CESCA THERAPEUTICS INC.
Form 8-K
February 17, 2015

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): February 12, 2015

CESCA THERAPEUTICS INC.
(Formerly Known As ThermoGenesis Corp.)
(Exact name of registrant as specified in its charter)

Delaware	000-16375	94-3018487
(State or other jurisdiction of incorporation or organization)	(Commission File Number)	(I.R.S. Employer Identification No.)

2711 Citrus Road
Rancho Cordova, California 95742
(Address and telephone number of principal executive offices) (Zip Code)

(916) 858-5100
(Registrant's telephone number, including area code)

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 (see General Instruction A.2. below):

[ ] 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 9.01 Financial Statements and Exhibits.

(d) Exhibits.

99.1 Transcript for conference call titled, "Second Quarter Fiscal Year 2015 Financial Results Conference Call".

SIGNATURE

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.
a Delaware Corporation

Dated: February 17, 2015 /s/Dan Bessey
Robin Stracey, Chief Financial Officer

Cesca Therapeutics Inc.
Second Quarter Fiscal Year 2015 Financial Results Conference Call
Thursday, February 12, 2015, 5:00PM Eastern

Corporate Participants
Robin Stracey – Chief Executive Officer
Ken Harris – President
Dan Bessey – Chief Financial Officer

PRESENTATION

Operator
Good afternoon and welcome to the Cesca Therapeutics Second Quarter Fiscal Year 2015 Financial Results Conference Call. All sites are currently in a listen-only mode, but please note there will be a question-and-answer session later on in the call. Also note today's conference will be recorded and will be accessible both by phone and internet. If you require operator assistance please press "*" then "0." Please refer to the press release about this conference call on the company's website, cescathearapeutics.com for further detail.

The company has asked that I read the following statement. Management will make comments today that contain forward-looking statements. Forward-looking statements are any statements that are made that are not historical facts. These forward-looking statements are based on current expectations of the management team and there could be no assurance that such expectations will come to fruition. Because forward-looking statements involve risks and uncertainties Cesca's actual results could differ materially from management's current expectations.

Please refer to the press release, the company's Forms 10-K, 10-Q and other periodic SEC filings for information about factors that could cause different outcomes including risks associated with timing and commencement of clinical trials, design and requirements of clinical trials and required submissions which may be affected by changing FDA requirements and policy based on developments in the regenerative medicine industry as well as operating expenses and revenues that are impacted by such changing requirements. The information presented today is time sensitive and is current at this time. If any portion of this call is re-broadcast, re-transmitted or re-distributed at a later date Cesca will not be reviewing nor updating this material.

I would now like to turn the conference over to Mr. Robin Stracey, Chief Executive Officer of Cesca Therapeutics. Please go ahead, sir.

Robin Stracey
Thank you, operator and a very warm welcome to everyone on the call. I'm joined today by our President; Ken Harris who, as you know, oversees all of Cesca's clinical programs and our Chief Financial Officer, Dan Bessey. I plan to make a few introductory remarks touching on our vision for the company and the key elements of our strategy then highlight some of the key events and accomplishments since the last time we talked. Ken will then take you through a deeper dive into progress with our clinical programs before Dan discusses our financial results for the quarter.

I'll be back for a few wrap-up comments after Dan and then we'll open the call up for questions. Our vision, our intent, is that Cesca becomes a leading global supplier of autologous cellular therapies and automated delivery systems that advance the practice of Regenerative Medicine. Marketed therapies will include treatments for vascular indications such as critical limb ischemia, acute myocardial infarction, ischemic stroke and non-healing ulcers, treatments for orthopedic indications such as spinal fusion, osteoarthritis, non-union fracture and avascular necrosis and treatments for hematology and oncology indications including hematopoietic stem cell therapy. These

collectively add up to over $16 billion of addressable market opportunity worldwide. Our initial targets and the focus of the lion share of our current efforts are critical limb ischemia and acute myocardial infarction indications for which our proprietary point of care platform SurgWerks is particularly well suited.

I mentioned in our last call SurgWerks is built on three scientific and clinical fundamentals that we believe are critical for the successful commercialization of cell therapies. First, there's safety, we use the patient's own stem cells we therefore consider our therapies to be naturally safe and importantly believe that view to be shared by regulators such as the FDA.

