CESCA THERAPEUTICS INC.
Form 10-K
September 22, 2017
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SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

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

SECURITIES EXCHANGE ACT OF 1934

For the Fiscal Year Ended: **June 30, 2017**

Commission File Number: 000-16375

Cesca Therapeutics Inc.

(Exact name of registrant as specified in its charter)

Delaware	**94-3018487**
(State of incorporation)	(I.R.S. Employer Identification No.)

2711 Citrus Road

Rancho Cordova, California 95742

(Address of principal executive offices) (Zip Code)

(916) 858-5100

(Registrant's telephone number, including area code)

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

Title of each class	Name of each exchange on which registered

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

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

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

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

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files.) [X] Yes [ ] No

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

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

Large accelerated filer [ ]	Accelerated filer [ ]	Smaller reporting company [X]
Non-accelerated filer [ ]	(Do not check if a smaller reporting company)	Emerging growth company [ ]

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. [ ]

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).

[ ] Yes [X] No

The aggregate market value of the common stock held by non-affiliates as of December 30, 2016 (the last business day of the most recently completed second quarter) was $10,334,000 based on the closing sale price on such day.

As of September 15, 2017, 9,946,193 shares of the registrant's Common Stock were outstanding.

Documents Incorporated By Reference: The registrant intends to file an amendment to this Annual Report on Form 10-K within 120 days after the end of the fiscal year ended June 30, 2017, which will include the information required by Part III of Form 10-K.

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PART I

CAUTIONARY STATEMENT REGARDING FORWARD LOOKING STATEMENTS

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

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

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

These forward-looking statements speak only as of the date of this report and we expressly disclaim any obligation or undertaking to release publicly any updates or revisions to any forward-looking statements contained herein to reflect any change in the expectations with regard thereto or any change in events, conditions, or circumstances on which any

such statement is based, except as otherwise required by law. Additional factors that could cause such results to differ materially from those described in the forward-looking statements are set forth in connection with the forward-looking statements.

TRADEMARKS

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

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ITEM 1. BUSINESS

Cesca Therapeutics Inc. ("Cesca Therapeutics," "Cesca," the "Company," "we," "our," "us"), a Delaware corporation, is a regenerative medicine company that was founded in 1986 and is headquartered in Rancho Cordova, CA. We develop, commercialize and market a range of automated technologies and products for cell-based therapeutics. ThermoGenesis Corp. ("ThermoGenesis"), our device division, provides the AutoXpress® platform for automated clinical biobanking, PXP™ platform for point-of-care cell-based therapies and CAR-TXpress™ platform under development for bio-manufacturing for immuno-oncology applications. Cesca is also leveraging its proprietary PXP™ technology platform to develop autologous cell-based therapies that address significant unmet needs in the vascular and orthopedic markets. Our strategy is to continue to enhance the performance and competitiveness of our flagship product lines in the cord blood banking arena while expanding into significant new growth opportunity areas in point-of-care therapies in hospitals and cellular processing for immune-oncology product development and manufacturing.

Cesca is an affiliate of the Boyalife Group, a China-based industry research alliance encompassing top research institutions for stem cell and regenerative medicine.

Cesca's Device Division- ThermoGenesis Corp.

ThermoGenesis owns and operates the Company's device division, a pioneer and market leader in the development and commercialization of automated technologies for cell-based therapeutics and bio-processing. ThermoGenesis' automated solution offerings include:

AutoXpress™ (AXP™) for Clinical BioBanking – a proprietary, automated system for the isolation, collection and storage of hematopoietic stem cell concentrates derived from cord blood and peripheral blood.

Point-of-CareXpress (PXP™) for Point-of-Care Applications – a proprietary, automated system for the rapid, automated processing of autologous peripheral or bone marrow derived stem cells for cell-based therapies at point-of-care situations, such as surgical centers or clinics.

CAR-TXpress™ (CXP™) for Immuno-Oncology Applications – a proprietary automated system under development that allows for the automated manufacturing, expansion and storage of cellular therapies for immuno-oncology,

including various T-cell and natural killer (NK) cell-based therapies. CAR-TXpress™ works in bulk volumes of cells, dramatically reducing both processing time and the cost of the required capital equipment.

Cesca's Clinical Development Division

Cesca is developing autologous (utilizing the patient's own cells) stem cell-based therapies that address significant unmet medical needs for applications within the vascular, cardiology and orthopedic markets.

Vascular Diseases - Critical Limb Ischemia ("CLI") – Cesca has a proprietary point-of-care, autologous stem cell-based therapy under development which is intended for the treatment of patients with CLI. The Company's 362 patient, multi-center pivotal Phase III Critical Limb Ischemia Rapid Stem Cell Treatment ("CLIRST") trial is designed to evaluate the safety and efficacy of autologous stem cell-based therapy to stimulate the regeneration of blood vessels, promote wound healing and prevent amputation. Previous clinical studies using Cesca's proprietary, point-of-care-technologies have demonstrated the regeneration of blood vessels and improved blood circulation in the limbs, using a patient's own bone marrow derived stem cells.

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Cardiology - Acute Myocardial Infarction – Cesca has a proprietary, point-of-care autologous stem cell-based therapy under development which is intended as an adjunct treatment for patients who have suffered an acute ST-elevated myocardial infarction ("STEMI"), the most serious type of heart attack. Such treatments are aimed at minimizing the adverse remodeling of the heart post-STEMI.

Orthopedics – OsteoArthritis (OA) - Cesca is in early stage development of an autologous stem cell based therapy intended to treat patients with cartilage tissue degeneration that may lead to progressive cartilage loss and painful joint diseases. Localized articular cartilage defects can potentially be repaired by transplantation of autologous cell therapy. Therapies in development using Cesca's proprietary PXP™ system are expected to delay further deterioration and repair the damaged joint cartilage. Treatment is typically via a single procedure in the hospital or clinic.

Our Strategy

Our business strategy involves:

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

Leveraging our expertise in clinical biobanking and cell-based therapeutics to introduce new automated manufacturing solutions to developers of CAR-T and other immuno-therapies.

Becoming the partner-of-choice for immune-oncology developers looking to achieve increased output while adhering to Cellular Manufacture Control (CMC) best practices

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

Partnering our clinical development with market leaders in selected medical areas to maximize internal values of our existing pipelines. Our protocols are based on the use of autologous (donor and recipient are the same individual), bone marrow derived stem cells which are potentially safer than alternative allogeneic approaches.

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

Expanding patent protection: In the US, we have 17 patents issued and a series of applications pending. In addition, we have a series of corresponding international patents issued and pending.

