CESCA THERAPEUTICS INC.
Form 10-K
September 29, 2014

SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K

ANNUAL REPORT PURSUANT TO SECTION 13 OR 15 (d) OF THE
SECURITIES EXCHANGE ACT OF 1934

For the Fiscal Year Ended: June 30, 2014

Commission File Number: 000-16375

Cesca Therapeutics Inc.
(Formerly known as ThermoGenesis Corp.)
(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. o Yes x No

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

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files.) x Yes o 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. o

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

Large accelerated filer o	Accelerated filer o
Non-accelerated filer o (Do not check if a smaller reporting company)	Smaller reporting company x

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

The aggregate market value of the common stock held by non-affiliates as of December 31, 2013 (the last business day of the most recently completed second quarter) was $16,790,804 based on the closing sale price on such day.

As of September 26, 2014, 40,268,811 shares of the registrant's Common Stock were outstanding.

Documents Incorporated By Reference: Portions of the registrant's proxy statement for its 2014 Annual Meeting of Stockholders are incorporated by reference into Part III hereof.

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

ITEM 1. BUSINESS

Business Overview

Cesca Therapeutics Inc. (the "Company", "we", "our", formerly known as ThermoGenesis Corp) is focused on the research, development, and commercialization of autologous cell-based therapeutics for use in regenerative medicine. We are a leader in developing and manufacturing automated blood and bone marrow processing systems that enable the separation, processing and preservation of cell and tissue therapy products. We focus in three target markets to serve patients, physicians and partners:

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

On February 18, 2014, TotipotentRX ("TRX") Corporation merged with and into ThermoGenesis Corp. In connection with the merger, ThermoGenesis changed its name from ThermoGenesis Corp. to Cesca Therapeutics Inc. The Company believes that TotipotentRX has the depth of clinical, scientific and biological engineering experience necessary to commercialize cell therapies with diseases having significant unmet medical needs. As a result of the merger, Cesca is a fully integrated regenerative medicine company with the ability and expertise to research, design, and develop devices and disposables necessary to facilitate clinical protocols and applications directed at cell therapies at the point of care.
Our business strategy includes:

• Practical, Commercializable Cell Therapies. Deliver proprietary, commercially viable, highly effective autologous (patient's own cells) cell therapies to treat major medical diseases.

• Ability to Rapidly and Cost-Effectively Implement New Clinical Trials. Rapidly initiate early clinical development of new cell therapies at its United States Food and Drug Administration ("FDA")-registered clinical research organization in India and generate high quality data at a fraction of the cost of clinical trials undertaken in the U.S. or Europe.

• Positioned to Commercialize in Both Developed and Emerging Markets. Utilize our existing U.S. and Asian footprints to uniquely position us to meet the needs of patients, hospitals and physicians across the globe. This footprint allows flexibility to meet the variable market demands in service and price.

• Proprietary and Protected. Possess an unmatched suite of proprietary technological and clinical assets to be deployed in the regenerative medicine markets. Our cell-therapy-related devices and platform technologies, unique cell formulations and treatment protocols are protected via a broad portfolio of patents and intellectual property filings.

Cesca Therapeutics Inc., formerly ThermoGenesis Corp., was founded in 1986, and our principal executive offices are located at 2711 Citrus Road, Rancho Cordova, California 95742. Unless otherwise indicated, information regarding us and our business includes information regarding TotipotentRX Corporation which merged with and into us on February 18, 2014.

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Key Events and Accomplishments

In addition to the merger with TotipotentRX discussed above, the following are key events and accomplishments that occurred in fiscal 2014:

·Announced Statistically Significant Phase 1b Clinical Trial Results in Critical Limb Ischemia

The trial achieved both its primary safety and secondary efficacy endpoints at 12 months, achieving statistical significance in five key areas including, major amputation free survival rates (82.4%), both resting and walking pain reduction, improved walking distance, open wound healing and vasculogenesis (generation of new blood vessels) in the treated leg. Also, there were no serious adverse events determined to be related to the therapy.

·Raised $16 million in Net Proceeds From Two Stock Offerings

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

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

·Formed Clinical and Scientific Advisory Board

In May 2014, we formed a Clinical and Scientific Advisory Board (“CSAB”) and appointed Solomon Hamburg MD, Ph.D. to the Board. The CSAB will serve to help set strategic goals for the advancement of research towards the development and commercialization of autologous cellular therapies to improve patient care in the fields of hematology/oncology, cardio/vascular and orthopedic indications.