Second, there is process control. Stem cells are fragile and must be handled with considerable care for maximum curative potential. Our protocol tightly controls handling steps and environmental exposure during cell harvesting, processing and readmission back into the patient. And third, there is practicality for adoption. Our protocol is typically conducted in a 90-minute procedure with a single use disposable kit inside the operating room and under the direct and continuous supervision of the treating physician.

These three fundamental characteristics put us on a pathway to commercialization of a product offering that we expect to be highly compelling. It also puts us on a regulatory pathway that we expect to be much shorter than most other cell therapies under development elsewhere.

In the last couple of months a substantial proportion of my time has been invested in building tighter alignment across our organization regarding Cesca's strategic direction in an effort to further accelerate our transformation into a fully integrated regenerative medicine company. This is a work in progress, but fundamentally achieving our vision boils down to successful implementation of what we have identified as four key imperatives. They are, first, clinical excellence in stem cell applications. This is a bold statement that should be self-evident as a priority and in case you weren't aware clinical excellence in stem cell applications or CESCA is the tagline from which the company's name itself is derived.

Second is optimal leverage of our base business. We are somewhat unusual among our peer group of companies in that we have a $16 million revenue base business that generates approximately $6 million in gross profit. That gross profit contributes nicely to the fixed costs associated with the infrastructure we need to support our ambitious clinical program. It provides the technology and intellectual property from which the VXP and associated bagset, integral components of SurgWerks are derived. It also supports our product development and supply chain infrastructure, our quality management system, our sales, marketing and technical support capability and some of the G&A functions associated with our continuing operations as a public company.

Third is world class business processes. There are many of course, but among those that stand out for us are the ability to design and run highly effective clinical trials including those that involve international sites and the ability to develop and commercialize clinically demanding and highly regulated therapeutic offerings. And fourth, is high performance team capability. Beyond the obvious requirements of talented employees fundamental to our transformation into a world class fully integrated and commercially oriented regenerative medicine company is clarity of purpose, a well defined vision, a robust game plan and rigorous performance management. We have organizational initiatives underway in all these areas.

Now, turning to recent events and highlights for the quarter. In our last call on November 13, 2014 I mentioned that our IDE submission to FDA for approval of our pivotal phase III clinical trial and the treatment of no-option patients with critical limb ischemia was imminent, while we submitted it a week later on November 20th, it was a huge undertaking 4000 or so pages and an effort for which Ken and the clinical team deserve a great deal of credit. We subsequently received feedback from the FDA and Ken will discuss their comments and our plans to address them in just a minute.

Suffice it to say at this point that we feel good about our iterative and ongoing dialogue with the agency and remain optimistic that we will be able to start the trial during the second calendar quarter of this year. As for our base business we had a good quarter with results pretty much in line with our expectations. The cord blood business is somewhat limited in terms of growth potential, but there are pockets of opportunity and we continue to seek to exploit those in order to maintain our solid position.

Also during the quarter we strengthened our Board with the addition of Michael Rhein. Michael has over 30 years of corporate banking and securities experience at Deutsche Bank and currently he has an investment management company based in Germany. He was a Director of TotiPotentRX Corporation until the merger with ThermoGenesis that resulted in the formation of Cesca Therapeutics. In addition to being a Director of the company Michael also serves on our audit committee.

At this point I'd like to turn the call over to Ken for a more detailed update on progress against our highest priority clinical milestones. Ken.

Ken Harris
Thank you, Robin. I am pleased to provide an update today on the progress we've made on our clinical program since the previous earnings call. I shall be updating you on three key initiatives, the progress with the FDA submission for the pivotal CLI clinical trial, the update on the India DCGI submission for the phase II feasibility AMI clinical trial and the update on our progress with the bone marrow transplant initiatives. Our main technology platforms are the SurgWerks kits and VXP system for the aspiration processing, testing and delivery of autologous bone marrow cells in the operating room in a procedure lasting approximately 90 minutes and our CellWerks platforms for the intra-laboratory processing or bioprocessing of blood or a bone marrow cells for clinical use.

Although we have nine target indications in our pipeline we are actively pursuing clinical development with the SurgWerks CLI kit and VXP system for the intramuscular delivery of autologous bone marrow cell concentrate into the afflicted leg of no-option critical limb ischemia patients, the SurgWerks AMI kit and VXP system for the intracoronary delivery of autologous bone marrow cell concentrate into the heart of patients suffering from a recent ST-elevated myocardial infarction otherwise known as STEMI and finally advancing our cell works platform for use in the preparation of improved bone marrow transplant in hematological oncology and hematological genetic disorder patients.

