

CESCA THERAPEUTICS INC.  
Form 10-KT  
March 22, 2018

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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

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934 FOR THE TRANSITION PERIOD FROM JULY 1, 2017 TO DECEMBER 31, 2017.

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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  No

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

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

Yes  No

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

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, 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   
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  No

As of June 30, 2017, the aggregate market value of the common equity held by non-affiliates of the registrant was approximately \$9,714,000 based on the closing sales price as reported on the NASDAQ Stock Market. As of March 20, 2018, there were 10,872,428 shares of common stock without par value outstanding.

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**CESCA THERAPEUTICS INC.**

**FORM 10-K**

**FOR THE TRANSITION PERIOD ENDED DECEMBER 31, 2017**

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## CAUTIONARY STATEMENT REGARDING FORWARD LOOKING STATEMENTS

This Transition 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 Transition 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 Transition 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,” “would,” “could,” “potential,” “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 Transition 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 Transition Report contains references to our trademarks and to trademarks belonging to other entities. Solely for convenience, trademarks and trade names referred to in this Transition 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.

## **PART I**

### **EXPLANATORY NOTE REGARDING THE TRANSITION REPORT**

In August 2017, we changed our fiscal year from June 30 to December 31. As a result, this Transition Report on Form 10-K is a transition report (Transition Report) and includes financial information for the transition period from July 1, 2017 through December 31, 2017. Subsequent to this Transition Report, our reports on Form 10-K will cover the period beginning January 1 and ending December 31, which will be our fiscal year. We refer in this Transition Report to the period beginning on July 1, 2017 and ended on December 31, 2017 as the "Transition Period." We refer in this Transition Report to the period beginning on July 1, 2016 and ended on June 30, 2017 as "fiscal 2017" and the period beginning on July 1, 2015 and ended on June 30, 2016 as "fiscal 2016." In this Transition Report, we compare financial results for the Transition Period, which are audited, with the financial results for July 1, 2016 through December 31, 2016, which are unaudited. We also compare the financial results for fiscal 2017 and fiscal 2016 which are audited.

### **ITEM 1. BUSINESS**

Cesca Therapeutics Inc. ("Cesca Therapeutics," "Cesca," the "Company," "we," "our," "us"), a Delaware corporation founded 1986, develops, commercializes and markets a range of automated technologies for cell-based therapies. Since the 1990's, Cesca has been the pioneer and one of the leading developers and suppliers of automation technologies for the isolation, purification and storage of stem cells for the cord blood banking industry. In July 2017, a Cesca subsidiary, ThermoGenesis Corp. (ThermoGenesis), completed the strategic acquisition of the business and substantially all of the assets of SynGen Inc., a research and development company for automated cellular processing, and the products from both companies were combined to develop a proprietary CAR-TXpress™ platform that addresses the critical unmet need for better chemistry, manufacturing and controls (CMC) for the emerging immuno-oncology field, in particular, the chimeric antigen receptor T cell (CAR-T) market.



Immunotherapy has become the “next pillar” of cancer treatment, in addition to the traditional surgical removal, radiation and chemotherapy. Immunotherapy stimulates the patient’s own immune system to fight cancer cells, and is fairly well-tolerated. Unlike chemotherapy and radiation, immunotherapy is designed to leave healthy cells unscathed. In 2017, two CAR-T cell based immunotherapeutic drugs were approved by the U.S. Food and Drug Administration (FDA). Kymriah<sup>®</sup> manufactured by Novartis was approved for the treatment of children with acute lymphoblastic leukemia (ALL) and Yescarta<sup>®</sup> manufactured by Kite Pharma for adults with advanced lymphomas. Both CAR-T drugs have reported over 80% response rate in the intended-to-treat cancer patient group. At the end of 2017, there were over 400 CAR-T cell related immune-oncology clinical trials globally registered on the National Institute of Health (NIH) [clinicaltrials.gov](https://clinicaltrials.gov) website. These trials target a wide variety of hematopoietic and solid tumors. However, the current high cost and low capacity of drugmakers to manufacture CAR-T cells are significant barriers affecting future applications and affordability of these new immunotherapies.

In November 2017, the Company introduced its CAR-TXpress™ system, a proprietary low-cost, functionally closed and semi-automated system for CAR-T cell manufacturing. The CAR-TXpress™ platform addresses critical unmet needs for improving CMC for the emerging CAR-T immuno-oncology field. CAR-TXpress™ eliminates the use of ficoll and replaces the use of magnetic beads for T cell isolation speeding up time-consuming steps using traditional methods in the cell manufacturing process. Such improvement may drastically reduce processing time and increase efficiency of the manufacturing process, which is intended to drive down the overall manufacturing cost as well as increase the manufacturing capacity for future CAR-T drugmakers.

Through ThermoGenesis, the Company is currently developing the X-Series™ of devices and reagent kits as part of the CAR-TXpress™ platform. The initial X-Series™ products are intended for research use and/or non-commercial manufacturing of cell-based products for clinical research. The Company expects to do a soft launch during first half of 2018, with initial shipments planned for research laboratories and key opinion leaders in the CAR-T research space. The Company is also developing commercial manufacturing devices and reagent kits for cGMP manufacturing of CAR-T for drug developers. In addition, ThermoGenesis is actively in discussions with potential global distribution partners for our X-Series™ products. More details of the X-Series™ products are described in the “Product” section below.

In addition to selling the “off-the-shelf” X-Series™ products, we are also planning to enter into the CAR-T third party cellular process development and manufacturing service business by collaborating with, and possibly establishing our own contract development and manufacturing organizations (CDMO) in the U.S. and China, the two leading markets with the highest numbers of active CAR-T clinical trials. For each first two approved CAR-T drug products, analysts estimate that each product could reach peak revenues exceeding \$1 billion. Analysts also estimate that cost of goods (COGS) for these new therapies exceed \$100,000 per patient presenting a significant challenge for health care payors and patients. Given the number of ongoing clinical trials registered globally, we believe this represents a significant growth opportunity for our CAR-TXpress™ platform to address the COGS issue for these exciting potential new treatments.

In the stem cell and regenerative medicine field, Cesca continues to provide automation technologies for cord blood banking and autologous stem cell applications. Our AutoXpress® (AXP®) technology platform is a leading automated stem cell isolation device product for the cord blood banking industry. Cesca also has a proprietary point-of-care, autologous stem cell-based therapy under development for the treatment of patients with critical limb ischemia (CLI). The Company’s 362 patient, multi-center pivotal Phase 3 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. Cesca’s CLI trial design was accepted and approved by the U.S. FDA. 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. The Company is in early stage development of autologous stem cell based therapy intended to treat patients with acute myocardial infarction and cartilage tissue degeneration, addressing significant unmet needs in the vascular, cardiology and orthopedic markets.

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

## **Our Business Strategy**

Our business strategy is to leverage our over 25 years of expertise, our strong intellectual property portfolio and significant know-how in the automated cellular processing field to develop automated cellular processing devices and processes for the fast evolving immunotherapeutic field, including more efficient methods of manufacturing CAR-T cells. Our CAR-TXpress platform addresses many of critical unmet needs for improving CAR-T cell manufacturing and reducing cost. Our intention is to aggressively pursue these new growth opportunities in this emerging field of immuno-oncology, while continuing to support the performance and competitiveness of our flagship product lines in the cord blood and stem cell banking arena.

In 2018, we plan to pursue business opportunities through two separate business divisions which focus on immuno-oncology and regenerative medicine, respectively.

