

A SECTOR OF ITS OWN: HEALTH-CARE DEFIES ECONOMIC CONDITIONS AND MOVES TO NEW HIGHS

NOVEMBER 17, 2015

Health-care Sector – Mergers and Acquisitions Drive Sector to New highs

Looking over the past year, the health-care sector has been a strong performer in the market, but there's pressure on the pharmaceutical and biotechnology subsectors. There's plenty of political pressure over pharmaceutical acquirers raising drug prices and doing everything they can to avoid taxes. In the recent past, outspoken politicians have dramatically hurt the sector with tweets about lowering prices of prescription drugs and other health-care related topics. In addition, recent news regarding revenue accounting by Valeant Pharmaceuticals International Inc. ([NYSE:VRX](#)) has also moved the sector downwards.

On the other hand, almost 1 in 4 dollars of the \$2 trillion in buyouts since January 2015, involved a company in healthcare, and the size of those deals is immense. The total value of healthcare mergers and acquisitions in the United States has more than tripled compared with five years ago, according to the data firm Dealogic. Even in the face of rising interest rates, which would make deal-making more expensive, business insiders see few reasons why momentum in the healthcare sector will ease any time soon. Drugmakers still need to buy drugs and companies that promise to give them a sizable competitive advantage and sell the ones that don't as they narrow their focus. Health insurers, doctors and hospitals are pushing to get bigger and bring more muscle to their negotiations with one another over the ever-rising cost of care. The Blue Cross-Blue Shield insurer Anthem Inc. ([NYSE:ANTM](#)) is spending \$51.9 billion to buy rival insurer Cigna ([NYSE:C](#)), a deal that would create a combined company with more than \$100 billion in revenue. These deals also enable companies to combine resources and cut expenses at a time when every element of the sector is feeling pressure to control healthcare costs.

Aging baby boomers are using more care, and a growing number of people are gaining insurance from the federal healthcare overhaul, and they're starting to return to the doctor's office. This is driving demand for healthcare services and is pushing the market upwards, regardless of economic conditions or events. This report focuses on four small cap companies in this sector that may boost the feeding frenzy Health-Care is experiencing at this time.

Harvard Apparatus Regenerative Technology Inc. – Takeover Candidate

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

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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.

Recent News and Analysis

Most recently the company reported third quarter financial results and provided a business update. HART's net loss in the third quarter of 2015 improved to \$2.3 million, or \$0.19 per basic share, compared to \$2.7 million, or \$0.34 per basic share, in the third quarter of 2014. The improvement was primarily due to decreases of \$0.2 million in payroll-related cost, \$0.2 million in recruiting expenses, \$0.1 million in legal fees associated with intellectual property, and \$0.1 million in other spending, offset by \$0.2 million in incremental spending related to animal studies. For the first nine months of 2015, HART's net loss increased to \$9.4 million, or \$0.91 per basic share, compared to a net loss of \$8.2 million, or \$1.05 per basic share, over the corresponding period in 2014. The higher net loss was primarily due to a \$1.6 million increase in non-cash stock-based compensation expense, principally related to the resignation of HART's Chief Executive Officer in April 2015, offset by a \$0.4 million reduction in other operating costs.

Additionally, the company announced significant results – including clear evidence of complete esophageal tissue regeneration – from recently conducted animal research on HART's 2nd Generation (Gen2) bioengineered implant platform. HART's Gen2 technology reflects design enhancements to improve the body's response to the implant and to better guide the repair of tissue in the healing process. The Company's recent animal studies tested all three of its Gen2 implants – esophagus, trachea, and bronchus – demonstrating resolution of the negative inflammatory response observed with the prior generation of the technology. Clinically significant evidence of tissue and nerve regeneration was observed in the esophageal implant, positioning the esophageal implant as the current lead development priority. Importantly, HART's esophageal implant is intended to address a very significant need as a potentially life-saving treatment for patients with esophageal cancer. Each year in the U.S. approximately 17,000 new cases of esophageal cancer are diagnosed, and more than 4,000 are addressed by surgery. The Company believes that these results underscore the value and potential of its platform technology to treat these patients and pave the way for further studies and its regulatory pathway for human clinical trials. The company also continued to advance its development partnerships, specifically collaborations with Mayo Clinic and Connecticut Children's Medical Center (CCMC). HART's collaboration with Mayo Clinic focuses on developing solutions for cancer and other life-threatening diseases affecting the esophagus, bronchus and trachea. HART has initiated its planned confirmatory

