

CESCA THERAPEUTICS INC.
Form 424B3
August 01, 2016
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Registration No. 333-207115

Prospectus Supplement No. 15

(to Prospectus dated November 24, 2015)

Shares of Common Stock Underlying

\$5,500,000 Senior Secured Convertible Debentures and Series B Warrants

This prospectus supplement supplements the prospectus dated November 24, 2015 (the “Prospectus”), which relates to the resale of up to 511,123 (post-split) shares of our common stock to be offered by the selling stockholders including 404,412 (post-split) shares of common stock upon the conversion of outstanding senior secured convertible debentures in the amount of \$5,500,000 (“Debentures”), and up to 106,711 (post-split) shares of common stock upon the exercise of Series B Warrants.

This prospectus supplement incorporates into our Prospectus the information contained in our Current Report on Form 8-K, filed with the Securities and Exchange Commission on August 1, 2016.

This prospectus supplement should be read in conjunction with the Prospectus. This prospectus supplement updates, amends and supplements the information included or incorporated by reference in the Prospectus. If there is any inconsistency between the information in the Prospectus and this prospectus supplement, you should rely on the information in this prospectus supplement.

This prospectus supplement is not complete without, and may not be delivered or utilized except in connection with, the Prospectus, including any supplements and amendments thereto.

Our common stock is listed on Nasdaq Capital Market under the symbol “KOOL.” The warrants will not be listed or quoted on any trading market. On July 29, 2016, the last reported sale price of our common stock on the Nasdaq Capital Market was \$4.18 per share.

Investing in our common stock is highly speculative and involves a high degree of risk. You should carefully consider the risks and uncertainties in the section entitled “Risk Factors” beginning on page 4 of this prospectus before making a decision to purchase our stock.

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.

The date of this prospectus supplement is August 1, 2016

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Item 8.01 Other Events.

On August 1, 2016, the Company issued a press release providing an update on the status of the U.S. Food and Drug Administration’s review of the Company’s Investigational Device Exemption Supplement for a phase III pivotal trial, designed to demonstrate the safety and effectiveness of the Company’s SurgWerk3™ system for the treatment of late stage, no option, critical limb ischemia patients. A copy of the press release is attached as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated by reference into this Item 8.01.

The information contained in this Item 8.01 and in Exhibits 99.1 attached to this Current Report on Form 8-K is being furnished to the SEC and shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “*Exchange Act*”), or otherwise subject to the liabilities of that Section, or incorporated by reference in any filing under the Exchange Act or the Securities Act, except as shall be expressly set forth by specific reference in such a filing.

Item 9.01. Financial Statements and Exhibits.

(a) Not Applicable.

(b) Not Applicable.

(c) Not Applicable.

(d) Exhibits.

99.1 Press Release of Cesca Therapeutics Inc. dated August 1, 2016

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

CESCA THERAPEUTICS INC.
(Registrant)

Dated: August 1, 2016 /s/ MICHAEL BRUCH
Michael Bruch, Chief Financial Officer

Exhibit Index

Exhibit Description

99.1 Press Release of Cesca Therapeutics Inc. dated August 1, 2016

Exhibit 99.1

CESCA THERAPEUTICS PROVIDES UPDATE ON FDA REVIEW OF INVESTIGATIONAL DEVICE EXEMPTION SUPPLEMENT FOR SURGWERKS™ CLI PIVOTAL TRIAL

FDA Approves Commencement of Phase III Pivotal Trial as Amended

Requires Additional Validation of TcPO2 as a Surrogate to Support Subsequent PMA Approval

RANCHO CORDOVA, CA, August 1, 2016 – Cesca Therapeutics Inc. (NASDAQ: KOOL), an autologous cell-based regenerative medicine company, is today updating investors on the status of the U.S. Food and Drug Administration’s (FDA) review of its Investigational Device Exemption (IDE) Supplement for a phase III pivotal trial, designed to demonstrate the safety and effectiveness of the Company’s SurgWerk3™ system for the treatment of late stage, no option, critical limb ischemia (CLI) patients.

In addition to a number of protocol changes intended to improve patient enrollment and study flow, the IDE Supplement, submitted at the end of May, proposed a change in the primary efficacy endpoint from Amputation Free Survival (AFS) to Change in Transcutaneous Oxygen Pressure (TcPO2). The Company believes that published literature in peer reviewed journals over many years has shown a strong correlation between improvements in TcPO2 over time and limb salvage, a correlation which has since been reinforced by Cesca’s own feasibility study data. The Company had previously concluded that Amputation-Free Survival (AFS) would not be practical as a primary endpoint for the study because it couples limb-related outcomes with all-cause mortality, a characteristic that unreasonably burdens the statistical analysis necessary to specifically demonstrate treatment effectiveness in preventing amputations among late stage CLI patients.