### **In the immune-oncology field:**

Launch X-Series™ devices and reagents for research use only, including the X-Mini™, X-Maxi™, X-Auto™ kits for cellular isolation and purification and non-commercial manufacturing of cell-based products for clinical research.

Develop and launch our X-Series™ devices and reagents for clinical use, including our X-Clini™ kit for cGMP commercial manufacturing of CAR-T cells for drug developers and manufacturers.

Expand into contract development and manufacturing services (CDMO) for immune-oncology through internal and external efforts, including but not limited to partnerships, licensing, or co-development transactions.

### **In the stem cell and regenerative medicine field:**

Sustain our market leadership position in automated devices for the separation and concentration of stem cell preparation for the cord blood banking market.

Continue supporting product registration and marketing of automated devices for the separation and concentration of bone marrow-derived stem cell preparation for the point-of-care clinical application market.

Partner our clinical development programs, including our lead Critical Limb Ischemia Rapid Stem Cell Treatment (CLIRST) phase III clinical trial, with third parties to maximize the value of our existing clinical development programs while eliminating our costs for running clinical trials.

***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.

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

*Received two new patent issuances for CAR-T cell processing.* In 2017, the U.S. Patent and Trademark Office (USPTO) awarded ThermoGenesis two new U.S Patents, No. 9,695,394 and 9,821,111, both entitled “Cell Separation Devices, Systems, and Methods.” These two new patents include our apparatus and method claims that protect our proprietary technology for isolating and harvesting purified populations of rare, therapeutically critical target cells from blood, bone marrow, leukapheresis product, and other cell sources, while maintaining the viability of the cells under aseptic conditions. This advanced cell separation technology, known as Buoyancy-Activated Cell Separation, is key to the ongoing development of Cesca’s CAR-TXpress™ platform.

*Introduced the CAR-TXpress™ platform.* In November 2017, we formally introduced the CAR-TXpress™ cellular manufacturing platform technology at the CAR-TCR Summit in Boston. CAR-TXpress™ is a proprietary, ficoll-free, magnetic beads free, functionally closed cellular processing platform that addresses the critical unmet need for improving manufacturing capacity and cost control for the emerging CAR-T cell based immune-oncology market.

*Raised \$2.4 Million in Equity Financing.* On December 1, 2017, we sold 898,402 shares of common stock at a price of \$3 per share. The net proceeds from the sale and issuance of the shares, after deducting the offering expenses borne by the Company were approximately \$2,368,000.

*Filed additional patents covering our CAR-T cell processing technology.* Most recently, we filed a fourth patent application for our CAR-T cell manufacturing technology addressing key issues to enhance cellular purification and activation. The provisional patent application is intended to expand patent coverage of our the ability of our CAR-TXpress™ platform to activate and transduce CD3+ T cells and expand genetically modified CART-cells.

*Expanded into CDMO business through exclusive license agreement in Asia.* In March 2018, we entered into an exclusive license agreement with IncoCell, a wholly owned subsidiary of the Boyalife Group, to implement our CDMO strategy for China and other regional countries in Asia. As of the end of 2017, more than 400 active CAR-T cell clinical trials were registered with clinicaltrials.gov, one third were originated from the U.S. and one third from China. IncoCell currently operates a 160,000 sq. ft. cGMP facility in Tianjin, China.

## **Our X-Series™ Products**

### ***Immuno-Oncology Products***

In November 2017, ThermoGenesis announced the development of a proprietary CAR-TXpress™ platform that addresses the critical unmet need to improve CMC manufacturing for the emerging CAR-T therapies for cancer

patients. CAR-TXpress™ eliminates the use of ficoll and magnetic beads for cell isolation procedures, and reduces processing time and increases cell recovery rates. The CAR-TXpress™ platform includes the following X-Series™ products:

**X-LAB™ for Cell Isolation** – a semi-automated, functionally-closed, ficoll-free, system for the rapid isolation of different target cells from various sources including blood and blood products.

**X-BACS™ for Cell Purification** – a semi-automated, “functionally closed” system that employs a single-use sterile, injection molded plastic disposable cartridge in which streptavidin coated lipid microbubbles and biotinylated antibodies bind to, and make buoyant, target cells (such as CD3+ T-cells) so they separate from non-target cells during centrifugation with great efficiency. Simultaneously, the non-target cells are automatically transferred to a separate cartridge chamber leaving a highly-purified and viable population of target cells for research or clinical use.

**X-WASH™ for Washing and Reformulation** – a semi-automated, functionally-closed system that washes and volume-reduces fresh or thawed cells or cell cultures to a user-defined final volume.

**BioArchive® for Cryogenic Cellular Product Storage** – an automated, controlled-rate-freezing, liquid nitrogen freezer intended for the cryopreservation and single-cassette based storage of clinical samples. The BioArchive® provides customers who need to store therapeutic cell populations in cryogenic storage (-196°C) with a solution that combines the individualized controlled rate freezing of each sample, robotic storage and retrieval of each sample and real-time chain of custody management.

ThermoGenesis is also developing a series of “off the shelf” single use kits that are comprised of different combinations of X-Series™ products depending on different customer use cases. These X-Mini™, X-Maxi™ and X-Auto™ kits are currently intended for research use and non-commercial manufacturing of cell-based products for clinical research. The Company is also developing the X-Clini™ kit intended for cGMP commercial manufacturing of CAR-T for drug developers. The Company expects to introduce these kits to the market during 2018, with initial shipments planned for key opinion leaders in the CAR-T research space. ThermoGenesis is also in active discussions with potential global distribution partners for the X-Series™ kits.

In addition to selling the X-Series™ products, we have future plans to enter the contract development manufacturing organization (CDMO) space utilizing our proprietary and patented technology. The U.S. and China are currently the two largest markets for active clinical trials for CAR-T and therefore we will target these two regions for our manufacturing operations. In March 2018, Cesca entered into an exclusive license agreement with IncoCell, a fully owned subsidiary of the Boyalife Group, to implement a CDMO strategy in China and other regions in Asia. Cesca’s CDMO business model is to introduce our CAR-TXpress™ automated manufacturing solutions on both a fee-for-service or co-development basis.

### **Stem Cell and Regenerative Medicine**

Cesca is also leveraging its proprietary AutoXpress® technology platform for stem cell banking and for the development of autologous (utilizing the patient’s own cells) stem cell-based therapies that address significant unmet needs in the vascular, cardiology and orthopedic markets.



**AXP® for Stem Cell Banking** – a proprietary, automated system for the isolation, collection and storage of hematopoietic stem cell concentrates derived from cord blood and peripheral blood.

**VXP® for Critical Limb Ischemia (CLI)** – Cesca has a proprietary point-of-care, autologous (donor and recipient are the same individual) stem cell-based therapy under development which is intended for the treatment of patients with CLI. The FDA has cleared the Company to proceed with a 362 subject, multi-center pivotal Phase III CLIRST study, which is designed to evaluate the safety and efficacy of Cesca’s autologous stem cell-based therapy in patients with no-option or poor option late stage CLI. 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.

**VXP® for 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.

**PXP™ for 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.

### **Cell Manufacturing and Banking Services (India)**

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 MXP® 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 CLI 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 addition 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.

