CESCA THERAPEUTICS INC.
Form S-3
February 26, 2014

As filed with the Securities and Exchange Commission on February 26, 2014 Registration No. 333-

SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM S-3
REGISTRATION STATEMENT UNDER THE SECURITIES ACT OF 1933

CESCA THERAPEUTICS INC.
(Formerly ThermoGenesis Corp.)
(Exact name of the Company as specified in its charter)

Delaware	94-3018487
(State or other jurisdiction or incorporation or organization)	(I.R.S. Employer Identification Number)

2711 Citrus Road
Rancho Cordova, California 95742
(916) 858-5100
(Address, including zip code, and telephone number, including
area code, of registrant's principal executive offices)

Matthew Plavan
Chief Executive Officer
Cesca Therapeutics Inc.
2711 Citrus Road
Rancho Cordova, California 95742
(916) 858-5100
(Name, address, including zip code, and telephone number, including
area code, of agent for service)

Copies to:

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Approximate date of commencement of the proposed sale to the public: As soon as practicable and from time to time after the effective date of this Registration Statement.

If the only securities being registered on this Form are being offered pursuant to dividend or interest reinvestment plans, please check the following box: o

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, other than securities offered only in connection with dividend or interest reinvestment plans, check the following box: x

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering: o

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering: o

If this Form is a registration statement pursuant to General Instruction I.D. or a post-effective amendment thereto that shall become effective upon filing with the Commission pursuant to Rule 462(e) under the Securities Act, check the following box: o

If this Form is a post-effective amendment to a registration statement filed pursuant to General Instruction I.D. filed to register additional securities or additional classes of securities pursuant to Rule 413(b) under the Securities Act, check the following box: 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.

Large accelerated filer o Accelerated filer o
Non-accelerated filer o Smaller reporting company x

CALCULATION OF REGISTRATION FEE

Title of each class of securities to be registered	Amount to be registration	Proposed maximum offering price per share[1]	Proposed maximum aggregate offering price	Amount of registration fee
Common Stock	3,336,800		$8,175,160	
Common Stock Underlying Warrants	1,668,400		$4,087,580	
Total	5,005,200	$ 2.45	$12,262,740	$1,579.44

[1] Calculated in accordance with Rule 457(c) of the Securities Act of 1933, as amended ("Securities Act"). Estimated for the sole purpose of calculating the registration fee and based upon the average of the high and low price per share of our common stock on February 21, 2014, as reported on the Nasdaq Capital Market.

The registrant hereby amends this registration statement on such date or dates as may be necessary to delay its effective date until the registrant shall file a further amendment which specifically states that this registration statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act or until the registration statement shall become effective on such date as the Securities and Exchange Commission (the "Commission"), acting pursuant to said Section 8(a), may determine.

The information in this prospectus is not complete and may be changed. Selling securityholders may not sell these securities until the registration statement filed with the Commission becomes effective. This prospectus is not an offer to sell these securities and we are not soliciting an offer to buy these securities in any state where the offer or sale is not permitted or would be unlawful prior to registration or qualification under the securities laws of any such state.

Subject to completion dated February 26, 2014 PROSPECTUS

5,005,200 shares Common Stock

The selling securityholders named herein may offer and sell from time to time up to 3,336,800 shares of our common stock and 1,668,400 shares of common stock underlying the warrants covered by this prospectus. The selling securityholders will receive all of the proceeds from any sales of the shares offered hereby. We will not receive any of the proceeds, but we will incur expenses in connection with the offering.

Our registration of the shares of common stock covered by this prospectus does not mean that the selling securityholder will offer or sell any of the shares or warrants. The selling securityholder may sell the shares of common stock covered by this prospectus in a number of different ways and at varying prices. Some of the shares covered by this prospectus currently are subject to issuance upon exercise of a currently outstanding warrant held by the selling securityholder. We provide more information about how the selling securityholder may sell the shares in the section entitled "Plan of Distribution".

Our common stock is traded and listed on the Nasdaq Capital Market, under the symbol "KOOL." On February 24, 2014, the last reported sale price for a share of our common stock was $2.37.

INVESTING IN OUR COMMON STOCK INVOLVES A HIGH DEGREE OF RISK.
SEE "RISK FACTORS" AT PAGE 2.

