CESCA THERAPEUTICS INC.
Form 424B5
June 12, 2014
The information in this preliminary prospectus supplement and the accompanying prospectus is not complete and may be changed. A registration statement relating to these securities has been declared effective by the Securities and Exchange Commission. This preliminary prospectus supplement and the accompanying prospectus are not an offer to sell these securities and we are not soliciting an offer to buy these securities in any state or jurisdiction where the offer or sale is not permitted.

Subject To Completion, Dated June 12, 2014
Preliminary Prospectus Supplement Filed pursuant to Rule 424(b)(5)
(To Prospectus Dated June 4, 2014) File No. 333-196148

_____ Units Consisting of
_____ shares of Common Stock and
Warrants to Purchase _____ shares of Common Stock

We are offering _____ shares of our common stock, par value $0.001 per share ("Common Stock"), and warrants ("Warrants") to purchase up to ____ shares of our Common Stock at an exercise price of $___ per share of Common Stock. The Common Stock and Warrants will be sold in units ("Units"), with each Unit consisting of one share of Common Stock and a Warrant to purchase 0.__ shares of Common Stock. Each unit will be sold at a price of $____ per Unit. The shares of Common Stock and Warrants comprising the Units are immediately separable and will be issued separately but can only be purchased together as a Unit in this offering. The Warrants will be exercisable by the holders ____ after the date of the closing of the offering and will expire on the ____ anniversary of the closing of the offering. The shares of Common Stock issuable from time to time pursuant to the exercise of the Warrants are also being offered pursuant to this prospectus supplement and the accompanying base prospectus.

Our shares of Common Stock are listed on the NASDAQ Capital Market under the symbol "KOOL". On June 12, 2014, the last reported sale price for a share of our Common Stock on the NASDAQ Capital Market was $___. There is no established public trading market for the Warrants and we do not expect a market to develop. In addition, we do not intend to apply for listing of the Warrants on any national securities exchange.

The aggregate market value of our outstanding shares of Common Stock held by non-affiliates was approximately $47,877,000 based on 32,641,379 shares of Common Stock outstanding of which 9,400,096 shares of Common Stock were held by non-affiliates, and a per share price of $2.06 based on the closing sale price of a share of our Common Stock on April 24, 2014. We have sold no securities pursuant to General Instruction I.B.6 of Form S-3 during the prior 12 calendar month period that ends on, and includes, the date of this prospectus supplement.

Investing in our securities involves a high degree of risk. Before making an investment decision, please read "Risk Factors" beginning on page S-3 of this prospectus supplement and any other risk factor included in our base prospectus and in the documents incorporated by reference into this prospectus supplement and base prospectus.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus supplement is truthful or complete. Any representation to the contrary is a criminal offense.

Price to Public	Underwriting Discounts and Commissions	Proceeds to Cesca Therapeutics

			Inc. [1]
Per Unit	$	$	$
Total	$	$	$

[1] Before estimated expenses related to this offering of $244,600.

Sole Book Running Manager

Maxim Group LLC

The date of this prospectus supplement is June __, 2014.

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ABOUT THIS PROSPECTUS SUPPLEMENT

This prospectus supplement is part of a registration statement that we filed with the Securities and Exchange Commission ("SEC") utilizing a "shelf" registration process. Under this shelf registration statement process, we may from time to time offer to sell up to $50,000,000 of our shares of common stock, shares of preferred stock, warrants to purchase common shares, debt securities (not to exceed $10,000,000) and units consisting of shares of common stock, shares of preferred stock, warrants or debt securities or any combination of these securities in one or more transactions.