**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.

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## **Research and Development**

Our research and development activities for the six months ended December 31, 2017 were geared towards expanding the automated platform for the immune-oncology applications while maintaining our biobanking and point-of-care automation solutions. In November 2017, we introduced the CAR-TXpress™ platform, which is the first functionally closed system for CAR-T cellular processing and manufacturing. We also improved our AXP®, BioArchive® and MXP® platforms with a focus on both performance improvements and ease of use. 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 for the six months ended December 31, 2017 were \$2,246,000 and \$2,497,000 and \$3,230,000 for the years ended June 30, 2017 and 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.

In addition, we are in process of building a 1,000 sq ft manufacturing clean room in our Rancho Cordova facility. We intend to expand our in-house manufacturing capacity for the X-Series™ kits and devices.

## **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.

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

### ***Class III Devices***

If a product is considered a Class III device, as is the case with the 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.



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.

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 October 12, 2017, we signed an agreement with Fortis which replaced the previous agreement that expired on August 1, 2017. The services agreement covers the areas of cord blood banking, point of care technology sales and support, bone marrow transplant and clinical/patient management of clinical trials for our internally developed therapeutics.

***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<sup>®</sup> 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<sup>®</sup> devices and disposables. The license is for the sole and limited purpose of ensuring continued supply of the AXP<sup>®</sup> 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 the Company, 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 December 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<sup>®</sup> (AutoXpress<sup>®</sup>) 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<sup>®</sup> Disposable Blood Processing Sets and use rights to the AutoXpress<sup>®</sup> System, BioArchive<sup>®</sup> 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.

**Employees**

As of December 31, 2017, we had 86 employees, 59 of whom were employed in the U.S. and 27 of whom were employed in India. We also utilize temporary employees throughout the year to address business needs and significant fluctuations in orders and product manufacturing. None of our employees are covered by a collective bargaining agreement, nor have we experienced any work stoppage.

## **Foreign Sales and Operations**

See footnote 11 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](http://www.cescatherapeutics.com). The information on its website is not incorporated into, and is not part of, this Transition Report on Form 10-K or our other filings with the SEC.

## **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 Transition 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 Transition Report is qualified in its entirety by these risk factors.

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

### ***Risks Related to Our Business***

*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 five persons, two of whom are designated by us, one of whom is designated 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.

*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 December 31, 2017, approximately 63% 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. Xiaochun 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.

*We Utilize Debt Financing from Outside the U.S. and an Inability to Obtain Funds when Requested Could Adversely Impact Operations.* We use debt financing for working capital and other cash requirements. Our ability to use this funding source may be impacted by reasons such as default or foreign government policies that restrict or prohibit transferring funds. In the event that we were not able to obtain funds as needed, it could result in delays to project funding or non-compliance with cash based covenants.



*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.

*We May Be Unable to Obtain Marketing Approval from the FDA For Our 510(k) Devices which may Delay or Reduce Future Sales.* 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.

*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 and product candidates 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.* For the six months ended December 31, 2017 sales to customers outside the U.S. comprised approximately 67% of revenues. This compares to 54% for the year ended June 30, 2017 and 57% for the year ended June 30, 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.

*The Loss of a Significant Distributor or End User Customer may Adversely Affect Financial Condition and Results of Operations.* Revenues from a significant distributor comprised 28% of revenues for the six months ended December 31, 2017. 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.

*Our Pending Litigation with Mavericks Capital could have a Material Adverse Effect on Us.* We are currently defending a lawsuit brought by Mavericks Capital LLC and Mavericks Capital Securities LLC against us and our CEO in California Superior Court arising from a July 2015 Agreement between us and Mavericks in which Mavericks agreed to assist our company in finding strategic partners. The complaint in the lawsuit alleges that we breached the Mavericks agreement by failing to pay Mavericks a \$1 million "Transaction Fee" in connection with investment transactions between us and the Boyalife companies. Mavericks alleges that the Boyalife investment and associated conversion of Boyalife debt was a "Sale of the Company" within the meaning of the Mavericks agreement and therefore allegedly triggered the payment of a fee to Mavericks. The complaint seeks compensatory and special damages, interest, costs, and attorneys' fees. On June 22, 2017, we answered the complaint, denying all material allegations. In October 2017, to streamline the case and without acknowledging any liability, we deposited \$1.0 million with the court in the case (obtained from drawing down our line of credit with Boyalife Investment Fund II, Inc.). Mavericks has also dismissed our CEO from the case without liability. As of January 31, 2018, the parties were engaged in discovery, and no trial date has been set. Although we deny liability in this case and intend to defend it vigorously, there is no assurance that the outcome of the case and resulting legal fees will not have a material adverse effect on our financial condition.

***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 Have Minimal 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 manufacturing, and currently 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 Capabilities which May Limit our Ability to Significantly Increase Sales Quickly.* We have limited internal capabilities in the sales, marketing, and distribution areas. There can be no assurance that we will be able to establish sales, marketing, and distribution capabilities internally or make arrangements with current collaborators or others to perform such activities or that such effort will be successful. If we decide to market any of our new products directly, we must either partner, acquire or internally develop a marketing and sales force with technical expertise and with supporting distribution capabilities. The acquisition or development of a sales, marketing and distribution infrastructure would require substantial resources, which may not be available to us or, even if available, divert the attention of our management and key personnel, and have a negative impact on further product development efforts.

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



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

*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.

*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.

*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 have purchased a new ERP system and are in the implementation process. Until the new system fully 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.

*Security Breaches and Other Disruptions Could Compromise our Information and Expose us to Liability, Which Would Cause our Business and Reputation to Suffer.* In the ordinary course of the Company's business, the Company collects and stores sensitive data, including intellectual property, our proprietary business information and that of our customers, suppliers and business partners and personally identifiable information of the Company's employees on its networks. The secure processing, maintenance and transmission of this information is critical to the Company's operations and business strategy. Despite the Company's security measures, its information, technology and infrastructure may be vulnerable to attacks by hackers or breached due to employee error, malfeasance or other disruptions. Any such breach could compromise the Company's networks and the information stored there could be accessed, publicly disclosed, lost or stolen. Any such access, disclosure or other loss of information could result in legal claims or proceedings or regulatory penalties and could disrupt the Company's operations and the services it provides to customers, damage the Company's reputation, and cause a loss of confidence in the Company's products and services, which could adversely affect the Company's business.

### ***Risks Related to Our Industry***

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

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

*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.

*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. Additionally, 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. We may be liable if any of our products or services 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.

### ***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 six months ended December 31, 2017, we had a net loss of \$2,770,000. For 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 December 31, 2017, of \$187,640,000. The report of independent auditors on our December 31, 2017 financial statements includes an explanatory paragraph indicating there is substantial doubt about our ability to continue as a going concern. We will continue to incur significant costs as we develop and market our current products and related applications. Although we are executing our business plan to develop, market and launch new products, continuing losses may impair our ability to fully meet our objectives for new product sales or threaten our ability to continue as a going concern in future years.

*We Will Need to Raise Additional Capital to Fund our Operations and in Furtherance of Our Business Plan.* We will need to raise additional capital in the near future to fund our future operations and in furtherance of our business plan, including progression of the 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 foregoing 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 reduce 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.

At December 31, 2017, we have a goodwill balance of \$13,976,000 and a net intangible assets balance of \$21,629,000, out of total assets of \$51,111,000. 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.

*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.