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Recent Key Events and Accomplishments

Acquired the assets of SynGen Inc. ("SynGen"). On July 7, 2017, our subsidiary, ThermoGenesis, acquired the business and substantially all of the assets of SynGen, a privately held Sacramento, California-based technology company that develops, markets, and sells advanced cell separation tools and accessories. In the transaction (the "SynGen Transaction"), ThermoGenesis acquired substantially all of SynGen's operating assets, including its proprietary cell processing platform. In exchange, ThermoGenesis issued to SynGen shares of ThermoGenesis common stock that, after giving effect to the issuance, constitute 20% of ThermoGenesis' outstanding common shares, and ThermoGenesis also made a one-time cash payment of $1.0 million to SynGen. Immediately prior to the SynGen Transaction, the Company contributed the assets, business, and current liabilities of its blood and bone-marrow processing device business to ThermoGenesis and will operate such business (together with the acquired business) through the ThermoGenesis subsidiary.

Established $5 Million Line of Credit. On March 6, 2017, we entered into a credit agreement with Boyalife Investment Fund II, Inc. (the "Lender"). The Lender is a wholly owned subsidiary of Boyalife Group Inc., which is owned and controlled by the Company's Chief Executive Officer and Chairman of the Board of Directors. The Credit Agreement grants to the Company the right to borrow up to $5 million on an unsecured basis (the "Loan") at any time prior to March 6, 2022.

Increased Line of Credit by $5 Million. On September 13, 2017, we entered into an amendment to the Credit Agreement with the Lender, Boyalife Investment Fund II, Inc. increasing our maximum borrowing availability thereunder from $5.0 million to $10.0 million.

Converted Debt to Equity. On August 22, 2016, all outstanding principal and interest payable under the debentures, which included the conversion of $12,500,000 of principal and $8,250,000 of interest up to and including the maturity date of the debentures was converted to equity. Upon conversion, 6,102,941 shares of common stock were issued and the debentures and all related security interest and liens were terminated.

Raised $2 Million in Equity Financing. On August 3, 2016, we sold 600,000 shares of common stock at a price of $4.10 per share. The net proceeds from the sale and issuance of the shares, after deducting the offering expenses borne by the Company of $369,000, were $2,092,000.

The Markets We Serve

Immuno-Oncology

Immuno-Oncology is an innovative area of research that seeks to help the body's own immune system to fight cancer. With the significant unmet medical need in the long-term survival of patients with advanced cancer, pharmaceutical developers are competing to bring cost-efficient immune-therapies rapidly to market. Cesca is leveraging its expertise in clinical biobanking and cell-based therapeutics to introduce CAR-TXpress,™ an automated manufacturing solution that can address a material challenge to developers of CAR-T and other immuno-therapies.

CAR-TXpress™ can also be customized to address each customer's unique needs. In addition to CAR-T cell processing, Cesca is also developing manufacturing solutions for contract manufacturing and co-development that may help accelerate the manufacture and the clinical development of novel therapies.

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Regenerative Medicine

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

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

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

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

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

Our growth strategy includes the development of autologous cell therapies for treatments intended to be carried out at the point of care. We believe that commercial opportunities for such therapies will emerge in cardiology, orthopedics, dermatology/wound healing and selective areas of oncology, followed by more complex pathologies such as those found in diabetes and central nervous system disorders.

We also believe that developments in the field of regenerative medicine will be critical in helping to address the global increase in health care costs. As emerging cell therapies are proven to be safe, effective, and a cost-effective

alternative to current standards of care, we believe adoption will accelerate. A fundamental requirement, however, will be the continued development of baseline clinical and cost-effectiveness data through comprehensive clinical studies.

Bio-Banking

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

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Cesca's ThermoGenesis division is an established leader in the development and manufacture of automated systems that enable the separation, processing and cryopreservation of stem cell preparations from cord blood. In recent years, however, the overall number of cord blood samples being collected has decreased.

Our Products

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

- The AutoXpress™ System (AXP™) – a proprietary automated device and companion sterile disposable for concentrating hematopoietic stem cells from cord blood.
- The Point-of-CareXpress™ System (PXP™) – a proprietary automated device and companion sterile disposable for the isolation and concentration of hematopoietic stem cells from bone marrow.
- The CAR-TXpress™ System (CXP™) – a full suite of multi-component automated system that allows for the automated manufacturing, expansion and storage of cellular therapies for immuno-oncology, including various T-cell and natural killer (NK) cell-based therapies.
- The BioArchive® System - an automated cryogenic device approved for single-cassette based cryo-storage of biological license applications (BLA) products, including the storage of cord blood units for stem cell applications and CAR-T cellular products for immune-oncology.
- Manual bag sets for use in the processing and cryogenic storage of cord blood.

Cell Manufacturing and Banking Services

Through our TotipotentRX subsidiary in Gurgaon, India, we operate an advanced clinical cell manufacturing, processing, testing, and storage facility, compliant with current Good Manufacturing Practices ("GMP"), Good Tissue Practices ("GTP"), and Good Laboratory Practices ("GLP"). We can support the production of a small, personalized medicine cell prescription. Patient samples and therapeutic aliquots are all labeled in accordance with ISBT 128 and stored in our own cryogenics facility. In addition, our clinical research organization (CRO), also located in Gurgaon, is, to our knowledge, the only specialized, in-hospital, cell therapy CRO in the world. We have unique expertise in the design and management of cell based clinical trials, including the ability to support the device prototyping and validation typically required for a combination product. These services ensure patient safety under Good Clinical Practices ("GCP"), quality laboratory documentation under GLP, and quality cell processing and handling under both GMP and GTP. In partnership with Fortis Healthcare and through our 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").

Our Clinical Programs

Our therapeutic development initiatives, focused in the fields of cardiovascular diseases and orthopedic cartilage regeneration, are based on our proprietary PXP™ platform for the point-of-care harvesting, processing, and delivery of cells from the patient's own peripheral blood or bone marrow. A key advantage of our point-of-care system is that it is capable of delivering high cell viability and potency through a short intra-operative procedure, including bone marrow collection, target cell selection, characterization of the final cell concentrate, and re-injection into the patient. Based on our point-of-care platform, our critical limb ischemia clinical program has received FDA clearance to initiate a phase III clinical trial to demonstrate efficacy in "no-option" or "poor-option" CLI patients. In additional to vascular diseases, we are also conducting early phase studies in orthopedic and wound healing areas. We are actively looking for strategic partners to co-develop our clinical programs.

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Sales and Distribution Channels

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

Competition

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

Research and Development

Our research and development activities in fiscal 2017 were geared towards expanding the automated platform for point-of-care applications and immune-oncology applications. Each of these development initiatives leveraged our existing AXP™ and PXP™ 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.

