CESCA THERAPEUTICS INC.
Form S-1
April 06, 2018
As filed with the Securities and Exchange Commission on April 6, 2018.

Registration No. 333-

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

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:

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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**
Units, each Unit consisting of one share of common stock, par value $0.001 per share and one common warrant to purchase 0.5 shares of common stock[(3)]	$10,000,000	$ 1,245
(i) Common stock included in the Units[(4)]	—	—

(i) Common warrants included in the Units[4]	—	—	
Pre-funded Units, each Pre-funded Unit consisting of one pre-funded warrant to purchase one share of common stock and one common warrant to purchase 0.5 shares of common stock[3]	$10,000,000	$ 1,245	
(i) Pre-funded warrants included in the Pre-funded Units[4]	—	—	
(ii) Common warrants included in the Pre-funded Units[4]	—	—	
Shares of common stock underlying pre-funded warrants included in the Pre-funded Units[3]	—	—	
Shares of common stock underlying common warrants included in the Units and the Pre-funded Units[3]	$5,000,000	$ 623	
Total	$25,000,000	$ 3,113	*

(1) Estimated solely for the purpose of calculating the registration fee pursuant to Rule 457(o) under the Securities Act of 1933, as amended (the "Securities Act").

(2) Pursuant to Rule 416 under the Securities Act, the securities being registered hereunder include such indeterminate number of additional securities as may be issued after the date hereof as a result of stock splits, stock dividends or similar transactions.

(3) The proposed maximum aggregate offering price of the Units proposed to be sold in the offering will be reduced on a dollar-for-dollar basis based on the offering price of any Pre-funded Units offered and sold in the offering, and as such the proposed maximum aggregate offering price of the Units and Pre-funded Units (including the common stock issuable upon exercise of the pre-funded warrants included in the Pre-funded Units), if any, is $[*].

(4) No additional registration fee is payable pursuant to Rule 457(i) under the Securities Act.

*The Registrant previously filed a Form S-1/A (File No. 333-222658) on February 5, 2018, and paid a filing fee of $2,149. The Registrant did not sell any of the securities registered pursuant to that Form S-1/A, and that Form S-1/A was withdrawn on February 12, 2018. Pursuant to Rule 457(p), the Registrant hereby applies $2,149 of the previously paid filing fee against amounts due herewith.

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 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 APRIL 6, 2018

PRELIMINARY PROSPECTUS

Up to Units (each Unit contains One Share of Common Stock and One

Common Warrant to Purchase 0.5 Shares of Common Stock)

or

Up to Pre-funded Units (each Pre-funded Unit contains One Pre-funded Warrant to Purchase

One Share of Common Stock and One Common Warrant to purchase 0.5 Shares of Common Stock)

(Shares of Common Stock Underlying the Pre-funded Warrants) and

(Shares of Common Stock Underlying the Common Warrants)

We are offering units, each unit consisting of one share of our common stock and one common warrant to purchase 0.5 shares of our common stock (together with the shares of common stock underlying such common warrants). Each common warrant contained in a unit will have an exercise price per share equal to $ per share. The common warrants contained in the units will be exercisable immediately and will expire on the five year anniversary of the original issuance date. We are also offering the shares of our common stock that are issuable from time to time upon exercise of the common warrants contained in the units.

We are also offering the opportunity to purchase, if the purchaser so chooses, up to pre-funded units to purchasers whose purchase of units in this offering would otherwise result in the purchaser, together with its affiliates and certain related parties, beneficially owning more than 4.99% of our outstanding common stock immediately following the consummation of this offering (each pre-funded unit consisting of one pre-funded warrant to purchase one share of our common stock and one common warrant to purchase 0.5 shares of our common stock) in lieu of units that would otherwise result in a purchaser's beneficial ownership exceeding 4.99% of our outstanding common stock

(or at the election of the purchaser, 9.99%). Each pre-funded warrant contained in a pre-funded unit will be exercisable for one share of our common stock. The purchase price of each pre-funded unit is equal to the price per unit being sold to the public in this offering, minus $0.01, and the exercise price of each pre-funded warrant included in the pre-funded unit is $0.01 per share. The pre-funded warrants expire when exercised in full. This offering also relates to the shares of common stock issuable upon exercise of any pre-funded warrants contained in the pre-funded units sold in this offering. For each pre-funded unit we sell, the number of units we are offering will be decreased on a one-for-one basis. Because we will issue a common warrant as part of each unit or pre-funded unit, the number of common warrants sold in this offering will not change as a result of a change in the mix of the units and pre-funded units sold. Each common warrant contained in a pre-funded unit will have an exercise price per share equal to $ per share. The common warrants contained in the pre-funded units will be exercisable immediately and will expire on the five year anniversary of the original issuance date. We are also offering the shares of our common stock that are issuable from time to time upon exercise of the common warrants contained in the pre-funded units.

