

CESCA THERAPEUTICS INC.  
Form 10-K  
September 17, 2015  
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, 2015**

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

Edgar Filing: CESCA THERAPEUTICS INC. - Form 10-K

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  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  No

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

Indicate by check mark 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.)  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

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

Edgar Filing: CESCA THERAPEUTICS INC. - Form 10-K

The aggregate market value of the common stock held by non-affiliates as of December 31, 2014 (the last business day of the most recently completed second quarter) was \$30,860,000 based on the closing sale price on such day.

As of September 15, 2015, 40,616,730 shares of the registrant's Common Stock were outstanding.

Documents Incorporated By Reference: Portions of the registrant's proxy statement for its 2015 Annual Meeting of Stockholders are incorporated by reference into Part III hereof.

---

**TABLE OF CONTENTS**

	<u>Page Number</u>
<b>Part I</b>	
ITEM 1. Business	3
ITEM 1A. Risk Factors	17
ITEM 1B. Unresolved Staff Comments	28
ITEM 2. Properties	28
ITEM 3. Legal Proceedings	28
ITEM 4. Mine Safety Disclosures	28
<b>Part II</b>	
ITEM 5. Market for the Registrant’s Common Equity and Related Stockholder Matters and Issuer Purchases of Equity Securities	29
ITEM 6. Selected Financial Data	29
ITEM 7. Management’s Discussion and Analysis of Financial Condition and Results of Operations	29
ITEM 7A. Quantitative and Qualitative Disclosures about Market Risk	38
ITEM 8. Financial Statements and Supplementary Data	38
ITEM 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure	69
ITEM 9A. Controls and Procedures	69
ITEM 9B. Other Information	70
<b>Part III</b>	
ITEM 10. Directors, Executive Officers and Corporate Governance	71
ITEM 11. Executive Compensation	71
ITEM 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters	71
ITEM 13. Certain Relationships and Related Transactions, and Director Independence	71
ITEM 14. Principal Accounting Fees and Services	71
<b>Part IV</b>	
ITEM 15. Exhibits and Financial Statement Schedules	72

## **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 of 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 our 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.

## **ITEM 1. BUSINESS**

### **Business Overview**

Cesca Therapeutics Inc. (“Cesca Therapeutics”, “Cesca”, the “Company”, “we”, “our”, “us”), formerly known as ThermoGene Corp, is focused on the research, development, and commercialization of autologous cell-based therapies that advance the practice of regenerative medicine. The Company was founded in 1986 as ThermoGenesis Corp., a Delaware corporation, with principal offices in Rancho Cordova, California. It is an established leader in the development and manufacture of automated blood and bone marrow processing systems that enable the separation, processing and cryopreservation of cell and tissue therapy products, serving patients, physicians and partners in three target markets:

- Cellular Therapeutics
- Medical/Diagnostic Device Development and Commercialization
- Cell Manufacturing and Banking.

On February 18, 2014, TotipotentRX Corporation (“TotipotentRX”, “Totipotent” or “TRX”), merged with and into ThermoGenesis Corp (“ThermoGenesis”). TRX was a cellular therapeutics development organization with a pipeline of human point-of-care experimental therapies in early stage clinical studies using bone marrow and blood derived cells and growth factors. The merged company was renamed Cesca Therapeutics Inc. and is now positioned as a fully integrated regenerative medicine company with the ability to research, design and develop the devices, disposables and protocols necessary to facilitate the delivery of cell therapies at the point of care. Cesca remains a corporation organized under the laws of the State of Delaware and, unless otherwise noted, any information regarding us and our business includes information relating to TotipotentRX.

Our business strategy involves:

• A focus on 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: Cesca delivers all the hardware, software and disposable components necessary for the aspiration and processing of bone marrow and the separation and concentration of 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: Cesca's protocols are potentially safer because the donor and the recipient of the stem cell preparation is the same individual.

A highly resource efficient operating model: Cesca leverages its India based clinical research organization embedded within the Fortis network of hospitals for highly cost-effective approach to feasibility studies and early stage clinical trials.

Multiple shots on goal: Cesca has 9 protocols at various stages of clinical development.

Patent protection: Cesca has over 30 issued patents globally with several more applications in the pipeline.



***Key Events and Accomplishments***

The following are key events and accomplishments that occurred in fiscal 2015:

*Received Food and Drug Administration (“FDA”) Approval for Investigational Device Exemption (“IDE”) for a U.S. Pivotal Clinical Trial in Critical Limb Ischemia*

In June 2015 we received an IDE approval from the FDA to initiate a Phase III pivotal clinical trial for CLI in the U.S. The pivotal trial application was based on very promising results from the Company’s earlier CLI Phase 1b trial, conducted in India, which enrolled 17 patients who had exhausted all available medical treatments short of amputation and were considered “no option”.

*Received new U.S. Patent for the SurgWerks and CellWerks Product Patent Portfolio*

In June 2015 the U.S. Patent and Trademark Office issued a patent for “Stem and Progenitor Cell Compositions Recovered from Bone marrow or Cord Blood”. The patent has claims to the compositions of stem cells recovered from bone marrow and cord blood and the respective device and methods to achieve those compositions.

*Received Investigational Review Board (“IEC/IRB”) Approval to Initiate Acute Myocardial Infarction AMI Study*

In May 2015 we received approval from an Institutional Ethics Committee to initiate a phase II clinical trial for AMI using our SurgWerks-AMI and VXP system. This approval paves the way for the safety and preliminary six month efficacy study of 40 patients with certain conditions following a heart attack.

*Signed Master Collaboration Agreement with Fortis Healthcare*

On August 1, 2014, we extended our existing relationship with Fortis. The agreement renews our cord blood banking collaboration and launches stem cell therapy services for hematological diseases across the Fortis network.

*Indian Drug Controller General (“IDCG”) Approval of MarrowXpress (“MXP”)*

On January 23, 2015, the Indian Drug Controller General granted a marketing license for the Company’s MXP system. The on-label indication of use is specifically for use in a clinical laboratory or intraoperatively at the point-of-care for preparation of a cell concentrate from bone marrow.

And on August 31, 2015:

*Secured \$15 Million Financing from Institutional Life Sciences Fund*

We intend to use the gross proceeds from the private placement of senior secured convertible debentures and warrants for working capital in support of our ongoing clinical initiatives. We received \$5.5 million in gross proceeds at the initial closing. The remaining \$9.5 million of gross proceeds will be deposited in our deposit control account to be

released after receiving (i) stockholder approval of certain share issuances relating to the financing to meet Nasdaq listing requirements, (ii) stockholder approval of an amendment to the Company's certificate of incorporation increasing its authorized number of shares of common stock to 350,000,000 and (iii) approval from California Institute for Regenerative Medicine ("CIRM") of a grant in the amount of \$10,000 for the U.S. pivotal clinical trial in critical limb ischemia..

## **Market Overview**

### ***Regenerative Medicine Market***

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 regenerative medicine market is comprised of companies that develop devices or methods for harvesting, processing, purifying, expanding, modifying, cryopreserving, storing or administering cells, or companies that develop and commercialize the cellular 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, CGMP (Current Good Manufacturing Practice)-compliant therapeutic manufacturer, formulated into an effective, safe dose, and surgically 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 sterile field packaging, a minimal degree of processing, predictable target cell recovery rates, portability and speed of processing.

Cesca’s focus is 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 cell therapies will develop first in orthopedics, cardiology, skin and wound healing and select areas of oncology, followed by emerging opportunities in 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 and economic studies.

### ***Cord Blood Market***

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 been used in more than 30,000 medical procedures worldwide to treat a wide range of blood diseases, genetic and metabolic disorders, immunodeficiencies and cancers. Cord blood banks now exist in nearly every developed country as well as a growing number of developing nations.

It appears, however, that the overall number of annual transplants is leveling off. 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%.

Cord blood banking can be broadly divided into two categories; private banks serving individual families and public banks serving the broader public. Some banks embrace a hybrid approach, deriving a portion of their revenue from fee-paying families to complement what they receive in the form of public funding.

Cord blood use in clinical applications is now widely accepted. The FDA has now approved several Biologics License Applications (“BLAs”) for public cord blood products which we believe is a testament to improvements in clinical cord blood quality and a reflection of the maturation of the industry. Recently there have been several examples of significant pharma companies entering the space. In August 2014, Novartis signed a \$435 million investment with Gamida Cell for the first experimental expanded cord blood stem cell biological product which is co-transplanted with a single unit of cord blood. In June 2015, GTCR a private equity firm announced a definitive agreement to sell Cord Blood Registry, a private family cord blood bank, to AMAG Pharmaceuticals (“Nasdaq: AMAG”) for \$700 million.

### **Therapeutic Products – Clinical Development**

Our therapeutic development initiatives, focused in the fields of cardiovascular medicine, orthopedic regeneration, and oncological and hematological replacement of blood cells (i.e. bone marrow transplant) are based on a flexible platform of optimized disposable devices and ancillary equipment for the harvesting, preparation and processing, testing and delivery of cells and growth factors from either blood or bone marrow. Our SurgWerks<sup>™</sup> offering, currently in development, is a collection of single use disposable kits for intra-operative use, each specialized and optimized for the treatment of a specific indication. The performance of SurgWerks<sup>™</sup> 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 MXP platforms. The platform is unique in that it maintains high cell viability and potency throughout the 90 plus minute intra-operative patient procedure, including the bone marrow sourced tissue collection, target cell selection from the bone marrow, characterization/dose determination of the final cell product, and final delivery of the processed therapeutic cells into the patient.

We made the following advancements in the SurgWerk’s clinical development in fiscal 2015:

SurgWerks-CLI and VXP System: The pivotal IDE trial (similar to a Phase III for drugs) for no-option Rutherford 5 patients was approved in June 2015 by the U.S. FDA to begin in the U.S. The trial specifics are as follows:

- o Randomized 3:1; Double blinded; Placebo controlled
- o Primary endpoint of major amputation free survival
- o

224 subjects with an interim analysis for futility and statistical significance, including an adaptive design allowance for repowering the trial up to 312 subjects. 204 subjects must come from the U.S. population, with an allowance for 20 subjects to come from foreign sites.

oUp to 60 clinical trial sites; and

oAdjudicated interpretation of amputation by a blinded independent central review board.

SurgWerks-AMI: We received Investigational Review Board approval for a Phase II trial involving 40 patients to be conducted in our India-based Clinical Research Organization (“CRO”). The study is pending the Drugs Controller General (India) approval and is proposed as follows:

- o Randomized 1:1; Open Label; Active Control
- o Primary Endpoint is safety, secondary endpoints are cardiac volumetric assessments
- o 40 subjects
- o Up to 3 clinical trial sites

We intend to initiate the following SurgWerk’s clinical trials in fiscal 2016:

U.S. & India: SurgWerks-CLI and VXP System pivotal IDE trial on no-option Rutherford 5 patients suffering from non-reconstructable critical limb ischemia.

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.

Also in development is our CellWerks™ offering, an integrated collection of disposables that, when coupled with the MarrowXpress device platform and protocol, represents a significant advance in enabling routine bone marrow transplantation procedures. CellWerks™ can process a stem cell aspirate or mobilized blood harvest unit and allow the GMP laboratory to “dial in” the transplant physician’s cellular prescription, thereby achieving an optimized stem cell dose. The CellWerks™ and MXP System platform with its optimized cellular vision system and software package is being evaluated for use on non-manipulated as well as targeted, specific cell depleted units of mobilized peripheral stem cells and bone marrow aspirate.

We plan to complete or initiate the following internally sponsored CellWerk’s clinical studies in fiscal 2016:

To complete: Pilot study in pediatric allogeneic ABO mismatched bone marrow transplant

To Initiate: Feasibility study for T-Cell depleted Haploidentical bone marrow transplant.

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® and the VXP System – Rapid Intra-operative Use

CellWerks™ MXP System – Rapid Laboratory Use for specialized stem cell preparation under the direction of a GMP cellular laboratory or a licensed physician.

Our intention is to provide fully optimized therapeutic “kits” and highly specialized equipment for each clinical indication in our pipeline, ultimately seeking marketing approval from the FDA and/or the equivalent regulatory authorities in markets outside the U.S. Notably, in June 2015, the FDA determined that our regulatory pathway in the U.S. for its SurgWerks™ and VXP System intra-operative cell therapy kits and equipment will require Premarket Authorization (“PMA”) and must be studied in human clinical trials under the investigational device exemption

pathway.

7

---



*Cesca's Clinical Pipeline – An Estimated Addressable Market of over \$16 Billion*

<b>THERAPEUTIC PROGRAM</b>	<b>PRECLINICAL PILOT</b>	<b>FEASIBILITY (PHASE II)</b>	<b>PIVOTAL (PHASE III)</b>	<b>GLOBAL ESTIMATED OPPTY</b>
<b>CARDIOVASCULAR</b>				<b>\$8.7 B</b>
Critical Limb Ischemia				\$2 B
Acute Myocardial Infarction (STEMI)				\$700 M
Non-Healing Ulcers				\$800 M
Ischemic Stroke				\$5.2 B
<b>ORTHOPEDIC</b>				<b>\$7.6 B</b>
Spinal Fusion				\$800 M
Osteoarthritis				\$5 B
Non-Union Fractures (Long Bone)				\$975 M
Avascular Necrosis				\$800 M
<b>HEMATOLOGY/ONCOLOGY</b>				<b>\$100 M</b>
Bone Marrow Transplant				\$100 M

*The SurgWerks™ and VXP System Platform*

The SurgWerks™ and VXP System is a fully integrated, highly specialized and indication specific *protocol*, single use *disposable kit* and ancillary *equipment* platform that enables a rapid, door-to-door 90 plus minute intra-operative treatment with autologous bone marrow derived stem cells.

*SurgWerks O.R. Procedure*

*Disposable SurgWerks Kit*

*VXP Equipment System*

The SurgWerks™ offering consists of the following:

***Protocol:*** A defined standard operating procedure containing step-by-step instructions on the operation of all components necessary to produce a defined cellular dose starting from the autologous collection of source material (i.e. bone marrow) through final delivery to targeted tissue/organ in the same patient.

***Disposables:*** A complete sterile “single-use” kit containing all indication specific medical disposables for harvesting, processing and target/organ specific delivery of the autologous cells including the testing reagents necessary to ensure the production of a high quality defined cellular dose.

***Equipment:*** An easy-to-use equipment “cart” containing all equipment/devices necessary to produce and test the defined cellular dose (i.e. centrifuge for cell processing and purification).

### ***The CellWerks™ Platform***

The CellWerks™ Platform is designed for optimal laboratory processing and preparation of targeted cells used in the treatment of oncological and hematological disorders. The equipment platform includes a “smart vision” control module, and a corresponding disposable for processing blood and bone marrow sourced tissue.

