CESCA THERAPEUTICS INC.
Form S-1/A
February 05, 2018
As filed with the Securities and Exchange Commission on February 5, 2018.

Registration No. 333-222658

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Amendment No. 1

to

FORM S-1

REGISTRATION STATEMENT

UNDER

THE SECURITIES ACT OF 1933

CESCA THERAPEUTICS INC.

(Exact name of registrant as specified in its charter)

Delaware	**3821**	**94-3018487**
(State or other jurisdiction of incorporation or organization)	**(Primary Standard Industrial Classification Code Number)**	**(I.R.S. Employer Identification No.)**

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)

Vivian Liu

Chief Operating Officer

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:

Curt P. Creely, Esq.	**Barry I. Grossman, Esq.**
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Approximate date of commencement of proposed sale to the public:

As soon as practicable after this Registration Statement is declared effective.

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, as amended, check the following box:

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If this form is filed to register additional securities for an offering pursuant to Rule 462(b) 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.

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.

If this form is a post-effective amendment filed pursuant to Rule 462(d) 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.

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

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

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards pursuant to Section 7(a)(2)(B) of the Securities Act.

CALCULATION OF REGISTRATION FEE

Title of Each Class of Securities to be Registered	**Proposed Maximum Aggregate Offering Price[(1)(2)]**	**Amount of Registration Fee**
Common Stock, $0.001 par value per share	$ 17,250,000	$ 2,149
Total:	**$ 17,250,000**	**$ 2,149***

(1) Estimated solely for the purpose of calculating the registration fee in accordance with Rule 457(o) of the Securities Act of 1933, as amended (the "Act"). Includes the offering price of any additional securities that the underwriters have the option to purchase.

(2) Pursuant to Rule 416 under the Act, the shares being registered herein include such indeterminate number of shares as may be issued with respect to the shares being registered hereunder as a result of stock splits, stock dividends or similar transactions.

* $1,868 of fee previously paid

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 of 1933 or until the Registration Statement shall become effective on such date as the Commission acting pursuant to said Section 8(a), may determine.

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The information in this preliminary prospectus is not complete and may be changed. We may not sell these securities until the registration statement filed with the Securities and Exchange Commission is effective. This preliminary prospectus is not an offer to sell these securities and it is not soliciting an offer to buy these securities in any state where the offer or sale is not permitted.

SUBJECT TO COMPLETION, DATED FEBRUARY 5, 2018

PRELIMINARY PROSPECTUS

$15,000,000 of Shares of Common Stock

We are offering $15,000,000 of shares of our common stock, par value $0.001 per share, at an assumed public offering price of $2.80 per share (the last reported sale price of our common stock on February 2, 2018). Our common stock is listed on The Nasdaq Capital Market under the symbol "KOOL." On February 2, 2018, the closing sale price of our common stock on The Nasdaq Capital Market was $2.80 per share.

Investing in our common stock involves a high degree of risk. Please read "Risk Factors" beginning on page 6 of this prospectus and in the documents incorporated by reference into this prospectus.

	Per Share	Total
Public offering price	$	$
Underwriting discounts and commissions[(1)]	$	$
Proceeds to us, before expenses	$	$

(1) See "Underwriting" beginning on page 23 of this prospectus for a description of the compensation payable to the underwriters.

We have granted to the underwriters an option to purchase up to $2,250,000 of additional shares of common stock at the public offering price, less the underwriting discounts and commissions, for 45 days after the date of this prospectus.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or passed upon the adequacy or accuracy of this prospectus. Any representation to the contrary is a criminal offense.

Delivery of the shares of common stock is expected to be made on or about _____, 2018.

Maxim Group LLC

The date of this prospectus is _____, 2018

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Unless the context otherwise requires, references in this prospectus to “we,” “us,” “our” or similar terms, as well as references to “Cesca” or the “Company,” refer to Cesca Therapeutics Inc. and its consolidated subsidiaries. This prospectus is part of a registration statement that we have filed with the Securities and Exchange Commission, which we refer to as the SEC or the Commission, utilizing a registration process. It is important for you to read and consider all of the information contained in this prospectus and all documents incorporated by reference into this prospectus before making a decision whether to invest in the common stock. You should also read and consider the information contained in the exhibits filed with our registration statement, of which this prospectus is a part, as described in “Where You Can Find More Information” in this prospectus.

You should rely only on the information contained in this prospectus and any applicable prospectus supplement, including the information incorporated by reference. We have not authorized anyone to provide you with different information. We are not offering to sell or soliciting offers to buy, and will not sell, any securities in any jurisdiction where it is unlawful. You should assume that the information contained in this prospectus or any prospectus supplement, as well as information contained in a document that we have previously filed or in the future will file with the SEC is accurate only as of the date of this prospectus, any applicable prospectus supplement or the document containing that information, as the case may be.

