

Cesca Therapeutics Inc. (“Cesca Therapeutics”, “Cesca”, the “Company”, “we”, “our”, “us”), is a clinical stage biotechnology company which develops and markets integrated cellular therapies and delivery systems that advance the safe and effective practice of regenerative medicine. We are a leader in the development and manufacture of automated blood and bone marrow processing systems that enable the separation, processing and preservation of cell and tissue therapy products. Our two subsidiaries based in India, TotipotentRX and TotipotentSC, have a pipeline of human point of care experimental therapies in early stage clinical studies using bone marrow and blood derived cells and growth factors. We were founded in 1986 and are headquartered in Rancho Cordova, California. Our strategy is to continue to enhance the performance and competitiveness of our flagship product lines in the cord blood banking arena while expanding into significant new growth opportunity areas in point of care therapeutics. We are developing a number of offerings for the delivery of autologous cell therapies that address significant unmet medical needs and expect to partner with other pioneers in the stem cell arena to accelerate clinical evaluations, expedite regulatory approvals and penetrate the market.

Our Strategy

Our business strategy involves:

Sustaining our leadership position in automated devices for the separation and concentration of stem cell preparation from cord blood and bone marrow.

Expansion into development of cell therapies targeting insufficiently met medical needs: our initial focus is on ischemic cardiovascular indications (critical limb ischemia (“CLI”) and acute myocardial infarction (“AMI”)) with oncology and orthopedic protocols to follow.

A unique point of care approach; our CLI and AMI cell therapies require a single visit to the operating room for a treatment lasting only 90-120 minutes.

Delivery of a fully integrated offering: We deliver all the hardware, software and disposable components necessary for the aspiration and processing of autologous bone marrow to prepare a therapeutic dose of stem cells for re-injection into the patient at the point of care.

The use of autologous, bone marrow derived stem cells: Our protocols are potentially safer than alternative allogeneic approaches because, in our case, the donor and the recipient of the stem cell preparation is the same

individual.

A simpler regulatory path: Cesca's protocols are autologous and the stem cell preparations are minimally manipulated, allowing an investigational device exemption pre-market approval approach. This reduces costs and time to market when compared to investigational new drug or new drug application approaches.

A highly resource efficient operating model: We leverage our India based clinical research organization embedded within the Fortis Healthcare network of hospitals in Asia, as a highly cost-effective approach to conducting feasibility studies and early stage clinical trials.

Multiple shots on goal: We currently have 9 protocols at various stages of clinical development.

Patent protection: We have over 25 issued patents globally with several more applications in the pipeline.

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Recent Key Events and Accomplishments

Cesca's 2016 financial year ran from July 1, 2015 to June 30, 2016. The following are key events and accomplishments that occurred in fiscal 2016:

Submitted Investigational Device Exemption ("IDE") Supplement for the Surgwerks™ CLI Pivotal Trial In May 2016 we submitted an IDE Supplement to the U.S. FDA for our previously approved pivotal trial for the treatment of patients with CLI using our SurgWerks™ system. In the supplement, we proposed Transcutaneous Oxygen Pressure (TcPO2) as a surrogate endpoint for limb salvage as an alternative to Amputation-Free Survival. Subsequently, the FDA approved commencement of the Phase III pivotal trial as amended, but indicated that it would require additional validation of TcPO2 as a surrogate to support future PMA approval.

Regained Compliance with Nasdaq Minimum Bid Price Requirement

On March 21, 2016, we received notification from the Nasdaq Listing Qualifications Staff indicating that we had regained compliance with the $1.00 minimum bid price requirement for continued listing on the Nasdaq Capital Market. In order to regain compliance, we effected a one-for-twenty reverse stock split effective as of the close of business on March 4, 2016.

Closed a $15 Million Strategic Investment from Boyalife Group

In February 2016, in exchange for aggregate proceeds of $15 million, we sold and issued to Boyalife Investment Inc. and Boyalife (Hong Kong) Limited (i) 735,294 shares of common stock at a per share purchase price of $3.40 and (ii) senior secured convertible debentures for $12.5 million. From the proceeds, we repaid existing senior secured convertible debentures (see below) and the remaining proceeds are providing additional working capital to fund ongoing operations and strategic initiatives. In August 2016, we subsequently converted all of the principal and interest under the convertible debentures into 6,102,941 shares of our common stock, thereby cancelling all of our indebtedness to Boyalife Investment, Inc.

Restructured Existing Senior Secured Convertible Debentures and Retired Series B Warrants

In connection with the Boyalife financing transaction, we repaid existing thirty-year debentures and all related interest and liquidated damages. In addition, we terminated the related registration rights agreement, the exercise price of the associated Series A warrants was changed from $13.60 to $8.00 and all remaining Series B warrants which contained a cashless exercise feature were retired.

Implemented a Restructuring Initiative to Realign Resources Behind High Impact Clinical Programs. In September 2015, we implemented a restructuring initiative to reduce costs and better align our workforce with the evolving needs of our business. We reduced approximately 15 positions, which, combined with the elimination of a number of open positions that were not back-filled, reduced annual operating costs primarily related to our cord blood banking products by approximately $3.3 million.

Facilitated Ground-Breaking Haploidentical Bone Marrow Transplantations (BMT)

Our clinical cell therapy laboratory at the Fortis Memorial Research Institute (FMRI) in India performed three ex-vivo Haploidentical BMT cell therapy services for the treatment of thalassemia, acute myeloid leukemia (AML) and chronic myeloid leukemia and four ex-vivo cell enrichment cell therapy processing services for relapse AML.

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Secured Additional Sites for Cesca's Flagship AXP Technology or Cord Blood Processing Services. Among others, Houston based Texas Stem Cell, the first hybrid cord blood and tissue bank in Texas, adopted the AutoXpress ("AXP") technology for cord blood processing. Additionally, TotipotentRX expanded its private cord blood banking services to several additional hospitals in the Fortis Healthcare network throughout India.

The Markets We Serve

Regenerative Medicine

Regenerative cell therapy relies on the delivery of specific types of stem cells that have been shown to enable the repair, restoration or regeneration of diseased or damaged tissue. A broad range of cell types has been investigated, including cells found in peripheral blood, umbilical cord blood and bone marrow.

The field continues to contribute to meaningful advances in the practice of medicine, as evidenced by numerous FDA and European Union ("EU") therapeutic product approvals and the commercialization of a growing number of cell-based therapies. Most of the progress has been achieved through the broader application of adult stem cells, reflecting a greater awareness and appreciation of their therapeutic potential.

The market for regenerative medicine is supported by companies that develop devices or methods for harvesting, processing, purifying, expanding, modifying, cryopreserving, storing or administering cells, or by companies that develop and commercialize the therapeutic agents themselves. Key success factors for such companies include:

The ability to achieve high recovery and concentration of target cell types
Device ease-of use, efficiency and speed
Cell product purity, viability and potency
Cost effectiveness
Regulatory approval / FDA clearance

The delivery of a cell therapy typically involves a process whereby target cells are harvested from a donor or patient, processed or expanded (grown) either within a hospital laboratory or by an FDA regulated, therapeutic manufacturer, formulated into an effective, safe dose, and delivered to a patient through a specific delivery device. Cell preparations may also be formulated in a point of care setting such as an operating room. Requirements for the preparation and use of cell therapies at the point of care include system portability, sterile field packaging, minimal manipulation, swift cell processing and predictable target cell recovery rates.

Our growth strategy is focused on the development of autologous cell therapies for treatments intended to be carried out at the point of care.

We believe that commercial opportunities for such therapies will develop first in cardiology, orthopedics, dermatology/wound healing and selective areas of oncology, followed by more complex pathologies such as those found in diabetes and central nervous system disorders.

We also believe that developments in the field of regenerative medicine will be critical in helping to address the global increase in health care costs. As emerging cell therapies are proven to be safe, effective, and a cost-effective alternative to current standards of care, adoption will accelerate. A fundamental requirement, however, will be the continued development of baseline clinical and cost-effectiveness data through comprehensive clinical studies.

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Cord Blood Banking

Cord blood, the blood that remains in the umbilical cord after a baby is born, is rich in stem cells. Since the first cord blood transplant was carried out in 1988, stem cells derived from umbilical cord blood have become widely accepted for medical use and have been used regularly in medical procedures worldwide for the treatment of a wide range of blood diseases, genetic and metabolic disorders, immune-deficiencies and cancers. Cord blood use in clinical applications is now widely accepted and cord blood banks exist in nearly every developed country as well as a growing number of developing nations.

Cesca Therapeutics (formerly ThermoGenesis) is an established leader in the development and manufacture of automated systems that enable the separation, processing and cryopreservation of stem cell preparations from cord blood. In recent years, however, the overall number of cord blood samples being collected has decreased; Bioinformant reported in their 2015 Global Strategic Report on the U.S. Cord Blood Market that the number of cord blood transplants had declined year-over-year in spite of the fact that the number of scientific publications on cord blood stem cells had grown by 7.8%.

Nevertheless, there have been several recent examples of significant pharma companies entering the space. In August 2014, Novartis committed up to $435 million to Gamida Cell for development of an expanded cord blood stem cell product as a treatment for hematological malignancies such as leukemia and lymphoma, and in June 2015, AMAG Pharmaceuticals (“Nasdaq: AMAG”) announced a definitive agreement to acquire Cord Blood Registry (an existing Cesca Therapeutics customer), from GTCR, a private equity firm, for $700 million.

Our Clinical Programs

Our therapeutic development initiatives, focused in the fields of cardiovascular medicine and orthopedic regeneration, are based on a flexible platform of equipment and optimized disposable components for the harvesting, processing, testing and delivery of cells and growth factors from either blood or bone marrow.

Our proprietary SurgWerks™ System (in development) includes a broadly-capable processing platform of devices and analytics designed for use at the point of care, coupled with indication-specific, single use, disposable procedure kits for a variety of vascular and orthopedic conditions. The performance of SurgWerks™ is enabled by the availability of a next generation cell processing device (referred to as the VXP System), derived from our existing and well established AutoXpress (AXP) and MarrowXpress (MXP) platforms. A key advantage of an optimized and integrated system such as SurgWerks is that it is intended to maintain high cell viability and potency through each and every step of the 90-120 minute intra-operative procedure, including bone marrow collection, target cell selection, characterization of the final cell concentrate, and re-injection into the patient.

We made the following advancements in the SurgWerks System's clinical development in fiscal 2016:

- An IDE Supplement was submitted to the FDA proposing a change in primary endpoint to a surrogate endpoint of TcPO2, with associated changes in the statistical plan.
- Significant progress was made in assessment and engagement of clinical trial sites for our phase III pivotal clinical trial (CLIRST III). Over 30 sites are currently involved in various stages of engagement and Institutional Review Board ("IRB") approvals and trial agreements have already been finalized for a subset of these 30 sites.
- Training programs to support the study were defined for our clinical team and the site staff involved in the study.

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We intend to initiate the following SurgWerks System's clinical trials in fiscal 2017:

U.S.: SurgWerks-CLI and VXP System pivotal IDE trial for patients with critical limb ischemia (CLIRST III).
India: SurgWerks-AMI feasibility (Phase II) trial on AMI patients having low ejection fractions three to ten days after the heart attack and having successful reperfusion of the affected heart artery (AMIRST II)

Also in development is our CellWerks™ offering, an integrated collection of devices and disposables that we believe represents a significant advance in enabling routine bone marrow transplantation procedures. The CellWerks™ System is being developed to enable the processing of a stem cell aspirate or mobilized blood harvest unit while allowing the clinical laboratory to "dial in" the transplant physician's cellular prescription, thereby achieving an optimized granulocyte, monocyte and red blood cell (RBC) cocktail composition. The CellWerks™ platform and software package is being evaluated for use on minimally manipulated as well as targeted, specific cell depleted units of mobilized peripheral stem cells and bone marrow aspirate.

To advance the approval of both SurgWerks™ and CellWerks™, we are pursuing a rigorous, science-based clinical development program, designed around two models of clinical delivery:

SurgWerks™ – intended for rapid intra-operative use
CellWerks™– intended for rapid laboratory use for specialized stem cell preparation under the direction of a GMP cellular laboratory protocol or a licensed physician.