The units and the pre-funded units will not be issued or certificated. The shares of common stock or pre-funded warrants, as the case may be, and the common warrants can only be purchased together in this offering but the securities contained in the units or pre-funded units will be issued separately.

Our common stock is listed on the Nasdaq Capital Market under the symbol “KOOL”. On April 5, 2018, the closing sale price of our common stock on the Nasdaq Capital Market was $1.67 per share. The public offering price per unit or pre-funded unit, as the case may be, will be determined between us and the placement agent based on market conditions at the time of pricing, and may be at a discount to the current market price of our common stock. 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 or other trading market. Without an active trading market, the liquidity of the warrants will be limited.

You should read carefully this prospectus and any applicable prospectus supplement or free writing prospectus, together with the additional information described in this prospectus under the headings “Incorporation of Certain Information by Reference” and “Where You Can Find More Information,” before you invest in any of our securities.

Investing in our securities involves risks. You should carefully read and consider the “Risk Factors” beginning on page 9 of this prospectus before investing. You should also consider the risk factors described or referred to in any documents incorporated by reference in this prospectus, and in any applicable prospectus supplement, before investing in these securities.

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.

We have retained H.C. Wainwright & Co., LLC to act as our exclusive placement agent in connection with this offering. and to use its "best efforts" to solicit offers to purchase the securities being offered pursuant to this prospectus. The placement agent has no obligation to buy any of the securities from us or to arrange for the purchase or sale of any specific number or dollar amount of the securities. There is no required minimum number of securities that must be sold as a condition to completion of this offering. Because there is no minimum offering amount required as a condition to the closing of this offering, the actual offering amount, placement agent fees and proceeds to us are not presently determinable and may be substantially less than the maximum amounts set forth above. We may sell fewer than all of the securities offered hereby, which may significantly reduce the amount of proceeds received by us, and investors in this offering will not receive a refund in the event that we do not sell an amount of securities sufficient to pursue the business goals outlined in this prospectus. In addition, because there is no escrow account and no minimum offering amount in this offering, investors could be in a position where they have invested in our Company, but we are unable to fulfill our objectives due to a lack of interest in this offering. Also, any proceeds from the sale of securities offered by us will be available for our immediate use, despite uncertainty about whether we would be able to use such funds to effectively implement our business plan.

	Per Unit	**Per Pre-Funded Unit**	**Total**
Public offering price	$	$	$
Placement agent fees [(1)]	$	$	$
Proceeds, before expenses, to us [(2)]	$	$	$

(1) See "Plan of Distribution" beginning on page 30 for more information on this offering and the placement agent fees and expenses.

(2) We estimate the total expenses of this offering payable by us, excluding the placement agent fee, will be approximately $. All costs associated with the registration will be borne by us.

Delivery of the securities offered hereby is expected to be made on or about , 2018.

H.C. Wainwright & Co.

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.

You should rely only on the information contained in this prospectus. We have not, and the placement agent has not, authorized anyone to provide you with any information other than that contained or incorporated by reference in this prospectus or in any applicable prospectus supplement or free writing prospectus prepared by or on behalf of us to which we have referred you. We are offering to sell, and seeking offers to buy, the securities covered hereby only in jurisdictions where offers and sales are permitted. You should not assume that the information contained in this prospectus or any prospectus supplement or free writing prospectus is accurate as of any date other than the date on the front cover of those documents, or that the information contained in any document incorporated by reference is accurate as of any date other than the date of the document incorporated by reference, regardless of the time of delivery of this prospectus or any sale of a security. Our business, financial condition, results of operations and prospects may have changed since those dates. We are not, and the placement agent is not, making an offer of these securities in any jurisdiction where the offer is not permitted.