We provide information to you about this offering of our Common Stock and Warrants in two separate documents that are bound together: (1) this prospectus supplement, which describes the specific details regarding this offering of shares of Common Stock and Warrants; and (2) the accompanying base prospectus dated June 4, 2014, included in our registration statement on Form S-3 (SEC File No. 333-196148), which provides general information regarding our shares of common stock, shares of preferred stock, warrants to purchase shares of common stock or preferred stock, debt securities and units consisting of shares of common stock, shares of preferred stock, warrants or debt securities or any combination of these securities and other information some of which may not apply to this offering. If information in this prospectus supplement is inconsistent with the accompanying base prospectus, you should rely on this prospectus supplement. However, if any statement in one of these documents is inconsistent with a statement in another document having a later date, for example, a document incorporated by reference in this prospectus supplement, the statement in the document having the later date modifies or supersedes the earlier statement as our business, financial condition, results of operations and prospects may have changed since the earlier dates.

You should read this prospectus supplement, together with the accompanying base prospectus, the documents incorporated by reference in this prospectus supplement and the base prospectus and any free writing prospectus that we have authorized for use in connection with this offering before making an investment decision. You should also read and consider the information in the documents referred to in the sections of this prospectus supplement and the accompanying base prospectus entitled "Where You Can Find Additional Information" and "Incorporation of Certain Information by Reference". When we refer to this "prospectus", we are referring to both this prospectus supplement and the base prospectus combined.

You should rely only on the information contained or incorporated by reference in this prospectus supplement or in any free writing prospectus that we have authorized for use in connection with this offering. We have not, and Maxim Group LLC has not, authorized anyone to provide you with different information. If anyone provides you with different or inconsistent information, you should not rely on it.

We are not making an offer to sell the securities covered by this prospectus supplement in any jurisdiction in which an offer or solicitation is not permitted or in which the person making the offer or solicitation is not qualified to do so or to anyone to whom it is unlawful to make an offer or solicitation.

The information appearing in this prospectus supplement, the documents incorporated by reference in this prospectus supplement, and in any free writing prospectus that we have authorized for use in connection with this offering is accurate only as of its respective date, regardless of the time of delivery of the respective document or of any sale of securities covered by this prospectus. You should not assume that the information contained in or incorporated by reference in this prospectus supplement or in any free writing prospectus that we have authorized for use in connection with this offering, is accurate as of any date other than the respective dates thereof.

In this prospectus supplement, "we", "us", "our", "the company", and "Cesca" refer to Cesca Therapeutics Inc. and its subsidiaries, unless the context otherwise requires.

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PROSPECTUS SUMMARY

This summary highlights certain information about us, this offering and information appearing elsewhere in this prospectus supplement and in the documents we incorporate by reference in this prospectus supplement. This summary is not complete and does not contain all of the information that you should consider before investing in our securities. After you read this summary, to fully understand our company and this offering and its consequences to you, you should read this entire prospectus supplement and any related free writing prospectus carefully, including the information referred to under the heading "Risk Factors" in this prospectus supplement beginning on page S-3, and any related free writing prospectus, as well as the other documents that we incorporate by reference into this prospectus supplement, including our financial statements and the exhibits to the registration statement of which this prospectus supplement is a part.

On February 18, 2014, TotipotentRX Corporation merged with and into ThermoGenesis Corp. In connection with the merger, ThermoGenesis changed its name from ThermoGenesis Corp. to Cesca Therapeutics Inc. 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, or integrate into the design of clinical protocols and applications directed at cell therapies at the point of care, managing both risk of regulatory approval, and channel distribution. Cesca has the ability to develop new products, devices and disposables, and support existing products, while directing new development of products and services to clinical trials.

Our business strategy includes:

- Practical, Commercializable Cell Therapies. To deliver proprietary, commercially viable, highly effective autologous (patient's own cells) cell therapies to treat major diseases within the existing healthcare delivery system.

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

- Positioned to Commercialize in Both Developed and Emerging Markets. To 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 – To 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 was founded in 1986, and our principal executive offices are located at 2711 Citrus Road, Rancho Cordova, California 95742. Our telephone number is (916) 858-5100. Our website is located at www.cescatherapeutics.com. Information contained on, or that can be accessed through, our website is not part of this prospectus.

