Biotech Sector Analyst Review
Focus on 4 Emerging Biotech Companies

Biotech Sector

The vast majority of biotech revenue is generated in Europe and the United States (where the segment has exhibited growth since 2009). Major players have, however, recently reported slower growth rates for U.S. sales compared with other parts of the world. This trend in revenue growth from emerging markets is expected to continue over the next five years as living standards and health care access improve, particularly in India, China, Brazil, and other emerging markets.

Revenues for the global biotechnology segment are projected to grow at an annual rate of 9 percent leading to 2019, to $444.9 billion. Greater overall investment, particularly in emerging economies, will largely drive this growth. In addition, a projected increase in the total number of adults aged 65 and older will likely cause an increase in demand for medical care and, in turn, biotechnology health products. Despite the growing proliferation of biosimilars (generic versions of biotech drugs for which patent protection has expired), biotech products are becoming increasingly difficult to duplicate and will likely prompt pharmaceutical companies to prioritize biotech-based product development in coming years.

While biotech R&D risks exist (e.g., manufacturing complexity, social and ethical issues), the segment continues to see great potential and that is representative of market innovation and investment. However, investor confidence lags pre-recession levels and limits revenue growth somewhat. Nonetheless, recent years have seen some positive news in relation to FDA approvals and U.S. IPOs, which may improve the segment's attractiveness. Biotechnology companies need to focus on improving R&D efficiency in the face of limited resources and investor skepticism.

Key success factors of the biotech industry include R&D, Medicare/Medicate, orphan drugs, the FDA approval process, and the company's current cash on hand for R&D funding. Analysts prefer a biotech firm that produce drugs that cure common diseases to orphan drugs that cure obscure disease. Also, analysts prefer treatment drugs to vaccines. Treatment drugs are used continuously and repeatedly, whereas vaccines are a one-time shot and are not nearly as lucrative from a financial perspective. A desirable company should have several products in development. There is a happy medium between a company being too focused, and a company having so many developing ideas and products that it

loses focus and spreads itself too thin. Investors should look at which stage the product pipeline is at on the FDA approval process. If a company is relatively new at the FDA process, investors can expect it to take longer for it to gain approval. It is for this reason that many small biotech companies will partner with larger, more experienced ones. The difference of one year in gaining approval can mean millions of dollars. Most biotech companies use equity financing instead of borrowing, partly because equity is cheaper and partly because many banks and creditors usually refuse to finance such high-risk ventures for which there is a gross lack of collateral.

KaloBios Pharmaceuticals Inc (NASDAQ:KBIO)

Summary

KaloBios is an American biopharmaceutical company that focuses on the development of monoclonal antibody therapeutics. The Company has a portfolio of patient targeted antibodies using its Humaneered antibody technology to treat serious medical conditions. The Company's principal pharmaceutical product candidates that are advanced to the clinical development stage include KB004 and KB003. KB004 is a Humaneered, anti-EphA3 monoclonal antibody, being investigated for treating both hematologic malignancies and solid tumors and is in simultaneous Phase I dose escalation study and Phase II trial. KB003 is a Humaneered anti-granulocyte macrophage colony-stimulating factor (anti-GM-CSF) monoclonal antibody that was developed for the treatment of severe asthma inadequately controlled by corticosteroids and is being investigated for other disease indications.

Recent News and Analysis

Earlier in January this year, the company’s President and CEO, David Pritchard, has decided to retire and also resign his position as a member of the company's Board of Directors. Around the same time, KaloBios also announced that its Phase 2 study of KB001-A for Pseudomonas aeruginosa infections in cystic fibrosis patients failed to meet its primary endpoint and that it would discontinue further development of KB001-A. Its share took a big hit in January due to the departure of Pritchard and the news on KB001-A.

On May 28, 2015, the company declared the appointment of Ronald A. Martell, to the position of Executive Chairman. Martell was serving as a member of the KaloBios Board of Directors. In this new role, he would work directly with the company's senior management team to refine and execute on the strategic plan to transition KaloBios to a focused monoclonal antibody company developing therapeutics for orphan oncology indications with high unmet medical need.

The company announced a reverse stock split on July 13, 2015 at a ratio of one share of newly issued common stock for each eight shares of issued and outstanding common stock. This proportionally reduced the total number of shares outstanding from approximately 33.0 million shares to approximately 4.1 million shares. Proportional adjustments were also made to all shares of common stock issuable under KaloBios' equity incentive plans.