·Signed Direct Agreement with Cord Blood Registry Systems, Inc. (“CBR”)

On December 31, 2013, we entered into a Sale and Purchase Agreement with CBR in which we will supply CBR with the AXP cord blood processing system and disposables. The agreement is for 5 years with automatic two-year renewal options unless CBR provides a 6 month notice of non-renewal.

Market Overview

Regenerative Medicine Market

Regenerative cell therapy relies on replacing diseased, damaged or dysfunctional cells with healthy, functioning ones or repairing damaged or diseased tissue. A great range of cells and cell components can serve in cell therapy, including cells found in peripheral blood, umbilical cord blood and bone marrow.

The regenerative medicine market continues to experience meaningful advances in clinical efficacy using cells and cell components as measured by the number of FDA and European Union (“EU”) therapeutic product approvals and product commercialization of cell based therapies. The vast majority of this progress has been achieved through the broader application of adult stem cells, reflecting a greater awareness and appreciation of their therapeutic potential.

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Positive results generated from the application of adult stem cells have resulted in greater government and private sector investment in the research and development of new cell therapies, including the continued advancement of existing treatments.

The regenerative medicine market is comprised of companies developing components that harvest, process, purify, expand, modify, cryopreserve, store or administer cells (i.e. devices and methods) or therapeutic providers commercializing cellular therapeutic agents (i.e. cell therapeutics). These cells and cell constituents can be stem cells, modified autologous cells and cell carrier packages for therapeutic cytokines and growth factors, i.e. platelets, cytokine or growth factor(s) as purified biologicals, and gene or plasmid therapies for in vivo production of protein having a direct impact on regeneration. Key success factors in regenerative medicine include:

·Target or purified cell recovery rates
·Efficiency of cell processing, including time
·Cost of care
·Product quality and dose specific efficacy
·Purity, viability and potency of stem cells
·Obtaining regulatory approval / FDA clearance

Generally, cell therapies include a process whereby, target cells are harvested from a donor or patient, further processed or expanded, manufactured into an effective safe dose, and implanted into a patient through a specific device. Cells are processed in the laboratory as well as in the operating room or point-of-care setting. Point-of-care applications involve the processing of patient cells in conjunction with a surgical procedure in an operating room or in an outpatient clinical setting. Requirements for the point-of-care include sterile field packaging, portability, minimal processing steps, predictable target cell recovery rates, and speed of processing. These market requirements must be considered and translated into product features and benefits for successful market adoption. Laboratory applications require Good Manufacturing Practices (“cGMP”), objective quality assurance and the ability to process multiple samples at one time.

The availability of therapeutic cells, including stem cells, at the point-of-care enables physicians to apply cells across an array of applications. In the United States the regulations governing the use of tissue and cells are defined in the Public Health Services Act under Sections 351 and 361. Cells intended to treat patients which are autologous, minimally manipulated, homologous and not combined with another regulated article are categorized as 361 agents and may be prescribed by physicians without a PreMarket Approval (“PMA”) or Biological License Approval (“BLA”). All other cell products are therefore regulated as 351 tissue or cell treatments and can only be used within an approved clinical trial or as defined in the PMA/BLA license. Therefore, many physicians are now choosing to study patient outcomes to understand the benefits of the therapeutic cells under their own independently-sponsored and regulated studies. Such research efforts are growing and include studies using cells derived from bone marrow, peripheral blood, cord blood, adipose, and placenta sources in diverse areas such as spinal fusion, non-healing fractures, wound healing, radiation injury, breast reconstruction and augmentation, cardiovascular applications, peripheral vascular disease and liver disease among many others.

With respect to large market opportunities, we believe that commercial products will come first in orthopedics, cardiology, skin and wound healing, diabetes and central nervous system disorders.

We believe regenerative medicine will be a critical catalyst in addressing the global increase in health care costs. As healthcare costs rise, there has been an increase in efforts to limit expenses by employers, payers and the government. If regenerative medicine therapies can provide a cost-effective alternative to current standards of care, we believe physicians and hospitals will have an incentive to more readily adopt these therapies. The need for baseline clinical and cost data developed through comprehensive studies is critical for the successful adoption of regenerative medicine therapies.