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THE OFFERING

Securities offered by us	_____ Units, each consisting of: One share of Common Stock; and One Warrant to purchase 0.____ shares of Common Stock at an exercise price of $__ per share. This prospectus supplement also relates to the offering of the shares of Common Stock issuable upon exercise of the Warrants.
Public Offering Price	$___ per Unit
Shares of Common Stock outstanding before this offering	32,657,984 shares
Shares of Common Stock to be outstanding after this offering	_____ shares [(1)]
Warrants	We will issue Warrants exercisable in the aggregate for _____ shares of Common Stock. The exercise price of each of the Warrants will be $__ per share. The Warrants will be exercisable by the holders ____ after the date of the closing of the offering and will expire on the ____ anniversary of the closing of the offering.
Use of Proceeds	We currently intend to use the net proceeds of this offering for the purposes of funding our stem cell clinical programs including, but not limited to, Critical Limb Ischemia, Acute Myocardial Infarction and Bone Marrow Transplant, and for general corporate purposes and working capital needs. See ‘‘Use of Proceeds’’ on page S-17 of this prospectus supplement.
Risk Factors	Investing in our securities involves a high degree of risk. See “Risk Factors” beginning on page S-4 of this prospectus supplement for a discussion of factors you should consider carefully when making an investment decision.
NASDAQ Symbol	KOOL There is no established public trading market for the Warrants and we do not expect a market to develop. In addition, we do not intend to apply for listing of the Warrants on the NASDAQ Capital Market or on any other national securities exchange.
Lock- Up	Certain of our officers have agreed to a 90-day “lock-up” period from the closing of this offering with respect to any of our securities that they beneficially own, including the issuance of Common Stock upon the exercise of convertible securities and options that are currently outstanding or which may be issued.

[(1)] The number of shares of Common Stock to be outstanding immediately after this offering as shown above is based on 32,657,984 shares of Common Stock outstanding as of June 12, 2014, and assumes the sale of all Units being offered pursuant to this prospectus supplement. Unless otherwise indicated, the number of shares of Common

Stock presented in this prospectus supplement excludes (i) 1,253,035 shares of Common Stock issuable upon exercise of stock options outstanding under our stock plans, at a weighted average exercise price of $ 2.08 per share; (ii) 2,854,420 shares of Common Stock issuable upon exercise of warrants outstanding at a weighted average exercise price of $ 2.73 per share; (iii) 653,331 unvested shares of restricted stock granted under our equity plans; (iv) 840,642 shares of Common Stock available for future grant or issuance pursuant to our equity incentive plan; and (v) none of the Warrants being offered hereby being exercised.

Except as otherwise indicated herein, this prospectus supplement assumes the sale of the maximum number of Units offered hereunder.

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RISK FACTORS

An investment in our Common Stock is subject to risks inherent to our business. The material risks and uncertainties that management believes affect us are described below. Before making an investment decision, you should carefully consider the risks and uncertainties described below together with all of the other information included or incorporated by reference in this report. The risks and uncertainties described below are not the only ones facing us. Additional risks and uncertainties that we are not aware of or focused on or that we currently deem immaterial may also impair our business operations. Due to the recent completion of the merger with TotipotentRX, its significance to us and that we have just begun to integrate its business and operations, our risk factors also relate to TotipotentRX's operations. We also update risk factors from time to time in our periodic reports on Forms 10-K, 10-Q and 8-K which will be incorporated by reference to this prospectus.

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 Market Price of Our Common Stock May Decline As a Result Of the Merger.

We recently merged with TotipotentRX. Our Common Stock may decline as a result of the merger for a number of reasons, including the following:

- we do not achieve the perceived benefits of the merger as rapidly or to the extent anticipated by financial or industry analysts or the investment community; or
- we are unable to obtain additional financing to implement our business plan.

An Inability to Successfully Integrate TotipotentRX's Operations Could Adversely Affect Us.

Our ability to integrate TotipotentRX's business and operations to fulfill our strategy and business plan is dependent on our ability to successfully integrate TotipotentRX's operations. Failure to quickly and adequately integrate TotipotentRX's operations and personnel could adversely affect our business and our ability to achieve our objectives and strategy.