Collectively, research and development expenses were $2,497,000 and $3,230,000 for the years ended June 30, 2017 and June 30, 2016, respectively. Research and development activities include expenses associated with the engineering, regulatory, scientific and clinical affairs functions.

Manufacturing

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

Quality System

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

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

Regulatory Scheme and Strategy

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

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

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

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

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

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

Class I Devices

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

Class II Devices

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

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Class III Devices

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

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

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

Higher risk clinical trials conducted inside the U.S. are subject to FDA IDE regulation (21 C.F.R. Part 812), or an IND application (21 C.F.R. Part 312). Clinical trials conducted outside the U.S., and the data collected therefrom are allowed in accordance with applicable FDA requirements. The FDA or the Sponsor may suspend a clinical trial at any time if either believes that study participants may be exposed to an unacceptable health risk.

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

Other U.S. Regulatory Information

Medical device manufacturers must register with the FDA and submit their manufacturing facilities to biennial inspections to ensure compliance with applicable regulations. Failure to comply with FDA requirements can result in withdrawal of marketing clearances, fines, injunctions, civil penalties, recall or seizure of products, total or partial suspension of production or loss of distribution rights. In addition, device manufacturing facilities in the state of California must be registered with the California State Food and Drug Branch of the California Department of Public

Health and submit to an annual inspection by the State of California to ensure compliance with applicable state regulations. We are also subject to a variety of environmental laws as well as workplace safety, hazardous material, and controlled substances regulations.

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

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

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

International Regulatory Requirements

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

In India, the regulatory body having oversight of medical devices, therapies, and cell banking is the Central Drugs Standard Control Organization ("CDSCO"), and specifically the Drugs Controller General India office. Our marketing and facilities licenses are subject to revocation by the applicable state Drug Controller in Haryana or DCGI.

Patents and Proprietary Rights

We believe that patent protection is important for our products and current and proposed business. We currently have over thirty issued patents globally. The patent positions can be uncertain because they involve interpretation of complex factual information and an evolving legal environment. The coverage sought in a patent application can be denied or significantly reduced either before or after the patent is issued. There can be no assurance that any of our pending patent applications will actually result in an issued patent. Furthermore, there can be no assurance that any existing or future patent will provide significant protection or commercial advantage, or that any existing or future patent will not be circumvented by a more basic patent. Generally, patent applications can be maintained in secrecy for at least 18 months after their earliest priority date. In addition, publication of discoveries in the scientific or patent literature often lags behind actual discoveries. Therefore, we cannot be certain that we were the first to invent or the

first to file a patent application for the subject matter covered by each of our pending U.S. and foreign patent applications.

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

Licenses

The following are certain material agreements involving our business.

Fortis Healthcare Limited ("Fortis")

On August 1, 2014 we entered into an agreement with Fortis which renews and expands our existing services agreement with them in areas including, but not limited to, cord blood banking, point of care technology sales and support, bone marrow transplant and clinical/patient management. The agreement expired on August 1, 2017 and we are in the process completing another contract with Fortis.

CBR Systems, Inc. ("CBR")

Effective May 15, 2017 we entered into a Manufacturing and Supply Agreement with CBR which replaced the prior December 31, 2013 Sale and Purchase Agreement in which we agreed to supply CBR with the AXP cord blood processing system and disposables. The term of the current agreement is for 3 years and will automatically renew in one-year increments unless either party provides written notice of intention not to renew six months prior to the end of the term.

In June 2010, we entered into a License and Escrow Agreement in order to alleviate CBR's concerns about potential long term supply risk. We are the sole supplier of critical devices and disposables used in the processing of cord blood samples in CBR's operations. Under the License and Escrow Agreement, we granted CBR a perpetual, non-exclusive, royalty-free license to certain intellectual property necessary for the manufacture of AXP devices and disposables. The license is for the sole and limited purpose of ensuring continued supply of the AXP and related disposables for use by CBR. The licensed intellectual property is held in escrow and available to CBR only in the event of a default under the agreement. Effective May 15, 2017 we entered into a Sixth Amended and Restated Technology License and Escrow Agreement with CBR. This amendment, among other things, changes the circumstances that constitute a "Default" thereunder and conditions the circumstances under which CBR may, upon a default by Cesca, purchase licensed products from other manufacturers and suppliers. The events or conditions of default include: a cash balance coupled with short-term investments net of debt or borrowed funds that are payable within one year of less than two million dollars at any month end or we fail to provide products pursuant to the Manufacturing and Supply Agreement. We

were in compliance with the License and Escrow Agreement at June 30, 2017 and through August 31, 2017.

Boyalife W.S.N.

On August 21, 2017, ThermoGenesis entered into an International Distributor Agreement with Boyalife W.S.N., a Chinese corporation and affiliate. Under the terms of the agreement, Boyalife W.S.N. was granted the exclusive right, subject to existing distributors and customers (if any), to develop, sell to, and service a customer base for ThermoGenesis' AXP® (AutoXpress®) System and BioArchive System in the People's Republic of China (excluding Hong Kong and Taiwan), Singapore, Indonesia, and the Philippines (the "Territories"). The agreement replaced our prior distribution agreement with Golden Meditech, which expired in August 2017 and had granted similar exclusive distribution rights in the Territories. Boyalife W.S.N. is an affiliate of Dr. Xiaochun Xu, our Chief Executive Officer and Chairman of our Board of Directors, and Boyalife (Hong Kong) Limited, our largest stockholder. Boyalife W.S.N,'s rights under the agreement include the exclusive right to distribute AXP® Disposable Blood Processing Sets and use rights to the AXP® (AutoXpress®) System, BioArchive System and other accessories used for the processing of stem cells from cord blood in the Territories. Boyalife W.S.N. is also appointed as the exclusive service provider to provide repairs and preventative maintenance to ThermoGenesis products in the Territories. The term of the agreement is for three years with ThermoGenesis having the right to renew the agreement for successive two-year periods at its option. However, ThermoGenesis has the right to terminate the agreement early if Boyalife W.S.N. fails to meet specified minimum purchase requirements.

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Employees

As of June 30, 2017, we had 70 employees, 36 of whom were employed in the U.S. and 34 of whom were employed in India. On July 7, 2017 in conjunction with the SynGen transaction, we added approximately 14 employees in the U.S. We also utilize temporary employees throughout the year to address business needs and significant fluctuations in orders and product manufacturing. None of our employees are covered by a collective bargaining agreement, nor have we experienced any work stoppage.

Foreign Sales and Operations

See footnote 10 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 its website, www.cescatherapeutics.com. The information on its website is not incorporated into, and is not part of, this annual report.