Now, turning to the updates on each of these initiatives. In late December we announced receiving the response of the US FDA to the CLI IDE application for the course-3 pivotal trial. The FDA did not approve the company to begin the trial for a few key reasons. The most significant in our opinion being their need to see additional cell characterization data of our SurgWerks CLI kit and VXP system after each cell handling step. Additionally they are evolving their thinking in how point of care procedure should be implemented and desire that we established intra-operative rapid diagnostic testing around certain safety and dose parameters prior to the injection in the patient.

We have spoken in the past about our opinion that intra-operative quality control is important and that the company has been working for over two years on methods and systems to achieve this. Since the December response letter we've been working diligently to gather the requested data in actual human donors. Our first step in this process requires a need to establish procedures and reviews for gathering donor bone marrow representative of a sample size and the evaluation being conducted in a clinical setting.

The process includes harvesting a donor's bone marrow, testing it for various characteristics at each handling step including after aspiration, cell concentration and then in a simulated injection. We continue to believe that one of our unique SurgWerks components is our ability to do intra-operative diagnostics on the patient cells and subsequent cell therapy injectate.

In addition to the process, which we are happy now appears critical to the FDA's thinking, the agency is also directly requesting that the company should have a method for determining rapid assessment of sterility prior to injection. This sounds easier than it actually is, but we are currently evaluating an approach in the donor samples under preparation now to satisfy this requirement. We've been in consultation with the FDA since the November letter for agreement on the method and are now utilizing the steps to make it practical in the operating room.

In the December press release, the company did highlight that the overall trial design appeared satisfactory to the FDA with a steady design of a randomized double-blinded placebo-controlled trial of 224 subjects at 60 clinical trial sites using an adjudicated, blinded, independent central review committee to determine the primary endpoint of amputation-free survival at 12 months.

The 224 subjects have been determined based on the assumption of a 20% difference in response between the treated and placebo arms at an 80% power. The proposed study has an interim analysis for both utility and re-powering as required when 50% of the subjects have completed the 12-month follow-up exam. All in all, we remain optimistic barring any additional unplanned issues to submit the IDE amendment addressing each open issue by the end of March. We continue to identify qualify and prepare the first 20, course III clinical trial sites for starting as soon as practical after the FDA approval is received.

Turning to the AMI program, we are approximately 60 days behind our earlier guidance on the Phase II feasibility submission to the Indian Drug Controller General, primarily driven by the availability of the central IRB hearing dates. The current date for the first IRB scheduled hearing for our application on the SurgWerks, AMI and VXP System is March 3.

We assume it will take the IRB approximately 30 days to give a final clearance assuming there are no major concerns and the DCGI application will follow immediately thereafter. We anticipate DCGI to take approximately six months to review and approve the trial so our first human treated target is late Q3 2015. The AMIRST trial design is a randomized double-blinded placebo-controlled trial with a two-to-one randomization.

The study is focused on safety and may give some insight into preliminary efficacy for STEMI patients, who have a poorly responding left ventricular ejection fraction 72 hours after re-perfusion. The primary endpoint for safety is MACE or Major Adverse Cardiovascular Events and the efficacy endpoint is LVEF or Left Ventricular Ejection Fraction change. We have changed the randomization from one-to-one to two-to-one at the request of our advisory panel and this will have a slight impact on the number of subjects.

We anticipate this to move a bit higher from 30 to a range of 35 to 45 patients, but as the trial is in India the overall patient cost of additional subjects is not a significant driver to the overall trial cost. The largest cost component for this trial are the blinded US based core lab assessment of the cardiac MR or Magnetic Resonance Imaging and the electronic capture and management of the clinical data.

Lastly, specifically to our bone marrow transplant program, we are pleased to announce that we did receive approval by the Indian Drug Controller General or DCGI for the import and commercialization of our MarrowXpress MXP system. The approval of our bone marrow cell processing device is important to us because it's the foundation for our cell works Platform and the cornerstone of our partnership with Fortis Healthcare to advance our bone marrow transplant initiative in India where we are seeking first-louver status to enable a growing number of bone marrow transplants in the region.

In traditional bone marrow transplants, the better the match, the better the outcome. The cell type match has historically been critical for two reasons, faster engraftment time and thus minimizing the risk of infectious disease mortality and second, the reduction of graft versus host disease, otherwise known as GVHD. And once the patient and once the donor and the patient are a perfect match in both red blood cell types called ABO match and white blood cell types called HLA matching, additional laboratory and pharmaceutical adjunct steps are required.