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PROSPECTUS SUMMARY

This summary highlights selected information contained elsewhere in this prospectus, and does not contain all of the information that you should consider before investing in our common stock. You should read this summary together with the entire prospectus, including our financial statements, the notes to those financial statements and the additional information described in this prospectus under the heading "Where You Can Find More Information," before making an investment decision. See the "Risk Factors" section of this prospectus beginning on page 6 and in the documents incorporated by reference into this prospectus for a discussion of the risks involved in investing in our securities.

Overview

Cesca develops, commercializes and markets a range of automated technologies for cell-based therapeutics. Cesca's device subsidiary, ThermoGenesis Corp. ("ThermoGenesis"), provides a full suite of solutions for automated clinical biobanking, point-of-care applications, and automation for immuno-oncology. Through the acquisition of the assets and business of SygGen Inc. in July 2017, Cesca is now developing its proprietary CAR-TXpress™ platform as an automated system for manufacturing cell therapies such as chimeric antigen receptor therapies ("CAR-T"). We believe our CAR-TXpress™ platform will improve the efficiency and cost of manufacturing these novel cell therapies and increase the number of patients who can receive them. Our strategy is to expand into new growth areas in cellular processing for immune-oncology product development and manufacturing while continuing to support the performance and competitiveness of our product lines in the cord blood banking arena.

Recent Developments

On July 7, 2017, our then wholly-owned subsidiary, ThermoGenesis, acquired the business and substantially all of the assets of SynGen Inc., a privately held Sacramento, California-based technology company that developed, marketed, and sold advanced cell separation tools and accessories ("SynGen"). In the transaction (the "SynGen Transaction"), ThermoGenesis acquired substantially all of SynGen's operating assets, including its proprietary cell processing platform. In exchange, ThermoGenesis issued to SynGen shares of ThermoGenesis common stock that, after giving effect to the issuance, constitute 20% of ThermoGenesis' outstanding common shares, and ThermoGenesis also made a one-time cash payment of $1.0 million to SynGen. Immediately prior to the SynGen Transaction, Cesca contributed the assets, business, and current liabilities of its blood and bone-marrow processing device business to ThermoGenesis now operates such business (together with the acquired business) through the ThermoGenesis subsidiary. Prior to the SynGen Transaction, Cesca's device business was owned and operated directly by Cesca, and from and after the SynGen Transaction, Cesca's device business (together with the business acquired from SynGen) is and will be owned and operated by ThermoGenesis.

In August 2017, our board of directors approved changing our fiscal year from a year ending on June 30 to a calendar year ending on December 31. As a result, we will file a transition report on Form 10-K for the six month period ended December 31, 2017.

On August 21, 2017, ThermoGenesis entered into a new distribution agreement with Boyalife WSN Ltd. to market and distribute Cesca's biobanking and point-of-care solutions in China, India, Singapore and the Philippines (the "Territory"). This agreement will combine Cesca's technology leadership in cellular processing with Boyalife WSN's distribution capabilities in the Territory. The agreement replaced our prior distribution agreement with Golden Meditech, which expired in August 2017. The term of the agreement is for three years with ThermoGenesis having the right to renew the agreement for successive two-year periods at its option. In December 2017, we learned from China Cord of their intention to discontinue purchases of AXP. As a result, we expect AXP revenue in China to decline in 2018. However, we anticipate this decline will be partially offset by higher domestic AXP sales.

On September 13, 2017, we entered into an Amendment No. 1 to Revolving Credit Agreement (the "Amended Credit Agreement") with Boyalife Investment Fund II, Inc., an Illinois corporation (the "Lender"). The Amended Credit Agreement amended the Revolving Credit Agreement originally entered into by Cesca and Lender on March 6, 2017, by increasing our maximum borrowing availability thereunder from $5.0 million to $10.0 million. In connection with such amendment, Cesca and Lender entered into an Amended and Restated Convertible Promissory Note to reflect the new aggregate maximum principal amount of $10.0 million. As of January 31, 2018, an aggregate of $6.7 million in principal amount has been borrowed and was outstanding under the Amended Credit Agreement.

On November 21, 2017, the U.S. Patent and Trademark Office (USPTO) awarded our ThermoGenesis subsidiary a new U.S Patent, No. 9,821,111, entitled "Cell Separation Devices, Systems, and Methods." This new patent covers ThermoGenesis' proprietary method for separating rare, therapeutically critical target cells from blood, bone marrow, leukapheresis product, and other cell sources, while maintaining the viability of the cells under asceptic conditions. This advanced cell separation technology, known as Buoyancy-Activated Cell Separation, is key to the ongoing development of Cesca's CAR-TXpress™ platform.