The company announced on July 31, 2015 the FDA clearance of the investigational new drug (IND) application for KB003. The acceptance of this IND allows KaloBios to initiate an open-label Phase I study designed to evaluate the safety, pharmacokinetics and clinical activity of KB003 in patients with chronic myelomonocytic leukemia (CMML).

KaloBios's 2015 Q1 results shown that a net loss for the quarter ended March 31, 2015 was $9.6 million or $0.29 per common share, as compared to $10.4 million or $0.32 per common share for the same period in 2014. Research and development (R&D) expenses were $5.9 million for the quarter, as compared to $7.7 million for the same quarter in 2014. The decrease in R&D expense was primarily due to decreased clinical trial activity compared with the prior period, largely as a result of the completion of the KB003 Phase 2 study in patients with severe asthma in the first quarter of 2014. General and administrative (G&A) expenses were $3.4 million for the first quarter of 2015, compared to $2.5 million for the first quarter of 2014. The increase in G&A expenses was primarily due to costs incurred as a result of restructuring activities and due to the retirement of our former Chief Executive Officer, both of which occurred in the first quarter of 2015. As of March 31, 2015, KaloBios had cash, cash equivalents and investments totaling $30.2 million. KaloBios' shares have shown a high EPS growth of 42.9 percent in the last 5 years and the company has earnings growth of 9.4 percent YOY.

Verdict

The stock 20-day-moving average crossed the 60-day-moving average at the beginning of Jul 2015, predicting a fall in stock price. The share price dropped from $4.00 on Jul 1, 2015 to $2.10 on Jul 31, 2015. However, the Clearance of Investigational New Drug Application for KB003 in Patients with Chronic Myelomonocytic Leukemia from the FDA on Jul 29, 2015 send a positive signal to investor. A Hold position is recommended, and it is suggested that investors should watch the market closely for other signals.

Immunomedics Inc (NASDAQ:IMMU)

Summary

Immunomedics is an American clinical-stage biopharmaceutical company developing monoclonal antibody-based products for the targeted treatment of cancer, autoimmune disorders and other serious diseases. Using its technologies, the company has built a pipeline of nine clinical-stage product candidates. Its advanced product candidate is 90Y-clivatuzumab tetraxetan. It initiated a Phase III registration trial in January 2014 in patients with advanced pancreatic cancer. Its portfolio of wholly owned product candidates also includes antibody-drug conjugates (ADCs). Its advanced ADCs are IMMU-132 and IMMU-130, which are in Phase II trials for a number of solid tumors and metastatic colorectal cancer (mCRC), respectively. It also has a number of other product candidates that target solid tumors and hematologic malignancies, as well as other diseases, in various stages of clinical and pre-clinical development.

Recent News and Analysis

Immunomedics shares fell by more than 15% in early February after the company reported that it lost $0.12 per share during the fourth quarter and proposed an $85 million secondary convertible debt offering that could dilute current investors. The $85 million dollar offering will help provide stable funding for Immunomedics' R&D pipeline programs, which include the company's ongoing Phase 3 clinical trial for clivatuzumab tetraxetan as a pancreatic cancer drug, and the Phase 2 clinical trials for IMMU-132 and IMMU-130. During the company's recently finished fiscal second quarter, total costs, including spending on these trials, totaled $12.5 million, up from $9.8 million the year before. During the first six months of the company's fiscal year, total expenses reached $26 million, up from $20.9 million a year ago.

Shares have declined -17.25% to $2.11 on July 30, 2015, during its last trading session, after analysts at Jefferies downgraded the stock from Buy to Hold, while reducing the price target from $6 to $2, noting that their drug epratuzumab failed in phase three for chronic inflammatory disease lupus. Although there are few details at this point, Jefferies believes that partner UCB will likely discontinue this program with Immunomedics given the clearly negative outcome. Potential risks to Immunomedics' performance include clinical trial failure and risks related to regulatory approvals and commercial launch.

Company’s EPS declined by 18.2% in the most recent quarter compared to the same quarter a year ago. Earnings per share have declined over the last two years, the same is expected to continue in the coming year. During the past fiscal year, Immunomedics reported poor results of -$0.41 versus -$0.15 in the prior year. For the next year, the market is expecting a contraction of 24.4% in earnings (-$0.51 versus -$0.41).

The company, on the basis of change in net income from the same quarter one year ago, has underperformed when compared to that of the S&P 500 and greatly underperformed compared to the Biotechnology industry average. The net income has decreased by 23.7% when compared to the same quarter one year ago, dropping from -$9.51 million to -$11.76 million.