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Cord Blood Market

Since the first cord blood transplant was carried out in 1988, stem cells derived from umbilical cord blood have been used in more than 30,000 transplants worldwide to treat a wide range of blood diseases, genetic and metabolic disorders, immunodeficiency's and various forms of cancer. Today over 4,000 cord blood transplants are performed annually and that number is expected to grow.

Cord blood banks now exist in nearly every developed country, as well as in a large number of developing nations.

Cord blood banking can be divided into two categories; private banks serving individual families and public banks serving the broader public. In some cases a third model exists which is referred to as a hybrid private/public bank. Various hybrid models are possible; however, all derive a portion of their revenue from individual family sales as well as in part from public funding.

Cord blood use in clinical applications is now widely acceptable as a standard treatment for blood-based cancers and genetic disorders; an important but limited application base. To support this usage the FDA has approved several BLA licenses for certain public cord blood products which is considered a critical step in the maturation of the industry as well as a testament to the improvements in clinical cord blood quality. To address further growth and adoption of cord blood as a valuable therapeutic cell source, additional research and clinical trials are essential and currently underway in the United States and other countries.

Therapeutic Products, Approach and Clinical Delivery

Our clinical program is designed with two models of clinical delivery:

·SurgWerks® – Rapid Intra-operative Use
·CellWerks™ – Rapid Laboratory Use under the direction of a licensed physician

Our vision is to provide fully optimized therapeutic "kits", which are under investigational use, ultimately seeking marketing approval with the FDA (or appropriate equivalent in markets outside the U.S.). We believe SurgWerks® and CellWerks™ kits will revolutionize how autologous cellular therapies are administered to patients. At the core of successful clinical outcomes is the achievement to rapidly harvest, process and deliver an autologous therapeutic dose at the bedside. The SurgWerks® process maintains cell viability and potency throughout the process of source material collection, target cell selection, characterization/dose determination, and final delivery of the therapeutic cells to the patient. We are developing a unique and patent protected system designed to achieve cGMP cell manufacturing process control in a rapid 60-90min process either intra-operatively (SurgWerks®) or in the processing lab (CellWerks™).

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Cesca Clinical Pipeline

The SurgWerks® Platform
We have designed a fully integrated protocol, disposable and equipment product for rapid intra-operative use in 60-90 minutes called SurgWerks.®

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SurgWerks consists of the following:

- Protocol : A defined standard operating procedure containing step-by-step instructions on the operation of all components necessary to produce a defined cellular dose starting from the autologous collection of source material (i.e. bone marrow) through final delivery to targeted tissue/organ in the same patient.
- Disposables : A complete sterile "single-use" kit containing all medical disposables for harvesting, processing and delivery of the autologous cells including the testing reagents necessary to ensure the production of a high quality defined cellular dose.
- Equipment : An easy-to-use equipment "cart" containing all equipment/devices necessary to produce and test the defined cellular dose (i.e. centrifuge for cell processing and purification).

We completed the following SurgWerk's clinical trials in fiscal 2014:

- SurgWerks-AMI pilot trial for acute myocardial infarction in patients having low ejection fractions three to ten days after an ST elevated heart attack and having successful reperfusion of the affected heart artery. The goal of this study was to prove proof of principle.
- SurgWerks-CLI feasibility trial on no-option Rutherford 4 and 5 patients suffering from non-reconstructable critical limb ischemia. This study met the primary endpoints of demonstrating safety, while also demonstrating the salvage of the afflicted limb in 82.4% of the Intent-To-Treat ("ITT") study patients.

We intend to initiate the following SurgWerk's clinical trials in fiscal 2015:

SurgWerks-AMI feasibility (Phase II) trial on acute myocardial infarction patients having low ejection fractions three to ten days after the heart attack and having successful reperfusion of the affected heart artery.

SurgWerks-CLI pivotal trial on no-option Rutherford 5 patients suffering from non-reconstructable critical limb ischemia.

The company plans to initiate the following SurgWerk's pre-clinical evaluations in fiscal 2015:

- SurgWerks-Stroke pre-clinical development targeting patients with sub-acute ischemic brain injury

The CellWerks™ Platform

We offer the CellWerks ™ Platform for the optimal processing of targeted cells used in the treatment of oncological and hematological disorders. The equipment platform includes a "smart vision" control module and a corresponding disposable to process blood and bone marrow sourced tissue.

