



In case you missed the call here is the transcript with a full update on Bioheart's activities...

Feb. 3rd, 2009 BIOHEART, INC. SHAREHOLDER UPDATE CALL

JON CUNNINGHAM: Good afternoon and welcome to the Bioheart Incorporated 2008 year-end highlights conference call. With me today is Howard Leonhardt, Bioheart's –Chairman of the Board, Chief Executive Officer and Chief Technology Officer. Before I turn the call over to Howard, may I remind our listeners that in this call, management's prepared remarks contain forward-looking statements, which are subject to risks and uncertainties, and management may make additional forward-looking statements in response to your questions. Information Regarding Forward-Looking Statements will be read by Mr. Andrew Smith of Sichenzia Ross Friedman Ference LLP, Bioheart's outside counsel.

ANDREW SMITH: The statements made during the course of this conference call may include our hopes, intentions, beliefs, expectations or projections of the future, that (along with other statements that are not historical facts) are forward looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. An example of such forward-looking statements would be management's estimation as to the timing for completion of studies or estimates sales revenues. It is important to note that the Company's actual results could differ materially from those projected in such forward looking statements. Information concerning factors that could cause actual results to differ materially from those forward looking statements can be found in our Annual Report on Form 10-K for the fiscal year ended December 31, 2007, as well as in our other filings with the SEC. You should not place undue reliance on forward-looking statements, which reflect our view only as of the date hereof. We undertake no obligation to publicly release revisions to these forward-looking statements to reflect future events or circumstances or reflect the occurrence of unanticipated events.

HOWARD J. LEONHARDT: Thank you Andy. Good afternoon, ladies and gentlemen,. I want to welcome all of our shareholders listening and all other interested parties. I would like to introduce the Senior Management of the Company who are present during this call: Doug Owens, Director of Clinical Affairs, Matt Fendrich, Vice President of Sales and Marketing, Kristin Comella, Vice President of R&D and Corporate Development, Catherine Sulawske-Guck, Vice President of Administration and Human Resources, Jason Griffith, Associate Director of Business and Product Development, and Angel Rodriguez, our Financial Controller.

The past year has been a period of enormous progress for Bioheart.

- In the United States, we successfully implemented an increase from 5 clinical sites evaluating our MyoCell product for heart failure to 35 sites and have advanced to a Phase II/III randomized, double-blind, placebo-controlled clinical trial. The MARVEL Trial, which is intended to enroll up to 330 patients, is one of the largest clinical trials of its kind ever undertaken. Provided needed funding is received we are on track to complete the minimum number of patients expected to be needed for commercial approval by the end of Spring of this year.
- In Europe we have regulatory approval for MyoCell™ tissue processing at our affiliated cGMP facility in The Netherlands. Additionally we applied for reimbursement approval in 4 countries this past quarter for the indications of use of treating advanced heart failure patients that have tried all available drugs and continue to decline and do not qualify for a bi-V pacemaker or left ventricle assist device.
- Our next generation MyoCell SDF-1 composition, developed in collaboration with the Cleveland Clinic and the University of Florida, proved out in animal studies to offer up to double the functional improvement of our first generation composition and is preparing to enter clinical trials in Switzerland. In the USA our IND application with the FDA for this product has been filed and is pending review of additional data. In animal studies the MyoCell SDF-1 composition provided 54% improvement in cardiac function compared to 27% for the original MyoCell composition and -10% decline with placebo injections. We believe there will be available several million dollars of grant funding to help support this research.
- Our Bioheart TGI-1200 bedside apparatus for preparing stem cells and endothelial progenitor cells from adipose tissue received CE Mark commercial approval with our corporate partner, Tissue Genesis, Inc. We are currently initiating studies for the applications of lower limb ischemia, Acute MI and chronic ischemia which are necessary to obtain reimbursement codes for these indications of use.

- We completed our transition to becoming a commercial enterprise with the market release of the Bioheart 3370 heart failure monitoring products and services utilizing Bioheart's exclusive proprietary software program. These products are fully approved for commercial sale both in the United States and Europe. Being in heart failure physician offices representing this product line is also serving to drive enrollment in the MARVEL Trial.
- We secured rights to distribute the FDA authorized Bioheart-Monebo Cardiobelt™ for monitoring the electrical activity of a patient's heart. This device integrates via Bluetooth® with our Bioheart 3370 heart failure monitoring system. The agreement with Monebo includes a license to their 16 parameter ECG analyzer and call center management software packages.
- We continue to believe we represent the best hope for a better quality of life for the more than 23 million patients suffering of heart failure worldwide.
- We presented at numerous medical industry meetings this past year the results from our U.S. Phase I MYOHEART Trial and our European Phase IIa SEISMIC Trial, which included control patients.
- In these studies it was reported that 83 to 94% of the MyoCell treated heart failure patients improved, or did not worsen, in the Six Minute Walk, Quality of Life and/or heart failure class while only 6 to 17% worsened.
- In the SEISMIC Trial control group, 69% of the patients that received drugs only, worsened in exercise capacity and/or quality of life.
- MyoCell treated patients in both studies demonstrated substantial improvement in six-minute walk exercise testing and quality of life, which are the primary end points of our new Phase II/III MARVEL Trial.
- Bioheart just this month shipped our first Bioheart A&C Bioscience TPLS true pulsatile and percutaneous life support system to Italy for testing. This product is designed to work in conjunction with our Bioheart TGI-1200 cell isolation system to reduce scar size following an Acute MI (heart attack). This product has CE Mark commercial approval and has successfully been utilized in more than 300 patients to date.