ITEM 1A. RISK FACTORS

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

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

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Risks Related to Our Business

The Equity in our ThermoGenesis Subsidiary is 20% Owned by a Third Party that Holds Certain Minority Investor Rights in that Subsidiary, and Those Rights Could Limit or Delay Our Ability to Take Certain Major Actions Relating to ThermoGenesis. Immediately prior to our acquisition of the assets and business of SynGen Inc. in July 2017, we contributed the assets and business of our blood and bone-marrow processing device business to our ThermoGenesis Corp. subsidiary. Substantially all of our historical revenues are attributable to our device business, and as a result of such contribution, the device business is now owned and operated by ThermoGenesis. In connection with the SynGen asset acquisition, we issued shares of ThermoGenesis common stock to SynGen resulting in SynGen owning 20% of the outstanding stock of ThermoGenesis on a post-transaction basis, and such common stock was thereafter transferred to Bay City Capital Fund V, L.P. and an affiliated fund ("Bay City"). Under the agreements relating to the SynGen asset acquisition, although we continue to own 80% of the outstanding capital stock of ThermoGenesis, Bay City was granted certain minority investor rights in ThermoGenesis. These rights include board representation rights, a right of first refusal over sales of ThermoGenesis stock by us, co-sale rights with respect to any sale of ThermoGenesis stock by us, and supermajority protective voting rights over certain major decisions, such as a sale of ThermoGenesis, raising capital in ThermoGenesis with preferred stock, transfers of ThermoGenesis assets, or redemptions of ThermoGenesis stock. In addition, the board of directors of ThermoGenesis is comprised of 5 persons, two of whom are designated by us, one of whom is designed by Bay City, one of whom is designated by us but must be independent, and one of whom is designated by Bay City but must be independent. The foregoing minority investor rights in ThermoGenesis could limit or delay our ability or flexibility to take certain major actions or make major decisions relating to ThermoGenesis that might be beneficial to our stockholders, unless such actions or decisions have the consent or support of Bay City. Accordingly, the minority investor rights in ThermoGenesis could have a negative impact on the market price of our common stock.

We May Not be Able to Successfully Recognize the Anticipated Benefits from the SynGen Asset Acquisition or Retain Key Acquisition Employees. On July 7, 2017, our ThermoGenesis subsidiary acquired the business and substantially all of the assets of SynGen, a privately held Sacramento, California-based technology company that develops, markets, and sells advanced cell separation tools and accessories. The success of the SynGen asset acquisition depends on our ability to leverage the intellectual property, other assets, and acquired personnel of SynGen in order to increase our sales and profitability. In order to successfully achieve this, we will need to integrate the businesses and employees of SynGen and ThermoGenesis and motivate such employees. This will place significant demands on our management, our operational and financial systems, our infrastructure, and our other resources. If we do not effectively manage this process, our ability to grow the consolidated business in the manner anticipated by the acquisition will suffer, and we may lose key employees that we acquired from SynGen.

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. 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.

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Our Controlling Stockholder Has Significant Influence Over Us Which Could Limit Your Ability to Influence the Outcome of Key Transactions, Including a Change of Control, and Could Negatively Impact the Market Price of Our Common Stock By Discouraging Third Party Investors. As of June 30, 2017, approximately 70% of our outstanding common stock is owned by Boyalife (Hong Kong) Limited. In addition, pursuant to the terms of a Nomination and Voting Agreement we entered into with Boyalife (Hong Kong) Limited and Boyalife Investment Inc. in February 2016, Boyalife (Hong Kong) Limited and Boyalife Investment Inc. have the right to designate up to three of the seven members to our board of directors until such time as they collectively no longer hold at least 50% of our common stock.

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

Our Potential Cell Therapy 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 an agreement with Fortis Healthcare Limited, a hospital chain networked throughout India and Asia, for contract clinical trial services programs among other services. The agreement expired in August 2017 and we are currently in discussions to renew the agreement. Termination, or non-renewal, of this agreement could jeopardize or delay development of our products.

We May Be Unable to Obtain Marketing Approval from the FDA For Our Point-of-Care System for Critical Limb Ischemia (CLI) Indication. At the end of 2016, the Company received approval from the U.S. Food and Drug

Administration (FDA) for the Company's amended pivotal study protocol for treatment of CLI. The amended CLI clinical trial is designed to demonstrate the safety and efficacy of the Company's point-of-care system for the treatment of CLI patients with limited or no treatment options. The changes approved by the FDA are intended to increase patient enrollment by expanding the patient pool from Rutherford Category 5 patients only, to also include Rutherford Category 4 patients, or patients with a less severe form of the disease. The study population has been expanded to include patients who are poor candidates for either surgery or endovascular therapies. The sample size of the CLI trial was increased from 224 to 362 patients. With the FDA approval of our amended phase III clinical trial protocol of CLI, the company is actively looking for an external strategic partner to move forward with the CLI clinical trial program. The marketing approval of point-of-care device for the treatment of CLI indication is subject to a successful strategic partnership, successful completion of our phase III study with statistical significant results and acceptance of the results by the FDA for the disease indication. Our inability to successfully complete any of the above mentioned steps can affect our ability to obtain marketing approval in the United States.

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

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

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

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

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

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

A Significant Portion of Revenue is Derived from Customers Outside the United States. We may Lose Revenues, Market Share, and Profits due to Exchange Rate Fluctuations and Political and Economic Changes Related to its Foreign Business. In the year ended June 30, 2017, sales to customers outside the U.S. comprised approximately 54% of revenues. This compares to 57% in fiscal 2016. Our foreign business is subject to economic, political and

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

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The Loss of a Significant Distributor or End User Customer may Adversely Affect Financial Condition and Results of Operations. Revenues from a significant distributor and a significant customer comprised 42% of revenues for the year ended June 30, 2017. In August 2017, we did not renew the contract with this significant distributor and signed a contract with a new distributor which is an affiliate of the Company. The loss of a large end user customer or distributor may decrease 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 our employees, consultants, sales agents or distributors may engage in conduct for which we might be held responsible. Violations of the FCPA may result in severe criminal or civil sanctions and we may be subject to other liabilities, which could negatively affect our business, operating results and financial condition.

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

Risks Related to Our Operations

Our Ability to Conduct a CLIRST III Clinical Trial Is Substantially Dependent on Our Ability to Enter into a Strategic Partnership and There Are No Assurances That Such Funding Source will Materialize. We will need additional funding to commence the CLIRST III clinical trial and we are actively looking for a strategic partner to co-sponsor the trial with us. We cannot assure that such funding will be available on a timely basis, in needed quantities, or on terms favorable to us, if at all.

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

of potential product revenues and resulting in additional losses.