We plan to complete the following internally sponsored CellWerk's clinical study in fiscal 2015:

- Pilot study in pediatric allogeneic ABO mismatched bone marrow transplant

In fiscal 2014 the company completed an optimization of its CellWerks Platform that included several significant upgrades to address the emerging needs of the cell banking, biopharmaceutical and cellular therapeutic manufacturing sectors. Our goal for this Generation II automated platform is that CellWerks will be beneficial to cellular manufacturers in increasing cell yield over currently available commercial cell processing systems without the necessity to add any extraneous chemicals.

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Our Product Overview

We design, manufacture and sell advanced devices created specifically for the regenerative medicine bioprocessing market. This market includes biologic collection, transport, processing/washing, characterization/analysis, and cryopreservation. We view the regenerative medicine bioprocessing market as essential to the success of clinical trials through the control of quality of small and large scale cellular manufacturing. Our current product offering includes:

- The MarrowXpress® or MXP System, a derivative product of the AXP and its accompanying disposable bag set, isolates and concentrates stem cells from bone marrow. The product is an automated, closed, sterile system that volume-reduces blood from bone marrow to a user-defined volume in 30 minutes, while retaining over 90% of the MNCs, a clinically important cell fraction. Self-powered and microprocessor-controlled, the MXP System contains flow control optical sensors that achieve precise separation. We have received the CE-Mark, enabling commercial sales in Europe, and we received authorization from the FDA to begin marketing the MXP as a Class I device in the U.S. for the preparation of cell concentrate from bone marrow. However, the safety and effectiveness of this device for in vivo use has not been established.

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

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

- The Res-Q 60 BMC, is a rapid, reliable, and easy to use product for cell processing. The product is a centrifuge-based disposable device designed for the isolation and extraction of specific stem cell populations from bone marrow. The key advantages of the Res-Q 60 BMC include (a) delivering a high number of target cells from a small sample of bone marrow, and (b) providing a disposable that is highly portable and packaged for the sterile field. These features allow users to process bone marrow to isolate and capture certain cells in 15 minutes. However, the safety and effectiveness of this device for in vivo use has not been established.

- The Res-Q 60 PRP is designed to be used for the safe and rapid preparation of autologous platelet rich plasma (PRP) from a small sample of blood at the point of care. The product allows PRP to be mixed with autograft and/or allograft bone prior to application to a bony defect in the body. The Res-Q 60 PRP received FDA 510(k) clearance in June of 2011.

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Cell Manufacturing and Banking Services

At our international subsidiaries, we operate advanced clinical cell manufacturing, processing, testing, and storage facilities compliant with cGMP, Good Tissue Practices ("GTP"), and Good Laboratory Practices ("GLP"). We can support the production of a personalized medicine cell prescription or a large scale batch process. Patient samples, batch samples, and therapeutic aliquots are all labeled in accordance with ISBT 128 and stored in our cryogenics facility. In addition, our clinical research organization ("CRO") is the only specialized, in-hospital, cell therapy CRO globally. We have the unique expertise in designing, managing, and completing cell based clinical trials including the ability to support various device prototyping and validation typically required in 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 cGMP and GTP. In partnership with Fortis Healthcare we have assembled the industry's only fully integrated cell therapy CRO team to execute all elements in our in-house clinical trials, providing complete and seamless cellular drug and device clinical services.

Sales and Distribution Channels

We market and sell our products primarily through independent distributors, except in North America. We utilize integrated distribution arrangements whereby our suite of cord blood products are distributed into specific territories by a single distributor. These arrangements have improved the customer experience by streamlining their product, service and support needs through a single point of contact.

Competition

The regenerative medicine market is characterized by rapidly evolving technology and intense competition from medical device companies, pharmaceutical companies and stem cell companies operating in the fields of cardiac, vascular, orthopedics and neural medicine. The primary competitors for our current product mix include automated cell processing systems from BioSafe SA, MacoPharma, BioE, SynGen and Pall Corporation. Our competitors in the field of cell therapy development are MesoBlast, Ltd., Osiris Therapeutics, Inc., Baxter International, Inc., Athersys, Ltd., Neostem, Inc., Aastrom Biosciences, Inc., Cytori Therapeutics, Inc., Cytomedix, Inc., Pluristem Therapeutics Inc., and Bioheart, Inc.