For investors outside the United States: We have not, and the placement agent has not, taken any action that would permit this offering or possession or distribution of this prospectus in any jurisdiction where action for that purpose is required, other than in the United States. Persons outside the United States who come into possession of this prospectus must inform themselves about, and observe any restrictions relating to, the offering of the securities covered hereby the distribution of this prospectus outside the United States.

We further note that the representations, warranties and covenants made by us in any agreement that is incorporated by reference or filed as an exhibit to the registration statement of which this prospectus is a part were made solely for the benefit of the parties to such agreement, including, in some cases, for the purpose of allocating risk among the parties to such agreements, and should not be deemed to be a representation, warranty or covenant to you. Moreover, such representations, warranties or covenants were accurate only as of the date when made. Accordingly, such representations, warranties and covenants should not be relied on as accurately representing the current state of our affairs.

Information contained in, and that can be accessed through, our web site *www.cescatherapeutics.com* shall not be deemed to be part of this prospectus or incorporated herein by reference and should not be relied upon by any prospective investors for the purposes of determining whether to purchase the shares offered hereunder.

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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 securities. 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 9 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 therapies. Since the 1990's, Cesca has been the pioneer and one of the leading developers and suppliers of automation technologies for the isolation, purification and storage of stem cells for the cord blood banking industry. In July 2017, a Cesca subsidiary, ThermoGenesis Corp. (ThermoGenesis), completed the strategic acquisition of the business and substantially all of the assets of SynGen Inc., a research and development company for automated cellular processing, and the products from both companies were combined to develop a proprietary CAR-TXpress™ platform that addresses the critical unmet need for better chemistry, manufacturing and controls (CMC) for the emerging immuno-oncology field, in particular, the chimeric antigen receptor T cell (CAR-T) market.

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

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

manufacturing capacity for future CAR-T drugmakers.

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

In addition to selling the "off-the-shelf" X-Series™ products, we are also planning to enter into the CAR-T third party cellular process development and manufacturing service business by collaborating with, and possibly establishing our own contract development and manufacturing organizations (CDMO) in the U.S. and China, the two leading markets with the highest numbers of active CAR-T clinical trials. Given the number of ongoing clinical trials registered globally, we believe this represents a significant growth opportunity for our CAR-TXpress™ platform to address the COGS issue for these exciting potential new treatments.

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In the stem cell and regenerative medicine field, Cesca continues to provide automation technologies for cord blood banking and autologous stem cell applications. Our AutoXpress® (AXP®) technology platform is a leading automated stem cell isolation device product for the cord blood banking industry. Cesca also has a proprietary point-of-care, autologous stem cell-based therapy under development for the treatment of patients with critical limb ischemia (CLI). The Company's 362 patient, multi-center pivotal phase 3 Critical Limb Ischemia Rapid Stem Cell Treatment (CLIRST) trial is designed to evaluate the safety and efficacy of autologous stem cell-based therapy to stimulate the regeneration of blood vessels, promote wound healing and prevent amputation. Cesca's CLI trial design was accepted and approved by the FDA. Previous clinical studies using Cesca's proprietary, point-of-care-technologies have demonstrated the regeneration of blood vessels and improved blood circulation in the limbs, using a patient's own bone marrow derived stem cells. The Company is in early stage development of autologous stem cell based therapy intended to treat patients with acute myocardial infarction and cartilage tissue degeneration, addressing significant unmet needs in the vascular, cardiology and orthopedic markets.

Cesca is an affiliate, through common controlling ownership, of the Boyalife Group, a China-based industry research alliance encompassing top research institutions for stem cell and regenerative medicine. As of March 29, 2018, approximately 60% of our outstanding common stock is owned by Boyalife (Hong Kong) Limited.

Business Strategy

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

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

In the immuno-oncology field:

Launch X-Series™ devices and reagents for research use only, including the X-Mini™, and X-Auto™ kits for cellular isolation and purification and non-commercial manufacturing of cell-based products for clinical research.
Develop and launch our X-Series™ devices and reagents for clinical use, including our X-Clini™ kit for cGMP commercial manufacturing of CAR-T cells for drug developers and manufacturers.

Expand CDMO for immuno-oncology through internal and external efforts, including, but not limited to, partnerships, licensing, or co-development transactions.