We Will Need to Raise Additional Capital in Furtherance of Our Business Plan.

We will need to raise additional capital in furtherance of our business plan, including the development of new products. Any proposed financing may include shares of common stock, shares of preferred stock, warrants to purchase shares of common stock or preferred stock, debt securities, units consisting of the forgoing securities, equity investments from strategic development partners or some combination of each. Any additional equity financings may be financially dilutive to, and will be dilutive from an ownership perspective to, our stockholders.

We Have Incurred Net Losses For a Significant Period and Losses May Continue.

We have not been profitable since 1994. For the fiscal year ended June 30, 2013, we had a net loss of $3,086,000 and an accumulated deficit at June 30, 2013, of $114,191,000. We will continue to incur significant costs as we develop and market our current products and related applications, continue our research and development activities and seek regulatory approval for our product candidates. 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.

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Demand For Most Of Our Products Depends On Capital Spending Policies Of Our Customers And On Government Funding Policies.

Our customers include stem cell banks (both private and non-profit), laboratories, universities, healthcare providers, government agencies and public and private research institutions. Many factors, including public policy spending priorities, available resources and product and economic cycles, have a significant effect on the capital spending policies of these entities. These policies in turn can have a significant effect on the demand for our products. Further, the current economic crisis heightens the risk that our customers may lack the funding or credit facilities that they may have previously used for acquiring our products. Such credit or funding restrictions could delay or lower our future revenues.

Lack of demonstrated clinical utility of cord blood derived stem cells beyond hematopoietic transplantation may result in a decline in demand for cord blood banking services, adversely affecting sales of our products.

Transplants using stem cells derived from cord blood and cord tissue have become a standard procedure for treating blood cell lineage disorders, including leukemia, lymphoma and anemia. However, clinical research demonstrating the utility of cord blood stem cells for use in treating other diseases or injury has been minimal, leaving claims of broad clinical utility of cord blood stem cells by cord blood banks largely unsubstantiated. The low utilization rate of banked cord blood samples coupled with the lack of demonstrated clinical results for multiple treatment indications has led to consumer skepticism regarding the benefits of cord blood banking and in turn, a significant reduction in collection rates in a number of geographies in Europe and the United States. A continued lack of investment in the research and development of supporting clinical data for additional applications may lead to greater skepticism globally, further adversely affecting demand for cord blood banking services and revenues to us.

Our Future Revenue Growth is Dependent on our New Products and our Existing Products being Accepted for New Indications or into New Markets.

The acceptance of our products into new markets or for new indications will depend upon the medical community and third-party payers accepting the products as clinically useful, reliable, accurate, and cost effective compared to existing and future products or procedures. Acceptance will also depend on our ability to adequately train technicians on how to use our existing and future products. Even if our products are released for sale, their use may not be recommended by the medical profession or hospitals, unless acceptable reimbursement from healthcare and third-party payers is available. Failure of these products to achieve significant market share could have material adverse effects on our long term business, financial condition, and results of operation.

Outcomes of Pending or Future Clinical Trials or Evaluations May be Negative and the Regenerative Medicine Market May not Expand, or May Not Expand in the Areas Targeted by Our Products.

The marketing and sales of new products may depend on successful clinical trials or evaluation outcomes in the regenerative medicine areas targeted by our products and the approval of regulators. Clinical trials also represent a significant expenditure of resources. Negative clinical trial results in connection with our products or in the areas targeted by it could negatively impact regulatory approval or market acceptance of our products. Unfavorable clinical trials or failure of study results to obtain regulatory approval in a targeted clinical application and/or geographical area even with successful clinical trials, could have material adverse effects on our long-term business, financial condition, and results of operations.

A Significant Portion of Our Revenue is Derived from Customers in Foreign Countries. We May Lose Revenues, Market Share, and Profits Due to Exchange Rate Fluctuations, Political and Economic Changes Related to Our Foreign Business.