Research and Development

Our research and development activities in fiscal 2014 focused on AutoXpress AXP and MXP platform improvements, transitioning the platform to Point-of-Care applications, and compliance with new environmental regulations. Also, the activities were aimed to develop or expand contract manufacturing capabilities for low cost disposables and building on our product quality leadership position. Significant investments were made to support product registration in China, Taiwan, India and South Korea. In fiscal 2015, we plan to introduce new features and enhancements to the AXP and MXP platforms to support our clinical trial initiatives and the expansion of the platform applications. Research and development expenses were $3,468, $2,991 and $3,729 for the years ended June 30, 2014, 2013 and 2012, respectively. Research and development activities include expenses related to engineering, regulatory, scientific and clinical affairs.

Manufacturing

Our long-term manufacturing strategy continues to utilize high quality, low cost contract manufacturers for production of high volume, consumable products while maintaining in-house manufacturing capabilities for low volume, high complexity devices. We will continue to evaluate in-house manufacturing versus out-sourcing programs to balance cost, quality, capacity and assurance of supply. As we expand our product offering in the point-of-care area, our third party sourcing of complex, hardware devices will increase. This will be accomplished by signing strategic, long-term

supply agreements.

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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. These requirements are intended to ensure that finished devices will be safe and effective and otherwise in compliance with the FDA Quality System Regulation ("QSR") (21 CFR 820) administered by the FDA and the applicable rules of other governmental agencies.

We and our contract manufacturers are subject to inspections by the FDA and other regulatory agencies for compliance with applicable regulations, codified in the QSR which include requirements relating to manufacturing processes, testing, documentation control and other quality assurance processes. 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. Failure to obtain or maintain necessary regulatory approvals to market our products would have a material adverse impact on our business.

Regulatory Scheme and Strategy

The development, clinical trials and marketing of our cell therapy products are subject to the laws and regulations of the FDA, European Medicine Agencies (EMEA) and other countries including India.

Our trials conducted in India are compliant with the applicable Indian Council for Medical Research, and Ministry of Health Order No. V.25011/375/2010-HR rules specific to oversight and rulemaking related to stem cell research and therapy in addition to requisite institutional ethics board and institutional stem cell committee approvals. Both the U.S. and E.U. regulatory agencies are experienced with accepting Indian clinical trial data. The FDA issued a Final Rule in October 2008 revising §21 CFR 312.120(a) and further clarifying their position in a Guidance Document in March 2012, where they will accept as support for an Investigational new Drug (IND) or application for marketing approval a well-designed and well-conducted foreign clinical study not conducted under a U.S. IND if the study is conducted in accordance with the GCP and where the sponsor is able to validate the data from the study through an onsite inspection by FDA if necessary. GCP includes review and approval by an IEC before initiating a study, continuing review of an ongoing study by an IEC, and obtaining and documenting the freely given informed consent of the subject before initiating a study.

Our regulatory activities focus on obtaining PMA from the FDA or the equivalent via the EMEA and national authorities in Europe as well as other national territories. Therefore, we have designed our studies to comply with the guidelines of these regulatory authorities per the Combination Products as defined by the FDA.

We have a quality and regulatory compliance management system that complies with the requirements of the ISO 13485: 2012 standard, the FDA's QSR, the EU MDD, the Canadian Medical Device Regulations ("SOR 98-282"), and other applicable local, state, national and international regulations.

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Our medical devices are subject to regulation by numerous government agencies, including the FDA and comparable state and foreign agencies. To varying degrees, each of these agencies requires us to comply with laws and regulations governing the development, testing, manufacturing, labeling, marketing, distribution, installation and servicing, clinical testing, post-market surveillance and approval of our products, including investigational, and commercially-distributed medical devices. These international, national, state, and local agencies set the legal requirements for ensuring our products are safe and effective, as well as manufactured, packaged and labeled in conformity with cGMP established by the FDA, as well as comparable regulations under the MDD of the EU. Virtually every activity associated with the manufacture and sale of our products and services are scrutinized on a defined basis and failure to implement and maintain a Quality Management System could subject the Company to civil and criminal penalties.