On December 1, 2017, we closed a public offering of common stock consisting of an aggregate of 898,402 shares of common stock at a price to the public of $3.00 per share for aggregate offering proceeds of $2.7 million. After deducting the placement agent's commission and other estimated offering expenses payable by us, the net proceeds to us in the offering were approximately $2.4 million.

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Cesca's Device Segment

The operations and assets of Cesca's device segment are conducted through our ThermoGenesis subsidiary, which is a pioneer and market leader in the development and commercialization of automated technologies for cell-based therapeutics and bio-processing. The device segment's automated solution offerings include:

Clinical BioBanking

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

Point-of-Care Solutions for Cell-Based Therapeutics

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

Cellular Processing for Immuno-Oncology Applications

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

The device segment's product pipeline includes:

AutoXpress® System ("AXP®") – a proprietary, automated system for the isolation and collection of hematopoietic stem cells from cord blood and peripheral blood.

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

CAR-TXpress ("CXP™") – a proprietary, automated system for the isolation and collection of cells derived from biological sources, for various laboratory based downstream applications and novel cell therapies such as CAR-T. CXP uses advanced cell separation technology, known as Buoyancy-Activated Cell Separation, which is key to the ongoing development of Cesca's CAR-TXpress™ platform.

BioArchive® System – an automated, cryogenic system used by cord blood banks for the cryopreservation and storage of cord blood stem cell concentrate for future use.

Cesca's Clinical Development Segment

Using its proprietary AutoXpress® technology platform, Cesca's clinical development segment is developing autologous (utilizing the patient's own cells) stem cell-based therapeutics that Cesca believes will address significant unmet medical needs for applications within the vascular, cardiology and orthopedic markets. Cesca is currently looking for co-development partners to advance each of its clinical development programs.

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

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

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

Corporate Information

We are a Delaware corporation with principal executive offices located at 2711 Citrus Road, Rancho Cordova, CA 95742. Our telephone number is (916) 858-5100 and our web site is www.cescatherapeutics.com. The information contained in, and that which can be accessed through, our website is not incorporated into and does not form a part of this prospectus.

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THE OFFERING

Common stock offered by us	5,357,142 shares assuming a public offering price of $2.80 per share (the last reported sale price of our common stock on February 2, 2018).
Offering price	$ per share.
Underwriters' option to purchase additional shares of common stock from us	We have granted the underwriters an option for a period of 45 days from the date of this prospectus to purchase an additional 803,571 shares of common stock assuming a public offering price of $2.80 per share (the last reported sale price of our common stock on February 2, 2018).
Common stock to be outstanding after this offering	16,229,570 shares, or 17,033,141 shares if the underwriters exercise their option to purchase additional shares of our common stock in full assuming a public offering price of $2.80 per share (the last reported sale price of our common stock on February 2, 2018).
Use of proceeds	We intend to use the net proceeds from this offering for general corporate purposes, including working capital. See "Use of Proceeds" on page 17.
Market for our common stock	Our common stock is quoted and traded on The Nasdaq Capital Market under the symbol "KOOL."
Risk factors	You should read the "Risk Factors" section of this prospectus and in the documents incorporated by reference into this prospectus for a discussion of factors to consider before deciding to invest in our common stock.

The number of shares of common stock outstanding after this offering as reflected in the table above, is based on the actual number of shares outstanding as of January 31, 2018, which was 10,872,428, and does not include, as of that date:

81,325 shares of our common stock issuable upon the exercise of outstanding stock options under our 2006 Incentive Plan, having a weighted average exercise price of $12.98 per share;

416 shares of our common stock issuable upon the vesting of restricted stock units under our 2006 Equity Incentive Plan;

12,396 shares of our common stock issuable upon the exercise of outstanding stock options under our 2012 Independent Director Plan, having a weighted average exercise price of $21.87 per share;

1,055,392 shares of our common stock issuable upon the exercise of outstanding stock options under our 2016 Equity Incentive Plan, having a weighted average exercise price of $3.01 per share; and

4,130,194 shares of our common stock issuable upon the exercise of outstanding vested warrants, having a weighted average exercise price of $9.60 per share.

Unless otherwise indicated, all information contained in this prospectus assumes no exercise by the underwriters of the option to purchase additional shares of our common stock.

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RISK FACTORS

An investment in our securities involves a high degree of risk. Before deciding to invest in our securities or to maintain or increase your investment, you should carefully consider the risks described below, in addition to the other information contained in this prospectus, our Annual Report on Form 10-K, our Quarterly Reports on Form 10-Q, our Current Reports filed on Form 8-K, and in our other filings with the Securities and Exchange Commission. The risks and uncertainties described below are not the only ones that we face. Additional risks and uncertainties not presently known to us or that we currently deem immaterial may also affect our business and results of operations. If any of these risks actually occur, our business, financial condition or results of operations could be seriously harmed. In that event, the market price for our common stock could decline and you may lose all or part of your investment.