Each of these manipulations and therapies comes with their own risks. In normal routine lab and chemical processing practice today, as one depletes the unwanted red blood cells and plasma they also inadvertently deplete significant numbers of the desired stem cells. The lower the stem cells count becomes, the longer the patient takes to reestablish a newly engrafted blood and immune system resulting in increased risk of illness and potential death.

Our CellWerks product using the MarrowXpress system can effectively address the inadvertent stem cell loss in traditional bone marrow transplants and more efficiently prepare a transplant unit, specifically our stem cell yields are between 30% to 40% higher than current laboratory methods, leading to an anticipated better engraftment rate. Typical engraftment rates in mismatched units can be as low as 70% which is a very troubling failure rate.

With respect to India, the success rates appear even lower driven by the unavailability of unrelated donors and their requirement to use the less than ideal six-of-six matched units. And plus, we will be seeking to advance our Haploidentical transplant program in partnership with Fortis Healthcare. Haploidentical Hematopoietic Stem Cell Transplantation otherwise known as HSCT provides an opportunity for nearly all patients to benefit from stem cell transplant, when an HLA genotypically matched sibling is not available.

Initial results with the use of mismatched allografts lead to a limited enthusiasm, less than limited enthusiasm due to GVHD an infectious complication resulting in unacceptable treatment-related morbidity and mortality. Recent advances with effective T-cell depletion and we believe in combination with MarrowXpress to support the use of mega doses of stem cells, better antimicrobial therapy and reduced intensity conditioning can significantly decrease the early transplant-related mortality and GVHD. This type of treatment is critical to cure hematological genetic disorders.

The Company plans to utilize in partnership with Fortis, its unique GMP laboratory in Gurgaon, India to enable this advanced treatment. The Indian market itself which is evolving can be broken down into the adult hematological malignancy market, where B-cell malignancies have roughly 50,000 new diagnoses per year in the Indian urban areas and the combined pediatric hematological genetic disorder including Sickle Cell Disease, Beta Thalassemia and severe combined immunodeficiency or SCID account for an additional 12,000 new cases per annum.

So, can this relatively large market translate into commercial value? We believe so, in India, in the near term. The target market can be calculated as follows: The focus is on families living in urban centers with sufficient education and wealth to support a private care program enrolling all the numbers together we estimate that approximately 6,000 such transplants could be requested across the country.

The addressable market is approximately $150 million. The Company currently has the capacity to do approximately 700 high-dose standard processes and 365 Haploidentical cases per annum. In the meantime, the Company will use the current regulatory clearance to provide standard laboratory bone marrow transplant services for Fortis' applications.

In closing, I would like to say that at Cesca, we believe that our cell therapies can make a life changing difference in patients with diseases such as severe vascular and hematological and oncological indications. Believing that our approach to stem cell therapies is unique and highly effective, providing measurable cost benefits for insurance providers and easy for physician adoption, we are confident that Cesca SurgWerks and CellWerks platforms will play a leading role in successfully transforming the emerging field of regenerative medicine.

I would now like to turn the call over to Dan for review of the quarter's financial performance.

Dan Bessey
Thank you, Ken, and good afternoon everyone. Our financial results for the quarter were largely driven by two core strategic objectives. The first objective is to drive the advancement of our cell therapy clinical programs with a

particular focus on obtaining FDA approval to commence our pivotal Phase III trial for treating Critical Limb Ischemia. While this represents our primary near-term focus, we also continue to make important clinical progress on our AMI and BMT programs.

As Ken mentioned earlier, we are preparing to seek approval from the DCGI to conduct a feasibility study in India treating patients who have suffered a STEMI heart attack, you will note that the financial impacts of these initiatives primarily reflect themselves in Research and Development and General and Administrative financial line items. Secondly, we sell automated and manual cell processing and storage systems to cord blood banks and hospitals throughout the world. The growth profit generated by these cord blood product lines is used to partially fund our clinical trial programs and corporate infrastructure.

Moving now to our financial results for the second quarter of our fiscal year, net revenues for the quarter ended December 31, 2014 were $4.6 million compared to $4.5 million for the same period in the prior year. The modest increase in revenues was due to sales from cord blood products and services generated from the company's new Indian business that are the result of the merger with TotipotentRX. Recall that the merger with TotipotentRX occurred in February of 2014. So there were no revenues relating to our cord blood business in India in the second fiscal quarter of last year.