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large-animal studies of its Gen2 implants in collaboration with Mayo Clinic. The study design has been completed, prerequisite tests are underway and the Company expects the animal surgeries to occur in December. The Company's collaboration with CCMC is focused on developing a solution for a congenital childhood condition, pediatric esophageal atresia, a condition in which a significant or complete separation of a child's esophagus prevents normal eating function. Initial tests with CCMC commenced during the third quarter.



Verdict

Investors reacted favorably to the recent announcements made by the company. Shares of HART skyrocketed nearly 115% in the last five days and have held that trading range for the past week. This is certainly a reversal of trends and is expected to continue holding for the foreseeable future. The Company's products are gaining traction and should lead to profitability in the near future. With a market cap of only \$15.15M, expect the big fish to have their eye on this one.

Arena Pharmaceuticals Inc. – Upcoming Turnaround

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Summary

Arena Pharmaceuticals, Inc., incorporated on April 14, 1997, is a biopharmaceutical company focused on discovering, developing and commercializing drugs that target G protein-coupled receptors (GPCRs). The Company's drug, BELVIQ (lorcaserin HCl), was approved by the United States Food and Drug Administration for marketing in the United States. In addition to BELVIQ, the Company has other drug candidates and compounds at various stages of research and development. The Company is exploring lorcaserin's once-a-day, extended release formulation, as an aid to smoking cessation, in combination with phentermine and other agents for weight management, and for other possible indications. The Company's other drug candidates include ralinepag for vascular diseases, APD334 for autoimmune diseases, APD371 for pain and fibrotic diseases, and temanogrel for thrombotic diseases. The Company has completed an initial study to evaluate the safety, tolerability and pharmacokinetic properties of different formulations of lorcaserin 20 milligram extended release tablets, and selected a once-daily formulation for further development. The Company has completed dosing in two additional Phase I clinical trials to determine the pharmacokinetic properties and bioequivalence of the selected once-daily formulation. The Company and Eisai demonstrated results from a Phase II trial to assess the efficacy and safety of lorcaserin as an aid to smoking cessation. In this 12-week, randomized, double-blind, placebo-controlled study, 603 active smokers were randomized to receive lorcaserin 10 mg once daily, lorcaserin 10 mg twice daily or placebo in a 1:1:1 ratio. The Company and Eisai demonstrated results from Eisai's pilot study to assess as the primary endpoint the safety of lorcaserin and phentermine when co-administered.

Recent News

ARNA reported a loss of 11 cents per share in the third quarter of 2015, narrower than the year-ago loss of 13 cents per share. Total revenues grew 11.9% year over year to \$9.1 million, surpassing analyst estimates of \$8 million. In addition, Arena recently announced a restructuring plan to improve efficiencies and cut costs. The company said that it will remain focused on key R&D programs including the APD334 program (phase II study ongoing for ulcerative colitis, potential for additional indications beyond inflammatory bowel disease through small pilot studies), ralinepag (phase II study ongoing for pulmonary arterial hypertension (PAH), APD371 (in a multiple-ascending dose study with top-line results expected in the first quarter of 2016) and the Belviq CVOT – CAMELLIA. The company also plans to submit an application for FDA approval of a once-daily formulation of Belviq by year end. The company plans to cut its U.S. workforce by 35% (approximately 80 employees). Arena expects this move to reduce annualized cash expenditures for personnel by about \$11 million. The company intends to implement additional cost control measures like reductions at its Swiss manufacturing facility. Arena also announced that it will not be pursuing certain lifecycle management programs for Belviq including for use in combination with phentermine for weight management and smoking cessation. Research &

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development expenses declined 10.1% year over year to \$22.1 million. General & administrative (G&A) expenses increased 12.4% year over year to \$9.0 million.