We Have Limited Sales, Marketing and Distribution Experience in Pharmaceutical Products. We have limited experience in the sales, marketing, and distribution of pharmaceutical products. There can be no assurance that we will be able to establish sales, marketing, and distribution capabilities or make arrangements with current collaborators or others to perform such activities or that such effort will be successful. If we decide to market any of our new products directly, we must either partner, acquire or internally develop a marketing and sales force with technical expertise and with supporting distribution capabilities. The acquisition or development of a sales, marketing and distribution infrastructure would require substantial resources, which may not be available to us or, even if available, divert the attention of our management and key personnel, and have a negative impact on further product development efforts.

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

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

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

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

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

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

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

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

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.

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

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

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

Failure to Meet the Financial Covenant in our Technology License and Escrow Agreement could Decrease our AXP Revenues. Under our license and escrow agreement with Cbr Systems, Inc. if we fail to meet the financial covenant of cash balance and short-term investments net of debt or borrowed funds that are payable within one year of not less than $2,000,000, they may take possession of the escrowed intellectual property and initiate manufacturing of the applicable device and disposables. If this were to occur, our revenues would be negatively impacted. In order to remain compliant we may have to complete 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.

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

Failure to Maintain and/or Upgrade Our Information Technology Systems May Have an Adverse Effect on Our Operations. We rely on various information technology systems to manage our operations, and we evaluate these systems against our current and expected requirements. We are currently evaluating alternatives to our legacy ERP system. Until a new system is purchased and implemented, any information technology system disruptions, if not anticipated and appropriately mitigated, could have an adverse effect on our business and operations.

If we Fail to Maintain Proper and Effective Internal Controls, our Ability to Produce Accurate and Timely Financial Statements Could be Impaired, which Could Harm our Operating Results, our Ability to Operate our Business and Investors' Views of Us. We are required to establish and maintain adequate internal control over financial reporting, which are processes designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. We are also required to comply with Section 404 of the Sarbanes-Oxley Act of 2002, which (among other things) requires public companies to conduct an annual review and evaluation of their internal control over financial reporting. However, as a "smaller reporting company," we are not required to obtain an auditor attestation regarding our internal control over financial reporting. If, in the future, we require an attestation report from our independent registered public accounting firm and that firm is unable to provide an unqualified attestation report on the effectiveness of our internal controls over financial reporting, investor confidence and, in turn, our stock price could be materially adversely affected.

Risks Related to Our Industry

Our Business is Heavily Regulated, Resulting in Increased Costs of Operations and Delays in Product Sales. Many of our products require FDA approval or clearance to sell in the U.S. and will require approvals from comparable agencies to sell in foreign countries. These authorizations may limit the U.S. or foreign markets in which our products may be sold. Further, our products must be manufactured under requirements of our quality system for continued CE-Marking so they can continue to be marketed and sold in Europe. These requirements are similar to the QSR of both the FDA and California Department of Public Health. Failure to comply with or incorrectly interpret these quality system requirements and regulations may subject us to delays in production while we correct deficiencies found by the FDA, the State of California, or our notifying body as a result of any audit of our quality system. If we are found to be out of compliance, we could receive a Warning Letter or an untitled letter from the FDA or even be temporarily shut down in manufacturing and product sales while the non-conformances are rectified. Also, we may have to recall products and temporarily cease their manufacture and distribution, which would increase our costs and reduce our revenues. The FDA may also invalidate our PMA or 510(k) if appropriate regulations relative to the PMA

or 510(k) product are not met. The notified bodies may elect to not renew CE-Mark certification. Any of these events would negatively impact our revenues and costs of operations.

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

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

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

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

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

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

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

Risks Related to Operating Results and Financial Markets

We Have Incurred Net Losses and We Anticipate that our Losses will Continue. We have not been profitable for a significant period. For the fiscal years ended June 30, 2017 and 2016, we had a net loss of $29,095,000 and $18,588,000 respectively and an accumulated deficit at June 30, 2017, of $185,357,000. We will continue to incur significant costs as we develop and market our current products and related applications. Although we are executing our business plan to develop, market and launch new products, continuing losses may impair our ability to fully meet our objectives for new product sales or threaten our ability to continue as a going concern in future years.

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

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

As of June 30, 2017 we have a goodwill balance of $13,195,000 and a net intangible assets balance of $20,165,000, out of total assets of $46,932,000. As a result, the amount of any annual or interim impairment could be significant and could have a material adverse effect on our reported financial results for the period in which the charge is taken.

We may Incur Significant Non-operating, Non-cash Charges Resulting from Changes in the Fair Value of Warrants. Our Series A warrants are a derivative instrument; as such they have been recorded at their respective relative fair values at the issuance date and will be recorded at their respective fair values at each subsequent balance sheet date. Any change in value between reporting periods will be recorded as a non-operating, non-cash charge at each reporting date. The impact of these non-operating, non-cash charges could have an adverse effect on the Company's financial results. The fair value of the warrants is tied in large part to our stock price. If the stock price increases between reporting periods, the warrants become more valuable. As such, there is no way to forecast what the non-operating, non-cash charges will be in the future or what the future impact will be on our financial statements.

Risks Related to Our Common Stock

If the Price of our Common Stock does not Meet the Requirements of the NASDAQ Capital Market ("NASDAQ"), Our Shares may be Delisted. Our Ability to Publicly or Privately Sell Equity Securities and the Liquidity of Our Common Stock Could be Adversely Affected if We Are Delisted. The listing standards of NASDAQ provide, among other things,

that a company may be delisted if the bid price of its stock drops below $1.00 for a period of 30 consecutive business days. Delisting from NASDAQ could adversely affect our ability to raise additional financing through the public or private sale of equity securities, would significantly affect the ability of investors to trade our securities and would negatively affect the value and liquidity of our common stock. Delisting could also have other negative results, including the potential loss of confidence by employees, the loss of institutional investor interest and fewer business development opportunities.

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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 do not intend to pay cash dividends in the foreseeable future. Instead, we intend to apply earnings, if any, to the expansion and development of our business. Thus, the liquidity of your investment is dependent upon your ability to sell stock at an acceptable price. The price can go down as well as up and may limit your ability to realize any value from your investment, including the initial purchase price.

ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

ITEM 2. PROPERTIES

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

In Gurgaon India we lease approximately 5,800 square feet for an office facility for our clinical development segment. The lease expires March 1, 2018. In August 2017, we gave a 30 days notice of our intention to terminate this lease and entered into a lease for a different facility for approximately 1,500 square feet. The new lease expires September 14, 2023, however, either party can terminate the lease after September 2019 with three months notice.

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.

We believe our facilities are adequate for our present needs and expect them to remain adequate for the foreseeable future.

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 and while the outcome of such disagreements and disputes cannot be predicted with certainty, except as described below, we do not believe that any pending legal proceedings are material. Regardless of the outcome, litigation can have an adverse impact on us because of defense and settlement costs, diversion of management resources and other factors.