Gross profit for the quarter ended December 31, 2014 was $1.5 million compared to $1.8 million for the same period in the prior year. The decrease in gross profit of approximately $300,000 was primarily due to additional manufacturing costs that were expensed during the quarter.

Operating expenses for the quarter ended December 31, 2014 were $5.9 million compared to $3.4 million for the same period in the prior year, representing a year-over-year increase of $2.5 million. The increase in costs was primarily attributable to the development of our cell therapy clinical programs, including costs associated with preparing our IDE application for pivotal Phase III trial treating critical limb ischemia. Also contributing to the increase in operating expenses were legal costs associated with defending certain clients against our Res-Q product line and costs associated with employees severance.

These cost increases were partially offset by the absence of legal and advisory fees associated with consummating a merger with TotipotentRX in February of 2014. Adjusted EBITDA loss was $3.6 million for the quarter ended December 31, 2014 compared to $1.3 million for the same period in the prior year. Net loss for the quarter ended December 31, 2014 was $4.4 million compared to $1.6 million for the same prior year period.

The increase in the adjusted EBITDA loss of $2.3 million and the increase in the net loss of $2.8 million were due to our investments and the development and advancement of our clinical programs and legal costs associated with patent litigation. We ended the second quarter with $8.4 million in cash compared with $14.8 million at the end of fiscal 2014. Regarding our cost structure, our net cash outflows will increase over historical level at we advance our CLI, AMI and BMT programs into the next respective trial phases during the coming year.

Regarding future funding plans, we remain active in monitoring the capital market and expect to strengthen our balance sheet as a precursor to launching our pivotal trial treating Critical Limb Ischemia. As we approach the commencement of these trials we will provide further updates on our expectations of our cash expenditure levels and associated funding plans.

I will now turn the call back to Robin for his closing remarks.

Robin Stracey
Thank you, Dan. So, in summary before I turn over the call over for questions, 2014 was a year of enormous cultural and organizational change for us. Having completed the merger of ThermoGenesis and Totipotent to create Cesca Therapeutics and having set the Company on an exciting new growth trajectory, our focus now is on fully harnessing

the collective capabilities of each of our parent organizations to drive effective execution of our ambitious growth strategy.

Importantly, our base business in cord blood continues to perform in line with expectations as we direct more and more of our effort towards scaling up our activities in the therapeutic arena. And following dialogue with the FDA that has been both constructive and helpful, we hope soon to be able to begin enrolling patients in our first major US clinical trial the pivotal phase III trial for Critical Limb Ischemia.

With that, I would like to thank you all for your attention, and turn the call over to the Operator, who will open it up to questions.

QUESTION AND ANSWER

Operator
We will now begin the question-and-answer session. To ask a question you may press "*" then "1" on your touchtone phone. If you are using a speakerphone, please pick up your handset before pressing the keys, to withdraw your question, please press "*" then "2." At this time we will pause momentarily to assemble our roster.

First question comes from Jason Colbert from Maxim. Please go ahead.

Jason Kolbert
Kent, Robin, Dan thank you so much for the comprehensive review. I just want to dial in a little bit more on exactly what you're going to do in terms of the FDA response particularly when we talk about point of care in the OR and specifically I know that there were questions about sterility testing and product characterization. So, as much detail as you can give me in terms of where you are in that process is going to really help me understand kind of the timing of the turnaround and the initiation of the CLI trial which is where I think I and most investors are focused. Thanks.

Ken Harris
Alright, thanks Jason. I will start at the…you know, the FDA's request really was broken down into two needs, one was for characterization after each of the devices in our SurgeWerks works kit, and we believe their need for that information was to ensure that each device that we're using on or by the patient has minimal effect on cell quality. So, we had supplied data in our IDE application around final cell quality post the inject date needle. The FDA asked us to go back now and look in comparing contrast cellularity after aspiration after processing and after injection.

It's very straight forward analysis that we can do in the laboratory and what we needed to do was develop a statistically valid study plan around getting patient donors who could provide bone marrow at the same quantity or near the same quantity that we will use in the CLI treatment and do all of the testing in a point of care environment. So, that took us some time to get approval to do that and find the source to do the process. That is behind us now and we are more than 50% of the way through that donor population. Each donor is put through a battery of testing that lasts about three weeks. And those testing's include things like for flow cytometry analysis of different cell markers, cell potency for three different cell potency assays, bio activity assays, which we had already submitted to the FDA, but now we will conduct after each of these interim device steps.