Class III Devices

Before certain medical devices may be marketed in the U.S., they must be approved by the FDA. FDA approval depends on the classification of the device. If the product is a Class III device, such as the SurgWerks-CLI therapy kit, the FDA approval process includes the following:

·Extensive pre-clinical laboratory and animal testing,
·Submission and approval of an Investigational Device Exemption (“IDE”) application,
·Human clinical trials to establish the safety and efficacy of the medical device for the intended indication, and
·Submission and approval of a PMA application to the FDA.

Pre-clinical trials typically include laboratory evaluation, through in vitro and in vivo animal studies, to obtain safety and if possible dosage information about the product to justify future clinical trials in human subjects. Safety testing is performed to demonstrate the biocompatibility of the device, particularly if the device is intended to come into contact with blood or other body tissues. Pre-clinical studies must be performed by laboratories which comply with the FDA’s Good Laboratory Practices regulations. The results of the pre-clinical studies are submitted to the FDA as part of an IDE application and are reviewed by the FDA before human clinical trials can begin.

Clinical trials involve the application of the medical device or biologic produced by the medical device to patients by a qualified medical investigator, after approval from an Institutional Review Board (“IRB”), and in certain jurisdictions having authorization for the trial under investigational use. Medical device trials which are conducted inside the U.S. are subject to FDA preapproval under an IDE application (21 C.F.R. Part 812), or an Investigational New Drug (“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 the requirements outlined in 21 C.F.R. Part 312.120.

Medical device clinical trials are typically conducted as a Phase III clinical trial. A Phase II or combined Phase I/II safety pilot trial may be performed prior to initiating the Phase III clinical trial to determine the safety of the product for specific targeted indications or dosage optimization studies. The FDA, the clinical trial sponsor, the investigators, the IRB or the Data Safety Monitoring Board may suspend clinical trials at any time if any one of them believes that study participants are being exposed to an unacceptable health risk.

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The combined results of product development, pre-clinical studies, and Phase III clinical studies are submitted to the FDA as a PMA application for approval of the marketing and commercialization of the medical device in the U.S. The FDA may deny the approval of a PMA application if applicable regulatory criteria are not satisfied or it may require additional clinical testing. Even if the appropriate data is submitted, the FDA may ultimately decide the PMA application does not satisfy the criteria for approval. Product approvals, once obtained, may be withdrawn if compliance with regulatory standards is not maintained or if safety concerns arise after the product reaches the market. The FDA may require post-marketing testing and surveillance programs to monitor the effect of the medical devices that have been commercialized and has the power to prevent or limit future marketing of the product based on the results of such programs.

Class II Devices

Several of our medical devices, including the BioArchive, Res-Q 60 PRP and AXP are categorized as Class II. These devices have a lower potential safety risk to the patient, user, or caregiver. A PMA submission is not a requirement for these devices. A simpler and shorter process of premarket notification, known as a 510(k) submission, is required to demonstrate substantial equivalence to another legally U.S. marketed device. Substantial equivalence means that the new device is at least as safe and effective as the predicate. Once the FDA has notified us that the product file has been cleared, the medical device may be marketed and distributed in the U.S.

Class I Devices

Some of our products, including the MXP and Res-Q 60 BMC that have minimal risk to the intended user have been deemed by the FDA as being exempt from FDA approval or clearance processes. While submissions to the FDA are not a requirement for Class I devices (low risk), compliance with the QSR is still mandated.

Other U.S. Regulatory Information

Failure to comply with applicable FDA requirements can result in fines, injunctions, civil penalties, recall or seizure of products, total or partial suspension of production or loss of distribution rights. It may also include the refusal of the FDA to grant approval of a PMA or clearance of a 510(k). Actions by the FDA may also include withdrawal of marketing clearances and possibly criminal prosecution. Such actions, if taken by the FDA, could have a material adverse effect on our business, financial condition, and results of operation.

Each manufacturing establishment must register with the FDA and is subject to a biennial inspection for compliance with the Federal Food, Drug, and Cosmetic Act and the QSRs. In addition, each manufacturing establishment in California must be registered with the California State Food and Drug Branch of the California Department of Public Health and be subject to an annual inspection by the State of California for compliance with the applicable state regulations. Companies are also subject to various environmental laws and regulations, both within and outside the U.S. Our operations involve the use of substances regulated under environmental laws, primarily manufacturing. Workplace safety, hazardous material, and controlled substances regulations also govern our activities. We have a California Environmental Protection Agency Identification number for the disposal of bio-hazardous waste from our research and development biological lab. Our cost associated with environmental law compliance is immaterial. The California State Food and Drug Branch of the California Department of Public Health completed a quality system compliance audit resulting with zero observations in fiscal 2011. The FDA audited us in fiscal 2012 resulting in two minor non-conformances that were resolved before the end of the audit.