Following the optimization of the CellWerks Platform in 2014 that included several significant upgrades to address the emerging needs of the cell banking, biopharmaceutical and cellular therapeutic manufacturing sectors, the Company initiated a program with Fortis Healthcare aimed at establishing a bone marrow transplant business in India. The goal for the CellWerks™ platform is to provide a simple, cost effective, next generation cell processing system tailored to the needs of transplant laboratories around the world that need to enhance their programs’ ability to minimize red blood cell contamination, improve stem cell recoveries and optionally post-process a transplant unit after removal of certain undesirable cells such as T-Cells.

We have two commercial plans for the CellWerks platform:

1. Expansion of our stem cell transplant services business in collaboration with Fortis Healthcare, specifically targeting the underserved Indian population where up to 6,000 stem cell transplants could be performed per annum under a private payer system.
2. Expansion of our device sales to transplant service providers across the globe who are seeking a next generation stem cell processing device backed by clinical evidence.

### **Medical Device Portfolio Overview**

We design, manufacture and sell advanced devices created specifically for the separation, concentration and cryopreservation of cell types of interest for 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 product offering includes:

The **AXP System**, a medical device with an accompanying disposable bag set that separates and concentrates stem cells from umbilical cord blood. The AXP rapidly and cost-effectively captures stem cells with reduced risk of contamination under GMP conditions. The AXP retains over 97% of the mononuclear cells (“MNCs”) present in the umbilical cord blood sample. High MNC recovery is a critical requirement for a successful transplant. Self-powered and microprocessor-controlled, the AXP device contains optical sensor and flow control technology that enables precise separation of cord blood fractions.

The **MXP System**, a derivative of the AXP, separates and concentrates stem cells from bone marrow. The MXP is an automated, closed, sterile system that volume-reduces bone marrow to a user-defined volume in 30 minutes, while retaining over 90% of the clinically important MNCs. Self-powered and microprocessor-controlled, the MXP System contains optical sensor and flow control technology that enable precise separation of bone marrow fractions. The device is CE marked, facilitating commercial sales in Europe, and we received authorization from the FDA to begin marketing the MXP as a Class I device in the U.S. However, the safety and effectiveness of this device for in vivo use has not yet been established.

The **BioArchive System** is a robotic cryogenic freezer for the cryopreservation and archiving of stem cell concentrates for future transplant. Launched in 1998, BioArchive Systems have now been purchased by over 110 umbilical cord blood banks in over 35 countries.

The **Res-Q 60 BMC** is a rapid, reliable, and easy to use product for cell processing. The product is a centrifuge-based disposable device designed for the isolation and extraction of specific stem cell populations from bone marrow. We will be withdrawing this product from the United States market on or before May 31, 2016 in accordance with our settlement agreement with Harvest Technologies Corp.

### **Cell Manufacturing and Banking Services**

Through our 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 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 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, to our knowledge, the industry’s only fully integrated cell therapy CRO team to execute all elements for 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”).

### **Sales and Distribution Channels**

We market and sell our medical devices through independent distributors, except in North America and India, where we sell direct.

### **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, Nuo Therapeutics, Pluristem Therapeutics, Zimmer BioMet, and Bioheart.



## **Research and Development**

Our research and development activities in fiscal 2015 focused on achieving key development milestones tied to the 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. Investments were made to support MXP registration in India in addition to compliance with regulations associated with our SurgWerks clinical trials and CellWerks programs. Biologic clinical research and development activities focused on the initiation of protocol design and optimization associated with our AMI clinical trial program while CLI efforts focused on meeting milestones in support of achieving our recent U.S. FDA Phase 3 (“Pivotal”) IDE approval. We also invested effort in optimizing cell processing and delivery methods as well as advancing methods pertaining to our cell quality (cell analysis) technology. In fiscal 2016, we plan to introduce new features and enhancements to the AXP and MXP devices to support our upcoming clinical trial initiatives and the expansion of platform applications.

Collectively, research and development expenses were \$5,939 and \$3,468 for the years ended June 30, 2015 and June 30, 2014, respectively. Research and development activities include expenses related to engineering and to regulatory, scientific and clinical affairs.

## **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 may develop 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 CFR 820) and the applicable rules of other governmental agencies.

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 European Union ("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 board and institutional stem cell committee approvals. Both the U.S. and E.U. regulatory agencies are experienced in dealing with and accepting Indian clinical trial data. The FDA issued a Final Rule in October 2008 revising §21 CFR 312.120(a) and further clarified its position in a Guidance Document in March 2012, wherein the FDA confirmed that it will accept as support for an Investigational New Drug (“IND”) or application for marketing approval, a well-designed and well-conducted foreign clinical study not conducted under a U.S. IND, provided that the study is conducted in accordance with GCP and the sponsor is able to validate the data from the study through an onsite inspection by the FDA if considered necessary. GCP necessitates review and approval by an Independent Ethics Committee (“IEC”) before initiation of a study, continuing review of an ongoing study by an IEC, 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: 2012 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 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 (prior to, or not later than 30 days after, 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, as such, have been deemed by the FDA to be “exempt” from FDA approval or clearance processes prior to commercialization. While pre-marketing approval from the FDA is not mandatory for Class I medical devices, the manufacturer’s compliance with QSR is nevertheless a requirement.

### *Class II Devices*

Several of our products, including the BioArchive and the AXP are categorized as Class II medical devices. A relatively short and simple process of premarket notification, known as a 510(k) submission, is required to secure marketing approval from the FDA for Class II medical devices. Data submitted as part of a 510(k) approval process must demonstrate to the FDA'S satisfaction that the performance of the device is "substantially equivalent" to the performance of an alternative device that has already received a 510(k) approval (a so-called "predicate" device). Once 510(k) approval 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 SurgWerks<sup>TM</sup>-CLI and VXP System, the FDA approval process is more stringent 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. Pre-clinical testing must be performed by laboratories that comply with the FDA's regulations governing GLP. 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 GLP compliant facilities in Emeryville, CA and Gurgaon, India to conduct pre-clinical studies.

Human clinical trials involve the treatment of patients with the medical device, or a biologic produced by the medical device, by a qualified medical investigator, after approval of the intended protocol by an Institutional Review Board ("IRB"). Medical device trials conducted inside the U.S. are subject to FDA preapproval under an IDE application (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 outlined in 21 C.F.R. Part 312.120. The FDA, the clinical trial sponsor, the investigators, the IRB or the Data Safety Monitoring Board may suspend clinical trials at any time if any one of them believes that study participants are being exposed to an unacceptable health risk.

For 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 may 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.

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 audited 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 (“ACA”) 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, the 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 the CE-Mark. 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 to the MDD. Marketing authorization for our products is subject to revocation by the applicable governmental agency or notified body under the EU, which are subject to annual audit confirmations with respect to our quality system.

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.

### **Patents and Proprietary Rights**

We believe that patent protection is important for our products and our current and proposed business. We have over 30 issued patents globally.

Patent positions of regenerative medicine companies, such as ours, are uncertain and involve complex and evolving legal and factual questions. The coverage sought in a patent application can be denied or significantly reduced either before or after the patent is issued. Consequently, there can be no assurance that any of our pending patent applications will result in an issued patent. There is also no assurance that any existing or future patent will provide significant protection or commercial advantage, or whether any existing or future patent will be circumvented by a more basic patent, thus requiring us to obtain a license to produce and sell the product. 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.

### **Certain Agreements**

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 the existing agreement with them in the areas of cord blood banking services, point-of-care technology sales and support services, bone marrow transplant technology and laboratory services, and clinical/patient management of clinical trials for our internally developed therapeutics and third party marketed clinical research organization services. 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 will 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. Additionally, effective December 31, 2013 we entered into the Fourth Amended and Restated Technology License and Escrow Agreement to delete or reduce the financial covenants that we must meet in order to avoid an event of default to one financial covenant, maintain a cash balance and short-term investments net of debt or borrowed funds of not less than \$2,000 at any month end. We were in compliance with this covenant at June 30, 2015.

In June 2010, we entered into a License and Escrow Agreement with CBR as a method to provide assurances to CBR of continuity of product delivery and manufacturing for CBR's business, and to alleviate concerns about long term supply risk. We are the sole provider to CBR of devices and disposables used in the processing of cord blood samples in CBR's operations. Under the agreement, we granted CBR a non-exclusive, royalty-free perpetual license to certain intellectual property necessary for the potential manufacture and supply of AXP devices and certain AXP disposables. The license is for the sole and limited purpose of manufacturing and supplying the AXP and related disposables for use by CBR. The licensed intellectual property will be maintained in escrow and will be released to and used by CBR if and only if we default under the agreement.



***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 right includes the right to distribute AXP Disposable Blood Processing Sets and use rights to 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 and BioParadox entered into a License and Distribution Agreement. 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 will depend on the satisfaction by BioParadox of certain milestones, or the payment of extension fees. If certain delivery or financial metrics are not maintained, the agreement requires the Company to place in escrow the detailed instructions for manufacturing the products. BioParadox will have the right to manufacture the product for the cardiac field for the term of the agreement in the event of a default by the Company or if certain on-time delivery metrics or supply requirements are not met.

***Celling Technologies, LLC (“Celling”)***

In September 2008, we signed a distribution agreement for our MXP and Res-Q 60 BMC product lines with Celling. The distribution rights are for the field of use in orthopedic intraoperative or point-of-care applications. The agreement provides Celling with an initial two-year period of exclusive distribution rights in the U.S. and non-exclusive distribution rights throughout the rest of the world, excluding Central and South America, Russia and certain Eastern European countries. The exclusivity period and field of use may be extended under certain circumstances. The parties amended the agreement in July 2009 to provide shared funding for clinical studies to demonstrate the clinical effectiveness of the products in orthopedic applications. The parties amended the agreement in January 2012. The revised distribution rights are world-wide, non-exclusive within field of use for the MXP and exclusive within field of use in the United States and non-exclusive in Mexico for the Res-Q. On June 30, 2015 we gave a 90 day notice of our refusal to allow any further automatic extensions after September 30, 2015, in effect terminating the agreement March 31, 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 containers developed by us and NYBC for the processing of hematopoietic

stem cells sourced from placental cord blood (“PCB”). The system is designed to simplify and streamline the harvesting of stem cells from umbilical cord blood and the manual concentration, cryopreservation (freezing) and transfusion of the PCB stem cells while maintaining the highest stem cell population and viability from each PCB donation. In May 1999, we and Pall Medical amended the original agreement, and we regained the rights to distribute the bag sets outside North America and Europe under our 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.

## **Employees**

As of June 30, 2015, we had 111 employees, 73 of whom were employed in the U.S. and 38 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 represented by a collective bargaining agreement, nor have we experienced any work stoppage.

## **Foreign Sales and Operations**

See footnote 7 of our Notes to Consolidated Financial Statements for information on our sales and operations outside of the U.S.

## **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 our website, [www.cescatherapeutics.com](http://www.cescatherapeutics.com). The information on our website is not incorporated into, and is not part of, this annual report.

## **ITEM 1A. RISK FACTORS**

An investment in Cesca Therapeutics Inc. 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 facing us. 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 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 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 our products. In this regard, we have renewed and expanded our 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 of this agreement could jeopardize or delay development of our products.

*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 be pursuing.

*We May Seek To Enter Into Collaborative Arrangements To Develop and Commercialize Our 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 our current or future collaborative arrangements will be successful.

*A Significant Portion of our Revenue is Derived from Customers Outside the United States. We may Lose Revenues, Market Share, and Profits due to Exchange Rate Fluctuations, Political and Economic Changes Related to our Foreign Business.* In the year ended June 30, 2015, sales to customers outside the U.S. comprised approximately 47% of our revenues. This compares to 57% in fiscal 2014. 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 our 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 our Financial Condition and Results of Operations.* Revenues from three significant distributors/customers comprised 45% of our revenues for the year ended June 30, 2015. The loss of a large end user customer or distributor may decrease our revenues.

*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 the employees, consultants, sales agents or distributors of our Company 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 Receive a Grant from the California Institute for Regenerative Medicine (“CIRM”).* Under the terms of the August 31, 2015 financing, our ability to initiate the CLIRST III clinical trial and to access the \$9.5 million in gross proceeds from the second closing of the Debentures is dependent on our obtaining notice of a CIRM grant in the amount of \$10.0 million subject to adjustment for approved Medicare reimbursements. In the event that we do not obtain CIRM approval of a grant in the amount of \$10.0 million, we will be required to seek other alternative methods of financing in order to obtain funds for working capital and to initiate the CLIRST III clinical trial.

*The Debentures Contain Certain Restrictive Covenants that May Affect our Operations.* Under the terms of the Debentures, we are restricted from taking certain actions including incurring additional debt not in the ordinary course of business over a certain dollar threshold without the Debenture holders’ approval. This restriction may adversely affect our operations since the interests of the Debenture holders may be different from the interests of the Company.

*We may not Achieve the Benefits Expected from our Recent Restructuring.* In September 2015, we effected a strategic reorganization which resulted in the elimination of approximately 15 positions. Non-recurring severance costs of approximately \$245 are expected to be recorded in the first quarter of fiscal 2016. This action, combined with open positions that have been eliminated, is expected to reduce annual operating costs by approximately \$3.3 million. The timing of events, our anticipated reduction in costs and better alignment between our workforce and business, could differ materially from our estimates. This reduction in force and any future workforce and expense reductions may have an adverse impact on our clinical and commercial activities.

*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.

*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 our 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.

*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. 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. Other countries, such

as China, have enacted or may enact laws or regulations similar to RoHS. 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. Additionally, if we were found to be non-compliant with any such rule or regulation, we could be subject to fines, penalties and/or restrictions imposed by government agencies that could adversely affect our operating results.

*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.* The Company obtains certain disposable products and custom components from a limited number of suppliers. If the supplier raises the price or discontinues production, the Company 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 Certain Financial Covenants could Decrease our AXP Revenues.* Under certain license and escrow agreements, if we fail to meet certain financial covenants, other companies 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.

*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. Further, through the TotipotentRX merger, we have research, clinical and manufacturing operations in Emeryville, CA and Gurgaon, India. 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 regularly 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 the Company to delays in production while it corrects deficiencies found by the FDA, the State of California, or the Company's 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.

*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.* As a result of the merger, 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.

*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 for \$3,000 and a general liability policy that includes product liability coverage of \$3,000 per occurrence and \$3,000 per year in the aggregate. 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, does process 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.

***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 year ended June 30, 2015 and 2014, we had a net loss of \$14,852 and \$8,631 respectively and an accumulated deficit at June 30, 2015, of \$137,674. 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.

*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 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, such dilution may be significant based upon the size of such financing.

*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 based upon a fair value approach. 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 reduce our enterprise fair value below its 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 of goodwill, 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, 2015 we have a goodwill balance of \$13,195 and a net intangible assets balance of \$21,295, out of total assets of \$50,757. 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.