And…and then, moving onto the second major comment they had was, once they see consistency in the device output they then want to move on to the biological variability of a donor or a patient in the operating room. And a) ensure that the donor has enough stem cells to reach a therapeutic dose, so the assets to provide the minimum therapeutic dose that we would use in a trial and b) to provide the means with which we could test that in the operating room that work has already been done and that was provided in the IDE application, which is basically a rapid diagnostic where we will look at certain surrogate markers from the cell concentrate and see that it meets our minimum dose and therefore would be a green light to the physician to inject.

The sterility request was from left field, quite honestly, it was never anticipated to be a what we thought a reasonable plan for us to undertake early on because sterility today is a 14-day test there is no method and many companies including myself spent over a decade trying to develop these methods and they are very complicated. So, we have settled with the FDA to do a rapid Gram stain in the operating room on the final injectate product prior to injection to the patient. And, you know, the rubber hits the road really around timing, these patients are under general anesthesia and so we are going through different simulations and process optimization steps now jointly with the FDA to see how we can get that into an acceptable number of minutes. But suffice to say it's adding about 15 minutes to the procedure in total.

Jason Kolbert
Got it, Kent, thank you and that's really, really drawn. I have to tell it's granular and it's very helpful. Two other questions, you talked a little bit about the cardiac trial and I…I don't think I quite understood what you were saying. So, if you could take a minute and just kind of go back, what…what is the objective of the cardiac trial and I believe you were saying that that trial is going to occur in India on the Totipotent centers and then my last question is what do you do think the market opportunity is in India and what I really mean by that is, what does it take to get adoption of the products or what is the initial opportunity take. We…we know it's a big market opportunity but we know that culturally, you know, it's not BMTs are just not widely done in India, so help me understand how much resources you are willing to dedicate in order to kind of drive the…the volume of…of processing and kind of change the medical paradigm in Asia and particularly in India, so, two different questions. Thanks.

Ken Harris
Okay. So, let's start with the AMI question at the top. The goal of the study is to focus on a patient population that have had an ST-elevated MI an acute MI and have gotten to the hospital within 24 hours of an onset of symptoms and then received reperfusion therapy, and the reperfusion therapy could be stenting, angioplasty or thrombolysis. Once they have received that therapy normally a patient's ejection fraction will start to pop back up to a near normal level within 24 hours or so after reperfusion. However, in about 20% of the cases the patients for various reasons their ejection fraction remains very low and at a low level that they are on a path to chronic heart failure. And statistics show that 72 hours post reperfusion if the ejection fraction is not above 40% the patient has an 80% chance of mortality at the one year end point. So that is our patient population, it's this 20% of non-responders, and our goal is to do the intervention within seven days after that assessment, so total time from onset of the heart attack to our intervention is a maximum of 10 days. And it's, you know, basically no option patients. Our goal is to a) stop remodeling of the heart and remodeling is what drives chronic heart failure through the inflammatory response and we measure that through heart volume metrics and that includes ejection fraction or the strength the heart can pump, heart wall motions, so how floppy or rigid is the heart wall to be capable of squeezing the blood in and out. And second of all the hemodynamics between the different chambers of the heart and those are as a composite, are different end points.

However, in this study which is the Phase II study we are focusing only on safety with some efficacy evaluation. And there we will be looking at major cardiovascular adverse events which will be things like another heart attack, re-hospitalization, stroke, anything in the cardiovascular world. And we would anticipate to see, you know, statistically significant lower MACE in the treated arm than in the placebo arm. And I think that…

Jason Kolbert
Strikingly more to the dynamics of the neo stem trial but help me understand the basis for India versus the portability of this data to the US, which is where it would be a great marketed opportunity?

Ken Harris
Right, so portability of data I think we have now proven in our CLI admission that the FDA accepts data from India and how we design trials. So I'm very comfortable that that will port back over here for pivotal trial and we also remain very confident that the Indian market alone which is the largest cardiovascular market in the world in and of

itself would provide a very sufficient market for us to have justifiable ROI on our investment. Our goal would to bring once we have completed the safety aid study and remember the Cook Medical as our partner in the intracoronary catheter. So, we are sort of going to battle with a well respected experienced cardiovascular house.