*Recently Enacted Tax Reform Legislation in the U.S. Could Adversely Affect our Business and Financial Condition.* On December 22, 2017, the Tax Cuts and Jobs Act of 2017 (Tax Act) was signed into law, making significant changes to the Internal Revenue Code. Changes under the Tax Act include, but are not limited to, a corporate tax rate decrease from 35% to 21% effective for tax years beginning after December 31, 2017, a one-time transition tax on the mandatory deemed repatriation of cumulative foreign earnings, limitation of the tax deduction for interest expense to 30% of adjusted earnings (except for certain small businesses), limitation of the deduction for net operating losses to 80% of current year taxable income and elimination of net operating loss carrybacks, one time taxation of offshore earnings at reduced rates regardless of whether they are repatriated, elimination of U.S. tax on foreign earnings (subject to certain important exceptions), immediate deductions for certain new investments instead of deductions for depreciation expense over time, and modifying or repealing many business deductions and credits (including reducing the business tax credit for certain clinical testing expenses incurred in the testing of orphan drugs). The overall impact of the new federal tax law is uncertain, and our business and financial condition could be adversely affected. For example, because of the tax rate decrease, our deferred tax assets and our corresponding valuation allowance against these deferred tax assets have been reduced and may continue to be adversely impacted. In addition, it is uncertain if and to what extent various states will conform to Tax Act and what effect that legal challenges will have on the Tax Act, including litigation in the U.S. and international challenges brought at organizations such as the World Trade Organization. The impact of the Tax Act on holders of our common stock is also uncertain and could be adverse. Investors should consult with their legal and tax advisors with respect to this legislation and the potential tax consequences of investing in or holding our common stock.

*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 1,500 square feet for an office facility for our Clinical Development Segment. The 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. In October 2017, to streamline the case and without acknowledging any liability, we deposited \$1.0 million with the court in the case. Mavericks has also dismissed the Company's CEO from the case, without liability. The parties are currently engaged in discovery, and no trial date has been set.

**ITEM 4. MINE SAFETY DISCLOSURES**

Not applicable.

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

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.

| <b>Period</b>                  |                               | <b>High</b> | <b>Low</b> |
|--------------------------------|-------------------------------|-------------|------------|
| <b>Transition Period 2017:</b> |                               |             |            |
| First Quarter                  | July 1 - September 30, 2017   | \$3.85      | \$3.00     |
| Second Quarter                 | October 1 - December 31, 2017 | \$4.81      | \$2.63     |
| <b>Fiscal Year 2017:</b>       |                               |             |            |
| First Quarter                  | July 1 - September 30, 2016   | \$5.42      | \$2.75     |
| Second Quarter                 | October 1 - December 31, 2016 | \$3.90      | \$2.52     |
| Third Quarter                  | January 1 - March 31, 2017    | \$3.67      | \$2.75     |
| Fourth Quarter                 | April 1 - June 30, 2017       | \$3.28      | \$2.94     |
| <b>Fiscal Year 2016:</b>       |                               |             |            |
| First Quarter                  | July 1 - September 30, 2015   | \$16.44     | \$10.60    |
| Second Quarter                 | October 1 - December 31, 2015 | \$12.40     | \$3.64     |
| Third Quarter                  | January 1 - March 31, 2016    | \$6.20      | \$2.12     |
| Fourth Quarter                 | April 1 - June 30, 2016       | \$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 197 stockholders of record on December 31, 2017, not including beneficial owners who own their stock in street name through Cede & Co. and others.

During the six months ended December 31, 2017, we engaged in deemed repurchases of 16,456 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. The following table sets forth information regarding these deemed repurchases:

| <b>Period</b> | <b>Total</b>     | <b>Average</b> | <b>Total</b>     | <b>Maximum</b>   |
|---------------|------------------|----------------|------------------|------------------|
|               | <b>Number of</b> | <b>Price</b>   | <b>Number of</b> | <b>Number of</b> |



|                | shares<br>Purchased <sup>(1)</sup> | Paid per<br>Share | Shares<br>Purchased<br>as Part of<br>Publicly<br>Announced<br>Plans or<br>Programs <sup>(1)</sup> | Shares that<br>May Yet Be<br>Purchased<br>under Plans<br>or<br>Programs <sup>(1)</sup> |
|----------------|------------------------------------|-------------------|---|--|
| July 2017      | 16,456                             | \$ 3.17           | N/A   | N/A  |
| August 2017    | --                                 | N/A               | N/A   | N/A  |
| September 2017 | --                                 | N/A               | N/A   | N/A  |
| October 2017   | --                                 | N/A               | N/A   | N/A  |
| November 2017  | --                                 | N/A               | N/A   | N/A  |
| December 2017  | --                                 | N/A               | N/A   | N/A  |

All shares were deemed repurchased under a discretionary tax withholding right. No shares were repurchased through a formal repurchase program.

## **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 Transition 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 Transition Report.



## Overview

Cesca develops, commercializes and markets a range of automated technologies for cell-based therapies. Since the 1990's, Cesca has been the pioneer and one of the leading developers and suppliers of automation technologies for the isolation, purification and storage of stem cells for the cord blood banking industry. 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 then 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, Cesca 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 elected to change our fiscal year from June 30 to December 31. As a result, we are reporting a transition period for the six months beginning July 1, 2017 and ending December 31, 2017.

We have two reportable business segments: A "Device Segment" and a "Clinical Development Segment." The Device Segment engages in the development and commercialization of automated technologies for cell-based therapeutics and bio-processing. The Device Segment is operated through the Company's ThermoGenesis subsidiary. The Clinical Development Segment is developing autologous (utilizing the patient's own cells) stem cell-based therapeutics that address significant unmet medical needs for the applications within the vascular, cardiology and orthopedic markets.

## Device Segment

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 natural killer (NK) cell based therapies.

The Device Segment's product pipeline includes:

**BioArchive for Cryogenic Cellular Product Storage** – an automated, controlled-rate, liquid nitrogen freezer intended for the cryopreservation and single-cassette based storage of clinical samples. The BioArchive provides customers who need cryogenic cellular product storage (-196°C) with a solution that combines the individualized sample storage/retrieval capacity and real-time chain of custody management.

**CAR-TXpress** platform that addresses critical unmet needs for CMC improvement for the emerging CAR-T therapies for cancer patients. CAR-TXpress eliminates the need of ficoll and traditional magnetic beads based isolation procedures, and thereby dramatically reduces processing time and increases efficiency of the manufacturing process, which should reduce the overall manufacturing cost. The CAR-TXpress platform includes the following X-Series products:

**X-Lab for Cell Isolation** – a semi-automated, functionally-closed, ficoll-free, system for the rapid isolation of different target cells from various sources including blood samples, bone marrow aspirates, leukapheresis products.

**X-BACS for Cell Purification** – a semi-automated, functionally closed system employs microbubbles to isolate target cells by buoyancy-activated cell sorting (BACS). These microbubbles, through antibodies, bind specifically to desired target cells. Subsequent collection of the floating target cell coated with microbubbles provides a highly-purified preparation of target cells, with high recovery efficiency and cell viability.

**X-Wash for Washing and Reformulation** – a semi-automated, functionally-closed system that separates, washes, and volume-reduces frozen cells or cell cultures to a programmable volume.

Cesca is also leveraging its proprietary AutoXpress technology platform for stem cell banking and for the development of autologous (utilizing the patient's own cells) stem cell-based therapies that address significant unmet needs in the vascular, cardiology and orthopedic markets.

**AXP for Stem Cell Banking** – a proprietary, automated system for the isolation, collection and storage of hematopoietic stem cell concentrates derived from cord blood and peripheral blood.