Return on equity has greatly decreased when compared to its ROE from the same quarter one year prior. This is a signal of major weakness within the corporation. Compared to other companies in the Biotechnology industry and the overall market, Immunomedics's return on equity significantly trails that of both the industry average and the S&P 500.

Net operating cash flow has significantly decreased to -$10.81 million or 69.99% when compared to the same quarter last year. In addition, when comparing to the industry average, the firm's growth rate is much lower.

The debt-to-equity ratio is very high at 18.04 and currently higher than the industry average, implying increased risk associated with the management of debt levels within the company. Despite the company's weak debt-to-equity ratio, the company has managed to keep a very strong quick ratio of 11.81, which shows the ability to cover short-term cash needs.

Verdict

Multiple operating issues, a downgrade from Jefferies, and an investigation from law firm Levi & Korsinsky, lead to a share price plunge at the end of Jul 2015. The analysis above suggests the firm is currently in a difficult situation. If no further positive signals in the near future appears, it is suggested that investors should sell-off the company’s stock sooner rather than later.

Pluristem Therapeutics Inc. (NASDAQ: PSTI)

Summary

Pluristem Therapeutics Inc. was founded in 2001 and based in Haifa, Israel. The firm focuses on the research, development, clinical trial, and manufacture of cell therapeutics products and related technologies for the treatment of various ischemic and inflammatory conditions. PLacental eXpanded (PLX) is the company's patented commercial products. PLX cells function as a platform that releases a number of therapeutic proteins in response to various local and systemic inflammatory and ischemic signals generated by the patient. PSTI's pipeline products include PLX-RAD (preclinical study) and PLX-PAD (Phase-II clinical trial). The company is also involved in the development and commercialization of a PLX cell-based product for the treatment of pulmonary arterial hypertension through its license agreement with the United Therapeutics Corporation; and commercialization agreement with CHA Bio&Diostech for conducting clinical trials and commercialization of PLX-PAD products in South Korea. PSTI was listed on NASDAQ on 2003. The stock has been also traded on the Tel Aviv Stock Exchange as well as Frankfurt Stock Exchange.

Recent News and Analysis

The Fundamental: The firm has multiple positive headlines in the first half of 2015.

As of Jun 30, 2015, PSTI prices its public offering of 6.8M shares of common stock and warrants to purchase up to 4.08M shares of common stock at $2.50 per share and related warrants. Each warrant will be eligible to purchase 0.6 of a share of common stock at $2.85 per share.

Besides equity financing, another source of funding for the firm is government's grants. The Israeli Ministry of Economy's Office of the Chief Scientist (OCS) awards a 11.1M Shekel grant ($2.9M) to Pluristem (NASDAQ:PSTI) subsidiary Pluristem Ltd. to support R&D activities for calendar 2015. The OCS award is designed to promote hi tech and biotech research and development in Israel. Under the terms of the grant, Pluristem Ltd. is required to pay royalties of 3-4% on sales of products and services derived from the technology developed with these funds and other OCS grants until 100% of the dollar-linked awards plus interest are repaid. No payment is required if no sales are generated.

PSTI also gets green light for fast track clinical trial in both Japan and Europe. This will help the firm tap into multi-billion dollar medical markets. On May 18, 2015, the firm announced to be chosen by the European Medical Agency (EMA) to be one of the six participations for the new Adaptive Pathway pilot project.

On Jun 1, 2015, the firm announced to be granted key cell patents in Asia, Russia, Mexico, and Israel. "Pluristem has been granted key patents in multiple important markets. We believe the continued expansion of our intellectual property assets fortifies our position as a leader in the development, manufacturing, and clinical application of placental-derived cell therapies," stated Pluristem CEO Zami Aberman. "These newest additions to our IP portfolio are significant as we pursue our strategy to bring PLX cells to markets worldwide."

As of financial position, the company's Account Payable (AP) has been doubling since 2012, changing from $3.1 M to $6.8 M. This is a result of an increase in both production and CAPEX investment. Cash on hand is stable at around $9 M. PSTI shares are by 24 major institutions. As of Jul 24, 2015, the consensus forecast amongst 4 polled investment analysts covering Pluristem Therapeutics Inc. advises that the company will outperform the market. This has been the consensus forecast since the sentiment of investment analysts deteriorated on Jul 24, 2012. The previous consensus forecast advised investors to purchase equity in Pluristem Therapeutics Inc. Share price high target is $8.00, low target is $4.00, with a median of $5.00.

Technical Indicators: Upward momentum

After reaching its peak in Feb 2015 at $3.72 per share, the stock has lost 22.10% of its value and currently traded at $2.39 per share. Nevertheless, the stock has developed a double bottoms pattern

since mid-Jun 2015. After reaching its second trough at $2.27 on Jul 27, 2015, the stock price has been increasing and close at $2.39 on Jul 31, 2015. The price soar is confirmed by an elevation in traded volume.