Our intention is to provide fully optimized therapeutic "kits" and highly specialized equipment for each clinical indication (in the case of SurgWerks) and flexible cell preparation devices for clinical laboratory use (in the case of CellWerks), ultimately seeking marketing approval from the FDA and/or the equivalent regulatory authorities in markets outside the U.S.

SurgWerks O.R. Procedure *Disposable SurgWerks Kit VXP Equipment System*

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Our Products

We design, manufacture and sell advanced devices created specifically for the separation, concentration and cryopreservation of cell types used in the practice of regenerative medicine. Such automated devices are essential to the successful development of cell therapies because they ensure a high degree of quality control over both the preparation and storage of stem cell concentrate. Our current and future product offerings include:

- The SurgWerks™ System (in development) - a proprietary system comprised of the SurgWerks Processing Platform, including devices and analytics, and indication-specific SurgWerks Procedure Kits for use in regenerative stem cell therapy at the point of care for vascular and orthopedic diseases.
- The CellWerks™ System (in development) - a proprietary cell processing system with associated analytics for intra-laboratory preparation of adult stem cells from bone marrow or blood.
- The AutoXpress® System (AXP®) - a proprietary automated device and companion sterile disposable for concentrating hematopoietic stem cells from cord blood.
    - The MarrowXpress™ System (MXP™) - a derivative product of the AXP and its accompanying sterile disposable for the isolation and concentration of hematopoietic stem cells from bone marrow.
- The BioArchive® System - an automated cryogenic device used by cord blood banks for the cryopreservation and storage of cord blood stem cell concentrate for future use.
- Manual bag sets for use in the processing and cryogenic storage of cord blood.

Cell Manufacturing and Banking Services

Through our TotipotentRX subsidiary in Gurgaon, India, we operate an advanced clinical cell manufacturing, processing, testing, and storage facility, compliant with current Good Manufacturing Practices (“GMP”), Good Tissue Practices (“GTP”), and Good Laboratory Practices (“GLP”). We can support the production of a small, personalized medicine cell prescription or carry out a large scale batch process. Patient samples, batch samples, and therapeutic aliquots are all labeled in accordance with ISBT 128 and stored in our own cryogenics facility. In addition, our clinical research organization (CRO), also located in Gurgaon, is, to our knowledge, the only specialized, in-hospital, cell therapy CRO in the world. We have unique expertise in the design and management of cell based clinical trials, including the ability to support the device prototyping and validation typically required for a combination product. These services ensure patient safety under Good Clinical Practices (“GCP”), quality laboratory documentation under GLP, and quality cell processing and handling under both GMP and GTP. In partnership with Fortis Healthcare we have assembled what is, to our knowledge, the industry’s only fully integrated cell therapy CRO team capable of executing all elements of our in-house clinical trials, providing complete and seamless cellular drug and device clinical services. Through this advanced clinical infrastructure we also operate commercial service programs supporting bone marrow transplantation (hematopoietic stem cell transplantation) for hematological and oncological disorders as well as a licensed umbilical cord blood and tissue bank (“NovaCord”).

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Sales and Distribution Channels

We market and sell our products through independent distributors, except in North America and India, where we sell direct to end-user customers.

Competition

The regenerative medicine market is characterized by rapidly evolving technology and intense competition from medical device companies, pharmaceutical companies and stem cell companies operating in the fields of cardiac, vascular, orthopedic and neural medicine. The primary competitors for our current device offerings include BioSafe, SynGen and MacoPharma (for automated cell processing systems), and BioE, Terumo Harvest, Zimmer Biomet and Pall Corporation (for manual cell processing systems). Our competitors in the field of cell therapeutics development include MesoBlast, Osiris Therapeutics, Baxter International, Athersys, Caladrius, Capricor, Celyad, Juventas Therapeutics, Vericel, Cytori Therapeutics, Pluristem Therapeutics, Zimmer BioMet, and Bioheart.

Research and Development

Our research and development activities in fiscal 2016 were geared towards achieving key development milestones for our SurgWerks-CLI and SurgWerks-AMI clinical trial programs and the CellWerks laboratory device program. Each of these development initiatives leveraged our existing AXP and MXP platforms, with a focus on both performance improvements and ease of use in intraoperative applications. Emphasis was also placed on enhancing the capabilities of our contract manufacturing partners and building on our product quality leadership position. CLI efforts focused on development of an IDE supplement aimed at streamlining and simplifying our already approved Phase 3 (“Pivotal”) clinical trial (CLIRSTIII) and AMI activities focused on protocol design and optimization. We also invested effort in optimizing cell processing and delivery methods as well as advancing methods pertaining to our cell quality (cell analysis) technology.

Collectively, research and development expenses were $3,230 and $5,939 for the years ended June 30, 2016 and June 30, 2015, respectively. Research and development activities include expenses associated with the engineering, regulatory, scientific and clinical affairs functions.

Manufacturing

We expect to continue to use contract manufacturers for high volume, disposable products and in-house manufacturing for low volume, high complexity devices. In addition, we are exploring the potential for the development of in-house capabilities relating specifically to pilot scale disposable manufacturing in support of our clinical programs.

Quality System

Our quality system is compliant with domestic and international standards and is appropriate for the specific devices we manufacture. Our corporate quality policies govern the methods used in, and the facilities and controls used for, the design, manufacture, packaging, labeling, storage, installation, and servicing of all finished devices intended for human use. Such policies are intended to ensure that the products we market are safe, effective, and otherwise in compliance with the FDA Quality System Regulation ("QSR") (21 C.F.R. Part 820) and the applicable rules of other governmental agencies.

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We and our contract manufacturers are subject to inspections by the FDA and other regulatory agencies to ensure compliance with applicable regulations, codified in the FDA's Quality System Regulations ("QSRs"). Compliance requirements relate to manufacturing processes, product testing, documentation control and other quality assurance procedures. Our facilities have undergone International Organization of Standards ("ISO") 13485:2012 and EU Medical Device Directive ("MDD") (93/42/EEC) inspections and we have obtained approval to CE-Mark our products.

Regulatory Scheme and Strategy

The development, manufacture and marketing of our cell therapy products, as well as the design and implementation of our clinical trials, are subject to regulation by the FDA as well as the equivalent agencies of other countries including the countries of the European Union and India.

The trials we conduct in India are compliant with the applicable rules of the Indian Council for Medical Research, Ministry of Health Order No. V.25011/375/2010-HR and requisite institutional ethics committee (IEC) and institutional committee for stem cell research and therapy (IC-SCRT) approvals. Both the U.S. and E.U. regulatory agencies are experienced in dealing with and accepting Indian clinical trial data. GCP necessitates review and approval by an IRB before initiation of a study, continuing review of an ongoing study by an IRB, and the documented receipt of a freely given informed consent prior to participation in the study from each subject participant.

We have a quality and regulatory compliance management system that meets the requirements of the ISO 13485: 2003 standard, the FDA's QSRs, the EU MDD, Canadian Medical Device Regulations ("SOR 98-282"), and all other applicable local, state, national and international regulations.

Medical Devices. The FDA regulates medical devices to ensure their safety and efficacy under the Federal Food Drug and Cosmetic ("FD&C") Act. Medical devices are defined by language within the FD&C Act which essentially states that a product is considered a medical device if it is intended to provide a diagnosis or basis for treatment. Once a company determines that its product is a medical device, it is required to comply with a number of federal regulations. These include the following:

510(k) clearance or PMA approval from the FDA, prior to commercialization (unless the device is classified as "exempt")
Registration of the company and listing of the medical device with the FDA (within 30 days prior to commercialization)
Establishment and adherence to the FDA's labeling requirements, and
Establishment and adherence to the FDA's Quality Systems and Medical Device Reporting regulations.

The FDA classifies medical devices into three groups: Class I, II or III. These are stratified from lowest to highest safety risk, and regulatory controls increase based on Class.

Class I Devices

Some of our products are considered to pose little or no risk when used as directed and have been deemed by the FDA to be “exempt” from FDA approval or clearance processes prior to commercialization. While pre-marketing FDA review is not mandatory for Exempt Class I medical devices, the manufacturer’s compliance with QSR is nevertheless a requirement.

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Class II Devices

Several of our products, including the BioArchive and the AXP are categorized as US Class II medical devices and require premarket notification, also known as a section 510(k) clearance, prior to commercialization. Data submitted as part of a 510(k) process must demonstrate a device is "substantially equivalent" with a predicate device that is already on the market. Once 510(k) clearance has been secured, the new medical device may be marketed for its intended use and distributed in the U.S.

Class III Devices

If a product is considered a Class III device, as is the case with the CLI SurgWerks™- System, the FDA approval process is more stringent and time-consuming, and includes the following:

Extensive pre-clinical laboratory and animal testing
Submission and approval of an IDE application prior to the conduct of a clinical study
Human clinical studies (or trials) to establish the safety and efficacy of the medical device for the intended use, and
Submission and approval of a PMA application to the FDA.

Pre-clinical testing typically involves in vitro laboratory analysis and in vivo animal studies to obtain information related to such things as product safety, feasibility, biological activity and reproducibility. The results of pre-clinical studies are submitted to the FDA as part of an IDE application and are reviewed by the Agency before human clinical trials can begin. We use external third parties, as well as our own facility in Gurgaon, India (GLP Compliant) to conduct pre-clinical studies.

The CLIRST III trials will involve treatment of patients with bone marrow harvested and processed by company medical devices, employing critical quality control steps. The study will commence only after approval of an IRB. Higher risk clinical trials conducted inside the U.S. are subject to FDA IDE regulation (21 C.F.R. Part 812), or an IND application (21 C.F.R. Part 312). Clinical trials conducted outside the U.S., and the data collected therefrom are allowed in accordance with applicable FDA requirements. The FDA or the Sponsor may suspend a clinical trial at any time if either believes that study participants may be exposed to an unacceptable health risk.

For certain Class III devices, data generated during product development, pre-clinical studies, and human clinical studies must be submitted to the FDA as a PMA application in order to secure approval for commercialization in the U.S. The FDA may deny the approval of a PMA application if applicable regulatory criteria are not satisfied and in some cases may mandate additional clinical testing. Product approvals, once obtained, can be withdrawn if compliance with regulatory standards is not maintained or if safety concerns arise after the product reaches the market. The FDA might also require post-marketing testing and surveillance programs to monitor the safety and efficacy of a medical device and has the power to forbid or limit future marketing of the product based on the results of such

programs.

Other U.S. Regulatory Information

Medical device manufacturers must register with the FDA and submit their manufacturing facilities to biennial inspections to ensure compliance with applicable regulations. Failure to comply with FDA requirements can result in withdrawal of marketing clearances, fines, injunctions, civil penalties, recall or seizure of products, total or partial suspension of production or loss of distribution rights. In addition, device manufacturing facilities in the state of California must be registered with the California State Food and Drug Branch of the California Department of Public Health and submit to an annual inspection by the State of California to ensure compliance with applicable state regulations. We are also subject to a variety of environmental laws as well as workplace safety, hazardous material, and controlled substances regulations.

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The California State Food and Drug Branch of the California Department of Public Health completed a quality system compliance inspection at our Rancho Cordova facility in 2011 resulting in two minor observations which have since been corrected. The FDA inspected us in 2015 resulting in zero non-conformances.

If we are successful in securing Medicare reimbursement, we will be subject to federal and state laws, such as the Federal False Claims Act, state false claims acts, the illegal remuneration provisions of the Social Security Act, the federal anti-kickback laws, state anti-kickback laws, and the federal "Stark" laws, that govern financial and other arrangements among healthcare providers, their owners, vendors and referral sources, and that are intended to prevent healthcare fraud and abuse. Among other things, these laws prohibit kickbacks, bribes and rebates, as well as other direct and indirect payments or fee splitting arrangements that are designed to induce the referral of patients to a particular provider for medical products or services payable by any federal healthcare program, and prohibit presenting a false or misleading claim for payment under a federal or state program. They also prohibit some physician self-referrals. These laws are liberally interpreted and aggressively enforced by multiple state and federal agencies and law enforcement (including individual "qui tam" plaintiffs) and such enforcement is increasing. For example, the Affordable Care Act increased funding for federal enforcement actions and many states have established their own Medicare/Medicaid Fraud Units and require providers to conspicuously post the applicable Unit's hotline number. Possible sanctions for violation of any of these restrictions or prohibitions include loss of eligibility to participate in federal and state reimbursement programs and civil and criminal penalties.