Verdict

Although Arena's third quarter loss was narrower-than-expected, analysts remain concerned about challenges being faced in growing Belviq sales in the obesity market. Shares have been in a slump for the past five months, reaching a new 52 week low on Monday. Positive comments from management provide comfort for long investors, however time horizon is a key component of the investment strategy related to ARNA. A quick turnaround is not expected from this small cap, however be certain that the large players are watching for an opportunity to pounce on Companies with candidate drugs that have potential.

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Aeterna Zentaris Inc. – Struggling from the Sidelines

Summary

Aeterna Zentaris Inc., incorporated on September 12, 1990, is a Canada-based specialty biopharmaceutical company engaged in developing treatments in oncology, endocrinology and women's health. The Company has three wholly owned direct and indirect subsidiaries: AEZS GmbH, based in Frankfurt, Germany, Zentaris IVF GmbH, a direct wholly owned subsidiary of AEZS Germany based in Frankfurt, Germany, and Aeterna Zentaris, Inc. The Company's drug development efforts are focused on two compounds, zoptarelin doxorubicin and Macrilen, which are in clinical development, and on two oncology compounds (an Erk inhibitor and LHRH-disorazol Z product candidates), which are in pre-clinical development. The Company's principal product candidates include zoptarelin doxorubicin and Macrilen in oncology and endocrinology. The Company's Zoptarelin doxorubicin is a type of compound known as a cytotoxic conjugate. Zoptarelin doxorubicin represents a hybrid molecule composed of a synthetic peptide carrier and a chemotherapy agent, doxorubicin. The compound is an intravenous drug in advanced clinical development that directs the chemotherapy agent specifically to Luteinizing Hormone-Releasing Hormone-receptor expressing tumors, resulting in more targeted treatment with potentially less damage to healthy tissue. Macrilen (macimorelin acetate) is an orally available peptidomimetic ghrelin receptor agonist that stimulates the secretion of growth hormone by binding to the ghrelin receptor (GHSR-1a). Macrilen has been granted orphan-drug designation by the FDA for use in evaluating growth hormone deficiency.

Recent News and Analysis

Aeterna Zentaris recently announced that the holders of its issued and outstanding common shares ("Common Shares") approved a share consolidation (the "Consolidation") and that the Company has determined that the Consolidation ratio will be 100-for-1. The Company intends to implement the Consolidation in the coming days and will shortly provide all relevant details regarding the Consolidation, including its effective date and the date on which the Common Shares are expected to commence trading on a post-Consolidation basis on the NASDAQ Capital Market and the Toronto Stock Exchange and information for registered and beneficial shareholders to exchange their pre-Consolidation for post-Consolidation Common Shares. The Company also announces that Mr. Marcel Aubut is no longer a member of the Board of Directors effective today, November 16, 2015. Net finance costs were \$7.9 million for the three-month period ended September 30, 2015, as compared to net finance costs of \$1.8 million for the same period in 2014. The increase in net finance costs of \$6.1 million is mainly related to the change in the estimated fair value of the Company's warrant liability.

