BIOTECH HIT BY SENTIMENT RECOVERS ON STRONG FUNDAMENTALS

NOVEMBER 24, 2015

Biotech Sector – Strong Fundamentals Trump Opinions

When it comes to leadership in the stock market, the Biotech sector has filled that role quite well during this bull market. And it has been a great signal for market pullbacks and thrusts higher. Markets for both initial public offerings (IPOs) and mergers and acquisitions (M&A) in the biotech sector have been red-hot since last year. The biopharmaceutical industry posted $202 billion in M&A activity last year, with nearly a quarter (23.6%) of companies included on the NASDAQ Biotechnology Index taking part in M&A in 2015. Revenue among all biotechs jumped 44% to $67.1 million in 2014, up from $46.6 million the year before. Large biotechs (between $50 million and $300 million in revenue) saw the greatest increase, growing average revenue by 52% to $129.3 million. Small biotechs reported a 7% increase in average revenue, up from a decrease of 21% in 2013. Novel new drug approvals hit an 18-year high in 2014, with a total of 41 receiving (FDA) approval. 2015 has continued the high pace of drug approvals, with 29 approvals as of October 2015. A recent slump in the sector has temporarily stymied the IPO pipeline and caused valuations to drop. Notably, through mid-October, the NASDAQ Biotech Index has declined 23% from its all-time high in July 2015. This has set up the sector quite nicely for a rebound and a surge as the decline was likely due to sentimental factors while fundamentals for most companies remained strong. This report will look at four companies and their potential for breakouts.

Genetic Technologies Limited – History Repeating Itself

Summary

Genetic Technologies Limited, incorporated on January 5, 1987, is a molecular diagnostics company. The Company offers predictive testing and assessment tools to help physicians manage women's health. The Company's lead product, BREVAGenplus, is a clinically validated risk assessment test for non-hereditary breast cancer. The Company markets BREVAGenplus to healthcare professionals in breast healthcare and imaging centers, as well as to obstetricians/gynecologists (OBGYNs) and breast cancer risk assessment specialists, such as breast surgeons. The Company operates in Australia, the United States and Switzerland. The Company's subsidiaries include Genetic Technologies Corporation Pty. Ltd. and Phenogen Sciences Inc. The Company has launched the BREVAGen test across the United States through its subsidiary, Phenogen Sciences Inc.

Recent News and Analysis

The company recently commented on the American Cancer Society's recent changes to its breast cancer screening guidelines. These guidelines, which are aimed at women with an average risk of breast cancer, raised the recommended age for first mammogram to 45 and suggested women over age 55 switch to biennial mammograms. However, the recommendations also create clinical ambiguity by concluding that women between ages 40 and 44 should still have the choice to get annual mammograms, and that women 55 years and older should likewise have the opportunity to continue annual screenings.

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BREVAGenplus, a clinically-validated, genetically-based breast cancer risk assessment test, can help physicians resolve this ambiguity by identifying which women without a family history still warrant earlier and/or more frequent screening. BREVAGenplus offers a solution, by providing physicians with a more accurate assessment of a patient's risk of developing sporadic breast cancer. This assessment can help guide physicians and patients as they develop a personalized breast cancer screening plan.

Though this news is positive for the company, it doesn't quite warrant a 34% increase in the share price. The company has not recorded a profitable year since at least 2011, and has continue to exhibit a declining profit margin and a greatly increasing accumulated deficit; $-96.29 million as of Q2 2015. Reviewing the chart over the past several years, it can be seen that this stock gets pumped almost once a year around the same time and then falls back down to its steady share price of approximately $3.00. This is one to be cautious about.

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Verdict

Some time ago, this company was making headlines for generating spectacular gains in short burst before falling back down to its 200 day SMA. It appears that the time is upon us once again when GENE makes a massive move on relatively weak positive news before faltering back down. This is one that I will never support and will need a lot more than a few comments from management to change my opinion.

Can-Fite BioPharma Ltd. – Fundamentally Strong Long Term

Summary

Can Fite BioPharma Ltd is an Israel-based biopharmaceutical company. The Company develops new treatments for autoimmune diseases and cancer. The Company's drugs are CF101 for Psoriasis treatment, RA treatment, for the treatment of Keratoconjunctictivitis Sicca, for the treatment of Glaucoma, among others; and CF102 for the treatment of liver diseases. The Company has a research infrastructure including research laboratories and animal house facilities run by the development team. Can Fite BioPharma Ltd signed distribution contracts with a Kwang Dong Pharmaceutical Co. allowing distribution of CF101 for arthritis in Korea and Seikagaku Corp. for distribution in Japan. The Company operates three subsidiaries, Ultratrend Ltd, EyeFite Ltd and OphathaliX Inc.