Also, federal transparency requirements, sometimes referred to as the "Sunshine Act" under the Patient Protection and Affordable Care Act, require manufacturers of drugs, devices, biologics and medical supplies that are reimbursable under Medicare, Medicaid, or the Children's Health Insurance Program to report to the Department of Health and Human Services information related to physician payments and other transfers of value and physician ownership and investment interests.

Changes in these laws at all levels of government are frequent and could increase our cost of doing business. If we fail to comply, even inadvertently, with any of these requirements, we could be required to alter our operations, refund payments to the government, lose our licensure or accreditation, enter into corporate integrity, deferred prosecution or similar agreements with state or federal government agencies, and become subject to significant civil and criminal penalties.

International Regulatory Requirements

International regulatory requirements differ somewhat from those of the U.S. In the EU, a single regulatory approval process has been created and approval is represented by CE-Marking. To be able to affix the CE-Mark to our medical devices and distribute them in the EU, we must meet minimum standards for safety and quality (known as the essential requirements) and comply with one or more conformity rules. A notified body assesses our quality management system and compliance with the Medical Device Directive. Marketing authorization can be revoked by the applicable governmental agency or notified body in the event of an unsuccessful quality system annual audit.

In India, the regulatory body having oversight of medical devices, therapies, and cell banking is the Central Drugs Standard Control Organization ("CDSCO"), and specifically the Drugs Controller General India office. Our marketing and facilities licenses are subject to revocation by the applicable state Drug Controller in Haryana or DCGI. The Haryana State Drug Controller and the DCGI completed the latest blood banking license inspection of TotipotentRX GMP cord blood banking facility within Fortis Memorial Research Institute on November 11, 2014. No non-conformances were observed.

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Patents and Proprietary Rights

We believe that patent protection is important for our products and current and proposed business. We have over 25 issued patents globally.

The patent positions of regenerative medicine companies, such as ours, are uncertain because they involve interpretation of complex factual information and an evolving legal environment. The coverage sought in a patent application can be denied or significantly reduced either before or after the patent is issued. There can be no assurance that any of our pending patent applications will actually result in an issued patent. Furthermore, there can be no assurance that any existing or future patent will provide significant protection or commercial advantage, or that any existing or future patent will not be circumvented by a more basic patent. Generally, patent applications can be maintained in secrecy for at least 18 months after their earliest priority date. In addition, publication of discoveries in the scientific or patent literature often lags behind actual discoveries. Therefore, we cannot be certain that we were the first to invent or the first to file a patent application for the subject matter covered by each of our pending U.S. and foreign patent applications.

If a third party files a patent application relating to an invention claimed in our patent application, we may be required to participate in an interference or derivation proceeding conducted by the U.S. Patent and Trademark Office to determine who owns the patent. Such proceeding could involve substantial uncertainties and cost, even if the eventual outcome is favorable to us. There can be no assurance that our patents, if issued, would be upheld as valid in court.

Licenses

The following are certain agreements involving our business.

Fortis Healthcare Limited ("Fortis")

On August 1, 2014 we entered into an agreement with Fortis which renews and expands our existing services agreement with them in areas including, but not limited to, cord blood banking, point of care technology sales and support, bone marrow transplant and clinical/patient management. The term of the agreement is for three years.

Cord Blood Registry Systems, Inc. ("CBR")

On December 31, 2013, we entered into a Sale and Purchase Agreement with CBR in which we agreed to supply CBR with the AXP cord blood processing system and disposables. The term of the agreement is for 5 years with automatic two-year renewal options unless CBR provides a 6 month notice of non-renewal. On September 30, 2015, we entered into a Fifth Amended and Restated Technology License and Escrow Agreement with CBR which modified the financial covenant that we must meet in order to avoid an event of default. We must maintain a cash balance coupled with short-term investments net of debt or borrowed funds that are payable within one year of not less than two million dollars. We were in compliance with this covenant at June 30, 2016.

In June 2010, we entered into a License and Escrow Agreement in order to alleviate CBR's concerns about potential long term supply risk. We are the sole supplier of critical devices and disposables used in the processing of cord blood samples in CBR's operations. Under the License and Escrow Agreement, we granted CBR a perpetual, non-exclusive, royalty-free license to certain intellectual property necessary for the manufacture of AXP devices and disposables. The license is for the sole and limited purpose of ensuring continued supply of the AXP and related disposables for use by CBR. The licensed intellectual property is held in escrow and available to CBR only in the event of a default under the agreement.

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Golden Meditech

In August 2012, we entered into a Product Purchase and International Distributor Agreement with Golden Meditech. Under the terms of the agreement, Golden Meditech obtained the exclusive, subject to existing distributors and customers, rights to develop an installed base for our AXP System in specified countries. This includes the right to distribute AXP Disposable Blood Processing Sets and use the AXP System, and other accessories used for the processing of stem cells from cord blood. Golden Meditech has rights in the People's Republic of China (excluding Hong Kong and Taiwan), India, Singapore, Indonesia, and the Philippines and may begin selling once relevant approval has been obtained in each respective country. Additionally, Golden Meditech is subject to certain annual minimum purchase commitments. The term of the agreement is for 5 years with one year renewal options by mutual agreement.

BioParadox LLC ("BioParadox")

In October 2010, we entered into a License and Distribution Agreement with BioParadox. Under the terms of the agreement BioParadox obtained exclusive world-wide rights for the use, research and commercialization of the Res-Q technology in the production of PRP in the diagnosis, treatment and prevention of cardiovascular disease. The term of the agreement was to depend on the satisfaction by BioParadox of certain milestones, or the payment of extension fees. On December 22, 2015, we gave 30 days written notice to BioParadox, terminating the agreement effective January 21, 2016.

New York Blood Center ("NYBC")/Pall Medical

In March 1997, we and NYBC, as licensors, entered into a license agreement with Pall Medical, a subsidiary of Pall Corporation, as a licensee through which Pall Medical became the exclusive worldwide manufacturer (excluding Japan) for a system of sterile, disposable bag sets developed by us and NYBC for the processing of hematopoietic stem cells sourced from umbilical cord blood. The system is designed to simplify and streamline the harvesting concentration, cryopreservation (freezing) and transfusion of cells while maintaining the highest stem cell population and viability from each cord blood donation. In May 1999, we and Pall Medical amended the original agreement such that we regained the rights to distribute the bag sets outside North America and Europe under our own name. In fiscal 2012, we signed an agreement with NYBC which provides for the equal sharing of royalties between the two parties through the remaining term of the licenses, or June 2016. Therefore, we will not be receiving royalties on these products after June 2016.

Employees

As of June 30, 2016, we had 89 employees, 46 of whom were employed in the U.S. and 43 of whom were employed in India. We also utilize temporary employees throughout the year to address business needs and significant fluctuations in orders and product manufacturing. None of our employees are covered by a collective bargaining agreement, nor have we experienced any work stoppage.

Foreign Sales and Operations

See footnote 9 of our Notes to Consolidated Financial Statements for information on our sales and operations outside of the U.S.

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Where you can Find More Information

We are required to file annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and other information, including our proxy statement, with the Securities and Exchange Commission ("SEC"). The public can obtain copies of these materials by visiting the SEC's Public Reference Room at 100 F Street, NE, Room 1580, Washington, DC 20549, by calling the SEC at 1-800-732-0330, or by accessing the SEC's website at http://www.sec.gov. In addition, as soon as reasonably practicable after these materials are filed with or furnished to the SEC, we will make copies available to the public free of charge through its website, www.cescatherapeutics.com. The information on its website is not incorporated into, and is not part of, this annual report.

ITEM 1A. RISK FACTORS

An investment in our common stock is subject to risks inherent to our business. The material risks and uncertainties that management believes affect us are described below. Before making an investment decision, you should carefully consider the risks and uncertainties described below together with all of the other information included or incorporated by reference in this report. The risks and uncertainties described below are not the only ones we face. Additional risks and uncertainties that we are not aware of or focused on or that we currently deem immaterial may also impair our business operations. This report is qualified in its entirety by these risk factors.

If any of the following risks actually occur, our financial condition and results of operations could be materially and adversely affected. If this were to happen, the value of our common stock could decline significantly, and you could lose all or part of your investment.

Risks Related to Our Business

Lack of Demonstrated Clinical Utility of Cord Blood Derived Stem Cells Beyond Hematopoietic Transplantation May Result in a Decline in Demand for Cord Blood Banking Services, Adversely Affecting Sales of Our Products. Transplants using stem cells derived from cord blood and cord tissue have become a standard procedure for treating blood cell lineage disorders including leukemia, lymphoma and anemia. However, clinical research demonstrating the utility of cord blood stem cells for use in treating other diseases or injuries has been minimal, leaving claims of broad clinical utility of cord blood stem cells by cord blood banks largely unsubstantiated. The low utilization rate of banked cord blood samples coupled with the lack of demonstrated clinical results for multiple treatment indications has led to consumer skepticism regarding the benefits of cord blood banking and in turn, a significant reduction in collection rates in a number of geographies in Europe and the U.S. A continued lack of investment in the research and development of supporting clinical data for additional applications may lead to greater skepticism globally, further adversely affecting demand for cord blood banking services and our revenues.

We May Be Unable to Obtain Marketing Approval from the FDA For Our SurgWerks™ System. At the end of May 2016, we submitted to the U.S. Food and Drug Administration (FDA) an Investigational Device Exemption (IDE) Supplement for a phase III pivotal trial related to our SurgWerks™ system for the treatment of late stage, no option, critical limb ischemia (CLI) patients, which proposed a change in the primary efficacy endpoint from Amputation Free Survival to Change in Transcutaneous Oxygen Pressure (TcPO2). Upon completion of its review of the IDE Supplement, the FDA approved the changes in our pivotal trial design as proposed in the IDE Supplement, including the use of Change in TcPO2 as the primary measure of efficacy. However, in its feedback, the FDA also indicated that regardless of the outcome of the study, it would require us to further validate TcPO2 as a surrogate for clinical outcome for the proposed indication prior to granting marketing approval (PMA). As a result of the FDA's feedback, a successful outcome of the study will not, in and of itself, result in obtaining a PMA for the SurgWerks™ system. We may be unable to further validate TcPO2 as a surrogate for clinical outcome for the proposed indication necessary to obtain a PMA approval.

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We have Limited Operating History In the Emerging Regenerative Medicine Industry. Through the merger with TotipotentRX, we are in the business of research, development and commercialization of autologous cell-based therapeutics for use in the emerging regenerative medicine industry, and therefore, we have a limited operating history in such industry on which to base an evaluation of our business and prospects. We will be subject to the risks inherent in the operation of a company in an emerging industry such as regulatory setbacks and delays, fluctuations in expenses, competition, and governmental regulation.

Our Controlling Stockholder Has Significant Influence Over Us Which Could Limit Your Ability to Influence the Outcome of Key Transactions, Including a Change of Control, and Could Negatively Impact the Market Price of Our Common Stock By Discouraging Third Party Investors. As of August 22, 2016, approximately 70% of our outstanding common stock is owned by Boyalife (Hong Kong) Limited and Boyalife Investment Inc. On a fully-diluted basis Boyalife (Hong Kong) Limited and Boyalife Investment Inc. collectively own 72% of our common stock based on the right to acquire an aggregate of 3,529,412 shares of our common stock upon exercise of outstanding warrants. We would receive $28 million upon the exercise of the warrants. In addition, pursuant to the terms of a Nomination and Voting Agreement we entered into with Boyalife (Hong Kong) Limited and Boyalife Investment Inc. in February 2016, Boyalife (Hong Kong) Limited and Boyalife Investment Inc. have the right to designate up to three of the seven members to our board of directors until such time as they collectively no longer hold at least 50% of our common stock.