**VXP® for Critical Limb Ischemia (CLI)** – Cesca has a proprietary point-of-care, autologous (donor and recipient are the same individual) stem cell-based therapy under development which is intended for the treatment of patients with CLI. The FDA has cleared the Company to proceed with a 362 subject, multi-center pivotal Phase III CLIRST study, which is designed to evaluate the safety and efficacy of Cesca’s autologous stem cell-based therapy in patients with no-option or poor option late stage CLI. 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.

**VXP® for 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 STEMI, the most serious type of heart attack. Such treatments are aimed at minimizing the adverse remodeling of the heart post-STEMI.

**MXP for 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 MXP 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.

### ***Six Months Ended December 31, 2017 Compared to Six Months Ended December 31, 2016 (unaudited)***

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

Consolidated net revenues for six months ended December 31, 2017 were \$6,013,000 compared to \$7,772,000 for the six months ended December 31, 2016, a decrease of \$1,759,000. Device Segment revenues decreased primarily as a result of a single end user customer purchasing one-time larger than normal orders of AXP disposables to stock up inventory levels in the six months ended December 31, 2016, the distributor change in the China market and a one-time shipment of our remaining inventory associated with a discontinued product line (Res-Q) in the prior year six month period. In the short-term, we anticipate AXP revenues to remain lower than historical periods. Clinical development revenues consist of sales generated by our Totipotent subsidiaries. These sales declined due to lower manual bagset sales. Offsetting these decreases for the Device Segment was an increase in sales of our BioArchive devices as we sold eight during the six months ended December 31, 2017 as compared to none in the six months ended December 31, 2016.

Revenues were comprised of the following for the six months ended:

|                    | December<br>31,<br>2017 | December<br>31,<br>2016 |
|--------------------|-------------------------|-------------------------|
| Device Segment:    |                         |                         |
| AXP                | \$2,577,000             | \$4,814,000             |
| BioArchive         | 2,642,000               | 1,496,000               |
| Manual Disposables | 476,000                 | 590,000                 |

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|                               |             |             |
|-------------------------------|-------------|-------------|
| Bone Marrow                   | 53,000      | 582,000     |
| Other                         | 79,000      | 64,000      |
|                               | 5,827,000   | 7,546,000   |
| Clinical Development Segment: |             |             |
| Manual disposables            | 22,000      | 90,000      |
| Bone Marrow                   | 138,000     | 30,000      |
| Other                         | 26,000      | 106,000     |
|                               | 186,000     | 226,000     |
|                               | \$6,013,000 | \$7,772,000 |



### ***Gross Profit***

Consolidated gross profit was \$2,155,000 or 36% of revenues for the six months ended December 31, 2017 compared to \$2,934,000 or 38% of revenues for six months ended December 31, 2016. Our Device Segment gross profit margin decreased from \$2,938,000 or 39% to \$2,174,000 or 37% for the six months ended December 31, 2016 as compared to the six months ended December 31, 2017, respectively. The decrease was primarily due to higher overhead costs as a result of the merger with SynGen.

### ***Sales and Marketing Expenses***

Consolidated sales and marketing expenses were \$935,000 for the six months ended December 31, 2017, compared to \$775,000 for the six months ended December 31, 2016, an increase of \$160,000 or 21%. Predominantly all of the Company's sales and marketing expenses are generated by the Device Segment. The increase is primarily due to higher personnel costs related to filling previously open positions and the transition of the X-Series product lines to ThermoGenesis as a result of the SynGen acquisition.

### ***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 six months ended December 31, 2017, were \$2,246,000 compared to \$1,364,000 for 2016, an increase of \$882,000 or 65%. Research and development expenses in our Device Segment increased \$1,574,000, while our Clinical Development Segment decreased \$702,000. The changes are due to additional headcount and expenses in the Device Segment related to the development of our CAR-TXpress platform which we acquired as a result of the SynGen acquisition, and a shift in existing personnel from the Clinical Development Segment to the Device Segment as we are minimally funding clinical development projects until a strategic partner is located.

### ***General and Administrative Expenses***

Consolidated general and administrative expenses for the six months ended December 31, 2017 were \$3,572,000, compared to \$6,316,000 for 2016, a decrease of \$2,744,000 or 43%. The decrease is driven by severance and accelerated stock expenses of approximately \$1.8 million for the termination of the former CEO in November 2016, the elimination of positions and a decrease in legal expenses of approximately \$1 million primarily due to settlement of the SynGen litigation.

### ***Interest Expense***

The decrease in interest expense to \$541,000 for the six months ended December 31, 2017 from \$10,537,000 for 2016 was primarily due to the conversion in the quarter ended September 30, 2016 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 \$2,238,000 is due to the recent income tax reform measure which changed the federal income tax rate for all corporations to 21%. The Company's deferred tax liability related to indefinite life intangible assets was remeasured at the 21% rate.

**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 Six Months Ended December 31,<br>2017 |               |               |
|----------------------------------|---|---------------|---------------|
|                                  | Clinical<br>Development                       | Device        | Total         |
| Loss from operations             | \$(2,157,000)                                 | \$(2,441,000) | \$(4,598,000) |
| Add:                             |   |               |               |
| Depreciation and amortization    | 152,000                                       | 170,000       | 322,000       |
| Stock-based compensation expense | 164,000                                       | 127,000       | 291,000       |
| Adjusted EBITDA                  | \$(1,841,000)                                 | \$(2,144,000) | \$(3,985,000) |

|                                  | For the Six Months Ended December<br>31, 2016 |             |               |
|----------------------------------|---|-------------|---------------|
|                                  | Clinical<br>Development                       | Device      | Total         |
| Loss from operations             | \$(5,268,000)                                 | \$(253,000) | \$(5,521,000) |
| Add:                             |   |             |               |
| Depreciation and amortization    | 274,000                                       | 199,000     | 473,000       |
| Stock-based compensation expense | 719,000                                       | 314,000     | 1,033,000     |
| Adjusted EBITDA                  | \$(4,275,000)                                 | \$260,000   | \$(4,015,000) |

**Adjusted EBITDA**

The decrease in our consolidated adjusted EBITDA loss from \$4,015,000 to \$3,985,000 and the difference in our Device Segment adjusted EBITDA from \$260,000 profit to \$2,144,000 loss is primarily due to the headcount and project expenses added as a result of our July 7, 2017 SynGen acquisition. The decrease in the clinical development adjusted EBITDA loss from \$4,275,000 to \$1,841,000 is primarily due to the elimination or transfer of personnel to the Device Segment to work on those projects versus clinical studies.

**Results of Operations for the Fiscal Year Ended June 30, 2017 versus the Fiscal Year Ended June 30, 2016 (audited)****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,<br>2017 | June 30,<br>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.

***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 \$2,820,000 or 34%. 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 the 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<br>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<br>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 ) |

***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 December 31, 2017, we had cash and cash equivalents of \$3,513,000 and \$3,623,000 and \$5,835,000 at June 30, 2017 and June 30, 2016. At December 31, 2017, we had working capital of \$5,990,000 and \$6,658,000 and \$7,301,000 at June 30, 2017 and June 30, 2016. We have primarily financed operations through private and public

placement of equity securities and our line of credit facility.

On December 1, 2017, the Company closed a public offering of common stock consisting of an aggregate of 898,402 shares of common stock at a price to the public of \$3.00 per share for aggregate offering proceeds of \$2.7 million. After deducting the offering expenses the net proceeds in the offering were \$2,368,000.