NEITHER THE SECURITIES AND EXCHANGE COMMISSION NOR ANY STATE SECURITIES COMMISSION HAS APPROVED OR DISAPPROVED OF THESE SECURITIES OR DETERMINED IF THIS PROSPECTUS IS TRUTHFUL OR COMPLETE. ANY REPRESENTATION TO THE CONTRARY IS A CRIMINAL OFFENSE.

The date of this Prospectus is _____, 2014

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ABOUT THIS PROSPECTUS

This prospectus is part of a registration statement on Form S-3 that we filed with the Securities and Exchange Commission, or the "SEC". We have prepared the information contained in this prospectus and the documents incorporated by reference herein and therein that have been filed by us with the SEC. Neither we nor the selling securityholder has authorized anyone to provide you with any other information and neither we nor the selling securityholder takes any responsibility for other information others may give you.

The information contained in this prospectus or in any document incorporated by reference is accurate only as of its date, regardless of the time of delivery of this prospectus or any sale of common stock. Our business, financial condition, results of operations and prospects may have changed since the dates of such respective documents.

This prospectus is not an offer to sell or solicitation of an offer to buy these shares of common stock or warrants in any circumstances under which or jurisdiction in which the offer or solicitation is unlawful.

Unless the context otherwise indicates, the terms "Cesca Therapeutics," "Company," "we," "us," and "our" as used in this prospectus refer to Cesca Therapeutics (formerly known as ThermoGenesis Corp.), TotipotentRX which merged into Cesca Therapeutics, and its subsidiaries.

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CESCA THERAPEUTICS INC.

Cesca Therapeutics is a leading designer and supplier of clinical technologies for processing and storing stem cells used in the practice of regenerative medicine. Regenerative medicine is an emerging field using cell-based therapies to address a number of clinical indications, including the repair or restoration of diseased or damaged tissue and cell function. Our products isolate and automate the volume reduction and cryopreservation of adult stem cell concentrates from cord blood, bone marrow and peripheral blood for use in laboratory and point of care settings. Our primary business model is based on the sale of medical devices and the recurring revenues generated from their companion single-use, sterile disposable products. We currently sell our products in over 30 countries throughout the world to customers that include private and public cord blood banks, surgeons, hospitals and research institutions. Our worldwide commercialization strategy relies primarily on the utilization of distributors. We are located at 2711 Citrus Road, Rancho Cordova, California 95742 and our phone number is (916) 858-5100.

Acquisition of TotipotentRX

Effective February 18, 2014, Cesca Therapeutics acquired TotipotentRX Corporation (TotipotentRX) by merger. TotipotentRX, formerly known as MK Alliance, Inc., is engaged in the research, development, and commercialization of cell-based therapeutics for use in regenerative medicine. In addition, TotipotentRX sells medical devices and equipment for collection, transportation, and processing of cord blood, cord tissue, bone marrow, and peripheral blood stem cells; reagents for culturing and assaying stem cells; and services to hospitals and surgeons for processing autologous cellular therapies at the point of care. TotipotentRX also had two wholly-owned subsidiaries: TotipotentRX Cell Therapy, Pvt. Ltd. (cellular therapeutics) including its joint collaboration Fortis-TotipotentRX Centre for Cellular Medicine (cellular clinical trials), and TotipotentSC Scientific Product Pvt. Ltd. (medical devices).

As a result of the merger, we will be 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. We will have the ability to develop new products, devices, and disposables, and support existing products, while directing new development of products and services to clinical trials, and will have the following strategic benefits:

- One of the First Integrated Regenerative Medicine Companies. We are one of the first companies to bring together cell-therapy-related devices, patented platform technology, proprietary cell formulations and treatment protocols and a cell-therapy-specific clinical research organization increasing the likelihood that a safe and effective therapy can reach full commercialization.

- Practical, Commercializable Cell Therapies. We offer safe and effective therapies backed by clinical evidence, including eight clinical trials in osteoarthritis, avascular necrosis, cardiac and critical limb ischemia, among others, using patient and regulator friendly autologous cells and at the bedside, 60-90 minute protocol.

- Ability to Rapidly and Cost-Effectively Implement New Clinical Trials. We have the ability to rapidly initiate early clinical development of new cell therapies at its U.S. 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. Our existing U.S. and Asian footprints 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.

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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 Form 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.