Boyalife (Hong Kong) Limited is 100% owned by Yishu Li, the spouse of Dr. Xiachun Xu, a member of our board of directors. Boyalife Investment, Inc., is also controlled by Dr. Xu. As a result of their ownership and ability to designate up to three members of our board of directors, Boyalife (Hong Kong) Limited and Boyalife Investment Inc. (including Dr. Xu and his spouse Ms. Li) will be able to exercise significant influence over all matters affecting us, including the election of directors, formation and execution of business strategy and approval of mergers, acquisitions and other significant corporate transactions, which may have an adverse effect on our stock price and ability to execute our strategic initiatives. They may have conflicts of interest and interests that are not aligned with those of other investors in all respects. As a result of the concentrated ownership of our common stock, a relatively small number of stockholders, acting together, are able to control all matters requiring stockholder approval. This concentration of ownership may delay or prevent a change in control and may have a negative impact on the market price of our common stock by discouraging third party investors.

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We Have Received Proposals to Sell Our Cord Blood Banking Product Lines in the Past, and We May Receive Additional Proposals in the Future, Which If Accepted Would Result in the Loss of Significant Product Lines and Revenue Source. On June 23, 2016, we received from Boyalife Investment Inc. and Boyalife (Hong Kong) Limited, our controlling shareholders and affiliates of Dr. Xiachun Xu, one of our directors, a non-binding term sheet (the "Proposal"), relating to a proposed additional investment in Cesca, which also contemplated among other things the sale of our cord blood product lines to Boyalife Investment Inc., Boyalife (Hong Kong) Limited or one of their affiliates (the "Boyalife Affiliates") at a cost equal to its annual revenue. The independent directors had reservations about a number of aspects of the Proposal, and the Proposal expired by its terms on June 30, 2016. The Boyalife Affiliates may submit additional proposals to acquire our cord blood product lines in the future on similar or different terms as to those set forth in the original Proposal. Any proposal for the acquisition of our cord banking product lines by the Boyalife Affiliates or any other third party will need to be evaluated by our board of directors at the time such proposal is received based on the condition, financial and otherwise, of Cesca at the time such proposal is received. We cannot assure what terms and conditions would be acceptable to our board of directors with respect to the receipt of any future proposal to acquire our cord blood banking product lines, nor whether, based upon the then existing condition of Cesca, whether the prior Proposal would have been superior to what the board of directors may ultimately approve. Additionally, in the event the board of directors receives a proposal from a third party to acquire its cord blood banking product lines that it determines is superior to the Proposal or a subsequent competing proposal from the Boyalife Affiliates, the Boyalife Affiliates may use their significant control over us as our controlling shareholder to prevent the sale of our cord blood banking business unit to such third party. In any event, the sale or our cord blood banking product lines, if any and regardless of the terms, would result in the loss of a significant revenue source and operations.

Our Potential Products and Technologies Are In Early Stages Of Development. The development of new cell therapy products is a highly risky undertaking, and there can be no assurance that any future research and development efforts we may undertake will be successful. Our potential products in vascular, orthopedic, hematological/oncological and wound care indications will require extensive additional research and development and regulatory approval before any commercial introduction. There can be no assurance that any future research, development and clinical trial efforts will result in viable products or meet efficacy standards.

We Intend To Rely On Third Parties For Certain Functions In Conducting Clinical Trials Of Our Product Candidates. We intend to rely on third parties for certain clinical trial activities of its products. In this regard, we have an agreement with Fortis Healthcare Limited, a hospital chain networked throughout India and Asia, for contract clinical trial services programs among other services. The agreement expires in August 2017. Termination, or the non-renewal upon expiration, of this agreement could jeopardize or delay development of our products.

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Delays In The Commencement Or Completion Of Clinical Testing Of Our Products Could Result In Increased Costs To Us And Delay Our Ability To Generate Revenues. Delays in the commencement or completion of clinical testing could significantly impact our product development costs. We do not know whether current or planned clinical trials will begin on time or be completed on schedule, if at all. The commencement of clinical trials can be delayed for a variety of reasons, including delays in:

- Obtaining regulatory approval to commence a clinical trial;
- Having the necessary funding in place to conduct the clinical trial;
- Reaching agreement on acceptable terms with prospective contract research organizations and clinical trial sites for Phase II and III trials;
- Obtaining proper devices for any or all of the product candidates;
- Obtaining institutional review board approval to conduct a clinical trial at a prospective site; and
- Recruiting participants for a clinical trial.

In addition, once a clinical trial has begun, it may be suspended or terminated by us or the FDA or other regulatory authorities due to a number of factors, including:

- Failure to conduct the clinical trial in accordance with regulatory requirements;
- Inspection of the clinical trial operations or clinical trial site by the FDA or other regulatory authorities resulting in the imposition of a clinical hold;
- Failure to achieve certain efficacy and/or safety standards;
- Reports of serious adverse events including but not limited to death of trial subjects; or
- Lack of adequate funding to continue the clinical trial.

Our clinical therapy candidates may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical trials or abandon product development programs that we expect to pursue.

We May Seek To Enter Into Collaborative Arrangements To Develop and Commercialize Products Which May Not Be Successful. We may seek to enter into collaborative arrangements to develop and commercialize some of our potential products both in North America and international markets. There can be no assurance that we will be able to negotiate collaborative arrangements on favorable terms or at all or that current or future collaborative arrangements will be successful.

A Significant Portion of Revenue is Derived from Customers Outside the United States. We may Lose Revenues, Market Share, and Profits due to Exchange Rate Fluctuations and Political and Economic Changes Related to its Foreign Business. In the year ended June 30, 2016, sales to customers outside the U.S. comprised approximately 57% of revenues. This compares to 47% in fiscal 2015. Our foreign business is subject to economic, political and

regulatory uncertainties and risks that are unique to each area of the world. Fluctuations in exchange rates may also affect the prices that foreign customers are willing to pay, and may put us at a price disadvantage compared to other competitors. Potentially volatile shifts in exchange rates may negatively affect our financial position and results.

The Loss of a Significant Distributor or End User Customer may Adversely Affect Financial Condition and Results of Operations. Revenues from two significant distributors/customers comprised 44% of revenues for the year ended June 30, 2016. The loss of a large end user customer or distributor may decrease revenues.

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We may be Exposed to Liabilities under the Foreign Corrupt Practices Act and any Determination that we Violated these Laws could have a Material Adverse Effect on our Business. We are subject to the Foreign Corrupt Practices Act ("FCPA"), and other laws that prohibit improper payments or offers of payments to foreign governments and their officials and political parties by U.S. persons and issuers as defined by the statute, for the purpose of obtaining or retaining business. It is our policy to implement safeguards to discourage these practices by our employees. However, our existing safeguards and any future improvements may prove to be less than effective and our employees, consultants, sales agents or distributors may engage in conduct for which we might be held responsible. Violations of the FCPA may result in severe criminal or civil sanctions and we may be subject to other liabilities, which could negatively affect our business, operating results and financial condition.

Adverse Results of Legal Proceedings could have a Material Adverse Effect on Us. We are subject to, and may in the future be subject to, a variety of legal proceedings and claims that arise out of the ordinary conduct of our business. Results of legal proceedings cannot be predicted with certainty. Irrespective of their merits, legal proceedings may be both lengthy and disruptive to our operations and may cause significant expenditure and diversion of management attention. We may be faced with significant monetary damages or injunctive relief against us that could have a material adverse effect on a portion of our business operations or a material adverse effect on our financial condition and results of operations.

Risks Related to Our Operations

Our Ability to Conduct a CLIRST III Clinical Trial Is Substantially Dependent on Our Ability to Secure Additional Funding and There Are No Assurances That Such Funding will Materialize. Although a portion of the net proceeds we received from the February 2016 and August 2016 financings is expected to be used to fund our ongoing operations and CLIRST III trial, these proceeds will not be sufficient, and we will need to raise additional funding. We cannot assure that such funding will be available on a timely basis, in needed quantities, or on terms favorable to us, if at all.

We Do Not Have Commercial-Scale Manufacturing Capability And Lack Commercial Manufacturing Experience. We operate GMP manufacturing facilities for both devices and cellular production; however, they are not of sufficient size for medium to large commercial production of product candidates. We will not have large scale experience in cell-drug formulation or manufacturing, and will lack the resources and the capability to manufacture any of our product candidates on a clinical or commercial scale. Accordingly, we expect to depend on third-party contract manufacturers for the foreseeable future. Any performance failure on the part of our contract manufacturers could delay clinical development, regulatory approval or commercialization of our current or future products, depriving us of potential product revenues and resulting in additional losses.

We Have Limited Sales, Marketing and Distribution Experience in Pharmaceutical Products. We have limited experience in the sales, marketing, and distribution of pharmaceutical products. There can be no assurance that we will be able to establish sales, marketing, and distribution capabilities or make arrangements with current collaborators or others to perform such activities or that such effort will be successful. If we decide to market any of our new

products directly, we must either partner, acquire or internally develop a marketing and sales force with technical expertise and with supporting distribution capabilities. The acquisition or development of a sales, marketing and distribution infrastructure would require substantial resources, which may not be available to us or, even if available, divert the attention of our management and key personnel, and have a negative impact on further product development efforts.

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Our Inability to Protect our Patents, Trademarks, Trade Secrets and other Proprietary Rights could Adversely Impact our Competitive Position. We believe that our patents, trademarks, trade secrets and other proprietary rights are important to our success and our competitive position. Accordingly, we commit substantial resources to the establishment and protection of our patents, trademarks, trade secrets and proprietary rights. We use various methods, including confidentiality agreements with employees, vendors, and customers, to protect our trade secrets and proprietary know-how for our products. We currently hold patents for products, and have patents pending in certain countries for additional products that we market or intend to market. However, our actions to establish and protect our patents, trademarks, and other proprietary rights may be inadequate to prevent imitation of our products by others or to prevent others from claiming violations of their trademarks and proprietary rights by us. If our products are challenged as infringing upon patents of other parties, we may be required to modify the design of the product, obtain a license, or litigate the issues, all of which may have an adverse business effect on us.

We may be Subject to Claims that our Products or Processes Infringe the Intellectual Property Rights of Others, which may Cause us to Pay Unexpected Litigation Costs or Damages, Modify our Products or Processes or Prevent us from Selling our Products. Although it is our intention to avoid infringing or otherwise violating the intellectual property rights of others, third parties may nevertheless claim that our processes and products infringe their intellectual property and other rights. Our strategies of capitalizing on growing international demand as well as developing new innovative products across multiple business lines present similar infringement claim risks both internationally and in the U.S. as we expand the scope of our product offerings and markets. We compete with other companies for contracts in some small or specialized industries, which increase the risk that the other companies will develop overlapping technologies leading to an increased possibility that infringement claims will arise. Whether or not these claims have merit, we may be subject to costly and time-consuming legal proceedings, and this could divert management's attention from operating our business. In order to resolve such proceedings, we may need to obtain licenses from these third parties or substantially re-engineer or rename our products in order to avoid infringement. In addition, we might not be able to obtain the necessary licenses on acceptable terms, or at all, or be able to re-engineer or rename our products successfully.

We Commercially, in Co-Branding with Fortis Healthcare, Bank and Store Private Cord Blood Stem Cells in our TotipotentRX GMP Facility. We could be Subject to Unexpected Litigation Costs or Damages for Loss of One or More Family Owned Units of Cord Blood or if one of the Cord Blood Units We Store Causes Bodily Injury. We face an inherent business risk of exposure to product liability claims if our products or product candidates are alleged or found to have caused injury, or cannot be used for some reason within our control and are found to result in injury or death. While we believe that our current liability insurance coverage is adequate for our present clinical and commercial activities we may not be able to maintain insurance on acceptable terms or at all. If we are unable to obtain insurance or any claims against us substantially exceed our coverage, then our business could be adversely impacted.

If our Cord Blood Processing and Storage Facility in Gurgaon, India is Damaged or Destroyed, our Business, Programs and Prospects could be Negatively Affected. We process and store our customers' umbilical cord blood at our facility within Fortis Memorial Research Institute (a hospital) in Gurgaon, India. If this facility or the equipment in the facility were to be significantly damaged or destroyed, we could suffer a loss of some or all of the stored cord

blood units. Depending on the extent of loss, such an event could reduce our ability to provide cord blood stem cells when requested, could expose us to significant liability from our cord blood banking customers and could affect our ability to continue to provide umbilical cord blood preservation services.