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In the stem cell and regenerative medicine field:

Sustain our market leadership position in automated devices for the separation and concentration of stem cell preparation for the cord blood banking market.
Continue supporting product registration and marketing of automated devices for the separation and concentration of bone marrow-derived stem cell preparation for the point-of-care clinical application market.
Partner our clinical development programs, including our lead Critical Limb Ischemia Rapid Stem Cell Treatment (CLIRST) phase III clinical trial, with third parties to maximize the value of our existing clinical development programs while eliminating our costs for running clinical trials.

Recent Key Events and Accomplishments

Acquired the assets of SynGen Inc. (SynGen). On July 7, 2017, our subsidiary, ThermoGenesis, acquired the business and substantially all of the assets of SynGen, a privately held Sacramento, California-based technology company that develops, markets, and sells advanced cell separation tools and accessories. In the transaction (SynGen Transaction), ThermoGenesis acquired substantially all of SynGen's operating assets, including its proprietary cell processing platform. In exchange, ThermoGenesis issued to SynGen shares of ThermoGenesis common stock that, after giving effect to the issuance, constitute 20% of ThermoGenesis' outstanding common shares, and ThermoGenesis also made a one-time cash payment of $1.0 million to SynGen. Immediately prior to the SynGen Transaction, the Company contributed the assets, business, and current liabilities of its blood and bone-marrow processing device business to ThermoGenesis and will operate such business (together with the acquired business) through the ThermoGenesis subsidiary.

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

Received two new patent issuances for CAR-T cell processing. In 2017, the U.S. Patent and Trademark Office (USPTO) awarded ThermoGenesis two new U.S Patents, No. 9,695,394 and 9,821,111, both entitled "Cell Separation Devices, Systems, and Methods." These two new patents include our apparatus and method claims that protect our proprietary technology for isolating and harvesting purified populations of rare, therapeutically critical target cells from blood, bone marrow, leukapheresis product, and other cell sources, while maintaining the viability of the cells under 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.

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

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

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

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

Raised $1.2 Million in Equity Financing. On March 28, 2018, we closed a registered direct offering of common stock consisting of an aggregate of 609,636 shares of common stock at a price of $2.27 per share for gross proceeds of $1.38 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 $1.2 million. Additionally, the investors received unregistered warrants in a simultaneous private placement to purchase up to 304,818 shares of common stock. The warrants have an exercise price of $2.68 per share and shall be exercisable commencing six months following the issuance date and have a term of 5.5 years.

X-Series™ Products

Immuno-Oncology Products

In November 2017, we announced the development of a proprietary CAR-TXpress™ platform that addresses the critical unmet need to improve CMC manufacturing for the emerging CAR-T therapies for cancer patients. CAR-TXpress™ eliminates the use of ficoll and magnetic beads for cell isolation procedures, and reduces processing time and increases cell recovery rates. The CAR-TXpress™ platform includes the following X-Series™ products:

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

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

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

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

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

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

Stem Cell and Regenerative Medicine

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

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

VXP® for Critical Limb Ischemia (CLI) – Cesca has a proprietary point-of-care, autologous (donor and recipient are the same individual) stem cell-based therapy under development which is intended for the treatment of patients with CLI. The FDA has cleared the Company to proceed with a 362 subject, multi-center pivotal phase III CLIRST study, which is designed to evaluate the safety and efficacy of Cesca's autologous stem cell-based therapy in patients with no-option or poor option late stage CLI. Previous clinical studies using Cesca's proprietary, point-of-care-technologies have demonstrated the regeneration of blood vessels and improved blood circulation in the limbs, using a patient's own bone marrow derived stem cells.

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

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

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Cell Manufacturing and Banking Services (India)

Through our TotipotentRX subsidiary in Gurgaon, India, we operate an advanced clinical cell manufacturing, processing, testing, and storage facility, compliant with cGMP, Good Tissue Practices (GTP), and Good Laboratory Practices (GLP). We can support the production of a small, personalized medicine cell prescription. Patient samples and therapeutic aliquots are all labeled in accordance with ISBT 128 and stored in our own cryogenics facility. In addition, our clinical research organization (CRO), also located in Gurgaon, is, to our knowledge, the only specialized, in-hospital, cell therapy CRO in the world. We have expertise in the design and management of cell based clinical trials, including the ability to support the device prototyping and validation typically required for a combination product. These services ensure patient safety under Good Clinical Practices (GCP), quality laboratory documentation under GLP, and quality cell processing and handling under both cGMP and GTP. In partnership with Fortis Healthcare and through our advanced clinical infrastructure we also o