*A Material Weakness in our Internal Control Over Financial Reporting has been Identified and our Business and Stock Price may be Adversely Affected if We do not Adequately Address this Weakness or if We have other Material Weaknesses or Significant Deficiencies in our Internal Control Over Financial Reporting.* Subsequent to the completion of the audit of our consolidated financial statements for the year ended June 30, 2014, it was determined that a deficiency exists in our governance practices related to the timeliness and consistency of communications between the audit committee, management and the auditors. This deficiency was concluded to represent a material weakness in our internal control over financial reporting. This issue was discussed by the audit committee and we have developed and are implementing plans to remediate this material weakness, including the engagement of an independent outside counsel who reviewed our corporate governance procedures and recommended appropriate changes and the formation of a Disclosure Committee. This material weakness in our internal control, or any other material weakness or significant deficiencies in our internal control over financial reporting, could adversely affect our stock price and value.



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

*You May Experience Substantial Dilution Upon the Exercise of the Series B Warrants.* In connection with the August 31, 2015 financing, we issued Series B Warrants entitling the holders to purchase up to 12,132,353 shares of Common Stock at an exercise price of \$0.68. The number of Series B Warrants which may be exercised is subject to vesting in proportion to the amount of funds received by us under the Debentures. The Series B Warrants are exercisable upon the earlier of shareholder approval or the six month anniversary of the issuance date. Following shareholder approval, the Series B Warrants may be exercised on a cashless basis at market price at the time of exercise if it is lower than the conversion price, \$0.68, subject to a floor \$0.10 per share. In the event that our market price is substantially less than the conversion price, the cashless exercise of the Series B Warrants will result in substantial dilution to the other shareholders.

*The Debentures are Secured by All of our Assets.* The Debentures issued by us in our recent financing are secured by all of our assets. If we were to default under the Debentures, we could lose rights to all of our assets including our equipment, patents, trademarks and operations in India.

*If the Price of our Common Stock Does Not Meet the Requirements of the NASDAQ Capital Market Stock Exchange, 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. The bid price of our stock has been below \$1.00 for a period of greater than 30 consecutive business days. As such, on March 30, 2015, we received a notice from the NASDAQ Listing Qualifications Department informing us that we must regain compliance with listing requirements or face delisting. In order to regain compliance, at any time before September 28, 2015, the bid price of our common stock must close at a price of at least \$1.00 per share for a minimum of 10 consecutive business days. The notice states that NASDAQ will provide us with written notification when our common stock has regained compliance.

If compliance cannot be demonstrated by September 28, 2015, then NASDAQ will decide whether we meet all applicable standards for initial listing on the Capital Market (except the bid price requirement) based on our most recent public filings and market information. The notice states that, if we meet these standards, then we are eligible to have an additional 180 calendar day compliance period. NASDAQ can deny the extension if it does not appear to them that it is possible for us to cure the deficiency. 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.

*Certain Principal Stockholders Have Significant Influence Over Us.* As a result of the merger with TotipotentRX, Messrs. Harris and Sivilotti, our President and a key employee, respectively, own approximately 23% of our current outstanding common stock. As a result, they will be able to exert a significant degree of influence over our

management and affairs and over matters requiring stockholder approval, including the election of directors, any merger, consolidation or sale of all or substantially all of the combined company's assets, and any other significant corporate transaction. Their interests may not always coincide with those of our other stockholders.

*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**

The Company leases a facility with approximately 28,000 square feet of space located in Rancho Cordova, California. Approximately 50% of the facility is devoted to warehouse space and manufacturing of products. The other 50% is comprised of 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 expires April 30, 2020.

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.

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.

Effective June 1, 2015, the Company, 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 the Company and Celling asserted against Harvest. In the settlement agreement, the Company 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.

**ITEM 4. MINE SAFETY DISCLOSURES**

Not applicable.

**PART II****ITEM MARKET FOR THE REGISTRANT'S COMMON EQUITY,RELATED STOCKHOLDER  
5. MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES.**

The Company's 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 the Company's common stock for the past two fiscal years as reported on the NASDAQ Capital Market.

Fiscal 2015	High	Low	Fiscal 2014	High	Low
First Quarter (Sep. 30)	\$1.42	\$1.17	First Quarter (Sep. 30)	\$1.52	\$1.01
Second Quarter (Dec. 31)	\$1.29	\$1.00	Second Quarter (Dec. 31)	\$1.12	\$0.72
Third Quarter (Mar. 31)	\$1.10	\$0.79	Third Quarter (Mar. 31)	\$2.82	\$1.05
Fourth Quarter (June 30)	\$0.99	\$0.76	Fourth Quarter (June 30)	\$2.06	\$1.39

The Company has not paid cash dividends on its common stock and does not intend to pay a cash dividend in the foreseeable future. There were approximately 226 stockholders of record on June 30, 2015 (not including street name holders).

**ITEM 6. SELECTED FINANCIAL DATA**

Not applicable for Smaller Reporting Companies.

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

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

Certain statements contained in this section and other parts of this 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 are focused on the research, development, and commercialization of autologous cell-based therapies that advance the practice of regenerative medicine. We are a leader in developing and manufacturing automated blood and bone marrow processing systems that enable the separation, processing and preservation of cell and tissue therapy products. We serve patients, physicians and partners in three target markets:

Cellular Therapeutics  
Medical/Diagnostic Device Development and Commercialization  
Cell Manufacturing and Banking

We were founded in 1986 as ThermoGenesis Corp. as a Delaware corporation. On February 18, 2014, TotipotentRX Corporation, or TotipotentRX, merged with and into ThermoGenesis Corp. In connection with the merger, we changed our name from ThermoGenesis Corp. to Cesca Therapeutics Inc. and remained a corporation organized under the laws of the State of Delaware. As a result of the merger, we became a fully integrated regenerative medicine company with the ability and expertise to research, develop and commercialize the devices, disposables and protocols necessary to facilitate the delivery of cell therapies at the point of care.

TotipotentRX was a privately held biomedical technology company specializing in human clinical trials in the field of regenerative medicine and the exclusive provider of cell-based therapies to the Fortis Healthcare System. TotipotentRX had two wholly-owned subsidiaries, TotipotentRX Cell Therapy Pvt. Ltd. (TotiRX India) and TotipotentSC Product Pvt. Ltd. (TotiSC India). The two subsidiaries, now our wholly owned subsidiaries, are located in Gurgaon, a suburb of New Delhi, India. The operations of TotipotentRX have been included in our consolidated results as of February 18, 2014.

Our business strategy includes:

• A focus on 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: Cesca delivers all the hardware, software and disposable components necessary for the aspiration and processing of bone marrow and the separation and concentration of 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: Cesca's protocols are potentially safer because the donor and the recipient of the stem cell preparation is the same individual.

• A highly resource efficient operating model: we leverage our India based clinical research organization embedded within the Fortis network of hospitals for highly cost-effective approach to feasibility studies and early stage clinical trials.

• Multiple shots on goal: we have 9 protocols at various stages of clinical development.

• Patent protection: we have over 30 issued patents with several more applications in the pipeline.

## Stem Cell Therapies

We are currently focusing our clinical therapy efforts in three areas:

**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 and VXP System for the treatment of patients with late-stage (Rutherford 5), no option critical limb ischemia. The CLIRST III pivotal trial will involve 204 subjects at up to 60 hospital sites in the United States with additional enrollment to be conducted outside the U.S. up to the anticipated total subject enrollment of 224. The study will be a 3:1 randomized, double blinded, placebo-controlled trial, having an adaptive interim analysis for repowering (if necessary), and with a primary endpoint of major amputation-free survival.

CLI is the last progressive phase of peripheral vascular disease, where the leg is so deprived of blood flow and oxygen, that it has visible signs of gangrenous ulceration. The Company has supported or completed two prior feasibility studies in CLI, one delivering a Cesca platform prepared autologous bone marrow 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. The results of these studies as presented to the U.S. FDA in the IDE Application were as follows:

Intramuscular Delivery : an 82.4% major limb salvage at 12 months on a Per Protocol Basis (70% major limb salvage on an Intent-to-Treat assessment); statistically significant improvement in rest pain, walking distance improvement, limb blood perfusion, and vasculogenesis.

Intra-arterial Delivery : an 64% major limb salvage at 12 months on an Intent-to-Treat basis) and statistically significant improvement in blood perfusion.

**Acute Myocardial Infarction (AMI)** – This therapy is designed to treat patients who have suffered an acute ST-elevated myocardial infarction (STEMI), a particular and most threatening type of heart attack. Specifically, our target patient population is individuals who have not favorably responded to reperfusion therapy (stenting, balloon angioplasty, or thrombolysis), and remain at risk for high morbidity and mortality. The SurgWerks-AMI treatment is designed to minimize adverse remodeling of the heart from dysfunctional blood pumping action by minimizing the dysfunctional enlarging of the heart. Typically, the entire 4-step bedside treatment takes less than 90 minutes to complete in a single procedure in the heart catheterization laboratory.

**Bone Marrow Transplant (BMT)** – This multi-faceted program is characterized by two sub-programs, the CellWerks-BMT proprietary device system and the Fortis –TotipotentRX BMT service program. The CellWerks-BMT device platform is designed to satisfy an insufficiently met need in pediatric BMT therapy. Our BMT service initiative, a scalable collaboration with Fortis Memorial Research Institute, is focused on the critical, insufficiently met need for populations lacking access to qualified matched donors. Our program optimizes the laboratory processes and makes this life saving treatment using laboratory technology accessible to hospitals and patients in large developing regions.

## Our Products

The **SurgWerks Platform and VXP System**, a proprietary stem cell therapy point-of-care disposable kit and automated bone marrow cell isolation system for treating vascular and orthopedic indications that integrate the following indication specific devices with optimized protocols to ensure biological dose, purity and viability:

- Cell harvesting
- Cell processing and selection
- Cell diagnostics
- Cell delivery

The in vivo safety and effectiveness for this platform has not been established. It is available under clinical trial experimental use only for Critical Limb Ischemia in the United States.

The **MarrowXpress® or MXP System**, a derivative product of the AXP and its accompanying disposable bag set, isolates and concentrates stem cells from bone marrow. The product is an automated, closed, sterile system that volume-reduces blood from bone marrow to a user-defined volume in 30 minutes, while retaining over 90% of the

MNCs, a clinically important cell fraction. Self-powered and microprocessor-controlled, the MXP System contains flow control optical sensors that achieve precise separation. We have received the CE-Mark, enabling commercial sales in Europe, and we received authorization from the FDA to begin marketing the MXP as a Class I device in the U.S. for the preparation of cell concentrate from bone marrow. However, the safety and effectiveness of this device for in vivo use has not been established. MXP Platform is an integrated component of The SurgWerks Kit and performs the cell processing and selection.

The **AXP System** is a medical device with an accompanying disposable bag set that isolates and retrieves stem cells from umbilical cord blood. The AXP System provides cord blood banks with an automated method to separate and capture adult stem cells which reduces the overall processing and labor costs with a reduced risk of contamination under cGMP conditions. The AXP System retains over 97% of the mononuclear cells (MNCs). High MNC recovery has clinical importance to patient transplant survival rates. Self-powered and microprocessor-controlled, the AXP device contains flow control optical sensors that achieve precise separation of the cord blood fractions.



The **BioArchive System** is a robotic cryogenic medical device used to cryopreserve and archive stem cells for future transplant and treatment. Launched in fiscal 1998, our BioArchive Systems have been purchased by over 110 umbilical cord blood banks in over 35 countries to archive, cryopreserve and store stem cell preparations extracted from human placentas and umbilical cords for future use.

**Manual Disposables** include our non-AXP bag sets used for processing and freezing cord blood. They can be stored in the automated BioArchive device or in conventional dewars.

## **Results of Operations**

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

### ***Results of Operations for the Fiscal Year Ended June 30, 2015 versus the Fiscal Year Ended June 30, 2014***

#### ***Net Revenues***

Net revenues for 2015 were \$16,042 compared to \$15,987 for 2014, an increase of \$55. Revenues from AXP disposables increased primarily due to an increase in direct shipments to one of our end-user customers who used to purchase from GE. This increase was offset by a decrease in revenues on our BioArchive devices as we shipped fewer units in fiscal 2015 and we deferred revenue until the completion of installation services on four devices based on the payment terms for this particular customer. Revenues from the TotipotentRX subsidiaries were \$625 in fiscal 2015 versus \$351 in fiscal 2014.

The following represents the Company's revenues by product platform for the years ended:

	June 30, 2015	June 30, 2014
AXP	\$6,612	\$6,143
BioArchive	4,241	4,776
Manual Disposables	1,810	1,706
Bone Marrow	2,621	2,542
Other	758	820
	\$16,042	\$15,987

***Gross Profit***

Gross profit was \$4,749 or 30% of revenues for 2015 compared to \$5,886 or 37% of revenues for 2014. Our gross profit decreased primarily due to an increase in manufacturing overhead costs and a higher burden on volume of products sold.

***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 \$2,974 for 2015, compared to \$2,968 for 2014, an increase of \$6. Sales and marketing expenses increased due to additional marketing personnel added for the products and services associated with our stem cell therapies. These increases were largely offset by a reduction in severance payments accrued in the prior year.

### ***Research and Development Expenses***

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

Research and development expenses for 2015, were \$5,939 compared to \$3,468 for 2014, an increase of \$2,471 or 71%. The increase is primarily due to costs associated with developing our clinical therapies programs. Subsequent to the merger in fiscal 2014 and continuing through the first half of fiscal 2015 we increased the personnel in our clinical therapies function to support the continued development and improvement of our therapeutics products and to prepare our IDE application and amendment to the FDA for our forthcoming pivotal trial for our Critical Limb Ischemia Stem Cell Therapy (“CLIRST III”). We anticipate R&D costs to continue to increase when we initiate the CLIRST III.

### ***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 \$10,695 for 2015, compared to \$8,490 for 2014, an increase of \$2,205 or 26%. The increase is primarily due to an increase in legal fees of \$2,000 mainly associated with patent litigation, an increase in professional and legal fees of \$450 to analyze and begin remediation on our material weakness in governance practices and an increase in employee severance costs of \$448. These increases were offset by a decline in costs associated with the merger with Totipotent RX of \$1,715.

### ***Deferred Income Tax Benefit***

Our deferred income tax benefit was \$0 for 2015, compared to \$403 for 2014. The decrease was due to certain intangible assets and the related deferred tax liabilities acquired in the merger with TotipotentRX in 2014. The recognition of a deferred income tax benefit resulted from netting the deferred tax liabilities against previously generated, but fully reserved, deferred tax assets.

### **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.

	2015	2014
Loss from operations	\$(14,859)	\$(9,040)
Add (subtract):		
Depreciation and amortization	1,351	993
Stock-based compensation expense	1,247	679
Impairment of intangible asset	117	--
Gain on sale of product lines	--	--
Adjusted EBITDA	\$(12,144)	\$(7,368)

***Adjusted EBITDA***

Our adjusted EBITDA loss was \$12,144 for 2015, compared to \$7,368 for 2014. The adjusted EBITDA loss increased compared to the prior year due to our investments to develop and advance our clinical program including the preparation of our IDE application and amendment to the FDA and legal fees associated with patent litigation.