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We may not be able to Protect our Intellectual Property in Countries Outside the United States. Intellectual property law outside the United States is uncertain and in many countries is currently undergoing review and revisions. The laws of some countries do not protect our patent and other intellectual property rights to the same extent as United States laws. This is particularly relevant to us as a significant amount of our current and projected future sales are outside of the United States. Third parties may attempt to oppose the issuance of patents to us in foreign countries by initiating opposition proceedings. Opposition proceedings against any of our patent filings in a foreign country could have an adverse effect on our corresponding patents that are issued or pending in the United States. It may be necessary or useful for us to participate in proceedings to determine the validity of our patents or our competitors' patents that have been issued in countries other than the U.S. This could result in substantial costs, divert our efforts and attention from other aspects of our business, and could have a material adverse effect on our results of operations and financial condition.

Any Failure to Achieve and Maintain the High Design and Manufacturing Standards that our Products Require may Seriously Harm our Business. Our products require precise, high-quality manufacturing. Achieving precision and quality control requires skill and diligence by our personnel as well as our vendors. Our failure to achieve and maintain these high manufacturing standards, including the incidence of manufacturing errors, design defects or component failures could result in patient injury or death, product recalls or withdrawals, delays or failures in product testing or delivery, cost overruns or other problems that could seriously hurt our business. Additionally, the large amount of AXP disposable inventory certain distributors and end-users maintain may delay the identification of a manufacturing error and expand the financial impact. A manufacturing error or defect, or previously undetected design defect, or uncorrected impurity or variation in a raw material component, either unknown or undetected, could affect the product. Despite our very high manufacturing standards, we cannot completely eliminate the risk of errors, defects or failures. If we or our vendors are unable to manufacture our products in accordance with necessary quality standards, our business and results of operations may be negatively affected.

Our Revenues and Operating Results may be Adversely Affected as a Result of our Required Compliance with the Adopted EU Directive on the Restriction of the Use of Hazardous Substances in Electrical and Electronic Equipment, as well as other Standards Around the World. A number of domestic and foreign jurisdictions seek to restrict the use of various substances, a number of which have been or are currently used in our products or processes. For example, the EU Restriction of Hazardous Substances in Electrical and Electronic Equipment ("RoHS") Directive now requires that certain substances, which may be found in certain products we have manufactured in the past, be removed from all electronics components. Other countries, such as China, have enacted or may enact laws or regulations similar to RoHS. Eliminating such substances from our manufacturing processes requires the expenditure of additional research and development funds to seek alternative substances for our products, as well as increased testing by third parties to ensure the quality of our products and compliance with the RoHS Directive. While we have implemented a compliance program to ensure our product offerings meet these regulations, there may be instances where alternative substances will not be available or commercially feasible, or may only be available from a single source, or may be significantly more expensive than their restricted counterparts. Therefore, we have focused our compliance efforts on those products and geographical areas in which we have the highest revenue potential. Our failure to comply with past, present and future similar laws could result in reduced sales of our products, substantial product inventory write-offs, reputation damage, penalties and other sanctions, any of which could harm our business and operating results.

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Compliance with Government Regulations Regarding the Use of "Conflict Minerals" may Result in Additional Expense and Affect our Operations. The SEC has adopted a final rule to implement Section 1502 of the Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010, which imposes new disclosure requirements regarding the use of "conflict minerals" mined from the Democratic Republic of Congo and adjoining countries. These minerals include tantalum, tin, gold and tungsten. We may incur significant costs associated with complying with the new disclosure requirements, including but not limited to costs related to determining which of our products may be subject to the rules and identifying the source of any "conflict minerals" used in those products. Additionally, implementing the new requirements could adversely affect the sourcing, supply and pricing of materials used in the manufacture of our products. We may also face reputational challenges if we are unable to verify through our compliance procedures the origins for all metals used in our products.

Our Products may be Subject to Product Recalls which may Harm our Reputation and Divert our Managerial and Financial Resources. The FDA and similar governmental authorities in other countries have the authority to order the mandatory recall of our products or order their removal from the market if the governmental entity finds our products might cause adverse health consequences or death. The FDA may also seize product or prevent further distribution. A government-mandated or voluntary recall by us could occur as a result of component failures, manufacturing errors or design defects (including labeling defects). In the past we have initiated voluntary recalls of some of our products and we could do so in the future. Any recall of our products may harm our reputation with customers, divert managerial and financial resources and negatively impact our profitability.

We are Dependent on our Suppliers and Manufacturers to Meet Existing Regulations. Certain of our suppliers and manufacturers are subject to heavy government regulations, including FDA QSR compliance, in the operation of their facilities, products and manufacturing processes. Any adverse action by the FDA against our suppliers or manufacturers could delay supply or manufacture of component products required to be integrated or sold with our products. Although we attempt to mitigate this risk through inventory held directly or through distributors, and audit our suppliers, there are no assurances we will be successful in identifying issues early enough to allow for corrective action or transition to an alternative supplier, or in locating an alternative supplier or manufacturer to meet product shipment or launch deadlines. As a result, our sales, contractual commitments and financial forecasts may be significantly affected by any such delays.

Dependence on Suppliers for Disposable Products and Custom Components May Impact the Production Schedule. We obtain certain disposable products and custom components from a limited number of suppliers. If the supplier raises the price or discontinues production, we may have to find another qualified supplier to provide the item or re-engineer the item. In the event that it becomes necessary for us to find another supplier, we would first be required to qualify the quality assurance systems and product quality of that alternative supplier. Any operational issues with re-engineering or the alternative qualified supplier may impact the production schedule, therefore delaying revenues, and this may cause the cost of disposables or key components to increase.

Failure to Meet the Financial Covenant in our Technology License and Escrow Agreement could Decrease our AXP Revenues. Under our license and escrow agreement with Cord Blood Registry ("CBR") if we fail to meet the financial covenant of cash balance and short-term investments net of debt or borrowed funds that are payable within one year of not less than $2,000 must be maintained, they may take possession of the escrowed intellectual property and initiate manufacturing of the applicable device and disposables. If this were to occur, our revenues would be negatively impacted. In order to remain compliant we may have to do additional financings or provide consideration to the counter party to modify the obligations.

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Failure to Retain or Hire Key Personnel may Adversely Affect our Ability to Sustain or Grow our Business. Our ability to operate successfully and manage our potential future growth depends significantly upon retaining key research, technical, clinical, regulatory, sales, marketing and managerial personnel. Our future success partially depends upon the continued services of key technical and senior management personnel. Our future success also depends on our continuing ability to attract, retain and motivate highly qualified managerial and technical personnel. The inability to retain or attract qualified personnel could have a significant negative effect upon our efforts and thereby materially harm our business and future financial condition.

Most of Our Operations Are Conducted At A Single Location. Any Disruption At Our Facilities Could Delay Revenues Or Increase Our Expenses. Our U.S. device operations are conducted at a single location although we contract the manufacturing of certain devices, disposables and components. We take precautions to safeguard our facilities, through insurance, health and safety protocols, and off-site storage of computer data. However, a natural disaster, such as a fire, flood or earthquake, could cause substantial delays in our operations, damage or destroy our manufacturing equipment or inventory, and cause us to incur additional expenses. The insurance we maintain against fires, floods, and other natural disasters may not be adequate to cover our losses in any particular case.

Failure to Maintain and/or Upgrade Our Information Technology Systems May Have an Adverse Effect on Our Operations. We rely on various information technology systems to manage our operations, and we evaluate these systems against our current and expected requirements. Although we have no current plans to implement modifications or upgrades to our systems, we will eventually be required to make changes to legacy systems and acquire new systems with new functionality. Any information technology system disruptions, if not anticipated and appropriately mitigated, could have an adverse effect on our business and operations.

Risks Related to Our Industry

Our Business is Heavily Regulated, Resulting in Increased Costs of Operations and Delays in Product Sales. Many of our products require FDA approval or clearance to sell in the U.S. and will require approvals from comparable agencies to sell in foreign countries. These authorizations may limit the U.S. or foreign markets in which our products may be sold. Further, our products must be manufactured under requirements of our quality system for continued CE-Marking so they can continue to be marketed and sold in Europe. These requirements are similar to the QSR of both the FDA and California Department of Public Health. Failure to comply with or incorrectly interpret these quality system requirements and regulations may subject us to delays in production while we correct deficiencies found by the FDA, the State of California, or our notifying body as a result of any audit of our quality system. If we are found to be out of compliance, we could receive a Warning Letter or an untitled letter from the FDA or even be temporarily shut down in manufacturing and product sales while the non-conformances are rectified. Also, we may have to recall products and temporarily cease their manufacture and distribution, which would increase our costs and reduce our revenues. The FDA may also invalidate our PMA or 510(k) if appropriate regulations relative to the PMA or 510(k) product are not met. The notified bodies may elect to not renew CE-Mark certification. Any of these events would negatively impact our revenues and costs of operations.

Changes in Governmental Regulations may Reduce Demand for our Products or Increase our Expenses. We compete in many markets in which we and our customers must comply with federal, state, local and international regulations, such as environmental, health and safety and food and drug regulations. We develop, configure and market our products to meet customer needs created by those regulations. Any significant change in regulations could reduce demand for our products or increase our expenses. For example, many of our instruments are marketed to the industry for enabling new regenerative therapies. Changes in the FDA's regulation of the devices and products directed at regenerative medicine, and development process for new therapeutic applications could have an adverse effect on the demand for these products.

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To Sell in International Markets, we will be Subject to Regulation in Foreign Countries. In cooperation with our distribution partners, we intend to market our current and future products both domestically and in many foreign markets. A number of risks are inherent in international transactions. In order for us to market our products in certain non-U.S. jurisdictions, we need to obtain and maintain required regulatory approvals or clearances and must comply with extensive regulations regarding safety, manufacturing processes and quality. These regulations, including the requirements for approvals or clearances to market, may differ from the FDA regulatory scheme. International sales also may be limited or disrupted by political instability, price controls, trade restrictions and changes in tariffs. Additionally, fluctuations in currency exchange rates may adversely affect demand for our products by increasing the price of our products in the currency of the countries in which the products are sold.

There can be no assurance that we will obtain regulatory approvals or clearances in all of the countries where we intend to market our products, or that we will not incur significant costs in obtaining or maintaining foreign regulatory approvals or clearances, or that we will be able to successfully commercialize current or future products in various foreign markets. Delays in receipt of approvals or clearances to market our products in foreign countries, failure to receive such approvals or clearances or the future loss of previously received approvals or clearances could have a substantial negative effect on our results of operations and financial condition.

To Operate In Foreign Jurisdictions, We Are Subject to Regulation by Non-U.S. Authorities. We have operations in India, and as such are subject to Indian regulatory agencies. A number of risks are inherent in conducting business and clinical operations overseas. In order for us to operate as a majority owned foreign corporation in India, we are subject to financial regulations imposed by the Reserve Bank of India. This includes the rules specific to the capital funding, pledging of assets, repatriation of funds and payment of dividends from and to the foreign subsidiaries and from and to us in the U.S.

In order for us to manufacture and/or market our services and products in India, we need to obtain and maintain required regulatory approvals or clearances and must comply with extensive regulations regarding safety, manufacturing processes and quality. These regulations, including the requirements for approvals or clearances to market, and/or export may differ from the FDA regulatory scheme. Additionally, in order for us to complete clinical trials, clinical trial services and cell banking in India, and other foreign jurisdictions, we need to obtain and maintain approvals and licenses which comply with extensive regulations of the appropriate regulatory body.

International operations also may be limited or disrupted by political, economic or social instability, price controls, trade restrictions and changes in tariffs as ordered by various governmental agencies. Additionally, fluctuations in currency exchange rates may adversely affect the cost of production for our products by increasing the price of materials and other inputs for our products in the currency of the countries in which the products are sold.

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If Our Competitors Develop and Market Products That Are More Effective Than Our Product Candidates Or Obtain Regulatory and Market Approval For Similar Products Before We Do, Our Commercial Opportunity May Be Reduced Or Eliminated. The development and commercialization of new pharmaceutical products which target cardiovascular, orthopedic, chronic dermal wounds and other conditions addressed by our current and future products is competitive, and we will face competition from numerous sources, including major biotechnology and pharmaceutical companies worldwide. Many of our competitors have substantially greater financial and technical resources, and development, production and marketing capabilities than we do. In addition, many of these companies have more experience than we do in pre-clinical testing, clinical trials and manufacturing of compounds, as well as in obtaining FDA and foreign regulatory approvals. As a result, there is a risk that one of the competitors will develop a more effective product for the same indications for which we are developing a product or, alternatively, bring a similar product to market before we can. With regards to the BioArchive and AXP Systems, numerous larger and better-financed medical device manufacturers may choose to enter this market as it develops.