For the years ended June 30, 2013 and 2012, sales to customers in foreign countries comprised approximately 55.0% and 43.0%, respectively, of our revenues before the merger. 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 product prices that our foreign customers are willing to pay, and may put us at a price disadvantage compared to other competitors. Potentially volatile shifts in exchange rates may negatively affect our financial position and results.

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The Loss of a Significant Distributor or End User Customer May Adversely Affect Our Financial Condition and Results of Operations.

Revenues from four significant distributors comprised 56.0% of our revenues for the fiscal year ended June 30, 2013, and a significant portion of our largest distributor's revenue came from one customer. The loss of a large end user customer or distributor may decrease our revenues.

We are Reliant on Highly Specialized Distributors and Regulatory Approval to Market and Sell Our Bone Marrow Processing System.

Although we have added distributors in other territories, we may not be able to expand our sales of in vivo applications utilizing bone marrow processing devices until clinical trials are conducted. Since the MXP, Res-Q, and VXP products are projected as a significant portion of our revenue growth, a delay in finding competent distributors in the clinical space and/or a delay or failure to complete clinical trials and each on-label regulatory approval may adversely affect our future revenues and competitive advantage.

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 competitive position. Accordingly, we devote substantial resources to the establishment and protection of our patents, trademarks, trade secrets and proprietary rights. 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. We compete with other companies for contracts in some small or specialized industries, which increases the risk that the other companies will develop overlapping technologies leading to an increased possibility that infringement claims will arise. 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 may 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.

Adverse Results of Legal Proceedings could have a Material Adverse Effect on Us.

We are currently 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 business. Results of legal proceedings cannot be predicted with certainty. Irrespective of their merits, legal proceedings may be both lengthy and disruptive to 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 business operations or a material adverse effect on the financial condition and results of operations.

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We May Not Be Able to Protect Our Intellectual Property In Countries Outside the United States. Intellectual Property Law Outside the United States Is Uncertain and In Many Countries Is Currently Undergoing Review and Revisions.

The laws of some countries do not protect our patent and other intellectual property rights to the same extent as U.S. 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 United States. 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 European Union 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 European Union Restriction of Hazardous Substances in Electrical and Electronic Equipment ("RoHS") Directive now requires that certain substances, which may be found in certain products we have manufactured in the past, be removed from all electronics components. Eliminating such substances from our manufacturing processes requires the expenditure of additional research and development funds to seek alternative substances for our products, as well as increased testing by third parties to ensure the quality of our products and compliance with the RoHS Directive. Other countries, such as China, have enacted or may enact laws or regulations similar to RoHS. While we have implemented a compliance program to ensure our product offering meets 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 its restricted counterparts. Additionally, if we were found to be non-compliant with any such rule or regulation, we could be subject to fines, penalties and/or restrictions imposed by government agencies that could adversely affect our operating results.

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.

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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 Quality System Regulation ("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. There are no assurances we will be successful 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.

Our Dependence On Suppliers For Disposable Products And Custom Components May Impact Our 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 need to qualify the quality assurance systems and product quality of that alternative supplier. Any operational issues with re-engineering or the alternative qualified supplier may impact the production schedule, therefore delaying revenues, and this may cause the cost of disposables or key components to increase.

Failure To Meet Certain Financial Covenants Could Decrease AXP Product Revenues.

Under certain license and escrow agreements, if we fail to meet certain financial covenants, other companies may take possession of the escrowed intellectual property and initiate manufacturing of the applicable device and disposables. If this were to occur, our revenues would be negatively impacted.

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. operations are conducted at a single location although we contract the manufacturing of certain devices, disposables and components. Further, through the TotiPotentRX merger, we have clinical and manufacturing operations in India. We take precautions to safeguard our facilities, through insurance, health and safety protocols, and off-site storage of computer data. However, a natural disaster, such as a fire, flood or earthquake, could cause substantial delays in our operations, damage or destroy our manufacturing equipment or inventory, and cause us to incur additional expenses. The insurance we maintain against fires, floods, and other natural disasters may not be adequate to cover our losses in any particular case.