## **Liquidity and Capital Resources**

At June 30, 2015, we had cash and cash equivalents of \$3,357 and working capital of \$5,305. This compared to cash and cash equivalents of \$14,811 and working capital of \$18,947 at June 30, 2014. We have primarily financed operations through private and public placement of equity securities and the sale of certain non-core assets.

Our net cash used in operating activities for the year ended June 30, 2015 was \$10,649 compared to \$7,836 for the year end June 30, 2014. The increase is primarily due to costs to develop and advance our clinical program including the preparation of our IDE application and amendment to the FDA and legal fees associated with patent litigation.

Based on the initial \$5,500 financing that we received in August 2015, our cash balance, historical trends, the restructuring that occurred in September 2015, expected outflows for our clinical trial programs and projections for revenues, we believe our current funds are sufficient to provide for our projected needs to maintain operations and working capital requirements for at least the next 12 months. We are dependent on receiving the \$9,500 in funds from the second closing of the August financing in order to initiate our CLIRST III pivotal trial. If we do not receive the \$9,500 from the second closing we will need additional funding to initiate the CLIRST III pivotal trial and if we are unable to generate sufficient revenue or obtain additional funds for our working capital needs, we may have to further scale-back operations.

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 assure 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 its current products. In fiscal 2014, we spent \$402 primarily for tooling at a contract manufacturer and equipment to be used in our clinical trials. In fiscal 2015, we spent \$587 primarily for equipment to be used in our clinical trials.

At June 30, 2015, we had four distributors that accounted for 28%, 14%, 12% and 10% of accounts receivable. At June 30, 2014, we had four distributors that accounted for 16%, 16%, 14% and 10% of accounts receivable.

Revenues from a customer totaled \$2,549 or 16% and \$1,849 or 12% for the years ended June 30, 2015 and 2014. Revenues from one distributor totaled \$2,358 or 15% and \$2,102 or 13% of net revenues for the years ended June 30, 2015 and 2014, respectively. Revenues from another distributor totaled \$2,303 or 14% and \$2,288 or 14% of net

revenues for the years ended June 30, 2015 and 2014, respectively.

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.

On August 31, 2015, we sold senior secured convertible debentures of \$15,000 (“Debentures”), Series A warrants to purchase up to 22,058,823 shares of our common stock at an exercise price equal to \$0.68 per share for a period of five and one-half years (“Series A warrants”) and Series B warrants to purchase up to 12,132,353 shares of our common stock at an exercise price equal to \$0.68 per share for a period of eighteen months (“Series B warrants”). At the initial closing on August 31, 2015, we received gross proceeds of \$5,500. The remaining \$9,500 of gross proceeds will be deposited in our deposit control account and be released after receiving (i) stockholder approval of certain share issuances relating to the financing to meet Nasdaq listing requirements, (ii) stockholder approval of an amendment to our certificate of incorporation increasing its authorized number of shares of common stock to 350,000,000 and (iii) approval from California Institute for Regenerative Medicine (“CIRM”) of a grant in the amount of \$10,000, for the U.S. pivotal clinical trial in critical limb ischemia.

The debentures bear no interest, may be convertible into shares of our common stock at a conversion price of \$0.68 per share and are secured by all of our assets. The Series A and B warrants are subject to vesting based upon the amount of funds actually received by us in the sale of the senior secured convertible debentures and are exercisable upon the earlier of the approval of the transaction by our stockholders and the 6 month anniversary of the issuance date. Following shareholder approval, the Series B warrants may be exercised on a cashless basis at market price at the time of exercise if it is lower than the conversion price subject to a floor of \$0.10 per share.

On June 18, 2014, we completed a public offering of 7,530,000 shares of common stock at \$1.50 per share, together with warrants to purchase up to an aggregate of 2,259,000 shares of common stock. The warrants may be exercised by the holders at a price of \$1.55 per share immediately thru June 18, 2019. Net proceeds after expenses from the offering were approximately \$10.1 million after underwriting discount and estimated offering expenses.

On January 30, 2014, we completed a private placement of the sale of 3,336,800 shares of our common stock at \$2.00 per share, together with warrants to purchase up to an aggregate of 1,668,400 shares of common stock. The warrants may be exercised by the holders at a price of \$2.81 per share starting July 30, 2014 continuing through January 29, 2019. Net proceeds after expenses from the offering were approximately \$5.9 million.

### ***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. The Company bases its 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*, we can opt to perform a qualitative assessment, if we determine that the fair value of a reporting unit is more likely than not (i.e., a likelihood of more than 50 percent) to be less than its carrying amount, the two step impairment test will be performed. In the first step, we compare the fair value of our sole reporting unit to its carrying value. If the fair value of the reporting unit exceeds the carrying value, goodwill is not considered impaired and we are not required to perform further testing. If the fair value of the reporting unit does not exceed the carrying value, then we must perform the second step of the impairment test in order to determine the implied fair value of the goodwill. If the carrying value of goodwill exceeds its implied fair value, then we would record an impairment loss equal to the difference. Recoverability of finite lived intangible assets is measured by comparison of the carrying amount of the asset to the future undiscounted cash flows the asset is expected to generate.



### ***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 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 the Company, 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 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.

For licensing agreements pursuant to which we receive up-front licensing fees for products or technologies that will be provided by us over the term of the arrangements, we defer the up-front fees and recognizes the fees as revenue on a straight-line method over the term of the respective license. For license agreements that require no continuing performance on our part, license fee revenue is recognized immediately upon grant of the license.

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. The Company's 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.

### ***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 the Company operates. 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 the Company believes 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, the Company applies the change based on the years in which the temporary differences are expected to reverse. As the Company operates 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. The Company records 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 the Company's 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 the Company's pre-existing deferred tax assets.

### ***Inventory Valuation***

The Company states inventories at lower of cost or market value determined on a first-in, first-out basis. The Company provides inventory allowances 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, the Company provides 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 the Company's 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 the Company 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***

The Company provides for the estimated cost of product warranties at the time revenue is recognized. While the Company engages in extensive product quality programs and processes, including actively monitoring and evaluating the quality of its component suppliers, the Company's 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 the Company's estimates, revisions to the estimated warranty liability could have a material impact on the Company's financial position, cash flows or results of operations.

**Off Balance Sheet Arrangements**

The Company has 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**

	Page Number
Reports of Independent Registered Public Accounting Firms	39
Consolidated Balance Sheets at June 30, 2015 and 2014	41
Consolidated Statements of Operations and Comprehensive Loss for the years ended June 30, 2015 and 2014	42
Consolidated Statements of Stockholders' Equity for the years ended June 30, 2015 and 2014	43
Consolidated Statements of Cash Flows for the years ended June 30, 2015 and 2014	44
Notes to Consolidated Financial Statements	45

**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 sheet of Cesca Therapeutics Inc. and Subsidiaries (the “Company”) as of June 30, 2015, and the related consolidated statements of operations and comprehensive loss, stockholders’ equity and cash flows for the year then ended. These consolidated financial statements are the responsibility of the Company’s management. Our responsibility is to express an opinion on these consolidated financial statements based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. Our audit included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company’s internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audit provides a reasonable basis for our opinion.

In our opinion, the consolidated 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, 2015 and the consolidated results of its operations and its cash flows for the year then ended in conformity with accounting principles generally accepted in the United States of America.

/s/ Marcum LLP

New York, NY

September 17, 2015

39

---

**Report of Independent Registered Public Accounting Firm**

The Board of Directors and Stockholders of Cesca Therapeutics Inc.

We have audited the accompanying consolidated balance sheet of Cesca Therapeutics Inc. as of June 30, 2014 and the related consolidated statements of operations and comprehensive loss, stockholders' equity, and cash flows for the year ended June 30, 2014. 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 audit.

We conducted our audit 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. We were not engaged to perform an audit of the Company's internal control over financial reporting. Our audit included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. We believe that our audit provides 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. at June 30, 2014 and the consolidated results of its operations and its cash flows for the year ended June 30, 2014, in conformity with U.S. generally accepted accounting principles.

/s/ Ernst & Young LLP

Sacramento, California

September 29, 2014





**Cesca Therapeutics Inc.****Consolidated Balance Sheets**

(in thousands, except share and per share amounts)

	June 30, 2015	June 30, 2014
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$3,357	\$14,811
Accounts receivable, net of allowance for doubtful accounts of \$46 (\$47 at June 30, 2014)	5,133	4,693
Inventories	4,598	5,606
Prepaid expenses and other current assets	163	217
Total current assets	13,251	25,327
Equipment at cost less accumulated depreciation	2,937	2,298
Goodwill	13,195	13,254
Intangible assets, net	21,295	21,928
Other assets	79	81
Total assets	\$50,757	\$62,888
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable	\$5,079	\$3,590
Accrued payroll and related expenses	705	599
Deferred revenue	635	638
Other current liabilities	1,527	1,553
Total current liabilities	7,946	6,380
Noncurrent deferred tax liability	7,641	7,641
Other noncurrent liabilities	268	169
Total liabilities	15,855	14,190
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, \$0.001 par value; 2,000,000 shares authorized, none issued and outstanding at June 30, 2015 and 2014	--	--
Common stock, \$0.001 par value; 150,000,000 shares authorized; 40,501,730 issued and outstanding (40,200,529 at June 30, 2014)	41	40
Paid in capital in excess of par	172,540	171,422
Accumulated deficit	(137,674)	(122,822)
Accumulated other comprehensive (loss) income	(5 )	58

Total stockholders' equity	34,902	48,698
Total liabilities and stockholders' equity	\$50,757	\$62,888

See accompanying notes.

**Cesca Therapeutics Inc.****Consolidated Statements of Operations and Comprehensive loss**

(in thousands, except share and per share amounts)

Years ended June 30

	2015	2014
Net revenues	\$16,042	\$15,987
Cost of revenues	11,293	10,101
Gross profit	4,749	5,886
Expenses:		
Sales and marketing	2,974	2,968
Research and development	5,939	3,468
General and administrative	10,695	8,490
Total operating expenses	19,608	14,926
Loss from operations	(14,859 )	(9,040 )
Other income, net	7	6
Loss before income tax benefits	(14,852 )	(9,034 )
Deferred income tax benefit	--	403
Net loss	\$(14,852 )	\$(8,631 )
Net loss	\$(14,852 )	\$(8,631 )
Other comprehensive income:		
Foreign currency translation adjustments	(63 )	58
Comprehensive loss	\$(14,915 )	\$(8,573 )
Per share data:		
Basic and diluted net loss per common share	\$(0.37 )	\$(0.36 )
Weighted average common shares outstanding – Basic and diluted	40,351,946	24,234,348

See accompanying notes.

**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 July 1, 2013	16,557,627	\$ 16	\$127,493	\$ (114,191 )	\$ --	\$ 13,318
Issuance of common shares and compensation related to restricted common stock awards, net of stock surrenders	140,591	1	333	--	--	334
Stock-based compensation expense	--	--	209	--	--	209
Common stock issued to directors in lieu of cash compensation	52,582	--	68	--	--	68
Issuance of common shares and warrants in public offering	7,530,000	8	10,053	--	--	10,061
Issuance of common shares and warrants in private placement	3,336,800	3	5,940	--	--	5,943
Issuance of common shares and warrants pursuant to acquisition	12,490,841	12	27,118	--	--	27,130
Issuance of common shares for repayment of related party notes payable	82,713	--	187	--	--	187
Issuance of common shares for exercise of options	9,375	--	21	--	--	21
Foreign currency translation	--	--	--	--	58	58
Net loss	--	--	--	(8,631 )	--	(8,631 )
Balance at June 30, 2014	40,200,529	40	171,422	(122,822 )	58	48,698
Issuance of common shares and compensation related to restricted	256,013	1	413	--	--	414

common stock awards, net of stock  
surrenders

Stock-based compensation expense	--	--	660	--	--	660
Common stock issued to directors in lieu of cash compensation	45,188	--	45	--	--	45
Foreign currency translation	--	--	--	--	(63 )	(63 )
Net loss	--	--	--	(14,852 )	--	(14,852 )
Balance at June 30, 2015	40,501,730	\$ 41	\$172,540	\$ (137,674 )	\$ (5 )	\$ 34,902

See accompanying notes.

**Cesca Therapeutics Inc.****Consolidated Statements of Cash Flows**

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

	Years ended June 30,	
	2015	2014
Cash flows from operating activities:		
Net loss	\$(14,852)	\$(8,631 )
Adjustments to reconcile net loss to net cash used in operating activities:		
Deferred income tax benefit	--	(403 )
Depreciation and amortization	1,351	993
Stock-based compensation expense	1,247	679
Impairment of intangible asset	117	--
Net changes in operating assets and liabilities:		
Accounts receivable, net	(459 )	515
Inventories	416	(1,279 )
Prepaid expenses and other current assets	53	64
Other assets	1	(9 )
Accounts payable	1,410	(295 )
Accrued payroll and related expenses	105	96
Deferred revenue	43	282
Other liabilities	(81 )	152
Net cash (used in) operating activities	(10,649)	(7,836 )
Cash flows from investing activities:		
Capital expenditures	(587 )	(402 )
Cash acquired in acquisition	--	351
Net cash (used in) investing activities	(587 )	(51 )
Cash flows from financing activities:		
Payments on capital lease obligations	(60 )	--
Repayment of related party notes payable	--	(150 )
Repurchase of common stock	(129 )	(68 )
Exercise of stock options	--	21
Issuance of common stock	--	16,004
Net cash (used in) provided by financing activities	(189 )	15,807
Effects of foreign currency rate changes on cash and cash equivalents	(29 )	7
Net (decrease)increase in cash and cash equivalents	(11,454)	7,927
Cash and cash equivalents at beginning of year	14,811	6,884
Cash and cash equivalents at end of year	\$3,357	\$14,811
Supplemental non-cash financing and investing information:		
Transfer of inventories to equipment	\$539	\$99
Equipment acquired by capital lease	\$208	\$--

Stock issued for repayment of related party note payable	\$--	\$187
--	------	-------

See accompanying notes.



**Cesca Therapeutics Inc.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**(in thousands except shares and per share amounts)**

**1. Summary of Significant Accounting Policies**

***Organization and Basis of Presentation***

Cesca Therapeutics Inc. (Cesca, the Company) is focused on the research, development, and commercialization of autologous cell-based therapeutics for use in regenerative medicine. Cesca is a leader in developing and manufacturing automated blood and bone marrow processing systems that enable the separation, processing and preservation of cell and tissue therapy products. During the quarter ended March 31, 2014, Cesca Therapeutics Inc. was formed by the merger of ThermoGenesis Corp. and TotipotentRX. See footnote 2 for details of the transaction.