Recent News and Analysis

The company recently announced development of its drug candidate CF102, which is currently in Phase II trials for hepatocellular carcinoma (HCC) the most common form of liver cancer, will be expanded into treatment for non-alcoholic steatohepatitis (NASH). NASH is characterized by excess fat in the liver along with inflammation and liver damage. It resembles alcoholic liver disease; however, it occurs in people who drink little or no alcohol. If untreated, NASH can lead to cirrhosis and liver cancer. According to the National Institutes of Health, NASH affects between 2% and 5% of Americans and the prevalence of NASH has been increasing, potentially due to increasing rates of obesity and diabetes. By 2025, Deutsche Bank estimates the addressable pharmaceutical market for NASH will reach $35-40 billion in size. As of today, while there are several companies developing drugs to treat NASH that are in preclinical and clinical development, no specific FDA approved treatment for NASH exists. Can-Fite currently has a U.S. Investigational New Drug (IND) application active with the U.S. FDA for CF102. CF102 is currently being evaluated as a second-line treatment for HCC through a global Phase II trial. Can-Fite has received Orphan Drugs Designation for CF102 for this indication in Europe and the U.S., as well as Fast Track Status in the U.S. Data from the Phase II HCC study is expected in 2016.

Anlaysts favor this company based on several factors. Firstly, the company has a strong balance sheet with $7.75 million in cash as of Q2 2015. Additionally, the company closed a registered direct

offering with institutional investors for gross proceeds of $9 million in Sept 2015 and again in Oct 2015 for an additional $4.8 million. These two new financings not only boost Can-Fite's balance sheet immediately, but further validate its technology and clinical programs. Current cash at hand can carry the company's operations into mid-2017 based on projections.

Secondly, the company has an attractive valuation as per analysts at Zack's Research. The company has three lead candidates in each category: CF101 for autoimmune disease (RA and Psoriasis), CF102 for liver cancer, and CF602 for glaucoma. The most advanced candidate is CF101. Can-Fite has completed a couple of Phase II studies of CF101 for RA with the most recent one achieving statistically significance based on the A3AR expression level as enrollment criteria. The company plans to initiate a Phase III trial of CF101 for RA late this year using the same enrollment criteria.

Verdict

The valuation given by Zack's Research assumes the final approval of the company's three lead clinical programs including RA, psoriasis and liver cancer. Any clinical/regulatory failure or delay will may have a negative impact on the company's shares. But overall, the company has a favorable risk/award profile for investors with a long term investment horizon.

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Sarepta Therapeutics, Inc. – Taking Control with Some Help

Summary

Sarepta Therapeutics, Inc., incorporated on June 5, 2013, is a biopharmaceutical company. The Company is focused on the discovery and development of unique ribonucleic acid (RNA-targeted therapeutics for the treatment of rare, infectious and other diseases. The Company is primarily focused on advancing the development of its potentially disease-modifying Duchenne Muscular Dystrophy (DMD) drug candidates, including its lead DMD product candidate, eteplirsen, which is an antisense PMO therapeutic in Phase III clinical development for the treatment of individuals with DMD who have an error in the gene coding for dystrophin that is amenable to skipping exon 51. The Company is also developing therapeutics using its technology for the treatment of drug-resistant bacteria and infectious, rare and other human diseases. The Company's lead DMD product candidate Eteplirsen, is an antisense PMO therapeutic in Phase III clinical development for the treatment of individuals with DMD who have an error in the gene coding for dystrophin that is amenable to skipping exon 51. Eteplirsen targets the most frequent series of mutations that cause DMD. Eteplirsen has been granted orphan drug designation in the United States and European Union. The United States Food and Drug Administration (FDA) granted eteplirsen fast track status. The Phase llb open label extension study, Study 202, met its primary endpoint of increased novel dystrophin as assessed by the measurements taken of muscle biopsies at 48 weeks. Data showed that at 144 weeks patients evaluable on the 6MWT showed a decline in walking ability at a rate slower than would be expected based on available DMD natural history data and a continued stabilization of respiratory muscle function was observed, as assessed by pulmonary function tests. Data at 168 weeks demonstrated continued ambulation across all patients evaluable on the 6MWT was observed, however, all patients showed a decline in distance walked on this measure since the week 144 time point; stability of respiratory muscle function was observed, as assessed by pulmonary function tests and good tolerability and no clinically significant treatment-related adverse events or serious adverse events reported.