On May 4, 2017, Mavericks Capital LLC and Mavericks Capital Securities LLC filed suit against the Company in the Superior Court of the State of California for the County of Santa Clara (Case No. 17 CV 309652). The complaint relates to a July 20, 2015 agreement between the parties in which plaintiffs agreed to assist the Company in finding strategic partners. The complaint alleges that the Company breached the agreement by failing to pay plaintiffs a $1 million "Transaction Fee" in connection with what plaintiffs allege was a "Sale of the Company." The complaint seeks compensatory and special damages, interest, costs, and attorneys' fees. On June 22, 2017, the Company answered the complaint, denying all material allegations. The parties are currently engaged in discovery, and no trial date has been set.

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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 alleging misappropriation of trade secrets and breach of contract among other claims. On July 7, 2017, as part of the SynGen acquisition transaction and in consideration of the parties' agreement pursuant thereto, we settled this dispute and the parties granted each other customary mutual releases.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

PART II

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

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

Fiscal 2017	High	Low	Fiscal 2016	High	Low
First Quarter (Sep. 30)	$5.42	$2.75	First Quarter (Sep. 30)	$16.44	$10.60
Second Quarter (Dec. 31)	$3.90	$2.52	Second Quarter (Dec. 31)	$12.40	$3.64
Third Quarter (Mar. 31)	$3.67	$2.75	Third Quarter (Mar. 31)	$6.20	$2.12
Fourth Quarter (June 30)	$3.28	$2.94	Fourth Quarter (June 30)	$4.01	$1.91

We have not paid cash dividends on our common stock and do not intend to pay a cash dividend in the foreseeable future. There were approximately 206 stockholders of record on June 30, 2017 (not including street name holders).

During the fiscal year ended June 30, 2017, we engaged in deemed repurchases of 47,024 shares of our common stock as a result of permitting holders of restricted stock unit awards under our equity plans to surrender shares issuable pursuant to such awards in order to satisfy tax withholding obligations.

ITEM 6. SELECTED FINANCIAL DATA

Not applicable for Smaller Reporting Companies.

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

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

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Overview

Cesca is a regenerative medicine company that develops, commercializes and markets a range of automated technologies for cell-based therapeutics. Cesca's device division provides a full suite of solutions for automated clinical biobanking, point-of-care applications, and automation for immuno-oncology. Cesca is also leveraging its proprietary AutoXpress® technology platform to develop autologous stem cell-based therapies that address significant unmet needs in the vascular, cardiology and orthopedic markets.

On July 7, 2017, our wholly-owned subsidiary, ThermoGenesis Corp. ("ThermoGenesis"), acquired the business and substantially all of the assets of SynGen, a privately held Sacramento, California-based technology company that develops, markets, and sells advanced cell separation tools and accessories. In the transaction (the "SynGen Transaction"), ThermoGenesis acquired substantially all of SynGen's operating assets, including its proprietary cell processing platform. In exchange, ThermoGenesis issued to SynGen shares of ThermoGenesis common stock that, after giving effect to the issuance, constitute 20% of ThermoGenesis' outstanding common shares, and ThermoGenesis also made a one-time cash payment of $1.0 million to SynGen. Immediately prior to the SynGen Transaction, the Company contributed the assets, business, and current liabilities of its blood and bone-marrow processing device business to ThermoGenesis and will operate such business (together with the acquired business) through the ThermoGenesis subsidiary.

Prior to the SynGen Transaction, Cesca's device business was owned and operated directly by Cesca, and from and after the SynGen Transaction, Cesca's device business (together with the business acquired from SynGen) is and will be owned and operated by ThermoGenesis.

In August 2017, our Board of Directors approved changing our fiscal year from June 30 to a calendar year ending December 31. As a result, we will file a transition report on Form 10-K for the six month period ending December 31, 2017. Prior to filing the transition report, we will file a quarterly report on Form 10-Q for the quarter ending September 30, 2017.

Cesca's Device Division- ThermoGenesis Corp.

ThermoGenesis Corp. ("ThermoGenesis"), a wholly owned subsidiary of the Company that owns and operates the Company's device division, is a pioneer and market leader in the development and commercialization of automated technologies for cell-based therapeutics and bio-processing. The Device segment's automated solution offerings include:

Clinical BioBanking

AXP® + BioArchive® provide automated isolation, collection and storage of cord blood stem cell concentrates.

Point-of-Care Solutions for Cell-Based Therapeutics

PXP™ allows for the rapid, automated processing of autologous peripheral or bone marrow derived stem cells at the point-of-care, such as surgical centers or clinics.

Cellular Processing for Immuno-Oncology Applications

CXP™ BioArchive® allow for the automated manufacturing, expansion and storage of cellular therapies for immuno-oncology, including various T-cell and nature killer (NK) cell based therapies.

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The Device Segment's product pipeline includes:

AutoXpress® System (AXP®) - a proprietary, automated system for the isolation and collection of hematopoietic stem cells from cord blood and peripheral blood.
PXP™ for Point-of-Care Applications – a proprietary, automated system for the rapid, automated processing of autologous peripheral or bone marrow derived stem cells for cell-based therapies at point-of-care situations, such as surgical centers or clinics.
CAR-TXpress (CXP)™ - a proprietary, automated system for the isolation and collection of cells derived from biological sources, for various laboratory based downstream applications.
BioArchive® - an automated, cryogenic system used by cord blood banks for the cryopreservation and storage of cord blood stem cell concentrate for future use.

Cesca's Clinical Development Division

Using its proprietary AutoXpress® technology platform, Cesca is developing autologous (utilizing the patient's own cells) stem cell-based therapeutics that Cesca believes will address significant unmet medical needs for applications within the vascular, cardiology and orthopedic markets.

Vascular Diseases - Critical Limb Ischemia ("CLI") – Cesca is currently in late stage development of its proprietary, point-of-care, autologous stem cell-based therapeutic for the treatment of patients with CLI. The Company's 362 patient, multi-center pivotal Phase III Critical Limb Ischemia Rapid Stem Cell Treatment ("CLIRST") trial is designed to evaluate the safety and efficacy of autologous stem cell-based therapy to stimulate the regeneration of blood vessels, promote wound healing and prevent amputation. Previous clinical studies using Cesca's proprietary, point-of-care-technologies have successfully demonstrated the regeneration of blood vessels and improved blood circulation in the limbs, using a patient's own bone marrow derived stem cells. The Company is actively seeking strategic partners to co-develop CLIRST.

Cardiology - Acute Myocardial Infarction – Cesca is developing a proprietary, point-of-care autologous stem cell-based therapy intended as an adjunct treatment for patients who have suffered an acute ST-elevated myocardial infarction ("STEMI"), the most serious type of heart attack. Such treatments are aimed at minimizing the adverse remodeling of the heart post-STEMI.