We have Limited Operating History In the Emerging Regenerative Medicine Industry.

Through the merger with TotipotentRX, we are in the business of research, development and commercialization of autologous cell-based therapeutics for use in the emerging regenerative medicine industry, and therefore, we have a limited operating history in such industry on which to base an evaluation of our business and prospects. We will be

subject to the risks inherent in the operation of a company in an emerging industry such as regulatory setbacks and delays, fluctuations in expenses, competition, and governmental regulation.

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Our Potential Products And Technologies Are In Early Stages Of Development.

The development of new cell therapy combination products (pharmaceutical 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 cardiovascular, orthopedic 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 rely on third parties for clinical trial activities of our products. In this regard, we have, through our merger with TotipotentRX, entered into an agreement with Fortis Healthcare Limited, a hospital chain networked throughout India and Asia, where we act as an exclusive regenerative medicine service provider to Fortis Healthcare. Pursuant to the arrangement, which expires in May 2016, we receive certain discounts from Fortis Healthcare for clinical and hospital services specific to conducting early clinical trials in their organization. If the agreement is not renewed or is terminated by Fortis, we will have to find other entities or organizations to fulfill Fortis' favorable cost structure thus jeopardizing or delaying development of our products.

We rely on other third parties for various miscellaneous clinical trial activities. Any one of these third-party contractors may fail to comply with regulatory requirements or meet their contractual obligations with us in a timely manner or at all.

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;
- 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 combination 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 or 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, to conduct additional clinical trials or abandon product development programs that we expect to be pursuing.

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We Do Not Have Commercial-Scale Manufacturing Capability And Lack Commercial Manufacturing Experience.

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

We Have Limited Sales, Marketing and Distribution Experience in Pharmaceutical Products.

We have limited experience in the sales, marketing, and distribution of pharmaceutical products. There can be no assurance that we will be able to establish sales, marketing, and distribution capabilities or make arrangements with current collaborators or others to perform such activities or that such efforts 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.

We May Seek To Enter Into Collaborative Arrangements To Develop and Commercialize Our Products Which May Not Be Successful.

We may seek to enter into collaborative arrangements to develop and commercialize some of our potential products both in North America and international markets. There can be no assurance that we will be able to negotiate collaborative arrangements on favorable terms or at all or that our current or future collaborative arrangements will be successful.

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 (the “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.

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 inappropriately 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 premarket application (PMA) or 510(k) if appropriate regulations relative to the PMA or 510(k) product are not met. The notified bodies may elect to not renew CE-Mark certification. Any of these events would negatively impact our revenues and costs of operations.

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In addition, the production and marketing of our products and potential products and our ongoing research and development, pre-clinical testing and clinical trial activities are currently subject to extensive regulation and review by numerous governmental authorities in the United States and will face similar regulation and review for overseas approval and sales from governmental authorities outside of the United States. Our products under development must undergo rigorous clinical testing and an extensive regulatory approval process before they can be marketed. This process makes it longer, harder and more costly to bring our potential products to market, and we cannot guarantee that any of our potential products will be approved. If we or our collaboration partners do not comply with applicable regulatory requirements, such violations could result in non-approval, suspensions of regulatory approvals, civil penalties and criminal fines, product seizures and recalls, operating restrictions, injunctions, and criminal prosecution.

We may be subject to a more complex regulatory process since stem cell therapies are relatively new and regulatory agencies have less experience with them than with traditional pharmaceutical products and medical devices. Additionally, we believe that many of our therapies will be subject to the U.S. FDA Office of Combination Products, and there have not been any cellular biological-device combinations approved to date by this office.

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 U.S. 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.

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To Operate In Foreign Jurisdictions, We Are Subject to Regulation by Non-U.S. Authorities.

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

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 U.S. FDA regulatory scheme.

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 Marketing Approval For Similar Products Before We Do, Our Commercial Opportunity May Be Reduced Or Eliminated.

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

Influence By The Government And Insurance Companies May Adversely Impact Sales Of Our Products.