On July 7, 2017, our then wholly-owned 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 SynGen Transaction, ThermoGenesis acquired substantially all of SynGen's operating assets, including its proprietary cell processing platform. In exchange, ThermoGenesis issued to SynGen 2,000,000 shares of ThermoGenesis common stock which had a fair market value of \$2,528,000 based on an independent analysis and ThermoGenesis also made a one-time cash payment of \$1,000,000 to SynGen. As part of the Asset Acquisition Agreement, the two companies agreed to cease the mutual litigation.

The Company has a Revolving Credit Agreement with Boyalife Investment Fund II, Inc. As of December 31, 2017, the Company had drawn down \$6,700,000 of the \$10,000,000 available under the Credit Agreement. The Company has drawn down an additional \$500,000 subsequent to December 31, 2017 and through the date of this report. Future draw-downs may be limited for various reasons including default or government regulations in China. Boyalife Investment Fund II, Inc. 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.

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 \$23,903,000 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.

Our net cash used in operating activities for the six months ended December 31, 2017 was \$3,317,000. The increase in net cash used in operating activities was primarily due to a build-up of inventory to support sales in the AXP and MXP product lines.

At December 31, 2017, the Company had cash and cash equivalents of \$3,513,000 and working capital of \$5,990,000. The Company has incurred recurring operating losses and as of December 31, 2017 had an accumulated deficit of \$187,640,000. These conditions raise substantial doubt about the Company's ability to continue as a going concern within one year after the issuance date. The Company anticipates requiring additional capital to grow the device business, to fund other operating expenses and to make interest payments on the line of credit with Boyalife. The Company's ability to fund its cash needs is subject to various risks, many of which are beyond its control. The

Company plans to seek additional funding through bank borrowings or public or private sales of debt or equity securities or strategic partnerships. The Company cannot guarantee that such funding will be available on a timely basis, in needed quantities or on terms favorable to us, if at all.

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern; however, the above conditions raise substantial doubt about the Company's ability to do so. The consolidated financial statements do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts and classifications of liabilities that may result should the Company be unable to continue as a going concern.

We generally do not require extensive capital equipment to produce or sell our current cord blood banking products. During the six months ended December 31, 2017, we spent \$296,000 primarily for our new ERP system, which we expect to have implemented before the end of 2018, computers and manufacturing equipment.

A related party distributor had an accounts receivable balance of \$862,000 or 34% and \$308,000 or 8% at December 31, 2017 and June 30, 2017. A second distributor had an accounts receivable balance of \$464,000 or 18%, \$304,000 or 8% and \$320,000 or 10% at December 31, 2017, June 30, 2017 and June 30, 2016, respectively. A third distributor had an accounts receivable balance of \$1,388,000 or 38% and \$901,000 or 28% at June 30, 2017 and 2016, respectively. The Company did not renew the contract with this distributor in August 2017 and signed a contract with a new distributor. A customer had an accounts receivable balance of \$172,000 or 7%, \$259,000 or 7% and \$620,000 or 19% at December 31, 2017, June 30, 2017 and 2016, respectively.

Revenues from a related party distributor totaled \$1,679,000 or 28% and \$308,000 or 2% for the six months ended December 31, 2017 and the year ended June 30, 2017. Revenues from a customer totaled \$560,000 or 9%, \$3,263,000 or 22% and \$2,475,000 or 21% for the six months ended December 31, 2017 and the years ended June 30, 2017 and 2016, respectively. Revenues from one distributor totaled \$480,000 or 8%, \$2,842,000 or 20% and \$2,797,000 or 23% of net revenues for the six months ended December 31, 2017 and the years ended June 30, 2017 and 2016, respectively. The Company did not renew the contract with this distributor in August 2017 and replaced it with a different distributor.

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

### ***Critical Accounting Policies***

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

We believe the following critical accounting policies affect 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's history of adhering to the terms of its contractual arrangements with us, the level of inventories maintained by the distributor, whether we have a pattern of granting concessions for the benefit of the distributor, and whether there are other conditions that may indicate that the sale to the distributor is not substantive. We currently recognize revenue primarily on the sell-in method with our distributors.

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

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

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

### ***Stock-Based Compensation***

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

### ***Income Taxes***

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

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

### ***Inventory Valuation***

We state inventories at lower of cost or market value determined on a first-in, first-out basis. We provide write-downs of inventory when conditions indicate that the selling price could be less than cost due to physical deterioration, obsolescence, changes in price levels, or other causes, which it includes as a component of cost of revenues. Additionally, we provide valuation allowances for excess and slow-moving inventory on hand that are not expected to be sold to reduce the carrying amount of slow-moving inventory to its estimated net realizable value. The valuation allowances are based upon estimates about future demand from our customers and distributors and market conditions. Because some of our products are highly dependent on government and third-party funding, current customer use and

validation, and completion of regulatory and field trials, there is a risk that we will forecast incorrectly and purchase or produce excess inventories. As a result, actual demand may differ from forecasts and we may be required to record additional inventory valuation allowances that could adversely impact our gross margins. Conversely, favorable changes in demand could result in higher gross margins when those products are sold.



### ***Warranty***

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

### ***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**

|   |    |
|---|----|
| <u>Report of Independent Registered Public Accounting Firm</u>  | 41 |
| <u>Consolidated Balance Sheets for the Six Months Ended December 31, 2017, and the Years Ended June 30, 2017 and June 30, 2016</u>  | 42 |
| <u>Consolidated Statements of Operations and Comprehensive Loss for the Six Months Ended December 31, 2017 and 2016 (unaudited), and the Years Ended June 30, 2017 and 2016</u> | 43 |
| <u>Consolidated Statements of Stockholders’ Equity for the Six Months Ended December 31, 2017 and Years Ended June 30, 2017 and 2016</u>  | 44 |
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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Shareholders and Board of Directors of

Cesca Therapeutics Inc.

**Opinion on the Financial Statements**

We have audited the accompanying consolidated balance sheets of Cesca Therapeutics Inc. (the "Company") as of December 31, 2017, June 30, 2017 and 2016, the related consolidated statements of operations and comprehensive loss, stockholders' equity and cash flows for the transitional six months ended December 31, 2017 and the two years in the period ended June 30, 2017, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2017, June 30, 2017 and 2016, and the results of its operations and its cash flows for the transitional six months ended December 31, 2017 and the two years in the period ended June 30, 2017, in conformity with accounting principles generally accepted in the United States of America.

**Explanatory Paragraph – Going Concern**

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As more fully described in Note 1, the Company has incurred recurring losses and as of December 31, 2017 had an accumulated deficit of \$187,640,000. These conditions raise substantial doubt about the Company's ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 1. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

**Basis for Opinion**

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) ("PCAOB") and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting 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.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ Marcum LLP

We have served as the Company's auditor since 2015.