Orthopedics – OsteoArthritis (OA) - Cesca is in early stage development of an autologous stem cell based therapy intended to treat patients with cartilage tissue degeneration that may lead to progressive cartilage loss and painful joint diseases. Localized articular cartilage defects can potentially be repaired by transplantation of autologous cell therapy. Therapies in development using Cesca's proprietary PXP™ system are expected to delay further deterioration and repair

the damaged joint cartilage. Treatment is typically via a single procedure in the hospital or clinic.

Results of Operations

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

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Results of Operations for the Fiscal Year Ended June 30, 2017 versus the Fiscal Year Ended June 30, 2016

Net Revenues

Consolidated net revenues for 2017 were $14,525,000 compared to $11,929,000 for 2016, an increase of $2,596,000. Device segment revenues increased primarily as a result of increased shipments of AXP disposables to a single end-user customer and distributors in China and Europe. Also, contributing to the increase, we shipped three BioArchive devices during the year ended June 30, 2017 versus one during the year ended June 30, 2016. Clinical development revenues consist of sales generated by our Totipotent subsidiaries. The decrease is due to the loss of their largest manual bag set customer.

Revenues were comprised of the following for the years ended:

	June 30, 2017	June 30, 2016
Device Segment:		
AXP	$8,715,000	$6,924,000
BioArchive	3,318,000	2,465,000
Manual Disposables	1,034,000	1,203,000
Bone Marrow	582,000	341,000
Other	384,000	350,000
	14,033,000	11,283,000
Clinical Development Segment:		
Manual disposables	161,000	305,000
Bone Marrow	163,000	117,000
Other	168,000	224,000
	492,000	646,000
	$14,525,000	$11,929,000

Gross Profit

Consolidated gross profit was $5,839,000 or 40% of revenues for 2017 compared to $2,744,000 or 23% of revenues for 2016. Our device segment gross profit margin increased from $2,672,000 or 24% to $5,813,000 or 41% for fiscal 2016 to fiscal 2017 primarily due to higher average sales prices on our mix of products sold and a reduction in our overhead costs during the year ended June 30, 2017. Additionally, in the prior year, there was an increase to our inventory reserves and a provision for expected losses on non-cancelable purchase commitments. Gross profit for our clinical segment decreased from $72,000 or 11 % to $26,000 or 5% due to product mix and lower sales volumes.

Sales and Marketing Expenses

Consolidated sales and marketing expenses were $1,531,000 for 2017, compared to $2,148,000 for 2016, a decrease of $617,000 or 29%. The decrease is driven primarily by our device segment and is due to lower personnel costs during the year ended June 30, 2017 due to reorganizing the sales and marketing function in September 2016. Our clinical segment had an increase of $49,000 for 2017, due to higher costs related to our cord blood bank marketing in India.

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Research and Development Expenses

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

Consolidated research and development expenses for 2017, were $2,497,000 compared to $3,230,000 for 2016, a decrease of $733,000 or 23%. The decrease was primarily due to lower salaries and benefits in the clinical development segment of approximately $500,000 due to a decrease in headcount and a reduction in rent expense in the clinical development segment of approximately $350,000 associated with the consolidation of our US operations into our Rancho Cordova facility. Research and development expenses are expected to increase when the Company initiates additional clinical trials which the Company intends to fund through strategic partnerships.

General and Administrative Expenses

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

Consolidated general and administrative expenses were $11,051,000 for 2017, compared to $8,231,000 for 2016, an increase of $2,510,000 or 30%. The increase is primarily due to the termination of our former Chief Executive Officer in November 2016 and our former Chief Financial Officer in March 2017 which resulted in $2,200,000 of expense for severance and acceleration of stock options and restricted stock units. Additionally, legal expenses increased $1.1 million largely as a result of attorney fees associated with the SynGen litigation, which was settled on July 7, 2017. These expenses were allocated among both of our segments.

Interest Expense

The increase in interest expense from $1,864,000 for the year ended June 30, 2016 to $10,668,000 for the year ended June 30, 2017 was primarily due to the conversion in the first quarter of fiscal 2017 of all outstanding principal and non-cash interest accrued and otherwise payable under the debentures of $7,379,000 and additional non-cash interest expense of $3,153,000 recorded based on the fair market value of the common stock issued upon conversion.

Benefit for Income Taxes

The deferred income tax benefit of $673,000 is due to changes in the state tax rate over the last several years. Approximately $559,000 of the benefit relates to state rate changes prior to fiscal 2017, which was all recognized in the current year, of which $157,000 relates to fiscal 2016 and $402,000 relates to years prior to fiscal 2016.

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 Company defines adjusted EBITDA as loss from operations and before other income (expenses) adjusted for non-cash items that impact operations, including depreciation and amortization, stock-based compensation expenses and impairment of intangible assets. 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 US GAAP measure are provided below.

	For the Year Ended June 30, 2017		
	Clinical Development	Device	Total
Loss from operations	$(8,940,000)	$(300,000)	$(9,240,000)
Add:			
Depreciation and amortization	501,000	329,000	830,000
Stock-based compensation expense	970,000	491,000	1,461,000
Impairment of intangible asset	310,000	--	310,000
Adjusted EBITDA	$(7,159,000)	$520,000	$(6,639,000)

	For the Year Ended June 30, 2016		
	Clinical Development	Device	Total
Loss from operations	$(8,240,000)	$(2,625,000)	$(10,865,000)
Add:			
Depreciation and amortization	644,000	524,000	1,168,000
Stock-based compensation expense	548,000	194,000	742,000
Adjusted EBITDA	$(7,048,000)	$(1,907,000)	$(8,955,000)

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Adjusted EBITDA

Our consolidated adjusted EBITDA loss was $6,639,000 for 2017, compared to $8,955,000 for 2016. The reduction in the adjusted EBITDA loss was due primarily to our higher revenues and resulting higher gross profit margin.

Liquidity and Capital Resources

At June 30, 2017, we had cash and cash equivalents of $3,623,000 and working capital of $6,658,000. This compared to cash and cash equivalents of $5,835,000 and working capital of $7,301,000 at June 30, 2016. We have primarily financed operations through private and public placement of equity securities and our line of credit facility.

On March 6, 2017, Cesca entered into a Credit Agreement with Boyalife Investment Fund II, Inc. (the “Lender”) which grants to the Company the right to borrow up to $5,000,000 in amounts of $500,000 per advance on an unsecured basis at any time prior to March 6, 2022. On September 13, 2017, we entered into an amendment to the Credit Agreement with the Lender increasing our maximum borrowing availability thereunder from $5.0 million to $10.0 million. As of September 20, 2017 the Company had drawn down $5,000,000 of the $10,000,000 available under the Credit Agreement.