The FDA has approved the changes in Cesca’s pivotal trial design as proposed in the IDE Supplement, including the use of Change in TcPO2 as the primary measure of efficacy. There are now no regulatory impediments to the Company enrolling patients and beginning the trial. However, in its feedback, the FDA also indicated that regardless of the outcome of the study, it would require the Company to further validate TcPO2 as a surrogate for clinical outcome for the proposed indication prior to granting marketing (PMA) approval. In light of this, the Company is now engaged in a follow-on dialog with the FDA to explore various alternative pathways to securing a PMA.

“We are obviously very pleased to have regulatory approval to commence our Phase III pivotal clinical trial incorporating the changes detailed in our IDE Supplement”, said Robin Stracey, Cesca’s CEO. “Before we do so, however, we want to also be sure we have a clear and unambiguous pathway to marketing approval for the SurgWerks™ system once the study has concluded. We are therefore actively engaged in a dialog with the Agency to understand and evaluate alternative pathways to a PMA, including possible adaptation of our SurgWerks program to encompass earlier stage CLI patients, a change that could substantially increase our overall market opportunity. There may be several rounds of discussion with the FDA as we further refine our plan”, he added.

About Cesca Therapeutics Inc.

Cesca Therapeutics Inc. (www.cescatherapeutics.com) is engaged in the research, development, and commercialization of cellular therapies and delivery systems for use in regenerative medicine. The Company is a leader in the development and manufacture of automated blood and bone marrow processing systems that enable the separation, processing and preservation of cell and tissue therapeutics. These include:

The SurgWerks™ System (in development) - a proprietary system comprised of the SurgWerks Processing Platform, including devices and analytics, and indication-specific SurgWerks Procedure Kits for use in regenerative stem cell therapy at the point-of-care for vascular and orthopedic diseases.

The CellWerks™ System (in development) - a proprietary cell processing system with associated analytics for intra-laboratory preparation of adult stem cells from bone marrow or blood.

The AutoXpress® System (AXP®) - a proprietary automated device and companion sterile disposable for concentrating hematopoietic stem cells from cord blood.

The MarrowXpress™ System (MXP™) - a derivative product of the AXP and its accompanying sterile disposable for the isolation and concentration of hematopoietic stem cells from bone marrow.

The BioArchive® System - an automated cryogenic device used by cord blood banks for the cryopreservation and storage of cord blood stem cell concentrate for future use.

Manual bag sets for use in the processing and cryogenic storage of cord blood.

Forward-Looking Statements and Safe Harbor Statement under the Private Securities Litigation Reform Act of 1995

This press release includes statements of future expectations and other forward-looking statements regarding, among other things, the Company's SurgWerks™ system and the phase III pivotal clinical trial, that are within the meaning of the "safe harbor" provisions of the Private Securities Litigation Reform Act of 1995. These statements are based on management's current views and assumptions, speak only as of the date hereof and are subject to change. Forward-looking statements can often be identified by words such as "anticipates," "belief," "intend," "may," "could," "would," "potential," "continue," and similar expressions and include, but are not limited to, statements regarding research, development and commercialization of the SurgWerks™ system, the clinical literature concerning TcPO2, the Company's understanding of its feasibility study data, the initiation of Phase III pivotal clinical trial, if at all, the timing for the enrollment of patients, if any, the outcome of the trial, the overall market opportunity of the SurgWerks™ system, the status of any dialog with the FDA, and the progress, if any, towards PMA approval. These forward-looking statements are not guarantees of future results and are subject to known and unknown risks and uncertainties that could cause actual results, performance or events to differ materially and adversely from those expressed or implied in such statements. A more complete description of risks that could cause actual events to differ from the outcomes predicted by these forward-looking statements is set forth under the caption "Risk Factors" in our Annual Report on Form 10-K, in our Quarterly Reports on Form 10-Q, and in other reports filed with the Securities and Exchange Commission from time to time, and you should also consider each of those factors when evaluating the forward-looking statements. We undertake no obligation to revise or update publicly any forward-looking statements for any reason, except as required by law.

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