***Liquidity***

At June 30, 2015, the Company had cash and cash equivalents of \$3,357 and working capital of \$5,305. This compares to cash and cash equivalent of \$14,811 and working capital of \$18,947 at June 30, 2014. The Company has primarily financed operations through private and public placement of equity securities. Based on the initial \$5,500 financing that the Company received in August 2015, its cash balance, historical trends, the restructuring that occurred in September 2015, expected outflows for the Company's clinical trial programs and projections for revenues, the Company believes its current funds are sufficient to provide for its projected needs to maintain operations and working capital requirements for at least the next 12 months. The Company is dependent on receiving the \$9,500 in funds from the second closing of the August financing in order to initiate the CLIRST III pivotal trial. If the Company does not receive the \$9,500 from the second closing, the Company will need additional funding to initiate the CLIRST III pivotal trial and if the Company is unable to generate sufficient revenue or obtain additional funds for its working capital needs, the Company may have to further scale-back operations. The Company's ability to fund its longer-term cash needs is subject to various risks, many of which are beyond its control. Should the Company require additional funding, the Company may need to raise the required additional funds through bank borrowings or public or private sales of debt or equity securities.

***Principles of Consolidation***

The consolidated financial statements include the accounts of Cesca Therapeutics Inc., and the Company's wholly-owned subsidiaries, TotipotentRX Cell Therapy, Pvt. Ltd. and TotipotentSC Scientific Product Pvt. Ltd. All significant intercompany accounts and transactions have been eliminated upon consolidation.

*Use of Estimates*

Preparation of financial statements in conformity with accounting principles generally accepted in the United States of America and pursuant to the rules and regulations of the U.S. Securities and Exchange Commission (“SEC”) requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities at the date of the consolidated financial statements and the reported amounts of revenues and expenses during the reporting period. Estimates are used for, but not limited to, the allowance for doubtful accounts, slow-moving inventory reserves, depreciation, warranty costs, assumptions made in valuing equity instruments issued for services or acquisitions and the fair values of intangibles and goodwill. Actual results could materially differ from the estimates and assumptions used in the preparation of the Company’s consolidated financial statements. Events subsequent to the balance sheet date have been evaluated for inclusion in the accompanying consolidated financial statements through the date of issuance.

**Cesca Therapeutics Inc.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)**

**(in thousands except shares and per share amounts)**

**1. Summary of Significant Accounting Policies (Continued)**

***Revenue Recognition***

Revenues from the sale of the Company's 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. The Company generally ships 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 balance sheet.

There is no right of return provided for distributors or customers. For sales of products made to distributors, the Company considers 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 the Company, the level of inventories maintained by the distributor, whether the Company has 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. The Company currently recognizes revenue primarily on the sell-in method with the Company's distributors.

Revenue arrangements with multiple deliverables are divided into units of accounting if certain criteria are met, including whether the deliverable items 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. The Company accounts 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.

For licensing agreements pursuant to which the Company receives up-front licensing fees for products or technologies that will be provided by the Company over the term of the arrangements, the Company defers the up-front fees and recognizes the fees as revenue on a straight-line method over the term of the respective license. For license agreements that require no continuing performance on the Company's part, license fee revenue is recognized immediately upon grant of the license.

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.

**Cesca Therapeutics Inc.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)**

**(in thousands except shares and per share amounts)**

**1. Summary of Significant Accounting Policies (Continued)**

***Cash and Cash Equivalents***

The Company considers all highly liquid investments with a maturity of three months or less at the time of purchase to be cash equivalents. Financial instruments that potentially subject the Company to a concentration of credit risk consist of cash and cash equivalents. The Company's cash is maintained in checking accounts, money market funds and certificates of deposits with reputable financial institutions that may at times exceed amounts covered by insurance provided by the U.S. Federal Deposit Insurance Corporation. The Company has cash and cash equivalents of \$247 and \$707 at June 30, 2015 and 2014, respectively in India. The Company has not experienced any realized losses on the Company's deposits of cash and cash equivalents.

***Foreign Currency Translation***

The Company's reporting currency is the US dollar. The functional currency of the Company's subsidiaries in India is the Indian rupee (INR). Assets and liabilities are translated into US dollars at period end exchange rates. Revenue and expenses are translated at average rates of exchange prevailing during the periods presented. Cash flows were also translated at average exchange rates for the period, therefore, amounts reported on the consolidated statement of cash flows did not necessarily agree with changes in the corresponding balances on the consolidated balance sheet. Equity accounts other than retained earnings are translated at the historic exchange rate on the date of investment. A translation loss of \$63 and gain of \$58 was recorded for the years ended June 30, 2015 and 2014, respectively, as a component of other comprehensive income.

***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 the Company evaluates 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*, the Company can opt to perform a qualitative assessment, if the Company determines that the fair value of a reporting unit is more likely than not (i.e., a likelihood of more than 50 percent) to be less than its carrying amount, the two step impairment test will be performed. In the first step, the Company compares the fair value of the Company's sole reporting unit to its carrying value. If the fair value of the reporting unit exceeds the carrying value, goodwill is not considered impaired and Company is not required to perform further testing. If the fair value of the reporting unit does not exceed the carrying value, then the Company must perform the second step of the impairment test in order to determine the implied fair value of the goodwill. If the carrying value of goodwill exceeds its implied fair value, then the Company would record an impairment loss equal to the difference. Recoverability of finite lived intangible assets is measured by comparison of the carrying amount of the asset to the future undiscounted cash flows the asset is expected to generate. The Company concluded, as of April 1, 2015, as the fair value exceeded book value, there was no impairment of goodwill or the subject intangible asset.

**Cesca Therapeutics Inc.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)**

(in thousands except shares and per share amounts)

**1. Summary of Significant Accounting Policies (Continued)**

*Fair Value of Financial Instruments*

The carrying values of cash and cash equivalents, accounts receivable, accounts payable and accrued liabilities, approximate fair value due to their short duration. As of June 30, 2015 and 2014, the Company had approximately \$177 and \$354 in cash equivalents classified as Level 1 assets, which are based on quoted market prices in active markets for identical assets. As of June 30, 2015 and 2014, the Company did not have any Level 2 or 3 financial instruments.

*Accounts Receivable and Allowance for Doubtful Accounts*

The Company's receivables are recorded when billed and represent claims against third parties that will be settled in cash. The carrying value of the Company's receivables, net of the allowance for doubtful accounts, represents their estimated net realizable value. The Company estimates the allowance for doubtful accounts based on historical collection trends, age of outstanding receivables and existing economic conditions. If events or changes in circumstances indicate that a specific receivable balance may be impaired, further consideration is given to the collectability of those balances and the allowance is adjusted accordingly. A customer's receivable balance is considered past-due based on its contractual terms. Past-due receivable balances are written-off when the Company's internal collection efforts have been unsuccessful in collecting the amount due.

*Inventories*

Inventories are stated at the lower of cost or market and include the cost of material, labor and manufacturing overhead. Cost is determined on the first-in, first-out basis. The Company provides inventory allowances to write down inventory to its estimated net realizable value 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, the Company provides 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 the Company's 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 the Company 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.

***Equipment***

Equipment consisting of office furniture, computer, machinery and equipment is recorded at cost. Repairs and maintenance costs are expensed as incurred. Depreciation for office furniture, computer, machinery and equipment is computed under the straight-line method over the estimated useful lives. Leasehold improvements are depreciated under the straight line method over their estimated useful lives or the remaining lease period, whichever is shorter.

***Warranty***

The Company provides for the estimated cost of product warranties at the time revenue is recognized. The Company's warranty obligation is calculated based on estimated product failure rates, material usage and estimated service delivery costs incurred in correcting a product failure.



**Cesca Therapeutics Inc.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)**

**(in thousands except shares and per share amounts)**

**1. Summary of Significant Accounting Policies (Continued)**

***Stock-Based Compensation***

The Company has three stock-based compensation plans, which are described more fully in Note 6.

**Valuation and Amortization Method** – The Company estimates the fair value of stock options granted using the Black-Scholes-Merton option-pricing formula. This fair value is then amortized on a straight-line basis over the requisite service periods of the awards, which is generally the vesting period.

**Expected Term** – For options which the Company has limited available data, the expected term of the option is based on the simplified method. This simplified method averages an award's vesting term and its contractual term. For all other options, the Company's expected term represents the period that the Company's stock-based awards are expected to be outstanding and was determined based on historical experience of similar awards, giving consideration to the contractual terms of the stock-based awards, vesting schedules and expectations of future employee behavior.

**Expected Volatility** – Expected volatility is based on historical volatility. Historical volatility is computed using daily pricing observations for recent periods that corresponded to the expected term of the options.

**Expected Dividend** – The Company has not declared dividends and does not anticipate declaring any dividends in the foreseeable future. Therefore, the Company uses a zero value for the expected dividend value factor to determine the fair value of options granted.

**Risk-Free Interest Rate** – The Company bases the risk-free interest rate used in the valuation method on the implied yield currently available on U.S. Treasury zero-coupon issues with the same or substantially equivalent remaining term.

Estimated Forfeitures – When estimating forfeitures, the Company considers voluntary and involuntary termination behavior as well as analysis of actual option forfeitures.

***Research and Development***

Research and development costs, consisting of salaries and benefits, costs of clinical trials, costs of disposables, facility costs, contracted services and stock-based compensation from the engineering, regulatory, scientific and clinical affairs departments, that are useful in developing and clinically testing new products, services, processes or techniques, as well as expenses for activities that may significantly improve existing products or processes are expensed as incurred. Costs to acquire technologies that are utilized in research and development and that have no future benefit are expensed when incurred.

**Cesca Therapeutics Inc.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)**

**(in thousands except shares and per share amounts)**

**1. Summary of Significant Accounting Policies (Continued)**

***Acquired In-Process Research and Development***

Acquired in-process research and development (“clinical protocols”) that the Company acquires through business combinations represents the fair value assigned to incomplete research projects which, at the time of acquisition, have not reached technological feasibility. The amounts are capitalized and are accounted for as indefinite-lived intangible assets, subject to impairment testing until completion or abandonment of the projects. Upon successful completion of each project, the Company will make a determination as to the then useful life of the intangible asset, generally determined by the period in which the substantial majority of the cash flows are expected to be generated, and begin amortization. The Company tests clinical protocols for impairment at least annually, or more frequently if impairment indicators exist, by first assessing qualitative factors to determine whether it is more likely than not that the fair value of the clinical protocols intangible asset is less than its carrying amount. If the Company concludes it is more likely than not that the fair value is less than the carrying amount, a quantitative test that compares the fair value of the clinical protocol intangible asset with its carrying value is performed. If the fair value is less than the carrying amount, an impairment loss is recognized in operating results. The Company conducted the fiscal 2015 annual impairment assessment as of April 1, 2015. As the fair value exceeded book value, the Company concluded there was no impairment of the subject clinical protocol.

***Patent Costs***

The costs incurred in connection with patent applications, in defending and maintaining intellectual property rights and litigation proceedings are expensed as incurred.

***Credit Risk***

Currently, the Company primarily manufactures and sells cellular processing systems and thermodynamic devices principally to the blood and cellular component processing industry and performs ongoing evaluations of the credit worthiness of the Company’s customers. The Company believes that adequate provisions for uncollectible accounts have been made in the accompanying consolidated financial statements. To date, the Company has not experienced significant credit related losses.



**Cesca Therapeutics Inc.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)**

**(in thousands except shares and per share amounts)**

**1. Summary of Significant Accounting Policies (Continued)**

***Segment Reporting***

The Company has one reportable business segment: the research, development, and commercialization of autologous cell-based therapeutics for use in regenerative medicine.

***Income Taxes***

The tax years 1995-2014 remain open to examination by the major taxing jurisdictions to which the Company is subject; however, there is no current examination. The Company's policy is to recognize interest and penalties related to the underpayment of income taxes as a component of income tax expense. To date, there have been no interest or penalties charged to the Company in relation to the underpayment of income taxes. There were no unrecognized tax benefits during the periods presented.

The Company's estimates of income taxes and the significant items resulting in the recognition of deferred tax assets and liabilities reflect the Company's assessment of future tax consequences of transactions that have been reflected in the financial statements or tax returns for each taxing jurisdiction in which the Company operates. The Company bases the provision for income taxes on the Company's 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 the Company operates. The Company recognizes 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. The Company establishes valuation allowances when necessary to reduce the carrying amount of deferred income tax assets to the amounts that the Company believes are more likely than not to be realized. The Company evaluates 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, the Company applies the change based on the years in which the temporary differences are expected to reverse. As the Company operates 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. The Company records 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 the Company's 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 the Company's pre-existing deferred tax assets.

**Cesca Therapeutics Inc.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)**

(in thousands except shares and per share amounts)

**1. Summary of Significant Accounting Policies (Continued)*****Net Loss per Share***

Net loss per share is computed by dividing the net loss to common stockholders by the weighted average number of common shares outstanding. The calculation of the basic and diluted earnings per share is the same for all periods presented, as the effect of the potential common stock equivalents is anti-dilutive due to the Company's net loss position for all periods presented. Anti-dilutive securities consisted of the following at June 30,:

	2015	2014
Warrants	5,052,400	5,113,420
Stock options	2,952,062	1,253,035
Restricted stock awards	1,461,784	818,797
Total	9,466,246	7,185,252

***Recently Adopted Accounting Pronouncements***

In July 2013, the Financial Accounting Standards Board ("FASB") issued an Accounting Standards Update, ASU 2013-11, "*Presentation of an Unrecognized Tax Benefit When a Net Operating Loss Carryforward, a Similar Tax Loss, or a Tax Credit Carryforward Exists*". This amendment requires entities to present an unrecognized tax benefit or a portion of an unrecognized tax benefit, as a reduction to a deferred tax asset for a net operating loss carryforward or a similar tax loss or a tax credit carryforward, unless certain conditions exist. The Company adopted ASU 2013-11 effective July 1, 2014. The adoption of ASU 2013-11 did not have a material impact on the Company's results of operations or financial condition.

In March 2013, the FASB issued ASU 2013-05, "*Foreign Currency Matters*" (Topic 830) which provides guidance on a parent's accounting for the cumulative translation adjustment upon de-recognition of a subsidiary or group of assets within a foreign entity. This new guidance requires that the parent release any related cumulative translation adjustment into net income only if the sale or transfer results in the complete or substantially complete liquidation of the foreign entity in which the subsidiary or group of assets had resided. The new guidance was effective for the Company beginning July 1, 2014. The adoption of ASU 2013-05 did not have a material impact on the Company's results of operations or financial condition.

***Recently Issued Accounting Pronouncements***

In July 2015, the FASB issued ASU No. 2015-11, “*Inventory: Simplifying the Measurement of Inventory*”, that requires inventory not measured using either the last in, first out (LIFO) or the retail inventory method to be measured at the lower of cost and net realizable value. Net realizable value is the estimated selling prices in the ordinary course of business, less reasonably predictable cost of completion, disposal and transportation. The new standard will be effective for fiscal years beginning after December 15, 2016, including interim periods within those fiscal years, and will be applied prospectively. Early adoption is permitted. The Company is evaluating the impact that this standard will have on its consolidated financial statements.