International Regulatory Requirements

Internationally, we are required to comply with a multitude of other regulatory requirements. These regulations may differ from the FDA regulatory scheme. In the EU, a single regulatory approval process has been created and approval is represented by the CE-Mark. To be able to affix the CE-Mark to our medical devices and distribute them in the EU, we must meet minimum standards for safety and quality (known as the essential requirements) and comply with one or more conformity rules. A notified body assesses our quality management system and compliance to the MDD. Marketing authorization for our products is subject to revocation by the applicable governmental agency or

notified body under the EU which are subject to annual audit confirmations with respect to our quality system.

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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 as allowed by state and national laws 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 our current and proposed business. In the U.S., we currently hold 14 patents, and have 5 patents pending to protect our products. It is our policy to seek foreign patent protection in relevant markets around the world.

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

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

Certain Agreements

The following are certain agreements involving our business.

Fortis Healthcare Limited ("Fortis")
On August 1, 2014 we entered into an agreement with Fortis which renews and expands their existing agreement in the areas of cord blood banking services, point-of-care technology sales and support services, bone marrow transplant technology and laboratory services, and clinical/patient management of clinical trials for our internally developed therapeutics and third party marketed clinical research organization services. The term of the agreement is for three years.

Cord Blood Registry Systems, Inc. ("CBR")
On December 31, 2013, we entered into a Sale and Purchase Agreement with CBR in which we will supply CBR with the AXP cord blood processing system and disposables. The term of the agreement is for 5 years with automatic two-year renewal options unless CBR provides a 6 month notice of non-renewal. Additionally, we entered into the Fourth Amended and Restated Technology License and Escrow Agreement to delete or reduce the financial covenants that we must meet in order to avoid an event of default to one financial covenant, maintain a cash balance and short-term investments net of debt or borrowed funds of not less than $2,000 at any month end.

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

Golden Meditech

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

Asahi

Effective June 30, 2012 Asahi exercised its option to purchase certain intellectual property rights from us for the CryoSeal System, including, but not limited to, patents and patent applications, trademarks and any and all commercial and technical know-how. The intellectual property rights were sold for $2,000 which was received in August 2012.

In June 2010, we entered into an amendment to a Distribution and License Agreement with Asahi, originally effective March 28, 2005. Under the terms of the amendment, Asahi obtained exclusive rights to distribute the CryoSeal System in South Korea, North Korea, Taiwan, the People's Republic of China, the Philippines, Thailand, Singapore, India and Malaysia. These rights included the exclusive right to market, distribute and sell the processing disposables and thrombin reagent for production of thrombin in a stand-alone product. We will provide support to Asahi in the form of maintaining manufacturing capabilities of the CryoSeal System until the earlier of when Asahi receives regulatory approval from the Ministry of Health, Labour and Welfare ("MHLW") or December 31, 2012, upon which we shall have no further obligation to manufacture. Asahi received regulatory approval on August 31, 2011. Asahi shall continue to have the right to manufacture such products in Japan and shall additionally have a non-exclusive right to manufacture such products outside of Japan and would make royalty payments to us for products it manufactures and sells. The amendment extends the agreement eight years with automatic one year renewals. Asahi paid us a $1,000 license fee, which was fully earned and non-refundable as of June 30, 2012. Concurrent with exercising the purchase option, the terms and conditions of the amendment terminated.

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Arthrex

In January 2012, we entered into an agreement with Arthrex. Under the terms of the agreement, Arthrex obtained exclusive rights in certain territories to sell, distribute and service our Res-Q 60 System technology for use in the preparation of autologous PRP and BMC for sports medicine applications and orthopedic procedures. We granted Arthrex a limited license to use our intellectual property as part of enabling Arthrex to sell the products. Arthrex will purchase products from us to distribute and service at certain purchase prices, which may be changed after an initial period. The agreement contains purchase minimums that must be met on a yearly basis for Arthrex to maintain its exclusivity. Arthrex also pays a certain royalty rate based upon volume of products sold. The term of the agreement is for five years, subject to an extension right of an additional three years.