On August 22, 2016, the Company elected to convert all outstanding principal and interest accrued and otherwise payable under the Company’s Secured Convertible Debentures aggregating $23,905,000 dating back to Cesca’s February 2016 financing. Upon conversion, 6,102,941 shares of common stock were issued and the debentures plus all related security interests and liens were terminated.

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

The net proceeds to the Company from the sale and issuance of the shares, after deducting the offering expenses borne by the Company, were $2,092,000.

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

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

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

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Our net cash used in operating activities for the year ended June 30, 2017 was $7,215,000 compared to $9,625,000 for the year ended June 30, 2016. The improvement in net cash used in operating activities was primarily due to the higher revenue volume and a higher gross profit margin on our mix of products sold.

Based upon the additional funds available to draw down under the amended Credit Agreement, the Company's cash balance, historical trends, expected outflows and projections for revenues, management believes it will have sufficient cash to provide for its projected needs to maintain operations and working capital requirements for at least the next 12 months from the date of filing this annual report.

The Company will need additional funding to support its operations and its clinical development programs, in particular the Phase III Critical Limb Ischemia Rapid Stem Cell Treatment ("CLIRST III") trial. Accordingly, management has been exploring additional funding sources, with a primary focus on strategic partner relationships. The Company cannot assure that such funding will be available on a timely basis, in needed quantities, or on favorable terms, if at all.

On July 7, 2017, the Company entered into a transaction in which its wholly owned subsidiary, ThermoGenesis, acquired the business and substantially all of the assets of SynGen Inc. ("SynGen"), a privately held Sacramento, California-based technology company that develops, markets, and sells advanced cell separation tools and accessories. In the transaction (the "SynGen Transaction"), ThermoGenesis acquired substantially all of SynGen's operating assets, including its proprietary cell processing platform. In exchange, ThermoGenesis issued to SynGen shares of ThermoGenesis common stock that, after giving effect to the issuance, constitute 20% of ThermoGenesis' outstanding common shares, and ThermoGenesis also made a one-time cash payment of $1.0 million to SynGen (together with the issuance of common stock, the "Transaction Consideration").

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

We generally do not require extensive capital equipment to produce or sell our current cord blood banking products. In fiscal 2017 we spent $375,000 primarily for equipment to be used in our proposed clinical trials and improvements to our clinical laboratory in Rancho Cordova as a result of closing the Emeryville location. In fiscal 2016 we spent $710,000 primarily for tooling at a contract manufacturer and equipment to be used in our Point-of-Care development program.

At June 30, 2017, we had a distributor that accounted for 36% of accounts receivable. At June 30, 2016, we had three distributors/customers that accounted for 57% of accounts receivable.

Revenues from a customer totaled $3,263,000 or 22% and $2,475,000 or 21% for the years ended June 30, 2017 and 2016, respectively. Revenues from one distributor totaled $2,842,000 or 20% and $2,797,000 or 23% of net revenues for the years ended June 30, 2017 and 2016, 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.

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Critical Accounting Policies

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

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

Goodwill, Intangible Assets and Impairment Assessments

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

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

Revenue Recognition

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

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

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

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

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

Stock-Based Compensation

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

Income Taxes

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

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

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Inventory Valuation

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

Warranty

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

Recent Accounting Standards

See footnote 2 “Summary of Significant Accounting Policies”.

Off Balance Sheet Arrangements

We have no off-balance sheet arrangements.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

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

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Audit Committee of the

Board of Directors and Shareholders

of Cesca Therapeutics, Inc.

We have audited the accompanying consolidated balance sheets of Cesca Therapeutics, Inc. (the "Company") as of June 30, 2017 and 2016, and the related consolidated statements of operations, comprehensive loss, changes in stockholders' equity and cash flows for the years then ended. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

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

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of Cesca Therapeutics, Inc., as of June 30, 2017 and 2016, and the consolidated results of its operations and its cash flows for the years then ended in conformity with accounting principles generally accepted in the United States of America.

/s/ Marcum llp

Marcum llp

New York, NY

September 21, 2017

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Cesca Therapeutics Inc.

Consolidated Balance Sheets

	June 30, 2017	June 30, 2016
ASSETS		
Current assets:		
Cash and cash equivalents	$3,623,000	$5,835,000
Accounts receivable, net of allowance for doubtful accounts of $102,000 ($49,000 at June 30, 2016)	3,701,000	3,169,000
Inventories, net of reserves of $1,230,000 ($1,437,000 at June 30, 2016)	3,617,000	3,593,000
Prepaid expenses and other current assets	237,000	246,000
Total current assets	11,178,000	12,843,000
Equipment, net	2,330,000	2,962,000
Goodwill	13,195,000	13,195,000
Intangible assets, net	20,165,000	20,821,000
Other assets	64,000	78,000
Total assets	$46,932,000	$49,899,000
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$1,601,000	$2,648,000
Accrued payroll and related expenses	385,000	449,000
Deferred revenue	597,000	783,000
Related party payable	606,000	--
Other current liabilities	1,331,000	1,662,000
Total current liabilities	4,520,000	5,542,000
Long term debt-related party	3,500,000	--
Derivative obligations	730,000	670,000
Convertible debentures, net	--	2,489,000
Noncurrent deferred tax liability	6,968,000	7,641,000
Other noncurrent liabilities	377,000	1,284,000
Total liabilities	16,095,000	17,626,000
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, $0.001 par value; 2,000,000 shares authorized, none issued and outstanding at June 30, 2017 and 2016	--	--
Common stock, $0.001 par value; 350,000,000 shares authorized; 9,915,868 issued and outstanding (3,010,687 at June 30, 2016)	10,000	3,000

Paid in capital in excess of par	216,222,000	188,569,000
Accumulated deficit	(185,357,000)	(156,262,000)
Accumulated other comprehensive loss	(38,000)	(37,000)
Total stockholders' equity	30,837,000	32,273,000
Total liabilities and stockholders' equity	$46,932,000	$49,899,000

See accompanying notes to consolidated financial statements.

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Cesca Therapeutics Inc.

Consolidated Statements of Operations and Comprehensive loss

	For the years ended June 30	
	2017	2016
Net revenues	$14,525,000	$11,929,000
Cost of revenues	8,686,000	9,185,000
Gross profit	5,839,000	2,744,000
Expenses:		
Sales and marketing	1,531,000	2,148,000
Research and development	2,497,000	3,230,000
General and administrative	11,051,000	8,231,000
Total operating expenses	15,079,000	13,609,000
Loss from operations	(9,240,000)	(10,865,000)
Other income (expense):		