**Cesca Therapeutics Inc.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)**

**(in thousands except shares and per share amounts)**

**1. Summary of Significant Accounting Policies (Continued)**

In April 2015, the FASB issued ASU 2015-03, "*Interest -Imputation of Interest (Subtopic 835-30): Simplifying the Presentation of Debt Issuance Costs.*" ASU 2015-03 requires that debt issuance costs related to a recognized debt liability be presented in the balance sheet as a direct deduction from the carrying amount of the related debt liability, consistent with debt discounts, instead of being presented as an asset. ASU 2015-03 is effective for the Company on January 1, 2016. Once adopted, entities are required to apply the new guidance retrospectively to all prior periods presented. The retrospective application represents a change in accounting principle. Early adoption is permitted for financial statements that have not been previously issued. The Company is currently evaluating the effect that ASU 2015-03 will have on its consolidated financial statements and related disclosures

In August 2014, the FASB issued ASU 2014-15, "*Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern*". ASU 2014-15 is intended to define management's responsibility to evaluate whether there is substantial doubt about an organization's ability to continue as a going concern and to provide related footnote disclosures. For all entities, the ASU is effective for annual periods ending after December 15, 2016 and interim periods within annual periods beginning after December 15, 2016. Early adoption is permitted. The Company is currently assessing the potential impact, if any, the adoption of ASU 2014-15 may have on its condensed consolidated financial statements.

In June 2014, FASB issued ASU No. 2014-12, "*Compensation - Stock Compensation (Topic 718); Accounting for Share-Based Payments When the Terms of an Award Provide That a Performance Target Could Be Achieved after the Requisite Service Period*". The amendments in this ASU apply to all reporting entities that grant their employees share-based payments in which the terms of the award provide that a performance target that affects vesting could be achieved after the requisite service period. The amendments require that a performance target that affects vesting and that could be achieved after the requisite service period be treated as a performance condition. A reporting entity should apply existing guidance in Topic 718 as it relates to awards with performance conditions that affect vesting to account for such awards. For all entities, the amendments in this ASU are effective for annual periods and interim periods within those annual periods beginning after December 15, 2015. Earlier adoption is permitted.

Entities may apply the amendments in this ASU either (a) prospectively to all awards granted or modified after the effective date or (b) retrospectively to all awards with performance targets that are outstanding as of the beginning of the earliest annual period presented in the financial statements and to all new or modified awards thereafter. If

retrospective transition is adopted, the cumulative effect of applying this Update as of the beginning of the earliest annual period presented in the financial statements should be recognized as an adjustment to the opening retained earnings balance at that date. Additionally, if retrospective transition is adopted, an entity may use hindsight in measuring and recognizing the compensation cost. The Company is currently reviewing the provisions of this ASU to determine if there will be any impact on its results of operations, cash flows or financial condition.

**Cesca Therapeutics Inc.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)**

**(in thousands except shares and per share amounts)**

**1. Summary of Significant Accounting Policies (Continued)**

In May 2014, the FASB issued ASU 2014-09, “*Revenue from Contracts with Customers* (Topic 606)” which provides comprehensive guidance for revenue recognition. ASU 2014-09 affects any entity that either enters into contracts with customers to transfer goods or services or enters into contracts for the transfer of nonfinancial assets. The core principle of the guidance provides that a company should recognize revenue when promised goods or services are transferred to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. ASU 2014-09 is effective for fiscal years, and interim periods within those years, beginning after December 15, 2017, using either a full retrospective or modified retrospective method of adoption. The Company is currently evaluating the transition method it will adopt and the impact of the adoption of ASU 2014-09 on its consolidated financial statements.

**2. Acquisition of TotipotentRX**

On February 18, 2014, the Company consummated the acquisition of TotipotentRX by merger pursuant to the Agreement and Plan of Merger and Reorganization (Merger Agreement). TotipotentRX was a privately held biomedical technology company specializing in human clinical trials in the field of regenerative medicine and a provider of cell-based therapies to the Fortis Healthcare System. TotipotentRX had two wholly-owned subsidiaries, TotipotentRX Cell Therapy Pvt. Ltd. (TotiRX India) and TotipotentSC Product Pvt. Ltd. (TotiSC India). The two subsidiaries are located in Gurgaon, a suburb of New Delhi, India. The Company believes that TotipotentRX has the depth of clinical, scientific and biological experience necessary to fully develop and effectively navigate the evolving regulatory pathways necessary to commercialize approved blockbuster cell therapies.

The acquisition was accounted for under the acquisition method of accounting for business combinations in accordance with FASB ASC 805, *Business Combinations*, which requires, among other things, that the assets acquired and liabilities assumed be recognized at their fair values as of the acquisition date. Acquisition-related costs are not included as a component of the acquisition accounting, but are recognized as expenses in the periods in which the costs are incurred. Acquisition related costs of \$1,715 for the year ended June 30, 2014 were included in general and administrative expenses.

Pursuant to the Merger Agreement, TotipotentRX shareholders were issued in the aggregate 12,490,841 shares of the Company's common stock, or 38% of the then outstanding common stock of the combined company, in exchange for all the TotipotentRX common stock outstanding and the Company assumed warrants of TotipotentRX representing the right to purchase approximately 61,020 shares of the Company's common stock. All outstanding stock options to purchase shares of the TotipotentRX common stock were exercised or cancelled.

**Cesca Therapeutics Inc.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)**

(in thousands except shares and per share amounts)

**2. Acquisition of TotipotentRX (Continued)***Allocation of Consideration Transferred to Net Assets Acquired*

The following represents the consideration transferred to acquire TotipotentRX and its determination of the fair value of identifiable assets acquired and liabilities assumed at the acquisition date. The Company issued 12,490,841 shares of its common stock that had a total fair value of \$27,105 based on the closing market price on February 18, 2014, the acquisition date. The Company also assumed 2,004 TotipotentRX warrants, issuing 61,020 warrants to replace them. The warrants, which are convertible into 61,020 shares of common stock, had a total fair value of \$52. We also assumed \$130 for the settlement of existing receivables and payables between the parties pre-merger. Property and equipment was stated at its historical cost basis, less accumulated depreciation, until its appropriate fair value was determined in the second quarter of fiscal 2015. The Company acquired \$232 gross contractual amounts receivable. The difference between the gross contractual amount and the fair value of receivables is the best estimate of the contractual cash flows not expected to be collected. Certain adjustments related to TotipotentRX's opening balance sheet were finalized during the second quarter of fiscal 2015. As a result, the carrying amount of equipment acquired in the acquisition was increased by \$59, with a corresponding decrease to goodwill.

Purchase Price:	
ThermoGenesis common shares and warrants	\$27,287
Fair value of assets acquired:	
Cash	\$351
Receivables	171
Inventories	191
Clinical protocols	19,870
Other intangible assets	2,187
Property and equipment	384
Other assets	132
Total assets	23,286
Fair value of liabilities assumed:	
Accounts payable	514
Related party notes payable	337
Deferred tax liability	8,048
Other liabilities	295
Total liabilities	9,194
Net assets acquired	14,092
Goodwill	\$13,195



**Cesca Therapeutics Inc.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)**

(in thousands except shares and per share amounts)

**2. Acquisition of TotipotentRX (Continued)*****Supplemental Pro Forma Data***

The Company used the acquisition method of accounting to account for the Totipotent RX acquisition and, accordingly, the results of TotipotentRX are included in the Company's consolidated financial statements for the period subsequent to the date of acquisition. The following unaudited supplemental pro forma data for the year ended June 30, 2014 present consolidated information as if the acquisition had been completed on July 1, 2013. The pro forma results were calculated by combining the results of ThermoGenesis Corp with the stand-alone results of Totipotent RX for the pre-acquisition periods:

	Year Ended June 30, 2014
Net revenues	\$ 16,619
Net loss	\$(7,922 )

The unaudited pro forma financial information is based on the allocation of consideration transferred to net assets acquired and reflects certain adjustments related to the acquisition. Such adjustments include the incremental amortization expense in connection with recording acquired identifiable intangible assets at fair value, the incremental payroll expense associated with the new executive salaries resulting from the merger, and the elimination of the impact of historical transactions between ThermoGenesis and TotipotentRX that would have been treated as intercompany transactions had the companies been consolidated. The unaudited pro forma financial information also excludes certain non-recurring expenses directly attributable to the merger in the amount of \$1,958 for the year ended June 30, 2014.

***Repayment of Related Party Notes Payable***

As of February 18, 2014, TotipotentRX owed \$337 to two of its officers who have since joined the Company. In the Merger Agreement, Cesca agreed to pay off the notes payable at closing as follows: \$75 cash to each officer for a total of \$150 and the remainder in shares of common stock. Approximately 82,000 shares of common stock were issued to satisfy the remainder of the debt.





## Cesca Therapeutics Inc.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

(in thousands except shares and per share amounts)

3. Intangible Assets

Intangible assets consist of the following based on the Company's determination of the fair value of identifiable assets acquired (see footnote 2):

	June 30, 2015		
	Weighted		
	Average	Accumulated	Net
	Amortization	Amortization	
	Period		
	(in Amount		
	Years)		
Trade names	7 \$ 30	\$ 6	\$ 24
Licenses	7 490	96	394
Customer relationships	3 449	206	243
Device registration	7 92	20	72
Covenants not to compete	5 955	263	692
Amortizable intangible assets	2,016	591	1,425
Clinical protocols	19,870	--	19,870
Total	\$ 21,886	\$ 591	\$ 21,295

	June 30, 2014		
	Weighted		
	Average	Accumulated	Net
	Amortization	Amortization	
	Period		
	(in Amount		
	Years)		
Trade names	7 \$ 32	\$ 2	\$ 30
Licenses	7 550	29	521
Customer relationships	3 477	59	418
Device registration	7 218	12	206
Covenants not to compete	5 955	72	883
Amortizable intangible assets	2,232	174	2,058
Clinical protocols	19,870	--	19,870

Total	\$ 22,102	\$ 174	\$ 21,928
-------	-----------	--------	-----------

57

---

**Cesca Therapeutics Inc.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)**

(in thousands except shares and per share amounts)

**3. Intangible Assets (Continued)**

The change in the gross carrying amount is due to foreign currency exchange fluctuations and a \$117 impairment in the third quarter of fiscal 2015, of the device registration and licenses intangible assets due to discontinuing a cord-blood product. Amortization of intangible assets was \$458 and \$174 for the years ended June 30, 2015 and 2014. Clinical protocols have not yet been introduced to the market place and are therefore not yet subject to amortization. The Company's estimated future amortization expense for subsequent years ended June 30, as follows:

Year Ended June 30,

2016	\$448
2017	367
2018	273
2019	201
2020	83
Thereafter	53
Total	\$1,425

**4. Equipment**

Equipment consisted of the following at June 30:

	2015	2014	Estimated Useful Life  (in Years)
Machinery and equipment	\$5,895	\$4,746	2.5 - 10
Computer and software	897	775	2 - 5

Edgar Filing: CESCA THERAPEUTICS INC. - Form 10-K

Office equipment	741	616	5 - 10
Leasehold improvements	339	260	Shorter of 5 years or lease term
	7,872	6,397	
Less accumulated depreciation and amortization	(4,935)	(4,099)	
	\$2,937	\$2,298	

Depreciation and amortization expense for the years ended June 30, 2015 and 2014 was \$850 and \$788, respectively.

**Cesca Therapeutics Inc.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)**

(in thousands except shares and per share amounts)

**5. Commitments and Contingencies*****Operating Leases***

The Company leases the Rancho Cordova, Emeryville and Gurgaon, India facilities pursuant to operating leases, which contain scheduled rent increases. The leases expire in May 2019, April 2020 and March 2018, respectively. The Company recognizes rent expense on a straight-line basis over the term of the facility lease. The annual future minimum lease payments for the Company's non-cancelable operating leases are as follows:

2016	501
2017	541
2018	665
2019	629
2020	315
Total	\$2,651

Rent expense was \$652 and \$496 for the years ended June 30, 2015 and 2014, respectively.

***Financial Covenants***

On December 31, 2013, the Company entered into a Sale and Purchase Agreement with Cord Blood Registry ("CBR") in which the Company will 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. Effective December 31, 2013, the Company entered into the Fourth Amended and Restated Technology License and Escrow Agreement to delete or reduce the financial covenants that the Company must meet in order to avoid an event of default to one financial covenant, to maintain a balance of cash and short-term investments net of debt or borrowed funds of not less than \$2,000 at any month end.

***Employee Agreements***

As of June 30, 2015, the Company had employment agreements in place with three of its key executives. The agreements provide, among other things, for the payment of eighteen to twenty-four months of severance compensation for termination under certain circumstances. With respect to these agreements at June 30, 2015, potential severance amounted to \$1,900.

**Cesca Therapeutics Inc.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)**

(in thousands except shares and per share amounts)

**5. Commitments and Contingencies (Continued)***Contingencies*

Effective June 1, 2015, the Company, 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 the Company and Celling asserted against Harvest. In the settlement agreement, the Company 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.

In the normal course of operations, the Company may have disagreements or disputes with customers, employees or vendors. Such potential disputes are seen by management as a normal part of business. As of June 30, 2015, management believes any liability that may ultimately result from the resolution of these matters will not have a material adverse effect on the Company's consolidated financial position, operating results or cash flows.

*Warranty*

The Company offers a warranty on all of the Company's non-disposable products of one to two years. The Company warrants disposable products through their expiration date. The Company periodically assesses the adequacy of the Company's recorded warranty liabilities and adjusts the amounts as necessary.

Changes in the Company's product liability which is included in other current liabilities during the period are as follows:

	For years ended June 30,	
	2015	2014
Beginning balance	\$498	\$489
Warranties issued during the period	258	172

Edgar Filing: CESCA THERAPEUTICS INC. - Form 10-K

Settlements made during the period	(168)	(104)
Changes in liability for pre-existing warranties during the period	39	(59 )
Ending balance	\$627	\$498

60

---



**Cesca Therapeutics Inc.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)**

(in thousands except shares and per share amounts)

**6. Stockholders' Equity***Common Stock*

On June 18, 2014, the Company completed a public offering of 7,530,000 shares of common stock at \$1.50 per share, together with warrants to purchase up to an aggregate of 2,259,000 shares of common stock. The warrants may be exercised by the holders at a price of \$1.55 per share immediately thru June 18, 2019. Net proceeds after expenses from the offering were approximately \$10.1 million after underwriting discount and estimated offering expenses.

On January 30, 2014, the Company completed a private placement of the sale of 3,336,800 shares of the Company's common stock at \$2.00 per share, together with warrants to purchase up to an aggregate of 1,668,400 shares of common stock. The warrants may be exercised by the holders at a price of \$2.81 per share starting July 30, 2014 continuing through January 29, 2019. Net proceeds after expenses from the offering were approximately \$5.9 million.