Risks Related to Our Business

Lack of Demonstrated Clinical Utility of Cord Blood Derived Stem Cells Beyond Hematopoietic Transplantation May Result in a Decline in Demand for Cord Blood Banking Services, Adversely Affecting Sales of Our Products.

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

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

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

The Equity in our ThermoGenesis Subsidiary is 20% Owned by a Third Party that Holds Certain Minority Investor Rights in that Subsidiary, and Those Rights Could Limit or Delay Our Ability to Take Certain Major Actions Relating to ThermoGenesis.

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

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We May Not be Able to Successfully Recognize the Anticipated Benefits from the SynGen Asset Acquisition or Retain Key Acquisition Employees.

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

Our Controlling Stockholder Has Significant Influence Over Us Which Could Limit Your Ability to Influence the Outcome of Key Transactions, Including a Change of Control, and Could Negatively Impact the Market Price of Our Common Stock By Discouraging Third Party Investors.

As of January 31, 2018, approximately 63% of our outstanding common stock is owned by Boyalife (Hong Kong) Limited. In addition, pursuant to the terms of a Nomination and Voting Agreement we entered into with Boyalife (Hong Kong) Limited and Boyalife Investment Inc. in February 2016, Boyalife (Hong Kong) Limited and Boyalife Investment Inc. have the right to designate up to three of the seven members to our board of directors until such time as they collectively no longer hold at least 50% of our common stock.

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

Our Potential Cell Therapy Products and Technologies Are In Early Stages Of Development.

The development of new cell therapy products is a highly risky undertaking, and there can be no assurance that any future research and development efforts we may undertake will be successful. Our potential products in vascular, orthopedic, hematological/oncological and wound care indications will require extensive additional research and development and regulatory approval before any commercial introduction. There can be no assurance that any future research, development and clinical trial efforts will result in viable products or meet efficacy standards.

We Intend To Rely On Third Parties For Certain Functions In Conducting Clinical Trials Of Our Product Candidates.

We intend to rely on third parties for certain clinical trial activities of our products. In this regard, we have an agreement with Fortis Healthcare Limited, a hospital chain networked throughout India and Asia, for contract clinical trial services programs among other services. The agreement expired in August 2017 and we are currently in discussions to renew the agreement. Termination, or non-renewal, of this agreement could jeopardize or delay development of our products.

We May Be Unable to Obtain Marketing Approval from the FDA For Our Point-of-Care System for Critical Limb Ischemia (CLI) Indication.

At the end of 2016, the Company received approval from the U.S. Food and Drug Administration (FDA) for the Company's amended pivotal study protocol for treatment of CLI. The amended CLI clinical trial is designed to demonstrate the safety and efficacy of the Company's point-of-care system for the treatment of CLI patients with limited or no treatment options. The changes approved by the FDA are intended to increase patient enrollment by expanding the patient pool from Rutherford Category 5 patients only, to also include Rutherford Category 4 patients, or patients with a less severe form of the disease. The study population has been expanded to include patients who are poor candidates for either surgery or endovascular therapies. The sample size of the CLI trial was increased from 224 to 362 patients. With the FDA approval of our amended phase III clinical trial protocol of CLI, the company is actively looking for an external strategic partner to move forward with the CLI clinical trial program. The marketing approval of point-of-care device for the treatment of CLI indication is subject to a successful strategic partnership, successful completion of our phase III study with statistical significant results and acceptance of the results by the FDA for the disease indication. Our inability to successfully complete any of the above mentioned steps can affect our ability to obtain marketing approval in the United States.

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Delays In The Commencement Or Completion Of Clinical Testing Of Our Products Could Result In Increased Costs To Us And Delay Our Ability To Generate Revenues.

Delays in the commencement or completion of clinical testing could significantly impact our product development costs. We do not know whether current or planned clinical trials will begin on time or be completed on schedule, if at all. The commencement of clinical trials can be delayed for a variety of reasons, including delays in:

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

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

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

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

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

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

A Significant Portion of Revenue is Derived from Customers Outside the United States. We may Lose Revenues, Market Share, and Profits due to Exchange Rate Fluctuations and Political and Economic Changes Related to its Foreign Business.

In the year ended June 30, 2017, sales to customers outside the U.S. comprised approximately 54% of revenues. This compares to 57% in fiscal 2016. Our foreign business is subject to economic, political and regulatory uncertainties and risks that are unique to each area of the world. Fluctuations in exchange rates may also affect the prices that foreign customers are willing to pay, and may put us at a price disadvantage compared to other competitors. Potentially volatile shifts in exchange rates may negatively affect our financial position and results.

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