Influence by the Government and Insurance Companies may Adversely Impact Sales of our Products. Our business may be materially affected by continuing efforts by government, third party payers such as Medicare, Medicaid, and private health insurance plans, to reduce the costs of healthcare. For example, in certain foreign markets the pricing and profit margins of certain healthcare products are subject to government controls. In addition, increasing emphasis on managed care in the U.S. will continue to place pressure on the pricing of healthcare products. As a result, continuing efforts to contain healthcare costs may result in reduced sales or price reductions for our products. To date, we are not aware of any direct impact on our pricing or product sales due to such efforts by governments to contain healthcare costs, and we do not anticipate any impact in the near future.

Product Liability and Uninsured Risks May Adversely Affect the Continuing Operations. We operate in an industry susceptible to significant product liability claims. We may be liable if any of our products cause injury, illness, or death. These claims may be brought by individuals seeking relief or by groups seeking to represent a class. We also may be required to recall certain of our products should they become damaged or if they are defective. We are not aware of any material product liability claims against us. However, product liability claims may be asserted against us in the future based on events we are not aware of at the present time. We maintain a product liability policy and a general liability policy that includes product liability coverage. However, a product liability claim against us could have a material adverse effect on our business or future financial condition.

We Commercially Process Stem Cells under a Physician's Order for use in Clinical Applications in India. Our GMP laboratory within Fortis Memorial Research Institute in Gurgaon, India, processes stem cells for certain uses under a physician's order, and we charge for these services. This service is primarily focused on our growing initiative in bone marrow transplant. We could face product or service liability claim(s) for a bodily injury asserted by a claimant as a result from our GMP services. We mitigate our risks by adhering to international standards, maintain international certification by BSI to GMP, are U.S FDA registered for such activities and are inspected by the Drugs Controller General of India. We believe our global liability insurance is sufficient to cover claims, but in the event it is not it could materially impact our financial health.

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Risks Related to Operating Results and Financial Markets

We Have Incurred Net Losses and Losses will Continue. We have not been profitable for a significant period. For the fiscal years ended June 30, 2016 and 2015, we had a net loss of $18,588 and $14,852 respectively and an accumulated deficit at June 30, 2016, of $156,262. We will continue to incur significant costs as we develop and market our current products and related applications. Although we are executing our business plan to develop, market and launch new products, continuing losses may impair our ability to fully meet our objectives for new product sales or threaten our ability to continue as a going concern in future years.

We Will Need to Raise Additional Capital to Fund our Operations and in Furtherance of Our Business Plan. We will need to raise additional capital in the near future to fund our future operations and in furtherance of our business plan, including progression of the CLI and Acute Myocardial Infarction Rapid Stem Cell Therapy (“AMIRST”) clinical trials and development of other new products. The proposed financing may include shares of common stock, shares of preferred stock, warrants to purchase shares of common stock or preferred stock, debt securities, units consisting of the forgoing securities, equity investments from strategic development partners or some combination of each. Any additional equity financings may be financially dilutive to, and will be dilutive from an ownership perspective to our stockholders, and such dilution may be significant based upon the size of such financing. Additionally, we cannot assure that such funding will be available on a timely basis, in needed quantities, or on terms favorable to us, if at all.

Our Future Financial Results Could be Adversely Impacted by Asset Impairment Charges. We are required to test both goodwill and intangible assets for impairment on an annual basis. We have chosen to perform our annual impairment reviews of goodwill and other intangible assets during the fourth quarter of each fiscal year. We also are required to test for impairment between annual tests if events occur or circumstances change that would more likely than not reduces our fair value below book value. These events or circumstances could include results of our on-going clinical trials, activities and results of our competitor’s clinical trials, a significant change in the regulatory climate, legal factors, operating performance indicators, or other factors. If the fair market value is less than the book value, we could be required to record an impairment charge. The valuation requires judgment in estimating future cash flows, discount rates and estimated product life cycles. In making these judgments, we evaluate the financial health of the business, including such factors as industry performance, changes in technology and operating cash flows.

As of June 30, 2016 we have a goodwill balance of $13,195 and a net intangible assets balance of $20,821, out of total assets of $49,899. As a result, the amount of any annual or interim impairment could be significant and could have a material adverse effect on our reported financial results for the period in which the charge is taken.

We may Incur Significant Non-operating, Non-cash Charges Resulting from Changes in the Fair Value of Warrants. Our Series A warrants are a derivative instrument; as such they have been recorded at their respective relative fair values at the issuance date and will be recorded at their respective fair values at each subsequent balance sheet date. Any change in value between reporting periods will be recorded as a non-operating, non-cash charge at each reporting date. The impact of these non-operating, non-cash charges could have an adverse effect on the Company’s financial

results. The fair value of the warrants is tied in large part to our stock price. If the stock price increases between reporting periods, the warrants become more valuable. As such, there is no way to forecast what the non-operating, non-cash charges will be in the future or what the future impact will be on our financial statements.

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Risks Related to Our Common Stock

If the Price of our Common Stock does not Meet the Requirements of the NASDAQ Capital Market Stock Exchange ("NASDAQ"), Our Shares may be Delisted. Our Ability to Publicly or Privately Sell Equity Securities and the Liquidity of Our Common Stock Could be Adversely Affected if We Are Delisted. The listing standards of NASDAQ provide, among other things, that a company may be delisted if the bid price of its stock drops below $1.00 for a period of 30 consecutive business days. Delisting from NASDAQ could adversely affect our ability to raise additional financing through the public or private sale of equity securities, would significantly affect the ability of investors to trade our securities and would negatively affect the value and liquidity of our common stock. Delisting could also have other negative results, including the potential loss of confidence by employees, the loss of institutional investor interest and fewer business development opportunities.

Liquidity of our Common Stock. Although there is a public market for our common stock, trading volume has been historically low, which could impact the stock price and the ability to sell shares of our common stock. We can give no assurance that an active and liquid public market for the shares of the common stock will continue in the future. In addition, future sales of large amounts of common stock could adversely affect the market price of our common stock and our ability to raise capital. The price of our common stock could also drop as a result of the exercise of options for common stock or the perception that such sales or exercise of options could occur. These factors could also have a negative impact on the liquidity of our common stock and our ability to raise funds through future stock offerings.

We do not Pay Cash Dividends. We have never paid any cash dividends on our common stock and may not pay cash dividends in the future. Instead, we intend to apply earnings to the expansion and development of our business. Thus, the liquidity of your investment is dependent upon your ability to sell stock at an acceptable price. The price can go down as well as up and may limit your ability to realize any value from your investment, including the initial purchase price.

ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

ITEM 2. PROPERTIES

We lease a facility with approximately 28,000 square feet of space located in Rancho Cordova, California. The facility is devoted to warehouse space, manufacturing of products, office space, a biologics lab, and a research and development lab. The lease expires May 31, 2019.

We also sub-lease approximately 7,819 square feet for an office and research facility located in Emeryville, California. The sub-lease originally expired April 30, 2020, however, we have entered into an amendment in August 2016 and the sub-lease now expires September 30, 2016.

In Gurgaon India we lease approximately 5,800 square feet for an office facility. The lease expires March 1, 2018.

Additionally in Gurgaon India, as part of our agreement with Fortis Healthcare, we occupy and manage a 2,800 square foot cord blood banking and cellular therapy processing facility in the Fortis Memorial Research Institute.

ITEM 3. LEGAL PROCEEDINGS

In the normal course of operations, we may have disagreements or disputes with distributors, vendors or employees. Such potential disputes are seen by management as a normal part of business.

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Effective June 1, 2015, Cesca, Harvest Technologies Corp. (Harvest) and Celling signed an agreement settling the complaint Harvest filed on October 24, 2012 against the Company and the counter complaint Cesca and Celling asserted against Harvest. In the settlement agreement, we agreed to an immaterial settlement payment, which was accrued during the quarter ended March 31, 2015. The Company and Celling also agreed not to make, sell, import or license the Res-Q product in the United States after May 31, 2016.

On September 9, 2014, we filed a complaint against SynGen Inc., PHC Medical Inc., Philip Coelho and others (the Defendants) in the case captioned as *Cesca Therapeutics, Inc. v. SynGen, Inc., et al,* United States District Court, Eastern District of California, Case No. 2:14-cv-02085-GEB-KJN. In the complaint, we contend that SynGens' product the SynGenX-1000 and the patent application entitled "System for Purifying Certain Cell Populations in Blood or Bone Marrow by Depleting Others" were developed using our confidential information and that we are the equitable owner. The complaint is based on misappropriation of trade secrets, breach of contract and other claims. Mediation has failed to result in a mutually agreeable settlement of the case and we have therefore entered the discovery phase in order to further press our claim.

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.

Our common stock, $0.001 par value, is listed on the NASDAQ Capital Market under the symbol KOOL. The following table sets forth the range of high and low closing bid prices for our common stock for the past two fiscal years as reported on the NASDAQ Capital Market.

Fiscal 2016	High	Low	Fiscal 2015	High	Low
First Quarter (Sep. 30)	$16.44	$10.60	First Quarter (Sep. 30)	$28.40	$23.40
Second Quarter (Dec. 31)	$12.40	$3.64	Second Quarter (Dec. 31)	$25.80	$20.00
Third Quarter (Mar. 31)	$6.20	$2.12	Third Quarter (Mar. 31)	$22.00	$15.80
Fourth Quarter (June 30)	$4.01	$1.91	Fourth Quarter (June 30)	$19.80	$15.20

We have not paid cash dividends on our common stock and do not intend to pay a cash dividend in the foreseeable future. There were approximately 216 stockholders of record on June 30, 2016 (not including street name holders).

ITEM 6. SELECTED FINANCIAL DATA

Not applicable for Smaller Reporting Companies.

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ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

(amounts in thousands, except share and per share amounts)

Certain statements contained in this section and other parts of this annual report on Form 10-K which are not historical facts are forward looking statements and are subject to certain risks and uncertainties. Our actual results may differ significantly from the projected results discussed in the forward looking statements. Factors that might affect actual results include, but are not limited to, those discussed in ITEM 1A "RISK FACTORS" and other factors identified from time to time in our reports filed with the SEC. The following discussion should be read in conjunction with our consolidated financial statements contained in this report.

Overview

We develop and market integrated cellular therapies and delivery systems that advance the safe and effective practice of regenerative medicine. We are a leader in the development and manufacture of automated blood and bone marrow processing systems that enable the separation, processing and preservation of cell and tissue therapy products. We were founded in 1986 and are headquartered in Rancho Cordova, California. Our strategy is to continue to enhance the performance and competitiveness of our flagship product lines in the cord blood banking arena while expanding into significant new growth opportunity areas in point of care therapeutics. We are developing a number of offerings for the delivery of autologous cell therapies that address significant unmet medical needs and expect to partner with other pioneers in the stem cell arena to accelerate clinical evaluations, expedite regulatory approvals and penetrate the market.

In September 2015, we undertook a restructuring initiative to reduce the costs associated with our traditional cord blood banking products. The restructuring resulted in a reduction of approximately 15 positions in various functions. This action, combined with the elimination of a number of open positions that were not back-filled, has reduced annual operating costs primarily related to cord blood banking products by approximately $3.3 million.

On March 4, 2016, the Company effected a one (1) for twenty (20) reverse split of its issued and outstanding common stock. There were no changes to its authorized number of shares of common stock of 350,000,000. All historical share amounts disclosed herein have been retroactively recast to reflect the reverse split and subsequent share exchange.