*Warrants*

A summary of warrant activity is as follows:

	2015		2014	
	Number of Shares	Weighted-Average Exercise Price Per Share	Number of Shares	Weighted-Average Exercise Price Per Share
Beginning balance	5,113,420	\$ 2.21	1,125,000	\$ 2.64
Warrants granted	--	--	3,988,420	\$ 2.09
Warrants expired	(61,020 )	\$ 2.15	--	--
Outstanding at June 30	5,052,400	\$ 2.21	5,113,420	\$ 2.21
Exercisable at June 30	5,052,400	\$ 2.21	3,445,020	\$ 1.92

*Stock Options*

The 2012 Independent Director Plan (“2012 Plan”) permits the grant of stock or options to independent directors. A total of 500,000 shares were approved by the stockholders for issuance under the 2012 Plan. Options are granted at prices that are equal to 100% of the fair market value on the date of grant, and expire over a term not to exceed ten years. Options generally vest in monthly increments over one year, unless otherwise determined by the Board of Directors. As of June 30, 2015, there were 180,696 shares available for issuance.

The 2006 Equity Incentive Plan (“2006 Plan”) permits the grant of options, restricted stock, stock bonuses and stock appreciation rights to employees, directors and consultants. Under the 2006 Plan, the number of shares of common stock equal to 6% of the number of outstanding shares of the Company are authorized to be issued. The number of shares available to grant for awards adjusts at the beginning of each fiscal year if additional options to purchase shares of common stock were issued in the preceding fiscal year. As of June 30, 2015, there have been 5,223,074 shares approved under the 2006 Plan for issuance and 109,934 available for issuance.

**Cesca Therapeutics Inc.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)**

(in thousands except shares and per share amounts)

**6. Stockholders' Equity (Continued)***Stock Options (Continued)*

The 2002 Independent Directors Equity Incentive Plan ("2002 Plan") permits the grant of stock or options to independent directors. A total of 87,500 shares were approved by the stockholders for issuance under the 2002 Plan. Options are granted at prices which are equal to 100% of the fair market value on the date of grant, and expire over a term not to exceed ten years. Options generally vest immediately, unless otherwise determined by the Board of Directors. The 2002 Plan, but not the options granted, expired in January 2012.

Upon the appointment as Chief Executive Officer in June 2015, in accordance with his employment agreement, the Company's CEO received restricted stock units representing 1,000,000 shares of restricted common stock vesting in four equal installments based upon a combination of time and milestone based targets and a seven year option to acquire 1,000,000 shares of common stock, 25% of which vested immediately with the balance vesting in equal monthly installments during the following 24 months.

Upon the separation with the Company's Chief Executive Officer in October 2014, in accordance with his employment agreement, all outstanding options and restricted stock awards which would have otherwise vested by July 31, 2015, immediately vested. As a result, the Company recognized \$158 of stock compensation expense in general and administrative during the year ended June 30, 2015 as the vesting accelerated on 166,667 options and 70,000 restricted stock awards.

The Company issues new shares of common stock upon exercise of stock options. The following is a summary of option activity for the Company's stock option plans:

Number of Shares	Weighted- Average Exercise Price	Weighted- Average Remaining Contractual Life	Aggregate Intrinsic Value
---------------------	---	--	---------------------------------

Edgar Filing: CESCA THERAPEUTICS INC. - Form 10-K

Outstanding at June 30, 2014	1,253,035	\$ 2.08		
Granted	2,369,250	\$ 1.08		
Forfeited/cancelled	(394,473 )	\$ 1.44		
Expired	(275,750 )	\$ 3.00		
Exercised	--	--		
Outstanding at June 30, 2015	2,952,062	\$ 1.28	5.3	\$ 18
Vested and Expected to Vest at June 30, 2015	2,454,167	\$ 1.27	5.1	\$ 15
Exercisable at June 30, 2015	1,167,929	\$ 1.40	4.0	\$ 5

The aggregate intrinsic value is calculated as the difference between the exercise price of the underlying awards and the quoted price of the Company's common stock. There were no options that were exercised during the year ended June 30, 2015. During the year ended June 30, 2014, the aggregate intrinsic value of options exercised under the Company's stock option plans was \$4 determined as of the date of option exercise.

**Cesca Therapeutics Inc.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)****(in thousands except shares and per share amounts)****6. Stockholders' Equity (Continued)**

Non-vested stock option activity for the year ended June 30, 2015, is as follows:

	Non-vested Stock Options	Weighted-Average Grant Date Fair Value
Outstanding at June 30, 2014	638,739	\$ 1.02
Granted	2,369,250	\$ 0.62
Vested	(896,883 )	\$ 0.71
Forfeited	(326,973 )	\$ 0.69
Outstanding at June 30, 2015	1,784,133	\$ 0.61

The fair value of the Company's stock options granted for the years ended June 30, 2015 and 2014 was estimated using the following weighted-average assumptions:

	2015	2014
Expected life (years)	5	4
Risk-free interest rate	1.5 %	1.1 %
Expected volatility	75 %	75 %
Dividend yield	0 %	0 %

The weighted average grant date fair value of options granted during the years ended June 30, 2015 and 2014 was \$0.62 and \$1.15, respectively.

At June 30, 2015, the total compensation cost related to options granted under the Company's stock option plans but not yet recognized was \$628. This cost will be amortized on a straight-line basis over a weighted-average period of approximately two years and will be adjusted for subsequent changes in estimated forfeitures. The total fair value of options vested during the years ended June 30, 2015 and 2014 was \$678 and \$309.



**Cesca Therapeutics Inc.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)**

(in thousands except shares and per share amounts)

**6. Stockholders' Equity (Continued)***Common Stock Restricted Awards*

For the year ended June 30, 2014, the Company's Compensation Committee granted 692,968 shares of restricted common stock to director level and executive members of management, vesting in three equal installments on the first, second and third anniversary of the grant date.

The following is a summary of restricted stock activity:

	2015		2014	
	Number of Shares	Weighted-Average Grant Date Fair Value	Number of Shares	Weighted-Average Grant Date Fair Value
Balance at June 30	803,799	\$ 1.90	390,003	\$ 1.81
Granted	1,097,000	\$ 0.83	692,968	\$ 1.95
Vested	(376,558 )	\$ 1.82	(191,672)	\$ 1.86
Forfeited	(72,457 )	\$ 1.77	(87,500 )	\$ 2.00
Outstanding at June 30	1,451,784	\$ 1.12	803,799	\$ 1.90

In connection with the vesting of the restricted stock awards, the election was made by some of the employees to satisfy the applicable federal income tax withholding obligation by a net share settlement, pursuant to which the Company withheld 121,958 and 57,680 shares for the years ended June 30, 2015 and 2014, respectively and used the deemed proceeds from those shares to pay the income tax withholding. The net share settlement is deemed to be a repurchase by the Company of its common stock.

As of June 30, 2015, the Company had \$1,066 in total unrecognized compensation expense related to the Company's restricted stock awards, which will be recognized over a weighted average period of approximately one year.

**7. Concentrations**

At June 30, 2015, the Company had four distributors that individually accounted for 28%, 14%, 12% and 10% of accounts receivable. At June 30, 2014, the Company had four distributors that individually accounted for 16%, 16%, 14% and 10% of accounts receivable.

Revenues from a customer totaled \$2,549 or 16% and \$1,849 or 12% for the years ended June 30, 2015 and 2014, respectively. Revenues from one distributor totaled \$2,358 or 15% and \$2,102 or 13% of net revenues for the years ended June 30, 2015 and 2014, respectively. Revenues from another distributor totaled \$2,303 or 14% and \$2,288 or 14% of net revenues for the years ended June 30, 2015 and 2014, respectively.



**Cesca Therapeutics Inc.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)****(in thousands except shares and per share amounts)****7. Concentrations (Continued)**

The following represents the Company's revenues by product platform for the years ended June 30:

	2015	2014
AXP	\$6,612	\$6,143
BioArchive	4,241	4,776
Manual Disposables	1,810	1,706
Bone Marrow	2,621	2,542
Other	758	820
	\$16,042	\$15,987

The Company had sales to customers as follows for the years ended June 30:

	2015	2014
United States	\$8,428	\$6,909
China	2,500	3,169
Asia - other	1,955	1,864
Europe	2,147	3,072
South America	730	771
Other	282	202
	\$16,042	\$15,987

The Company attributes revenue to different geographic areas based on where items are shipped or services are performed.

Three suppliers accounted for approximately 75% of total inventory purchases during the year ended June 30, 2015 and two suppliers accounted for approximately 72% of total inventory purchases during the year ended June 30, 2014.

The Company has a contract manufacturer in Costa Rica that produces certain disposables. The Company provides AXP equipment to its distributor in China for use by end-user customers. The Company's equipment, net of accumulated depreciation, is summarized below by geographic area:

	June 30, 2015	June 30, 2014
United States	\$1,409	\$687
China	524	620
Costa Rica	594	567
India	296	251
All other countries	114	173
Total equipment, net	\$2,937	\$2,298

**Cesca Therapeutics Inc.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)****(in thousands except shares and per share amounts)****8. Income Taxes**

Loss before income tax benefits was comprised of \$14,041 from US and \$811 from foreign jurisdictions in 2015 and \$8,719 from US and \$315 from foreign jurisdictions in 2014.

The reconciliation of federal income tax attributable to operations computed at the federal statutory tax rate of 34% to income tax expense (benefit) is as follows for the years ended June 30:

	2015	2014
Statutory federal income tax benefit	\$(5,046)	\$(3,072)
Unbenefited net operating losses and credits	5,091	2,163
State and local taxes	(649 )	(326 )
Merger costs	--	757
Expiration of CA NOLs	616	--
Other	(12 )	75
Total income tax benefit	\$--	\$(403 )

A deferred income tax expense of \$0 was recorded for the year ended June 30, 2015. No tax benefit has been recorded through June 30, 2015 because of the net operating losses incurred and a full valuation allowance has been provided. A valuation allowance is provided when it is more likely than not that some portion of the deferred tax assets will not be realized.

At June 30, 2015, the Company had net operating loss carryforwards for federal and state income tax purposes of \$101,649 and \$60,885 respectively that are available to offset future income. The federal and state loss carryforwards expire in various years between 2016 and 2035.

At June 30, 2015, the Company has research and experimentation credit carryforwards of \$1,273 for federal tax purposes that expire in various years between 2019 and 2035, and \$1,363 for state income tax purposes that do not have an expiration date.

**Cesca Therapeutics Inc.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)**

(in thousands except shares and per share amounts)

**8. Income Taxes (Continued)**

Significant components of the Company's deferred tax assets and liabilities for federal and state income taxes are as follows:

	June 30, 2015	June 30, 2014
Deferred tax assets:		
Net operating loss carryforwards	\$38,317	\$34,154
Income tax credit carryforwards	2,143	1,995
Depreciation and amortization	--	--
Stock compensation	916	--
Other	1,479	1,750
Valuation allowance	(42,408)	(37,317)
Total deferred taxes	\$447	\$582
Deferred tax liabilities		
Depreciation and amortization	(8,088 )	(8,223 )
Net deferred taxes and liabilities	\$(7,641 )	\$(7,641 )

The valuation allowance increased by \$5,091 in 2015. As of June 30, 2015, the Company has a benefit of \$1,804 related to stock option deductions, which will be credited to paid-in capital when realized.

Because of the "change of ownership" provisions of the Tax Reform Act of 1986, a portion of the Company's federal net operating loss and credit carryovers may be subject to an annual limitation regarding their utilization against taxable income in future periods.

**9. Employee Retirement Plan**

The Company sponsors an Employee Retirement Plan, generally available to all employees, in accordance with Section 401(k) of the Internal Revenue Code. Employees may elect to contribute up to the Internal Revenue Service annual contribution limit. Under this Plan, at the discretion of the Board of Directors, the Company may match a portion of the employees' contributions. The Company made no discretionary or matching contributions to the Plan for the years ended June 30, 2015 and 2014.

**Cesca Therapeutics Inc.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)**

**(in thousands except shares and per share amounts)**

**10. Subsequent Events**

On August 31, 2015, the Company sold senior secured convertible debentures of \$15,000 (“Debentures”), Series A warrants to purchase up to 22,058,823 shares of the Company’s common stock at an exercise price equal to \$0.68 per share for a period of five and one-half years (“Series A warrants”) and Series B warrants to purchase up to 12,132,353 shares of the Company’s common stock at an exercise price equal to \$0.68 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. The remaining \$9,500 of gross proceeds will be deposited in our deposit control account and released after receiving (i) stockholder approval of certain share issuances relating to the financing to meet Nasdaq listing requirements, (ii) stockholder approval of an amendment to the Company’s certificate of incorporation increasing its authorized number of shares of common stock to 350,000,000 and (iii) approval from California Institute for Regenerative Medicine (“CIRM”) of a grant in the amount of \$10,000, for the U.S. pivotal clinical trial in critical limb ischemia.

The debentures bear no interest, may be convertible into shares of the Company’s common stock at a conversion price of \$0.68 per share and are secured by all of the Company’s assets. The Series A and B warrants are subject to vesting based upon the amount of funds actually received by the Company in the sale of the senior secured convertible debentures and are exercisable upon the earlier of the approval of the transaction by the Company’s stockholders and the 6 month anniversary of the issuance date. Following shareholder approval, the Series B warrants may be exercised on a cashless basis at market price at the time of exercise if it is lower than the conversion price subject to a floor of \$0.10 per share.

In September 2015, the Company effected a strategic reorganization which resulted in the elimination of approximately 15 positions. Non-recurring severance costs of approximately \$245 are expected to be recorded in the first quarter of fiscal 2016.

**ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE.**

On May 6, 2015, Ernst & Young LLP ("E&Y") informed our Chairman of the audit committee that E&Y was resigning as the Company's independent registered public accounting firm. E&Y's resignation has been accepted by the Company's audit committee. The report of E&Y on the Company's financial statements for the past two fiscal years did not contain an adverse opinion or a disclaimer of opinion and was not qualified or modified as to uncertainty, audit scope, or accounting principles. In connection with the audits of the Company's financial statements for each of the two fiscal years ended June 30, 2014 and 2013, and in the subsequent interim period through May 6, 2015, there were no disagreements with E&Y on any matters of accounting principles or practices, financial statement disclosure, or auditing scope and procedures which, if not resolved to the satisfaction of E&Y would have caused E&Y to make reference to the matter in their report.

On May 29, 2015 the Company engaged Marcum LLP ("Marcum") as its independent registered public accounting firm. During the Company's two most recent fiscal years ended June 30, 2013 and 2014, and during the subsequent interim period through May 29, 2015, the Company has not, and no one on the Company's behalf has, consulted with Marcum regarding: (i) the application of accounting principles to a specified transaction, either completed or proposed; or the type of audit opinion that might be rendered on the Company's financial statements, and neither a written report nor oral advice was provided to the Company that Marcum concluded was an important factor considered by the Company in reaching a decision as to the accounting, auditing or financial reporting issue; or (ii) any matter that was either the subject of a disagreement (as defined in Item 304(a)(1)(iv) of Regulation S-K and the related instructions) or a reportable event (as described in Item 304(a)(1)(v) of Regulation S-K).

