

Due Diligence Report: CEO Calls Meeting, Shares Skyrocket 48%

Summary

Harvard Apparatus Regenerative Technology, Inc., incorporated on May 3, 2012, is a clinical-stage biotechnology company making regenerated organs for transplant. The Company's product, the HART-Trachea, is intended to be used to restore the structure and/or function of a severely damaged trachea (windpipe). The HART-Trachea comprises the patient's own bone marrow cells seeded on the Company's InBreath porous plastic scaffold in its InBreath organ bioreactor. Its HART-Trachea addresses both of the challenges to trachea transplant, such as the shortage of suitable donor tracheas and the risk and expense of lifelong anti-rejection drug therapy. The Company has received orphan drug designation from the United States Food and Drug Administration (FDA) for the HART-Trachea in the United States market. The Company is engaged in pre-clinical development of its HART-Trachea. As of December 31, 2014, the HART-Trachea has been implanted in five adult human patients. Average survival among the three of these patients who have died to date has been 22 months. Of the three patients who have died, none of them have died because of a failure of its scaffold. Two of the patients are still alive. Of those two patients, one is at approximately 9 months and the other is at approximately two and one half years from being first implanted.

Harvard Apparatus Regenerative Technology Inc. has a current market capitalization of \$29.60 M with 13.45 M outstanding shares. Its daily average volume traded is 1.76 M shares.

Key Indicators (Q3 2015)

Shares Outstanding	13.45 M
Revenue	0.04 M
Gross Profit	0.02 M
Net Loss (basic/diluted)	-2.29 M
Cash and Short-term Inv	8.20 M
Total Debt	Nil

Performance (6 months)



Recent News and Analysis:

The company recently announced it has received written notification from The NASDAQ Stock Market that it has regained compliance with the minimum bid price requirements. The letter noted that as a result of the closing bid price of HART's common stock having exceeded \$1.00 per share for more than ten consecutive business days, the company has regained compliance and the matter is now closed. HART's CEO, Jim McGorry, commented, "Maintaining our NASDAQ listing is fundamental to our

corporate strategy. We are gratified by the investment community's response to our recent progress, including the positive animal research results on HART's second generation (Gen2) bioengineered esophageal, tracheal and bronchial implants." Mr. McGorry continued, "Going forward, our development plan is focused on getting our technology back into humans on a compassionate use basis and filing our first clinical trial application with the FDA during 2016. We are confident that we will meet these goals given the results of our recent studies using our Gen2 technology across all three applications, our strong scientific team and our collaborations with translational partners. We have initiated confirmatory large-animal studies of our Gen2 implants with Mayo Clinic. The study design has been completed, prerequisite tests are underway, and we expect the animal surgeries to occur in December."

In addition, CEO Jim McGorry is set to hold a special investor event on December 1 in Los Angeles, California. This apparently has given investors reason for hope, as the stock moved up nearly 48% on Monday, reaching a volume of 18.48 M shares; versus a daily average volume of 1.76 M shares. Shareholders are hoping for steady progress to be revealed by the company whose main line of business involves the development of bioengineered organ implants for transplantation.

Conclusions:

Investors reacted favorably to the recent announcements made by the company. Shares of HART skyrocketed nearly 82% in the last five days and appear to be moving higher in afterhours trading. This is certainly a reversal of trends compared to the past 52 weeks and is expected moving forward given the CEO announces favorable news during the conference on Dec 1, 2015. Despite what the CEO announces, the Company's products are gaining traction and should lead to profitability in the near future.

Sources:

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5. <http://www.reuters.com/finance/stocks/companyProfile?rpc=66&symbol=HART.O#6zLbGzSkcBEjqXde.97>
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- 7.

Risk Factors

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Disclosure: I, Robert Borowski, research analyst have no positions in any stocks mentioned, and no plans to initiate any positions within the next 72 hours. I wrote this article myself, and it expresses my own opinions and I have no business relationship with any company whose stock is mentioned in the article.

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