Our Ability 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 estimate a need for $10 million to $15 million of additional growth capital to execute our business plan over the next 24 to 36 months. The proposed financing may include shares of common stock and warrants to purchase additional shares of common stock, 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 US. 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 its New Products and its 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, before taking into effect the merger 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 its 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 United States laws. This is particularly relevant to us as a significant amount of our current and projected future sales are outside of the United States. Third parties may attempt to oppose the issuance of patents to us in foreign countries by initiating opposition proceedings. Opposition proceedings against any of our patent filings in a foreign country could have an adverse effect on our corresponding patents that are issued or pending in the United States. It may be necessary or useful for us to participate in proceedings to determine the validity of our patents or our competitors' patents that have been issued in countries other than the U.S. This could result in substantial costs, divert our efforts and attention from other aspects of our business, and could have a material adverse effect on our results of operations and financial condition.

Any Failure to Achieve and Maintain the High Design and Manufacturing Standards That Our Products Require May Seriously Harm Our Business.

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

Our Revenues and Operating Results May Be Adversely Affected As A Result of Our Required Compliance With the Adopted 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 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 Facility Could Delay Revenues Or Increase Our Expenses.

Most of our operations are conducted at a single location although we contract the manufacturing of certain devices, disposables and components. Further, through the merger, we have operations in India. We take precautions to safeguard our facility, 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.

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

Through the merger with TotipotentRX, we are in the business of research, development and commercialization of autologous cell-based therapeutics for use in the emerging regenerative medicine industry, and therefore, we have a limited operating history in such industry on which to base an evaluation of our business and prospects. We will be subject to the risks inherent in the operation of a company in an emerging industry such as regulatory setbacks and delays, fluctuations in expenses, competition, and governmental regulation.

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

The development of new cell therapy 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 a collaborative 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 and which arrangement expires in May 2016. Additionally, 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.

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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.

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

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

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

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

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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.

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.

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There Can Be No Assurance That We Will Obtain Regulatory Approvals Or Clearances In All Of The Countries Where We Intend To Market Our Products, Or That We Will Not Incur Significant Costs In Obtaining Or Maintaining Foreign Regulatory Approvals Or Clearances, Or That We Will Be Able To Successfully Commercialize Current Or Future Products In Various Foreign Markets.

Delays in receipt of approvals or clearances to market our products in foreign countries, failure to receive such approvals or clearances or the future loss of previously received approvals or clearances could have a substantial negative effect on our results of operations and financial condition.

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

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

In order for us to manufacture and/or market our services and products in India, we need to obtain and maintain required regulatory approvals or clearances and must comply with extensive regulations regarding safety, manufacturing processes and quality. These regulations, including the requirements for approvals or clearances to market, and/or export may differ from the 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 sales also may be limited or disrupted by political instability, price controls, trade restrictions and changes in tariffs as ordered by various governmental agencies. Additionally, fluctuations in currency exchange rates may adversely affect demand for its products by increasing the price of 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.

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

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

Product Liability And Uninsured Risks May Adversely Affect Our Continuing Operations.

We operate in an industry susceptible to significant product liability claims. We may be liable if any of our products cause injury, illness, or death. These claims may be brought by individuals seeking relief or by groups seeking to represent a class. We also may be required to recall certain of our products should they become damaged or if they are defective. We are not aware of any material product liability claims against us. However, product liability claims may be asserted against us in the future based on events we are not aware of at the present time. We maintain a product liability policy for $3,000,000 and a general liability policy that includes product liability coverage of $1,000,000 per occurrence and $2,000,000 per year in the aggregate. However, a product liability claim against us could have a material adverse effect on our business or future financial condition.

Risks Related to Our Common Stock

Trading Prices For Our Common Stock Have Been, And May Continue To Be, Volatile.

The trading price of our common stock has been subject to wide fluctuations and may continue to be volatile in the future. Trading price fluctuations can be caused by a variety of factors, many of which are beyond our control, including, among other things:

- Variations in operating results;
- Our common stock is thinly traded;
- Regulatory actions, such as product recalls;
- Governmental regulatory acts;
- Biological or medical discoveries; and
- Market conditions in our industry and the economy as a whole.

If our revenues or operating results fall below the expectations of securities analysts and investors, the price of our common stock would likely decline. In the last few years, the stock market experienced extreme price and volume