**ITEM 9A. CONTROLS AND PROCEDURES.**

**Disclosure Controls and Procedures**

We carried out an evaluation, under the supervision and with the participation of management, including our Chief Executive Officer along with our Chief Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedures (as defined by Exchange Act Rule 13a-15(e) and 15d-15(e)) as of the end of our fiscal quarter pursuant to Exchange Act Rule 13a-15. The term disclosure controls and procedures means our controls and other procedures that are designed to ensure that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that such information is accumulated and communicated to management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure. Based upon that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were not effective as of June 30, 2015 for the reason discussed below.



**Management's Report on Internal Control over Financial Reporting**

The Company's management is responsible for establishing and maintaining adequate internal control over financial reporting as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act. Under the supervision and with the participation of the Company's management, including the Company's Chief Executive and Financial Officers, the Company conducted an evaluation of the effectiveness of its internal control over financial reporting based on criteria established in the framework in *Internal Control – Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on this evaluation, the Company's management concluded that its internal control over financial reporting was not effective as of June 30, 2015 due to the existence of the material weakness discussed below.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate. All internal control systems, no matter how well designed, have inherent limitations. Therefore, even those systems determined to be effective can provide only reasonable assurance with respect to financial statement preparation and presentation.

Subsequent to the completion of the audit of our financial statements for the year ended June 30, 2014, it was determined that a deficiency existed in our governance practices related to the timeliness and consistency of communications between the audit committee, management and the auditors. This deficiency was concluded to represent a material weakness in our internal control over financial reporting. In order to remediate this material weakness, we have engaged independent outside counsel, who has reviewed our corporate governance procedures and has recommended appropriate changes, which we have implemented and we will evaluate such changes on an ongoing basis.

During the quarter ended March 31, 2014, we completed the acquisition of TotipotentRX. TotipotentRX was a private company and was not been subject to the Sarbanes-Oxley Act of 2002, the rules and regulations of the SEC, or other corporate governance requirements to which public reporting companies may be subject. During the audit of TotipotentRX's financial statements for the year ended December 31, 2012, TotipotentRX's independent registered public accounting firm determined that a material weakness existed in its internal control over financial reporting as TotipotentRX did not have adequate personnel and information systems in place to prepare financial statements on a timely basis, including accrual accounting, non-routine data processes and estimation processes and procedures over financial accounting and reporting. As part of our integration activities, we incorporated our controls and procedures into the TotipotentRX subsidiaries to augment our company-wide controls to reflect the risks inherent in an acquisition of this type including the hiring of adequate, competent personnel. This integration process has been implemented and the material weakness has been fully remediated as of June 30, 2015.

#### **Attestation Report of Independent Registered Public Accounting Firm**

Not applicable.

#### **Changes in Internal Control over Financial Reporting**

Other than as described above, there have been no changes in the Company's internal controls over financial reporting that occurred during the fiscal quarter ended June 30, 2015, that have materially affected, or are reasonably likely to materially affect its internal controls over financial reporting. We believe that a control system, no matter how well designed and operated, cannot provide absolute assurance that the objectives of the control system are met, and no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within any company have been detected.

**ITEM 9B. OTHER INFORMATION.**

None.

70

---

**PART III**

**ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE.**

The information required by this Item will be included in and is hereby incorporated by reference from our Proxy Statement for the 2015 Annual Meeting of Stockholders. We have adopted a Code of Ethics applicable to all employees including our CEO and CFO. A copy of the Code of Ethics is available at [www.cescatherapeutics.com](http://www.cescatherapeutics.com).

**ITEM 11. EXECUTIVE COMPENSATION.**

The information required by this Item will be included in and is hereby incorporated by reference from our Proxy Statement for the 2015 Annual Meeting of Stockholders.

**ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS.**

The information required by this Item will be included in and is hereby incorporated by reference from our Proxy Statement for the 2015 Annual Meeting of Stockholders.

**ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE.**

The information required by this Item will be included in and is hereby incorporated by reference from our Proxy Statement for the 2015 Annual Meeting of Stockholders.

**ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES.**

The information required by this Item will be included in and is hereby incorporated by reference from our Proxy Statement for the 2015 Annual Meeting of Stockholders.

**PART IV**

**ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES**

The following documents are filed as a part of this report on Form 10-K.

	<u>Page Number</u>
(a)	
(1) Financial Statements	
Reports of Independent Registered Public Accounting Firms	39
Consolidated Balance Sheets at June 30, 2015 and 2014	41
Consolidated Statements of Operations and Comprehensive Loss for the years ended June 30, 2015 and 2014	42
Consolidated Statements of Stockholders' Equity for the years ended June 30, 2015 and 2014	43
Consolidated Statements of Cash Flows for the years ended June 30, 2015 and 2014	44
Notes to Consolidated Financial Statements	45

Management's Report on Internal Control over Financial Reporting is contained as part of this report under Item 9A "Controls and Procedures."

- (a) Financial Statement Schedules
- (2)

Financial statement schedules have been omitted because they are not required.

- (b) Exhibits

Exhibits required by Item 601 of Regulation S-K are listed in the Exhibit Index on the next page, which are incorporated herein by this reference.

**EXHIBIT INDEX**

<b>Exhibit No.</b>	<b>Document Description</b>	<b>Incorporation by Reference</b>
2.1	Plan of Merger Agreement and Reorganization Agreement between ThermoGenesis Corp. and TotipotentRX, dated July 15, 2013	Incorporated by reference to Form 8-K dated July 16, 2013
3.1	Certificate of Amendment to the Amended and Restated Certificate of Incorporation of Cesca Therapeutics Inc.	Incorporated by reference to Form 8-K dated July 25, 2015
3.2	Bylaws of Cesca Therapeutics Inc.	Incorporated by reference to Form 8-K dated April 25, 2014 filed with the SEC on May 1, 2014
3.2.2	Restated Bylaws of Cesca Therapeutics Inc. <sup>(1)</sup>	Incorporated by reference to Form 8-K dated October 24, 2014 filed with the SEC on October 30, 2014
3.3	Certificate of Amendment to the Amended and Restated Certificate of Incorporation of Cesca Therapeutics Inc.	Incorporated by reference to Cesca's Current Report on Form 8-K filed with the SEC on August 26, 2010.
3.4	Certificate of Merger.	Incorporated by reference to Cesca Therapeutics Inc. Current Report Form 8-K filed with the SEC on February 18, 2014.
4.1	Form of Stock Grant Agreement; Common Stock Agreement	Incorporated by reference to Cesca's Current Report on Form 8-K filed with the SEC on November 5, 2010.
10.1	License Agreement with Pall/Medsep Corporation	Incorporated by reference to Form 8-K dated April 14, 1997.
10.2.1	License and Escrow Agreement between Cesca Therapeutics Inc. and CBR Systems, Inc., effective June 15, 2010	Incorporated by reference to Cesca's Quarterly Report on Form 10-Q for the quarter ended December 31, 2010.
10.2.2	First Amendment to Technology License and Escrow Agreement between Cesca Therapeutics Inc. and CBR Systems, Inc., effective February 6, 2013	Incorporate by reference to Form 8-K dated February 12, 2013.
10.2.3	Extension Addendum to Escrow Agreement, effective July 26, 2013	Incorporated by reference to Form 8-K dated August 1, 2013.
10.2.4	Forbearance Agreement to Technology License and Escrow Agreement dated November 26, 2013	Incorporated by reference to Form 8-K filed with the SEC on November 26, 2013
10.3	Amended 2002 Independent Directors Equity Incentive Plan	Incorporated by reference to Form 8-K dated December 15, 2004.
10.6	Amended and Restated 2006 Equity Incentive Plan	Incorporated by reference to Form 8-K dated April 25, 2014 filed with the SEC on May 1, 2014.
10.10+	Product Purchase and International Distribution Agreement between Cesca Therapeutics Inc. and Golden Meditech Holdings, Limited	Incorporated by reference to Form 8-K dated August 24, 2012 and amended October 24, 2012.
10.11	2012 Independent Director Plan	Incorporated by reference to Exhibit A of the Company's Definitive Proxy Statement filed

Edgar Filing: CESCA THERAPEUTICS INC. - Form 10-K

		October 23, 2012.
10.13	Employment Agreement between Cesca Therapeutics Inc. and Mitchel Sivilotti dated July 15, 2013	Incorporated by reference to Form 8-K dated July 16, 2013.
10.14	Employment Agreement between Cesca Therapeutics Inc. and Kenneth Harris dated July 15, 2013	Incorporated by reference to Form 8-K dated July 16, 2013.
10.16	Employment Agreement with Matthew T. Plavan	Incorporated by reference to Form 8-K dated October 30, 2013
10.17	Employment Agreement with Dan T. Bessey	Incorporated by reference to Form 8-K dated October 30, 2013
10.18	Sales and Purchase Agreement between ThermoGenesis Corp and CBR Systems, Inc. dated December 31, 2013+	Incorporated by reference to Form 8-K dated January 7, 2014.



<b>Exhibit No.</b>	<b>Document Description</b>	<b>Incorporation by Reference</b>
10.19	Employment Agreement with Robin C. Stracey	Incorporated by reference to Form 8-K dated June 15, 2015
10.20	Supplement to Employment Agreement with Dan T. Bessey	Incorporated by reference to Form 8-K dated December 1, 2014.
10.21	Form of Securities Purchase Agreement	Incorporated by reference to Form 8-K dated August 31, 2015.
10.22	Form of Debenture	Incorporated by reference to Form 8-K dated August 31, 2015.
10.23	Form of Series A Warrant	Incorporated by reference to Form 8-K dated August 31, 2015.
10.24	Form of Series B Warrant	Incorporated by reference to Form 8-K dated August 31, 2015.
10.25	Form of Registration Rights Agreement	Incorporated by reference to Form 8-K dated August 31, 2015.
10.26	Form of Security Agreement	Incorporated by reference to Form 8-K dated August 31, 2015.
23.1	Consent of Marcum LLP, Independent Registered Public Accounting Firm	Filed herewith.
23.2	Consent of Ernst & Young LLP, Independent Registered Public Accounting Firm	Filed herewith.
31.1	Certification by the Principal Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002	Filed herewith.
31.2	Certification by the Principal Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002	Filed herewith.
32	Certification of Principal Executive Officer and Principal Financial Officer pursuant to Section 906 of the Sarbanes Oxley Act of 2002	Filed herewith.
101.INS	XBRL Instance Document‡	
101.SCH	XBRL Taxonomy Extension Schema Document‡	
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document‡	
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document‡	
101.LAB	XBRL Taxonomy Extension Label Linkbase Document‡	
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document‡	

**Footnotes to Exhibit Index**

‡ XBRL information is furnished and not filed for purpose of Sections 11 and 12 of the Securities Act of 1933 and Section 18 of the Securities Exchange Act of 1934, and is not subject to liability under those sections, is not part of any registration statement or prospectus to which it relates and is not incorporated or deemed to be incorporated by reference into any registration statement, prospectus or other document.

The SEC has granted confidential treatment with respect to certain portions of this exhibit. Omitted portions have<sup>+</sup> been filed separately with the SEC.

**GLOSSARY OF CERTAIN TECHNICAL TERMS**

510(k): Formal notification to FDA to obtain clearance to market the medical device. The device must be substantially equivalent to devices manufactured prior to 1976, or which have been found substantially equivalent after that date.

ADIPOSE: Tissue in which fat is stored and which has the cells swollen by droplets of fat.

ADULT STEM CELLS: All non-embryonic stem cells.

ALLOGRAFT: A tissue graft from a donor of the same species as the recipient but not genetically identical.

AUTOGRAFT: A graft of tissue from one point to another of the same individual's body.

AUTOLOGOUS: Autogenous; related to self; originating within an organism itself, as obtaining blood from the patient for use in the same patient.

BONE MARROW ASPIRATE: When a small amount of bone marrow is removed and tested.

BONE MARROW CONCENTRATE (“BMC”): the product of subjecting bone marrow aspirate to the process of centrifugation. The process of centrifugation separates the aspirated cells into concentrated fractions that may then be separately preserved for research or therapeutic purposes.

CRITICAL LIMB ISCHEMIA (“CLI”): A severe obstruction of the arteries that seriously decreases blood flow to the extremities (arms, hands, legs, feet) and has progressed to the point of severe pain and even skin ulcers or sores.

CRYOPRESERVATION: Maintaining the life of excised tissue or organs by freezing and storing at very low temperatures.

**HEMATOPOIETIC:** The formation of blood.

**HOMOLOGOUS:** Coming from and going back into the same organ system.

**IN VITRO:** Occurring in an artificial environment outside a living organism.

**IN VIVO:** Occurring or made to occur within a living organism or natural setting.

**ISCHEMIA:** Deficient supply of blood and oxygen to a body part.

**MONONUCLEAR CELLS (“MNCs”):** A term used to refer to blood cells that under a microscope can be seen to have a large round shaped nucleus. These cells include monocytes and lymphocytes which are involved in fighting infections in the body and also stem cells which have the potential to replicate and to generate new tissues as part of the body’s healing process.

**PERIPHERAL BLOOD:** A term used to describe the blood that is contained in the body’s circulatory system. It can be collected by a health care professional by inserting a needle into a vein.

**PLATELET RICH PLASMA (“PRP”):** A volume of autologous plasma that has a platelet concentration above baseline.

**REGENERATIVE MEDICINE:** The process of creating living, functional tissues to repair or replace tissue or organ function lost due to age, disease, damage, or congenital defects.

**STEM CELLS:** Undifferentiated, primitive cells in the bone marrow or cord blood with the ability both to multiply and to differentiate into specific blood or tissue cells.

**SIGNATURES**

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

Cesca Therapeutics Inc.

Dated: September 17, 2015 By: /s/ CRAIG W. MOORE  
Craig W. Moore, Chairman of the Board

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

By: /s/ CRAIG W. MOORE Dated: September 17, 2015  
Craig W. Moore, Chairman of the Board

By: /s/ ROBIN C. STRACEY Dated: September 17, 2015  
Robin S. Stracey, Chief Executive Officer and Director  
(Principal Executive Officer)

By: /s/ MICHAEL BRUCH Dated: September 17, 2015  
Michael Bruch, Interim Chief Financial Officer  
(Principal Financial and Accounting Officer)

By: /s/ DENIS MICHAEL RHEIN Dated: September 17, 2015  
Denis Michael Rhein, Director

By: /s/ MAHENDRA S. RAO Dated: September 17, 2015  
Mahendra Rao, Director

By: /s/ KENNETH HARRIS Dated: September 17, 2015  
Kenneth Harris, President and Director