Marcum LLP

New York, NY

March 22, 2018

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

|  | December 31,<br>2017 | June 30,<br>2017 | June 30,<br>2016 |
|--|----------------------|------------------|------------------|
| <b>ASSETS</b>  |                      |                  |                  |
| Current assets:  |                      |                  |                  |
| Cash and cash equivalents  | \$3,513,000          | \$3,623,000      | \$5,835,000      |
| Accounts receivable, net of allowance for doubtful accounts of \$274,000 (\$102,000 and \$49,000 at June 30, 2017 and 2016)    | 1,687,000            | 3,393,000        | 3,169,000        |
| Accounts receivable – related party  | 862,000              | 308,000          | --               |
| Inventories, net of reserves of \$1,069,000 (\$1,230,000 and \$1,437,000 at June 30, 2017 and 2016)                            | 4,798,000            | 3,617,000        | 3,593,000        |
| Prepaid expenses and other current assets  | 594,000              | 237,000          | 246,000          |
| Total current assets   | 11,454,000           | 11,178,000       | 12,843,000       |
| Restricted cash  | 1,000,000            | --               | --               |
| Equipment, net   | 2,996,000            | 2,330,000        | 2,962,000        |
| Goodwill   | 13,976,000           | 13,195,000       | 13,195,000       |
| Intangible assets, net   | 21,629,000           | 20,165,000       | 20,821,000       |
| Other assets   | 56,000               | 64,000           | 78,000           |
| Total assets   | \$51,111,000         | \$46,932,000     | \$49,899,000     |
| <b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>  |                      |                  |                  |
| Current liabilities:   |                      |                  |                  |
| Accounts payable   | \$2,079,000          | \$1,601,000      | \$2,648,000      |
| Accrued payroll and related expenses   | 532,000              | 385,000          | 449,000          |
| Deferred revenue   | 384,000              | 597,000          | 783,000          |
| Related party payable  | 606,000              | 606,000          | --               |
| Other current liabilities  | 1,863,000            | 1,331,000        | 1,662,000        |
| Total current liabilities  | 5,464,000            | 4,520,000        | 5,542,000        |
| Long term debt-related party   | 6,700,000            | 3,500,000        | --               |
| Derivative obligations   | 597,000              | 730,000          | 670,000          |
| Convertible debentures, net  | --                   | --               | 2,489,000        |
| Noncurrent deferred tax liability  | 4,730,000            | 6,968,000        | 7,641,000        |
| Other noncurrent liabilities   | 408,000              | 377,000          | 1,284,000        |
| Total liabilities  | 17,899,000           | 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 December 31, 2017 and June 30, | --                   | --               | --               |

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2017 and 2016

|   |               |               |               |
|---|---------------|---------------|---------------|
| Common stock, \$0.001 par value; 350,000,000 shares authorized;<br>10,872,428 issued and outstanding (9,915,868 and 3,010,687 at<br>June 30, 2017 and 2016) | 11,000        | 10,000        | 3,000         |
| Paid in capital in excess of par  | 221,371,000   | 216,222,000   | 188,569,000   |
| Accumulated deficit   | (187,640,000) | (185,357,000) | (156,262,000) |
| Accumulated other comprehensive loss  | (43,000 )     | (38,000 )     | (37,000 )     |
| Total Cesca Therapeutics Inc. stockholders' equity  | 33,699,000    | 30,837,000    | 32,273,000    |
| Noncontrolling interests  | (487,000 )    | --            | --            |
| Total equity  | 33,212,000    | 30,837,000    | 32,273,000    |
| Total liabilities and stockholders' equity  | \$51,111,000  | \$46,932,000  | \$49,899,000  |

See accompanying notes to consolidated financial statements.

## Cesca Therapeutics Inc.

## Consolidated Statements of Operations and Comprehensive loss

|   | Six Months Ended<br>December 31, |                     | Years Ended<br>June 30, |                 |
|---|----------------------------------|---------------------|-------------------------|-----------------|
|   | 2017                             | 2016<br>(unaudited) | 2017                    | 2016            |
| Net revenues                                  | \$4,334,000                      | \$7,772,000         | \$14,217,000            | \$11,929,000    |
| Net revenues – related party                  | 1,679,000                        | --                  | 308,000                 | --              |
| Total net revenues                            | 6,013,000                        | 7,772,000           | 14,525,000              | 11,929,000      |
| Cost of revenues                              | 3,858,000                        | 4,838,000           | 8,686,000               | 9,185,000       |
| Gross profit                                  | 2,155,000                        | 2,934,000           | 5,839,000               | 2,744,000       |
| Expenses:                                     |                                  |                     |                         |                 |
| Sales and marketing                           | 935,000                          | 775,000             | 1,531,000               | 2,148,000       |
| Research and development                      | 2,246,000                        | 1,364,000           | 2,497,000               | 3,230,000       |
| General and administrative                    | 3,572,000                        | 6,316,000           | 11,051,000              | 8,231,000       |
| Total operating expenses                      | 6,753,000                        | 8,455,000           | 15,079,000              | 13,609,000      |
| Loss from operations                          | (4,598,000 )                     | (5,521,000 )        | (9,240,000 )            | (10,865,000 )   |
| Other income (expense):                       |                                  |                     |                         |                 |
| Interest expense                              | (541,000 )                       | (10,537,000 )       | (10,668,000 )           | (1,864,000 )    |
| Amortization of debt discount                 | --                               | (9,851,000 )        | (9,851,000 )            | (6,127,000 )    |
| Fair value change of derivative instruments   | 133,000                          | (174,000 )          | (60,000 )               | 3,395,000       |
| Registration rights liquidated damages        | --                               | --                  | --                      | (1,100,000 )    |
| Loss on cashless exercise of warrants         | --                               | --                  | --                      | (1,039,000 )    |
| Loss on extinguishment of debt                | --                               | --                  | --                      | (795,000 )      |
| Loss on modification of Series A warrants     | --                               | --                  | --                      | (149,000 )      |
| Other income and (expenses)                   | (2,000 )                         | 239,000             | 51,000                  | (44,000 )       |
| Total other expense                           | (410,000 )                       | (20,323,000 )       | (20,528,000 )           | (7,723,000 )    |
| Loss before benefit for income taxes          | (5,008,000 )                     | (25,844,000 )       | (29,768,000 )           | (18,588,000 )   |
| Benefit for income taxes                      | 2,238,000                        | --                  | 673,000                 | --              |
| Net loss                                      | (2,770,000 )                     | (25,844,000 )       | (29,095,000 )           | (18,588,000 )   |
| Loss attributable to noncontrolling interests | (487,000 )                       | --                  | --                      | --              |
| Net loss attributable to common stockholders  | \$(2,283,000 )                   | \$(25,844,000 )     | \$(29,095,000 )         | \$(18,588,000 ) |
| COMPREHENSIVE LOSS                            |                                  |                     |                         |                 |
| Net loss                                      | \$(2,283,000 )                   | \$(25,844,000 )     | \$(29,095,000 )         | \$(18,588,000 ) |
| Other comprehensive loss:                     |                                  |                     |                         |                 |
| Foreign currency translation adjustments      | (5,000 )                         | --                  | (1,000 )                | (32,000 )       |
| Comprehensive loss                            | (2,288,000 )                     | \$(25,844,000 )     | \$(29,096,000 )         | \$(18,620,000 ) |
|   | (487,000 )                       | --                  | --                      | --              |

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Comprehensive loss attributable to noncontrolling interests

|  |                      |                       |                       |                       |
|--|----------------------|-----------------------|-----------------------|-----------------------|
| Comprehensive loss attributable to common stockholders | <i>\$(1,801,000)</i> | <i>\$(25,844,000)</i> | <i>\$(29,096,000)</i> | <i>\$(18,620,000)</i> |
|--|----------------------|-----------------------|-----------------------|-----------------------|

Per share data:

|   |                 |                 |                 |                 |
|---|-----------------|-----------------|-----------------|-----------------|
| Basic and diluted net loss per common share | <i>\$(0.23)</i> | <i>\$(3.26)</i> | <i>\$(3.27)</i> | <i>\$(7.57)</i> |
|---|-----------------|-----------------|-----------------|-----------------|

|   |                   |                  |                  |                  |
|---|-------------------|------------------|------------------|------------------|
| Weighted average common shares outstanding— Basic and diluted | <i>10,108,329</i> | <i>7,932,300</i> | <i>8,904,508</i> | <i>2,455,548</i> |
|---|-------------------|------------------|------------------|------------------|

See accompanying notes to consolidated financial statements.