Stem Cell Therapies

We have nine cell therapies at various stages of clinical development, all but one with human data. These include critical limb ischemia (CLI), acute myocardial infarction (AMI), non-healing ulcers, ischemic stroke, spinal fusion, osteoarthritis, non-union fractures and avascular necrosis. We also have an active bone marrow transplantation (BMT) program. The current emphasis is in three particular areas, as follows:

Critical Limb Ischemia (CLI) – We received FDA approval on June 12, 2015 for an Investigational Device Exemption ("IDE") for our pivotal clinical trial (the "CLIRST III" study) to evaluate our SurgWerks™ CLI System for the treatment of patients with late-stage, no option, critical limb ischemia. CLI is the last progressive phase of peripheral artery disease, where the leg is so deprived of blood flow and oxygen, that it has visible signs of gangrenous ulceration. We have supported or completed two prior feasibility studies in CLI, one delivering a Cesca platform prepared autologous bone marrow cell dose into the afflicted leg artery of 13 human subjects and the other delivering a similar Cesca platform produced cell dose into the afflicted limb muscles of 17 human subjects. We submitted an IDE supplement in May 2016 which proposed a change in the primary efficacy endpoint from Amputation Free Survival to Change in Transcutaneous Oxygen Pressure (TcPO2). Subsequently, the FDA approved commencement of the Phase III pivotal trial as amended, but requires additional validation of TcPO2 as a surrogate to support subsequent PMA approval. We are currently engaged in an active dialog with the FDA regarding our options to move forward with this trial.

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Acute Myocardial Infarction (AMI) – The SurgWerks™ – AMI System has been designed to facilitate an adjunct treatment for patients who have suffered an acute ST-elevated myocardial infarction ("STEMI"), a particular and most threatening type of heart attack. Therapies delivered using the SurgWerks-AMI system are intended to minimize the adverse remodeling of the heart post-STEMI. The entire 4-step bedside treatment is designed to take less than 120 minutes to complete, in a single surgical procedure, in the heart catheterization laboratory of a hospital.

Bone Marrow Transplant (BMT) – We have two initiatives within our BMT program: development of the CellWerks™ technology platform for clinical and intra-laboratory use, and the delivery of BMT laboratory services through the our TotipotentRX subsidiary in India. The CellWerks Platform is designed for optimal laboratory preparation of hematopoietic stem cells used in BMT and bio-banking. The technology platform includes a "smart vision" control module, a corresponding disposable for processing blood and bone marrow sourced tissue and sample tracking software enabling GMP compliance. Cell analytics for laboratory and point of care use are under development and will complete the CellWerks offering. TotipotentRX laboratory services, a collaboration with Fortis Healthcare, are aimed at serving the Indian clinical market for cell therapy under good tissue practices compliance.

Products

Our product offerings include:

The **SurgWerks™ System** (in development) - a proprietary system comprised of the SurgWerks Processing Platform, including devices and analytics, and indication-specific SurgWerks Procedure Kits for use in regenerative stem cell therapy at the point of care for vascular and orthopedic diseases.
The **CellWerks™ System** (in development) - a proprietary cell processing system with associated analytics for intra-laboratory preparation of adult stem cells from bone marrow or blood.
The **AutoXpress® System (AXP®)** - a proprietary automated device and companion sterile disposable for concentrating hematopoietic stem cells from cord blood.
The **MarrowXpress™ System (MXP™)** - a derivative product of the AXP and its accompanying sterile disposable for the isolation and concentration of hematopoietic stem cells from bone marrow.
The **BioArchive® System** - an automated cryogenic device used by cord blood banks for the cryopreservation and storage of cord blood stem cell concentrate for future use.
Manual Disposables - bag sets for use in the processing and cryogenic storage of cord blood.

Results of Operations

The following is Management's discussion and analysis of certain significant factors which have affected our financial condition and results of operations during the periods included in the accompanying consolidated financial statements.

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Results of Operations for the Fiscal Year Ended June 30, 2016 versus the Fiscal Year Ended June 30, 2015

Net Revenues

Net revenues for 2016 were $11,929 compared to $16,042 for 2015, a decrease of $4,113. Primary contributors to the decline were BioArchive devices as we shipped ten fewer devices during the year ended June 30, 2016 versus the year ended June 30, 2015, and Res-Q as a result of reduced purchase from our largest distributor following our decision to withdraw the product from the United States market. The decision to withdraw Res-Q from the United States market was made in 2015 in accordance with a settlement agreement reached with Harvest Technologies Corp. related to a long-standing intellectual property dispute.

The following represents our revenues by product platform for the years ended:

	June 30, 2016	June 30, 2015
AXP	$6,932	$6,612
BioArchive	2,465	4,241
Manual Disposables	1,507	1,810
Bone Marrow (including Res-Q)	459	2,621
Other	566	758
	$11,929	$16,042

Gross Profit

Gross profit was $2,744 or 23% of revenues for 2016 compared to $4,749 or 30% of revenues for 2015. Our gross profit declined primarily due to changes in the mix of products sold and increases in inventory reserves primarily associated with the BioArchive product line. We expect gross margin to return to normal levels in fiscal 2017.

Sales and Marketing Expenses

Sales and Marketing expenses include costs primarily associated with generating revenues from the sale of cord blood and bone marrow disposables and BioArchive devices.

Sales and Marketing expenses were $2,148 for 2016, compared to $2,974 for 2015, a decrease of $826. The decrease was primarily due to lower personnel costs as a result of our September 2015 restructuring initiative, lower medical device excise taxes and reduction in travel expenses.

Research and Development Expenses

Research and development expenses include costs associated with our engineering, regulatory, scientific and clinical functions.

Research and development expenses for 2016, were $3,230 compared to $5,939 for 2015, a decrease of $2,709 or 46%. The decrease was primarily due to lower personnel costs driven by our September 2015 restructuring initiative and reduced spending associated with deferral of planned activities in our CLI program. Research and development expenses are expected to increase when we initiate the CLIRST III clinical trial.

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General and Administrative Expenses

General and administrative expenses include costs associated with our accounting, finance, human resources, information system and executive functions.

General and administrative expenses were $8,231 for 2016, compared to $10,695 for 2015, a decrease of $2,464 or 23%. The decrease was primarily due to a reduction in legal expenses of approximately $2,500 related to the settlement of certain patent litigation cases in fiscal 2015.

Non-GAAP Measures

In addition to the results reported in accordance with US GAAP, we also use a non-GAAP measure, adjusted EBITDA, to evaluate operating performance and to facilitate the comparison of our historical results and trends. This financial measure is not a measure of financial performance under US GAAP and should not be considered in isolation or as a substitute for loss as a measure of performance. The calculation of this non-GAAP measure may not be comparable to similarly titled measures used by other companies. Reconciliations to the most directly comparable GAAP measure are provided below.

	2016	2015
Loss from operations	$(10,865)	$(14,859)
Add:		
Depreciation and amortization	1,168	1,351
Stock-based compensation expense	742	1,247
Impairment of intangible asset	--	117
Adjusted EBITDA	$(8,955)	$(12,144)

Adjusted EBITDA

Our adjusted EBITDA loss was $8,955 for 2016, compared to $12,144 for 2015. The reduction in the adjusted EBITDA loss was due primarily to savings realized from our September 2015 restructuring, lower legal expenses due to the settlement of certain patent litigation cases in 2015 and deferral of the start of the CLIRST III trial.

Liquidity and Capital Resources

At June 30, 2016, we had cash and cash equivalents of $5,835 and working capital of $7,301. This compared to cash and cash equivalents of $3,357 and working capital of $5,305 at June 30, 2015. We have primarily financed operations through private and public placement of equity and convertible debt securities.

Our net cash used in operating activities for the year ended June 30, 2016 was $9,625 compared to $10,649 for the year ended June 30, 2015. The decrease was primarily due to savings realized from our September 2015 restructuring, the settlement of certain patent litigation cases and deferral of the start of the CLIRST III trial.

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In February 2016 in exchange for aggregate proceeds of $15 million, the Company sold and issued to Boyalife Investment Inc. and Boyalife (Hong Kong) Limited (i) 735,294 shares of common stock at a purchase price of $3.40 per share (the "Stock Price") for gross proceeds of $2.5 million, (ii) Secured Convertible Debentures for $12.5 million (the "Debentures") convertible into 3,676,471 shares of common stock and (iii) warrants to purchase 3,529,412 additional shares of common stock at an exercise price of $8.00 per share for a period of five years.

On August 31, 2015, the Company sold senior secured convertible debentures in a financing to raise up to $15,000 ("Thirty-Year Debentures"), Series A warrants to purchase up to 1,102,942 shares of the Company's common stock at an exercise price equal to $13.60 per share for a period of five and one-half years ("Series A warrants") and Series B warrants to purchase up to 606,618 shares of the Company's common stock at an exercise price equal to $13.60 per share for a period of eighteen months ("Series B warrants"). At the initial closing on August 31, 2015, the Company received gross proceeds of $5,500 and 404,412 Series A warrants vested and 222,427 Series B warrants vested. The second closing for up to an additional $9,500 was dependent on a number of items including receipt by the Company of approval from the California Institute for Regenerative Medicine ("CIRM") for a grant in the amount of $10,000, to support the Company's pivotal trial for CLIRST III. The Company applied for the CIRM grant in August 2015. However, the Company withdrew its application for the CIRM grant.

In connection with the February 2016 financing transaction described above, the Company concurrently entered into a Consent, Repayment and Release Agreement, pursuant to which the Company repaid the Thirty-Year Debentures and all related interest and liquidated damages. Upon the Company's payment of $7.5 million, the Thirty-Year Debentures were deemed repaid in full and cancelled, all liquidated damages due and payable were deemed paid and satisfied in full, the registration rights agreement was terminated and the exercise price of the Series A warrants was changed from $13.60 to $8.00.

On August 3, 2016, the Company sold 600,000 shares of common stock at a price of $4.10 per share.

The net proceeds to the Company from the sale and issuance of the shares, after deducting the estimated offering expenses borne by the Company are expected to be approximately $2.2 million.

On August 22, 2016, the Company elected to convert all outstanding principal and interest accrued and otherwise payable under the Debentures. Upon conversion, 6,102,941 shares of common stock were issued and the Debentures and all security interest and liens were terminated.

Based upon our cash balance, the August 2016 financing, historical trends, expected outflows and projections for revenues, management believes we will have sufficient cash to provide for our projected needs to maintain operations and working capital requirements for at least the next 12 months from the date of filing this annual report. We will need additional funding to support our phase III Critical Limb Ischemia (CLIRST III) trial. As such, management has

been exploring additional funding sources including strategic partner relationships.

Our ability to fund our longer-term cash needs is subject to various risks, many of which are beyond our control. Should we require additional funding, we may need to raise the required additional funds through bank borrowings or public or private sales of debt or equity securities. We cannot guarantee that such funding will be available on a timely basis, in needed quantities or on terms favorable to us, if at all (see Part I Item 1A – Risk Factors).

We generally do not require extensive capital equipment to produce or sell our current cord blood banking products. In fiscal 2016 and 2015, we spent $710 and $587, respectively, primarily for tooling at a contract manufacturer and equipment to be used in our SurgWerks™ development program.

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At June 30, 2016, we had three distributors/customers that accounted for 57% of accounts receivable. At June 30, 2015, we had four distributors that accounted for 64% of accounts receivable.

Revenues from one distributor totaled $2,797 or 23% and $2,358 or 15% of net revenues for the years ended June 30, 2016 and 2015, respectively. Revenues from a customer totaled $2,475 or 21% and $2,549 or 16% for the years ended June 30, 2016 and 2015, respectively. Revenues from another distributor totaled $2,303 or 14% of net revenues for the year ended June 30, 2015.

We manage the concentration of credit risk with these customers through a variety of methods including, letters of credit with financial institutions, pre-shipment deposits, credit reference checks and credit limits. Although management believes that these customers are sound and creditworthy, a severe adverse impact on their business operations could have a corresponding material effect on their ability to pay timely and therefore on our net revenues, cash flows and financial condition.

Critical Accounting Policies

The preparation of these consolidated financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses and related disclosure of contingent assets and liabilities. On an on-going basis, we evaluate our estimates, including those related to stock-based compensation, depreciation, fair values of intangibles and goodwill, bad debts, inventories, warranties, contingencies and litigation. We base our estimates on historical experience and on various other assumptions that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

We believe the following critical accounting policies affect its more significant judgments and estimates used in the preparation of its consolidated financial statements.