BioParadox LLC (“BioParadox”)

In October 2010, the Company and BioParadox entered into a License and Distribution Agreement. Under the terms of the agreement BioParadox obtained exclusive world-wide rights for the use, research and commercialization of the Res-Q technology in the production of PRP in the diagnosis, treatment and prevention of cardiovascular disease. The term of the agreement will depend on the satisfaction by BioParadox of certain milestones, or the payment of extension fees. If certain delivery or financial metrics are not maintained, the agreement requires the Company to place in escrow the detailed instructions for manufacturing the products. BioParadox will have the right to manufacture the product for the cardiac field for the term of the agreement in the event of a default by the Company or if certain on-time delivery metrics or supply requirements are not met.

GEHC

In January 2010, we signed an amendment with GEHC to extend the Amended and Restated International Distribution Agreement, effective February 1, 2010. Under the terms of the amendment, the contract ran through July 31, 2012, GEHC continued to distribute the AXP product line in the U.S., Canada and approximately 25 countries throughout the world, excluding certain countries in Latin America, Asia, CIS, Eastern Europe and the Middle East. The amendment provided incentives for both parties related to sales success, product quality and delivery. Under the original agreement, signed October 13, 2005, we received fees for the rights granted under the agreement. The amounts received are being recognized as revenue on the straight-line method over the initial five year term of the contract.

In January 2012, we signed an amendment, effective August 1, 2012. Under the terms of the amendment, GEHC will continue to distribute the AXP product line in the United States and Canada. The purchase prices for the products are fixed. The amendment will automatically renew for one year terms unless terminated by either party with 90 day notice. On August 26, 2013, the Company sent GEHC a 90 day notice of termination, which terminated the agreement effective November 24, 2013.

In May 2010, we signed a non-exclusive distribution agreement for the Res-Q 60 BMC System with GEHC. Under the agreement, GEHC had the right to distribute the Res-Q 60 BMC in the U.S., excluding orthopedic indications, Canada and 19 European countries. The agreement has a two and a half year term, with automatic one year renewals, unless terminated by either party with six months advance notice. The agreement provides for a price reduction mechanism should we fail to meet certain product quality and delivery metrics. The parties mutually agreed to terminate effective December 31, 2011.

Celling

In September 2008, we signed a distribution agreement for our MXP and Res-Q 60 BMC product lines with Celling. The distribution rights are for the field of use in orthopedic intraoperative or point-of-care applications. The agreement provides Celling with an initial two-year period of exclusive distribution rights in the U.S. and non-exclusive distribution rights throughout the rest of the world, excluding Central and South America, Russia and certain Eastern European countries. The exclusivity period and field of use may be extended under certain circumstances. The parties amended the agreement in July 2009 to provide shared funding for clinical studies to

demonstrate the clinical effectiveness of the products in orthopedic applications. The parties amended the agreement in January 2012. The revised distribution rights are world-wide, non-exclusive within field of use for the MXP and exclusive within field of use in the United States and non-exclusive in Mexico for the Res-Q. The parties have until January 31, 2015 to terminate the agreement otherwise it renews for another five years.

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

In March 1997, we and NYBC, as licensors, entered into a license agreement with Pall Medical, a subsidiary of Pall Corporation, as a licensee through which Pall Medical became the exclusive worldwide manufacturer (excluding Japan) for a system of sterile, disposable containers developed by us and NYBC for the processing of hematopoietic stem cells sourced from placental cord blood ("PCB"). The system is designed to simplify and streamline the harvesting of stem cells from umbilical cord blood and the manual concentration, cryopreservation (freezing) and transfusion of the PCB stem cells while maintaining the highest stem cell population and viability from each PCB donation. In May 1999, we and Pall Medical amended the original agreement, and we regained the rights to distribute the bag sets outside North America and Europe under our name. In fiscal 2012, we and NYBC signed an agreement which provides for the equal sharing of royalties between the two parties effective July 1, 2011, except for calendar 2012, in which NYBC received 75% and we received 25%.

Employees

As of June 30, 2014, we had approximately 95 employees, 60 of whom were employed in the U.S. and 35 in India. We also utilize temporary employees throughout the year to address business needs and significant fluctuations in orders and product manufacturing. None of our employees are represented by a collective bargaining agreement, nor have we experienced any work stoppage.

Foreign Sales and Operations

See footnote 8 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 ar