Verdict

From an investment standpoint, the picture looks positive for PSTI. Besides fundamental catalysts that indicate a potential growth for the firm, technical indicators point out a share price's upward momentum. With a price target ranging from $4.00 to $8.00 and the current trading price of $2.39, PSTI is obviously undervalued.

Arrowhead Research Corp (NASDAQ: ARWR)

Summary

Arrowhead Research Corporation develops novel drugs to treat intractable diseases in the United States. The company was formerly known as InterActive Group, Inc. Arrowhead Research Corporation was incorporated in 1989 and is headquartered in Pasadena, California. ARWR's principal products include ARC-520 (phase IIa clinical trial), Adipotide (phase I clinical trial), and CRLX-101 (phase II clinical trial). ARC-520 is an RNAi-based therapeutic that is in Phase IIa clinical trial to treat chronic hepatitis B virus infection; and ARC-AAT, a novel unlocked nucleobase analog containing RNAi-based therapeutic for the treatment of liver disease associated with alpha-1 antitrypsin deficiency. Its platform technology include Dynamic Polyconjugate platform, an RNAi delivery system that addresses multiple organ systems and cell types. While Adipotide is a clinical trial for the treatment for obesity and metabolic disorders, CRLX-101 is a clinical trial for various cancer types' treatment.

Recent News and Analysis

The Fundamental: An unstable financial position and a risky pipeline product

Company's financial position

As reported on May 11, 2015, the firm's net loss has been doubled since 2012, from a loss of $ 21.1 M to $ 53.3 M. This is mainly due to the firm increase in R&D expense (from $5.4 M in 2012 to $23.1 M), which is a good signal for a typical biotech company. However, ARWR need to come up with an efficient way for cost control. SG&A of the company nearly double within two years.

One of the company's advantage is its strong cash position. In 2012, the firm only had $3.4 M cash on hand. This number increases to $132.5 M in 2014. Also, as all three principal products of the firm are all in clinical phase, the main source of cash flow is from financing activity. The firm has been increasing sales purchase of stock from $10.9 M in 2012 to $185.5 M in 2014.

There were higher research and development expenses, primarily drug manufacturing costs, which increased $3.2 million, during the period, mostly related to ARC-520, as well as higher clinical costs, which increased $1.2 million. Clinical costs have increased, as we incur start-up cost from the CRO related to the planned ARC-520 Phase 2B studies. ARWR also incurred cost for second clinical candidate, ARC-AAT, of about $2.9 billion while ARC-AAT clinical trial costs in the comparable period were minimal. The primary drivers of the change in cash used in operating activities as compared to FY14 is consistent with the drivers of the change in operating expenses, aside from the $10.1 million acquired from process R&D cost.

The share price target ranges from $7.50 to $12.00 with a median of $9.00. Analysts consensus suggests a Hold with a performance expectation of Sector Performance.

Research and Development

The firm has been running multiple clinical trials but declined to disclose the result for data from the 3 and 4 mgs per kg cohorts for their main product ARC-520's clinical program. All the firm's products are in clinical phase, mostly in stage I and II. Source of cash for R&D funding is mainly from equity.

Technical Indicators: A risky short-term bet
ARWR reached its peak in mid-Jun 2015 at $7.44, then lost the momentum. Share price has lost 11.3% since May 2015, and currently is traded at $6.18 per share

Both MACD and MFI have been decreasing, confirming the share price's plunge as well as a cash outflow from the stock.

The 20-day-moving average (SMA) crossed the 60-day-moving average from the above on July 30, 2015, indicating a further decline of share price.

ARWR witnessed a decline in the market cap its shares dropped 1.51% on Jul 29, 2015. After the session commenced at $6.23, the stock reached the higher end at $6.3 while it hit a low of $6.01. With the volume soaring to 994,126 shares, the last trade was called at $6.185. The company has a 52-week high of $17.42. The company has a market cap of $368 million and there are 59,498,000 shares in outstanding. The 52-week low of the share price is $4.95.

Verdict

According to the fundamental analysis and technical indicator, ARWR is a risky bet. For speculative purpose, it is suggested that investors should wait for the firm Q3 earning conference and analyst-information day, when the firm's head of R&D deliver more in-depth information, to make investment

decision. On the other hand, with a one-year price target of $9.00, ARWR is currently undervalued and investor should watch out for an opportunity to enter the market.

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