## Cesca Therapeutics Inc.

## Consolidated Statements of Stockholders' Equity

|  | <i>Common Stock</i> |               | Paid in<br>capital in<br>excess of<br><i>par</i> | <i>Accumulated<br/>deficit</i> | Accumulated<br>other<br>comprehensive<br><i>loss</i> | Accumulated<br>Total<br>stockholders'<br><i>equity</i> | Noncontrolling<br>interests<br>in<br><i>subsidiary</i> | <i>Total<br/>equity</i> |
|--|---------------------|---------------|--|--------------------------------|--|--|--|-------------------------|
|  | <i>Shares</i>       | <i>Amount</i> |  |                                |  |  |  |                         |
| Balance at<br>June 30, 2015  | 2,027,386           | \$2,000       | \$172,579,000                                    | \$(137,674,000)                | \$(5,000)  | \$34,902,000   | --   | \$34,902,000            |
| Stock-based<br>compensation<br>expense, net<br>of stock<br>surrenders      | 11,577              | --            | 710,000  | --                             | --   | 710,000  | --   | 710,000                 |
| Discount due<br>to beneficial<br>conversion<br>features                    | --                  | --            | 7,262,000  | --                             | --   | 7,262,000  | --   | 7,262,000               |
| Discount due<br>to warrants  | --                  | --            | 4,434,000  | --                             | --   | 4,434,000  | --   | 4,434,000               |
| Issuance of<br>common<br>shares and<br>warrants in<br>financing            | 735,294             | 1,000         | 2,463,000  | --                             | --   | 2,464,000  | --   | 2,464,000               |
| Issuance of<br>common<br>shares for<br>exercise of<br>Series B<br>warrants | 231,710             | --            | 1,097,000  | --                             | --   | 1,097,000  | --   | 1,097,000               |
| Common<br>stock issued to<br>directors<br>in lieu of cash<br>compensation  | 4,720               | --            | 24,000   | --                             | --   | 24,000   | --   | 24,000                  |
| Foreign<br>currency<br>translation   | --                  | --            | --   | --                             | (32,000)   | (32,000)   | --   | (32,000)                |
| Net loss   | --                  | --            | --   | (18,588,000)                   | --   | (18,588,000)   | --   | (18,588,000)            |
| Balance at<br>June 30, 2016  | 3,010,687           | 3,000         | 188,569,000                                      | (156,262,000)                  | (37,000)   | 32,273,000   | --   | 32,273,000              |

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|   |           |        |             |               |          |              |    |              |
|---|-----------|--------|-------------|---------------|----------|--------------|----|--------------|
| Stock-based compensation expense, net of stock surrenders     | 125,368   | --     | 1,445,000   | --            | --       | 1,445,000    | -- | 1,445,000    |
| Shares issued upon debt conversion                            | 6,102,941 | 6,000  | 23,897,000  | --            | --       | 23,903,000   | -- | 23,903,000   |
| Issuance of common shares in financing, net of offering costs | 600,000   | 1,000  | 2,091,000   | --            | --       | 2,092,000    | -- | 2,092,000    |
| Common stock issued to directors in lieu of cash compensation | 5,463     | --     | 16,000      | --            | --       | 16,000       | -- | 16,000       |
| Common stock issued to employees for prior year bonus         | 71,409    | --     | 204,000     | --            | --       | 204,000      | -- | 204,000      |
| Foreign currency translation                                  | --        | --     | --          | --            | (1,000 ) | (1,000 )     | -- | (1,000 )     |
| Net loss  | --        | --     | --          | (29,095,000 ) | --       | (29,095,000) | -- | (29,095,000) |
| Balance at June 30, 2017                                      | 9,915,868 | 10,000 | 216,222,000 | (185,357,000) | (38,000) | 30,837,000   | -- | 30,837,000   |
| Stock-based compensation expense, net of stock surrenders     | 52,825    | --     | 239,000     | --            | --       | 239,000      | -- | 239,000      |
| Issuance of common shares in financing, net of offering costs | 898,402   | 1,000  | 2,367,000   | --            | --       | 2,368,000    | -- | 2,368,000    |
| Fair value of subsidiary common stock issued in acquisition   | --        | --     | 2,528,000   | --            | --       | 2,528,000    | -- | 2,528,000    |
| Exercise of stock options                                     | 5,333     | --     | 15,000      | --            | --       | 15,000       | -- | 15,000       |
|   | --        | --     | --          | --            | (5,000 ) | (5,000 )     | -- | (5,000 )     |

Foreign  
currency  
translation

|                   |            |          |               |                 |            |              |             |              |
|-------------------|------------|----------|---------------|-----------------|------------|--------------|-------------|--------------|
| Net loss          | --         | --       | --            | (2,283,000 )    | --         | (2,283,000 ) | (487,000)   | (2,770,000 ) |
| Balance at        |            |          |               |                 |            |              |             |              |
| December 31, 2017 | 10,872,428 | \$11,000 | \$221,371,000 | \$(187,640,000) | \$(43,000) | \$33,699,000 | \$(487,000) | \$33,212,000 |

See accompanying notes to consolidated financial statements.

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

|   | Six Months<br>Ended     | Years Ended           |                       |
|---|-------------------------|-----------------------|-----------------------|
|   | December<br>31,<br>2017 | June 30,<br>2017      | 2016                  |
| Cash flows from operating activities:                                       |                         |                       |                       |
| Net loss  | <i>\$(2,770,000)</i>    | <i>\$(29,095,000)</i> | <i>\$(18,588,000)</i> |
| Adjustments to reconcile net loss to net cash used in operating activities: |                         |                       |                       |
| Depreciation and amortization   | <i>322,000</i>          | <i>830,000</i>        | <i>1,168,000</i>      |
| Stock-based compensation expense  | <i>291,000</i>          | <i>1,461,000</i>      | <i>742,000</i>        |
| (Recovery of) reserve for excess and slow-moving inventories                | <i>(162,000 )</i>       | <i>(203,000 )</i>     | <i>566,000</i>        |
| Bad debt expense  | <i>170,000</i>          | <i>50,000</i>         | <i>7,000</i>          |
| Amortization of debt discount   | <i>--</i>               | <i>9,851,000</i>      | <i>6,127,000</i>      |
| Amortization of debt issue costs  | <i>--</i>               | <i>160,000</i>        | <i>800,000</i>        |
| Change in fair value of derivative  | <i>(133,000 )</i>       | <i>60,000</i>         | <i>(3,395,000 )</i>   |
| Deferred income tax benefit   | <i>(2,238,000)</i>      | <i>(673,000 )</i>     | <i>--</i>             |
| Non-cash accrued interest   | <i>--</i>               | <i>10,373,000</i>     | <i>1,031,000</i>      |
| Loss on disposal of equipment   | <i>8,000</i>            | <i>176,000</i>        | <i>--</i>             |
| Impairment of intangible asset  | <i>--</i>               | <i>310,000</i>        | <i>--</i>             |
| Loss on cashless exercise of warrants                                       | <i>--</i>               | <i>--</i>             | <i>1,039,000</i>      |
| Loss on extinguishment of debt  | <i>--</i>               | <i>--</i>             | <i>795,000</i>        |
| Loss on modification of Series A warrants                                   |                         |                       |                       |