Goodwill, Intangible Assets and Impairment Assessments

Goodwill represents the excess of the purchase price in a business combination over the fair value of net tangible and intangible assets acquired. Intangible assets that are not considered to have an indefinite useful life are amortized over their useful lives, which generally range from three to ten years. Clinical protocols are not expected to provide economic benefit until they are introduced to the marketplace or licensed to an independent entity. Each period we evaluate the estimated remaining useful lives of purchased intangible assets and whether events or changes in circumstances warrant a revision to the remaining periods of amortization.

The carrying amounts of these assets are periodically reviewed for impairment (at least annually) and whenever events or changes in circumstances indicate that the carrying value of these assets may not be recoverable. According to *ASC 350, Intangibles-Goodwill and Other*, for goodwill and indefinite-lived intangible assets, we can opt to perform a qualitative assessment or a quantitative assessment; however, if the qualitative assessment determines that it is more likely than not (i.e., a likelihood of more than 50 percent) the fair value is less than the carrying amount, a quantitative assessment must be performed. If the quantitative assessment determines that the fair value is less than the carrying amount, an impairment loss equal to the difference would be recorded.

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Revenue Recognition

Revenues from the sale of our products are recognized when persuasive evidence of an arrangement exists, delivery has occurred (or services have been rendered), the price is fixed or determinable, and collectability is reasonably assured. We generally ship products F.O.B. shipping point. There is no conditional evaluation on any product sold and recognized as revenue. Amounts billed in excess of revenue recognized are recorded as deferred revenue on the consolidated balance sheet.

There is no right of return provided for distributors or customers. For sales of products made to distributors, we consider a number of factors in determining whether revenue is recognized upon transfer of title to the distributor, or when payment is received. These factors include, but are not limited to, whether the payment terms offered to the distributor are considered to be non-standard, the distributor history of adhering to the terms of its contractual arrangements with us, the level of inventories maintained by the distributor, whether we have a pattern of granting concessions for the benefit of the distributor, and whether there are other conditions that may indicate that the sale to the distributor is not substantive. We currently recognize revenue primarily on the sell-in method with our distributors.

Revenue arrangements with multiple deliverables are divided into units of accounting if certain criteria are met, including whether the deliverable item(s) has (have) value to the customer on a stand-alone basis. Revenue for each unit of accounting is recognized as the unit of accounting is delivered. Arrangement consideration is allocated to each unit of accounting based upon the relative estimated selling prices of the separate units of accounting contained within an arrangement containing multiple deliverables. Estimated selling prices are determined using Vendor Specific Objective Evidence (VSOE), when available, or an estimate of selling price when VSOE is not available for a given unit of accounting. Significant inputs for the estimates of the selling price of separate units of accounting include market and pricing trends and a customer’s geographic location. We account for training and installation, and service agreements and the collection, processing and testing of the umbilical cord blood and the storage as separate units of accounting.

Service revenue generated from contracts for providing maintenance of equipment is amortized over the life of the agreement. Revenue generated from storage contracts is deferred and recorded ratably over the life of the agreement, up to 21 years. All other service revenue is recognized at the time the service is completed.

Revenues are net of normal discounts. Shipping and handling fees billed to customers are included in net revenues, while the related costs are included in cost of revenues.

Stock-Based Compensation

We use the Black-Scholes-Merton option-pricing formula in determining the fair value of our options at the grant date and apply judgment in estimating the key assumptions that are critical to the model such as the expected term, volatility and forfeiture rate of an option. Our estimate of these key assumptions is based on historical information and judgment regarding market factors and trends. If any of the key assumptions change significantly, stock-based compensation expense for new awards may differ materially in the future from that recorded in the current period. The compensation expense is then amortized over the vesting period.

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Income Taxes

Our estimates of income taxes and the significant items resulting in the recognition of deferred tax assets and liabilities reflect our assessment of future tax consequences of transactions that have been reflected in the financial statements or tax returns for each taxing jurisdiction in which we operate. We base our provision for income taxes on our current period results of operations, changes in deferred income tax assets and liabilities, income tax rates, and changes in estimates of uncertain tax positions in the jurisdictions in which we operate. We recognize deferred tax assets and liabilities when there are temporary differences between the financial reporting basis and tax basis of assets and liabilities and for the expected benefits of using net operating loss and tax credit loss carryforwards. We establish valuation allowances when necessary to reduce the carrying amount of deferred income tax assets to the amounts that we believe are more likely than not to be realized. We evaluate the need to retain all or a portion of the valuation allowance on recorded deferred tax assets. When a change in the tax rate or tax law has an impact on deferred taxes, we apply the change based on the years in which the temporary differences are expected to reverse. As we operate in more than one state, changes in the state apportionment factors, based on operational results, may affect future effective tax rates and the value of recorded deferred tax assets and liabilities. We record a change in tax rates in the consolidated financial statements in the period of enactment.

Income tax consequences that arise in connection with a business combination include identifying the tax basis of assets and liabilities acquired and any contingencies associated with uncertain tax positions assumed or resulting from the business combination. Deferred tax assets and liabilities related to temporary differences of an acquired entity are recorded as of the date of the business combination and are based on our estimate of the appropriate tax basis that will be accepted by the various taxing authorities and its determination as to whether any of the acquired deferred tax liabilities could be a source of taxable income to realize our pre-existing deferred tax assets.

Inventory Valuation

We state inventories at lower of cost or market value determined on a first-in, first-out basis. We provide write-downs of inventory when conditions indicate that the selling price could be less than cost due to physical deterioration, obsolescence, changes in price levels, or other causes, which it includes as a component of cost of revenues. Additionally, we provide valuation allowances for excess and slow-moving inventory on hand that are not expected to be sold to reduce the carrying amount of slow-moving inventory to its estimated net realizable value. The valuation allowances are based upon estimates about future demand from our customers and distributors and market conditions. Because some of our products are highly dependent on government and third-party funding, current customer use and validation, and completion of regulatory and field trials, there is a risk that we will forecast incorrectly and purchase or produce excess inventories. As a result, actual demand may differ from forecasts and we may be required to record additional inventory valuation allowances that could adversely impact our gross margins. Conversely, favorable changes in demand could result in higher gross margins when those products are sold.

Warranty

We provide for the estimated cost of product warranties at the time revenue is recognized. While we engage in extensive product quality programs and processes, including actively monitoring and evaluating the quality of our component suppliers, our warranty obligation is affected by product failure rates, material usage and service delivery costs incurred in correcting a product failure. Should actual product failure rates, material usage or service delivery costs differ from our estimates, revisions to the estimated warranty liability could have a material impact on our financial position, cash flows or results of operations.

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Off Balance Sheet Arrangements

We have no off-balance sheet arrangements.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

We are a smaller reporting company as defined by Rule 12b-2 of the SEC Act of 1934 and are not required to provide information under this item.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Audit Committee of the

Board of Directors and Shareholders

of Cesca Therapeutics Inc. and Subsidiaries

We have audited the accompanying consolidated balance sheets of Cesca Therapeutics Inc. and Subsidiaries (the "Company") as of June 30, 2016 and 2015, and the related consolidated statements of operations and comprehensive loss, stockholders' equity 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 audits 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 financial statements referred to above present fairly, in all material respects, the consolidated financial position of Cesca Therapeutics Inc. and Subsidiaries, as of June 30, 2016 and 2015 and the consolidated 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/ Marcum LLP

Marcum LLP

New York, NY

September 20, 2016

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Cesca Therapeutics Inc.

Consolidated Balance Sheets

(in thousands, except share and per share amounts)

	June 30, 2016	June 30, 2015
ASSETS		
Current assets:		
Cash and cash equivalents	$5,835	$3,357
Accounts receivable, net of allowance for doubtful accounts of $49 ($46 at June 30, 2015)	3,169	5,133
Inventories, net of reserves of $1,437 ($874 at June 30, 2015)	3,593	4,598
Prepaid expenses and other current assets	246	163
Total current assets	12,843	13,251
Equipment at cost less accumulated depreciation	2,962	2,937
Goodwill	13,195	13,195
Intangible assets, net	20,821	21,295
Other assets	78	79
Total assets	$49,899	$50,757
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$2,648	$5,079
Accrued payroll and related expenses	449	705
Deferred revenue	783	635
Other current liabilities	1,662	1,527
Total current liabilities	5,542	7,946
Noncurrent deferred tax liability	7,641	7,641
Derivative obligations	670	--
Convertible debentures, net	2,489	--
Other noncurrent liabilities	1,284	268
Total liabilities	17,626	15,855
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, $0.001 par value; 2,000,000 shares authorized, none issued and outstanding at June 30, 2016 and 2015	--	--
Common stock, $0.001 par value; 350,000,000 shares authorized; 3,010,687 issued and outstanding (2,027,386 at June 30, 2015)	3	2

Paid in capital in excess of par	188,569	172,579
Accumulated deficit	(156,262)	(137,674)
Accumulated other comprehensive loss	(37)	(5)
Total stockholders' equity	32,273	34,902
Total liabilities and stockholders' equity	$49,899	$50,757

See accompanying notes.

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Cesca Therapeutics Inc.

Consolidated Statements of Operations and Comprehensive loss

(in thousands, except share and per share amounts)

Years ended June 30		
	2016	2015
Net revenues	$11,929	$16,042
Cost of revenues	9,185	11,293
Gross profit	2,744	4,749
Expenses:		
Sales and marketing	2,148	2,974
Research and development	3,230	5,939
General and administrative	8,231	10,695
Total operating expenses	13,609	19,608
Loss from operations	(10,865)	(14,859)
Other income (expense):		
Amortization of debt discount	(6,127)	--
Fair value change of derivative instruments	3,395	--
Interest expense	(1,864)	(14)
Registration rights liquidated damages	(1,100)	--
Loss on cashless exercise of warrants	(1,039)	--
Loss on extinguishment of debt	(795)	--
Loss on modification of Series A warrants	(149)	--
Other income and (expenses)	(44)	21
Total other income (expense)	(7,723)	7
Net loss	$(18,588)	$(14,852)
COMPREHENSIVE LOSS		
Net loss	$(18,588)	$(14,852)
Other comprehensive income:		
Foreign currency translation adjustments	(32)	(63)
Comprehensive loss	$(18,620)	$(14,915)
Per share data:		
Basic and diluted net loss per common share	$(7.57)	$(7.36)
Weighted average common shares outstanding – Basic and diluted	2,455,548	2,017,597

See accompanying notes.

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Cesca Therapeutics Inc.

Consolidated Statements of Stockholders' Equity

(in thousands, except share and per share amounts)

	Common Stock		Paid in capital in excess of par	Accumulated deficit	Accumulated other comprehensive (loss) income	Total stockholders' equity
	Shares	Amount				
Balance at June 30, 2014	2,012,326	$ 2	$171,460	$ (122,822)	$ 58	$ 48,698
Issuance of common shares and compensation related to restricted common stock awards, net of stock surrenders	12,801	--	414	--	--	414
Stock-based compensation expense	--	--	660	--	--	660
Common stock issued to directors in lieu of cash compensation	2,259	--	45	--	--	45
Foreign currency translation	--	--	--	--	(63)	(63)
Net loss	--	--	--	(14,852)	--	(14,852)
Balance at June 30, 2015	2,027,386	2	172,579	(137,674)	(5)	34,902
Stock-based compensation expense, net of stock surrenders	11,577	--	710	--	--	710
Discount due to beneficial conversion features	--	--	7,262	--	--	7,262
Discount due to warrants	--	--	4,434	--	--	4,434
Issuance of common shares and warrants in financing	735,294	1	2,463	--	--	2,464
Issuance of common shares for exercise of Series B warrants	231,710	--	1,097	--	--	1,097
Common stock issued to directors in lieu of cash compensation	4,720	--	24	--	--	24
Foreign currency translation	--	--	--	--	(32)	(32)

Net loss	--	--	--	(18,588)	--	(18,588)
Balance at June 30, 2016	3,010,687	$ 3	$ 188,569	$ (156,262)	$ (37)	$ 32,273

See accompanying notes.

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Cesca Therapeutics Inc.

Consolidated Statements of Cash Flows

(amounts in thousands, except share and per share amounts)

	Years ended June 30,	
	2016	2015
Cash flows from operating activities:		
Net loss	$(18,588)	$(14,852)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	1,168	1,351
Stock-based compensation expense	742	1,247
Reserve for excess and slow-moving inventories		