Once we have shown the safety in the Phase II then we would expect to look at the global markets and determine where we would go for marketing license for the Phase III.

Jason Kolbert
And…thank you. I've got it. I don't want to take the…you know, too much time on the call. If you could just close with me on what you think the build out is going to look like in India and BMT that would be very helpful for my metrics.

Ken Harris
Okay, so I think you know, as I mentioned we have a capacity limitation, so there are we think when you look at affordability, education maybe the parameters to get the right patient to a Tertiary Care Hospital of which there are a handful in New Delhi, a handful in Mumbai, basically a handful in each of major cities in India and you sort of cull that all the way down you end up with about 6,000 or so patients that would fit all the criteria for being…for meeting the treatment and being able to pay for it and getting to a center that can do it. So we plan to start in our own center where we…we can do over 1000 of these a year in our own capacity and start with education programs combined with Fortis and we now have the largest and best primary or Tertiary Care BMT private center in India and presently the organization is doing you know, roughly 15 bone marrow transplants a month and we feel we can get that up to you know, 30 to 50 a month pretty quickly through you know more education, conferences and outreach to primary physicians. So I think you know, to be a stair-stepped approach it's going to take marketing, it's not going to happen overnight, but the infrastructure is there the DCGI approval is there and we now have a…we have a world class BMT team trained in Australia and Canada now that have almost two years under their belt in the Fortis center and then we are combining that with our own advisory panel that we've built here in the US that's going to start needing an exchange program where we are going to send fellows and we've had positive responses from Emory and Stanford as well as UCLA to send fellows over to our program for six months to one…one in the Indian market beneficial to them but we provide the academic support for us to train many more Indian physicians at a much quicker pace.

Jason Kolbert
Wow! That's really exciting guys, great rundown, really appreciate all the progress and I'm very excited to see the start of the CLI trial and the execution of all of these programs and development. Great job. Thank you.

Ken Harris
Thanks.

Operator
The next question comes from Ren Benjamin, of HC Wainwright. Please go ahead.

Ren Benjamin
Hi, good afternoon guys and thanks for taking the questions. I guess just maybe building on Jason's characterization question, you had talked about the sterility assay and it looks like…looks like after everything is sort of said and done the characterization sort of throughout the process won't add that much more time but the sterility assay looks to be like an open-ended question unless I heard you wrong, can you talk a little bit about how you are going to work with the FDA I guess on this what…I thought you had mentioned on the call that it…it typically takes about seven days you know, what kind of assays are there that could cut this down significantly and because I assume you would have to do that with…with each patient, with each procedure and are there any other assays there that look at things more than you know, just Gram staining…would you have to worry about that?

Ken Harris

Yes, it's a good question. So the current USP method that is accepted by FDA for a pharmaceutical sterility is a 14-day culture test and that is already in our protocol and so the FDA wants us to continue doing that, it's a much more sensitive assay but for some reason and I can't put my finger on the renewed sensitivity they have around sterility, they've come back now and said, we'd like some leading indicator in the operating room before the injection is done. We've had dialogue with the FDA that a) there aren't methods to do that and b) we are dealing with if there was a contamination level because we are only in 90 minutes the contamination level would be so low that in order to get an acceptable sensitivity you would need something like PCR and that's not acceptable, right? And we all agreed with that, the FDA agreed with that. So their position was do a Gram stain, let's see what the results look like do 10 patients or so and then come back to us and we'll make a decision whether we want you or need you to continue doing that through the whole trial. Now keep in mind that we've done over 650 patients with point-of-care treatments and we have done sterility assessment on all of them, and we've never had a single sterility issue. So, we are very comfortable as there is strong data to make the FDA, you know, ultimately come off of this but I don't know if something has happened in another study or what has led them to just want some additional box chat but they are pushing for it. A Gram stain is going to take you know, anywhere from 15 to 30 minutes and we are trying to optimize the method we can to get it done in under 15 because we do have a patient under general anesthesia and we worry about some risk of that.

Ren Benjamin
Right, so…

Robin Stracey
But that…

Ren Benjamin
Let me just follow up with, if the trial shows you know, you already submit the data for the 650 patients there's never been a sterility issue if the trial now shows let's say and replicates that data could it be possible that in the final you know approved process that you don't need to do a sterility assay to begin with or are you establishing sort of a new protocol and setting a new trend whereby a sterility assay would have to be done you know, once it's on the market?