Recent News and Analysis

The company recently announced that the Annals of Neurology published online positive efficacy and safety results from a Phase IIb long-term open-label extension study of eteplirsen in patients with Duchenne muscular dystrophy (DMD) amenable to exon 51 skipping. The study found that at three years of treatment, patients experienced a slower rate of disease progression when compared to untreated matched historical controls and the investigational drug continued to be well-tolerated. This analysis used historical data from the Italian Telethon Network and the Leuven Neuromuscular Reference Group for comparative analysis of 6MWT performance at baseline and Months 12, 24, and 36. Patients were matched to the eteplirsen group based on age, corticosteroid use and genotype. At 36 months, eteplirsen-treated patients demonstrated a statistically significant difference of 151 meters in

six minute walk test (6MWT), compared to the external cohort. The eteplirsen-treated patients experienced a lower incidence of loss of ambulation (16.7%) compared to natural history control patients (46.2%).

After the FDA report on Drisapersen, a product of BioMarin Pharmaceuticals (NASDAQ:BMRN) that as per clinical data on efficacy and safety profile did not meet FDA criteria for Duchenne Muscular Dystrophy (DMD) patients. After the announcement of this report, the stocks of Sarepta Therapeutics Inc., skyrocketed 27.96% to $33.36 on Friday and an additional 11.06% on Monday to close at $37.05. Drisapersen is a competitor product of Sarepta's eteplirsen for the same disease. Eteplirsen and Drisapersen belong to the same subgroup of patients with DMD. As both companies are in progress of developing the drug for the young boys has faced setbacks in the process. The critics raised very valuable question on a possibility of restrictions implemented by FDA, and then an approval comes for both medicines. This will raise a question on FDA NDA program status. Eteplirsen date of review is scheduled in 2016.

Verdict

One company's misfortune is another's golden ticket. This is the case with SRPT which has appreciated greatly after clinching most of the revenue and market segment from BioMarin. However, the final

verdict of FDA about the status of Drisapersen is still not very clear. If it is not approved by the FDA in next meeting, than there is a big chance for Sarepta to get hold of DMD market, but there is a big question mark as Sarepta's eteplirsen is under review. Investors must be very cautious before investing in both companies, as it may be a temporary hike in Sarepta's shares.

KaloBios Pharmaceuticals Inc. – Winding Down to Skyrocketing Way Up

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

Most recently, KBIO announced that it will wind down its operations and that it has engaged the Brenner Group to lead those efforts. Immediatley following that news release, the company's shares were experiencing significant volume and heavy price swings. This was the doing of infamous Martin Shkreli buying up shares in this dying company, only to gain control in the next several days. Once the news came out that Mr. Shkreli was involved, the stock soared absurd amounts. From as little as $0.90 on Nov 13, 2015 to as high as $45.82 on Nov 23, 2015; or an increase of 4991%.

Shkreli is best known for buying the rights to market drugs and raising their price as much as 5,000 percent. After buying the U.S. rights to Daraprim, which is used to fight infections in patients with weakened immune systems, Turing Pharmaceuticals raised its price from $13.50 to $750. It has since lowered it in response to the public outcry and Congressional concern.

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Verdict

Given the difficulties faced by KaloBios, whose drugs have underperformed in trials and whose CEO announced his retirement from the company in January, Shkreli could face an uphill battle turning the company around. Five-thousand percent has been a recurring figure in recent months for Shkreli. He, along with the broader pharmaceutical industry, became a lightning rod for criticism in September after Turing bought the 62-year-old drug Daraprim and quickly hiked the price by more than 5,000%. What the future holds for this company is anyone's guess. Certainly, there are a few out there kicking themselves for having missed out on a 5000% return in just 6 days; I know I am.

Conclusion

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The biotech sector is full of small and large companies that can at any time make massive gains. The very news and catalyst driven sector has certainly moved the overall market recently with large deals and large gains coming from every corner. Investment opportunities continue to present themselves in the sector and are waiting for the picking by patient investors who perform significant due diligence. Question every stock and question the activity. Using the past to predict the future can help many investors make the right decisions.

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Risk Factors

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