I will turn the floor over to Mr. Doug Owens our Directors of Clinical Affairs for a further update on our MyoCell™ clinical trials

- We believe that the Phase II/III MARVEL trial will remain on track, provided adequate additional funding is obtained, to complete enrollment of 150 patients by the last day of Spring this year. 3 months and 6 months thereafter we expect that we will be able to complete interim analysis and, if we reach statistical significance on our primary end points of 6 minute walk and quality of life, we expect that we will submit a BLA (biological license approval) application with the FDA. We have to achieve at least 30 meters improvement in 6 minute walk for statistical significance, and we have been achieving 62 meters to date. We have to achieve at least a 10 score improvement in quality of life, and we have been achieving better than 15 score improvement in previous trials. The MARVEL study is blinded and thus we cannot share results at this time other than the fact that we are now 15 months into the study and we have not had a single treatment patient death. Which is significant considering that the Class III and IV patient population we are treating statistically has had a 12.5 to 20% mortality rate during this time period.
- I do wish to share that our plan at this time is to complete the 15 patients in the pending MyoCell SDF-1 safety dose escalation study with one month follow-up and then to apply to complete the final 180 patients of the MARVEL study, to reach at total of 330 patients. If our timeline plans work out we expect that we will have the data from SDF-1 safety trial just in time after evaluating the interim analysis of the first 150 patients of the MARVEL trial utilizing the original composition. Both compositions are very similar. SDF-1 has been shown to be capable of recruiting other stem cells within a patient's own body to the cell transplanted area. The recruited stem cells further assist in the tissue repair process and help to increase blood vessel formation.

(Howard Leonhardt) Thank you Doug. We will now turn the floor over to Mr. Matt Fendrich our VP of Sales and Marketing.

- The launch of the Bioheart 3370 @ home Heart Failure Monitoring service has been a great success. 15 centers have expressed strong interest to move forward with adopting our disease management program. We believe our software is the best in the field. If all 15 centers gave us their Class III and IV patients to monitor as we hope for, this could represent greater than \$60 million in annual revenues. We expect that sales could reach \$20 million in 2009.

- We expect to fully launch the Bioheart-Monebo Cardiobelt™ in the second quarter of 2009. The portable system provides state of art 16 parameter monitoring of the electrical activity of a patient's heart. Monebo our corporate partner has shared with us that they expect to release a 24 hour beat to beat version before the end of the year. Our contract with Monebo provides Bioheart with distribution rights for this product. The current U.S. market for beat to beat monitoring systems exceeds \$100 million annually.
- We are preparing to launch the Bioheart TGI-1200 and Bioheart A&C Biosciences TPLS systems in Europe, both products already have CE Mark commercial approval. Both of these products are top in class performers and fit perfect into our line up of products.

(Howard Leonhardt) Thank you Matt. We will now turn the floor over to Ms. Kristin Comella our Vice President of R&D and Corporate Development.

(Kristin) ...2008 was a great year for advancement in corporate and research developments.

- Bioheart implemented an increase in the concentration of our MyoCell™ composition which improved retention and engraftment in myocardial scar tissue which was adopted in the MARVEL clinical study. This move from 50 million cells per ml to 200 million cells per ml duly serves to reduce the number of injections needed to deliver a full therapeutic dose from 32 down to 16. This serves to reduce inflammation which improves cell engraftment.
- Bioheart received a number of new patents in 2008 brining our total to more than 35, many of which are pioneering and broadest in the field. We believe our patent portfolio covers the use of myogenic cells to treat heart failure, electrical stimulation to enhance cell transplantation, use of an endothelial progenitor cell composition from fat tissue to treat ischemia and use of SDF-1 released from a myogenic cell to improve the treatment of heart failure. We also successfully avoided conflict with the Edge patent held by Advanced Cell Technologies, since we proved that our patented work preceded theirs.
- We moved forward our developing product platforms including MyoValve, Biopace, AortaCell, EndoCell and MyoStim. We are seeking corporate partners to move these products into clinical studies.
- We initiated two new research projects in Korea with our partner A&C Biosciences. One to develop a catheter implantable LV filling pressure sensor and the second to develop a catheter based LV heart pump. We are nearly ready, working with A&C Biosciences., to move the SVAD low cost left ventricle assist device into clinical trials. The company is seeking a corporate partner to help finance these trials.
- Our MyoCell™ production capacity increased from 15 patients per month to over 1000 with the development of our facilities in The Netherlands and Korea and the further expansion of our headquarters facility in Florida.

(Howard Leonhardt) Thanks Kristin.

- We have invested to date \$120 million in bringing to market our advanced technologies for treating and caring for heart failure patients.
- Bioheart, in the interest of our shareholders, is attempting to finance our 2009 budget primarily from profits from revenues instead of selling additional shares at this time.. This is a difficult time for companies to raise capital. We have been conserving our expenditures as we wait for revenues to take over in supporting the company. This strategy serves to preserve best the ownership position of our loyal shareholders and stock option holding employees that have served us for many years. We expect to have substantial cash revenues by the end of the 2nd Quarter of 2009.

(Howard Leonhardt) Our confidence in the future of Bioheart has never been stronger. We believe our strategic move to revenues from products that complement our flagship product MyoCell™ has been the right step in the right direction in these times where capital markets are very difficult. We are committed to being the "Go To technology partner for heart failure specialists". The heart failure market is expected to double from 23 million patients to 46 million in just the next 5 years. We believe Bioheart is positioned to be the leading heart failure company of the future. We thank you for your continued support.

(Howard Leonhardt) We will now open up the lines for questions.

The conference call moderator takes over and announces each question.