Ken Harris
Yes, it's a good question; I mean I will tell you my feeling from FDA is they would like to see it. However, they are cognizant of the fact that it takes time and I think they are in a risk benefit analysis themselves on it which is why they said do the 10 patient checkpoint and let's recalibrate. I think if there are no issues with doing it in the operating room and they remain more comfortable having it I think it will probably scale up with the procedure, but if anything goes wrong or they don't like it then I think it's probably going to not be required after that 10th patient.

Ren Benjamin
Got it…Just based on your discussions do you guys have any new thoughts regarding a discussion about an SPA prior to starting the pivotal study?

Ken Harris
I don't really see the need for an SPA at this point because we have our protocol has been vetted, it's gone through already full regulatory review, we have their feedback on what they want changed which was what I will call four major deficiencies of which two of them are really simple to address and these two around cellularity and all the rest were just little nit-picking things like change this line say that in your informed consent change this little piece of the protocol. So I think we really are close to having full agreement on the protocol.

Ren Benjamin
Got it. Do you…do you think that this is you know, something specific to…to you guys or…or your product specifically or do you think this is kind of a changing of the playing field and…and maybe a new standard is being set in terms of their

targets you know, therapy, targets of regenerative medicine market?

Ken Harris
Yes, I don't want to speak for the FDA I'll just tell you what they told us. I don't know what they are thinking however they did say to us in our discussions that they understand that they we are an IDE. They are considering that at every step, however for IDE point-of-care, CBER reviewed products they are going to require these intra-operative cell analysis steps and they didn't leave a lot of room for. It's up for discussion.

Ren Benjamin
Got it, got it. Just switching gears, I have just two more questions. One having to do with, you know, the bone marrow study, just sort of where are we I thought the last update we had 5 out of the 10 patients were indicated to maybe…maybe I'm off on that. Can you just give us…you know what exactly…what exactly is going on there, when we can expect some data? And I thought I had a milestone about submitting a 510 K bone marrow transplant 510-K application to the FDA…was I wrong on that one or has there been a change in thinking about that?

Ken Harris
You know you aren't wrong, there's been a slight change in thinking because we slowed down to go ahead and get the MXP approved as a platform rather than waiting for the clinical trial data and in so doing we stopped we put a hold on the trials in India for that approval now that it's on my update this morning is that we have three pediatric patients in the pipeline to go back in the trial now. So, we are ready to turn those back on, we also have interest for from one to two major national cancer centers here in the US to also contribute to those studies, so I think we will be broadening the clinical trial sites to be both US and India and that will strengthen our US application.

Ren Benjamin
So can you just give me that sort of like you know…how many patients total is going to be involved in this package and when do you think you might submit the application?

Ken Harris
Yes, so it's 10 patients for ABO and it's 10 patients for Haplo and we are at five for ABO four for Haplo and our main thrust because that's where the money is in the Haplo side and that's where we have the BMT specialty team now in place and the collaborations developing here in California and in Emeryville to speed them up, but it's enrollment is one of the issues in this whole process and that's what's led us to realize that we need a much more proactive marketing program as well to grow the business.

Ren Benjamin
Do you…you think you still might see data this year?

Ken Harris
Yes, that's the goal.

Ren Benjamin
Okay and there is one final question for you now, I don't want to leave Robin out of this, how is the CEO hunt doing…going or is he starting to like that chair?

Robin Stracey
Well its certainly is a lot of fun being in CESCA these days with Dan and Ken and everything that's going on in the company, so we are still in the early stages I've been involved now since the very end of October, we kind of slowed things down a little bit with Thanksgiving, Christmas, New Year, so we are still in the early stages. We are obviously more focused on the caliber of the individual and expediency run and I maybe created the Board but I am more than happy to pinch hit for as long as necessary to make sure we get the right person in. So it's ongoing but it's still early is the answer.

Ren Benjamin
Got it! Thanks very much and good luck.

Robin Stracey
Thank you.

Ken Harris
Thank you, Ren.

Operator
This concludes our question and answer session, I would like to turn the conference back over to Mr. Stracey for any closing remarks.

CONCLUSION

Robin Stracey
Well thank you all once again for joining us today for the great questions and for your continued interest and support of the company. We look forward to talking with you further and keeping you posted on our progress. So thank you all and have a very good evening.

Operator
The conference has now concluded. Thank you for attending today's presentation. You may now disconnect.