In addition to the share consolidation, the Company recently reported Q3 financials. Net loss for the three-month period ended September 30, 2015 was \$15.3 million or \$0.07 per basic and diluted share, as compared to \$11.3 million or \$0.20 per basic and diluted share for the same period in 2014. This increase is predominantly due to higher comparative net finance costs and to higher comparative selling expenses, partially offset by lower comparative R&D costs. At the opening of the third quarter, the

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Company had 139.9 million issued and outstanding common shares. On September 30 and November 4, 2015, the Company had 492.5 million and 632.7 million issued and outstanding common shares, respectively. The increase in the Company's outstanding shares during the quarter and subsequent to quarter-end through November 4, 2015, results from the issuance of 492.8 million common shares upon the alternate cashless exercise of Series B Warrants. Cash and cash equivalents were \$38.3 million as at September 30, 2015, compared to \$34.9 million as at December 31, 2014.



Verdict

Although the Company has made progress in transforming into a growth oriented pharmaceutical business, the share price remains under pressure due to dilution from exercise of 27 million Series B Warrants. At the beginning of the quarter, 26,812,308 Series B Warrants were outstanding. The Company finished the quarter with 6,880,170. As a result of the agreements reached with the major holders of the Series B Warrants on November 1, only approximately 0.8 million Series B Warrants will remain outstanding, representing approximately 2.7% of the number originally issued.

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While the dilution caused by the Series B Warrants is substantially ended, AEZS obtained shareholder approval for a share consolidation that should help the company remain listed on the NASDAQ-CM. Struggles and headwinds are keeping this stock low and helping it hold its falling trend. Maybe a turnaround is in the works following the consolidation.

KaloBios Pharmaceuticals Inc. – No Cash Leads to Wind-Down

Summary

KaloBios Pharmaceuticals, Inc., incorporated on September 19, 2001, is a biopharmaceutical company. The Company is focused on the development of monoclonal antibody therapeutics for diseases that represent a burden to society and to patients and their families. The Company has a portfolio of patient targeted antibodies using its Humaneered antibody technology to treat serious medical conditions. The Company operates through the development of pharmaceutical products segment. The Company's principal pharmaceutical product candidates that are advanced to the clinical development stage include: KB004, KB003 and KB001-A. The Company seeks to identify and develop products that may treat multiple indications through proof of concept studies.

Recent News and Analysis

The Company recently announced that it will wind down its operations and that it has engaged the Brenner Group to lead those efforts. Recent discussions around a number of possible strategic transactions have ended, and as a result, the company believes it is highly unlikely that continuing to explore strategic alternatives could generate a viable transaction within the time frame allowed by their limited cash resources. The company will discontinue its two current development programs, KB004, being studied in Phase 2 for certain hematologic malignancies, and lenzilumab, or KB003, scheduled to initiate Phase 1 development later this year in chronic myelomonocytic leukemia (CMML). KaloBios has engaged the restructuring firm of The Brenner Group to assist in the wind down of operations and liquidation of the company's assets. The company recently announced a reduction in operations and headcount affecting approximately 60% of the company's 28 employees. As a part of its wind down and handing over management of the wind down to The Brenner Group, the company expects to phase out the remaining employees over the next thirty to sixty days. As a result of these developments, the company will not be able to file its Form 10-Q for the third quarter, primarily due to resource constraints. As a part of its restructuring and winding down, the company has repaid in full its outstanding secured loan obligation to MidCap Financial, secured lender to the company, in the approximate amount of \$6.6 million

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Verdict

Not much left to say about KBIO; operations are winding down, assets are being liquidated, and debt has been repaid. Sometimes throwing in the towel is not the end of all good things but maybe the beginning of something better. A hard learned lesson for KBIO, but let us all learn the easy way.

Conclusion

Over the past year, the health-care sector has boomed with M&A activity and huge investment returns for those playing in this sector. Economic conditions have not been favorable for any particular sector, but health-care has dominated despite the general downtrends and speed bumps along the way. From recent social media attacks on the sector to scandals with some of the largest players, nothing has phased the growth. With aging baby boomers, care is more in demand than ever and companies will spot the opportunity and excel within. The four companies discussed in this report provide a glimpse of the opportunities available in health-care, even at the small cap level. Several have been identified as

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takeover candidates and some have discontinued all operations, but one thing remains; health-care will continue to thrive.

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