THE BIOTECH ROCKET IS RUNNING OUT OF FUEL: THREE STOCKS TO KEEP YOU SOARING

JULY 23, 2015

Biotech Sector – Growth leads to Instability

Investors are growing more nervous about the biotech sector with each passing day. New companies entering the public market are bringing with them immense growth paired with troublesome financials, resulting in later crashes. For examples, consider the IPO of Axovant Science (NYSE: AXON).

The company went public in October for 2014 and has already piled on $21 million in losses. The company has only one product candidate, an Alzheimer drug that was purchased from GlaxoSmithKline after it was tested on 1,250 patients in 13 trials and then stalled in development. What is incredible is that on the first day of trading AXON more than doubled the IPO price to $31.00 per share. Today, the shares of Axovant have retreated down to $17.00, following a rollercoaster ride between $16.75 and $31.17. Axovant is the epitome of the biotech sector; the sector is full of speculation, blind investing and significant losses.

Small to mid-cap biotech companies are most appealing to investors but also carry the most risk. The appeal comes from several biotech index trackers and ETFs which have experienced tremendous growth over the past year. The Fidelity Select Biotechnology fund (FBIOX), for example, has risen 27% so far this year, or nearly three times as much as the Nasdaq Composite. Several ETFs are doing as well or even better. The iShares Nasdaq Biotech ETF (IBB), which tracks biotech stocks on the Nasdaq, is up 26%. The SPDR Biotech ETF (XBI), which tracks the S&P Biotech Index, is up 39%. And the ALPS Medical Breakthrough ETF (SBIO), which began trading in early 2015, is up 47%.

This growth has attracted blind money into the sector with assumptions that if the entire sector does well, the chance of picking a company leading to significant returns is high, so just pick anyone of the bunch. However, Growth can be attributed to the 'easing' of regulation from the FDA in the US. The FDA approved 41 new drugs in 2014, up from 27 a year earlier. Companies and investors are trying to jump on this bandwagon in order to hit it big with the next blockbuster drug. However, many drugs in development will never attain FDA approval or are so narrow in their treatment specifics that the end result will never be a home run. For a junior biotech to succeed, the most important factor is reducing risk through developing a substantial pipeline of drugs. Focusing on one drug candidate is high unpredictable in the outcome, however, for whatever reason; investors continue to pile in money.

Despite the overwhelming amount of junior biotech companies, there is still money to be made by investors. To succeed within the explosive biotech sector, candidate companies need to be chosen carefully and with a strict set of guidelines.

Three companies immediately stand out from the pack of small – mid cap companies. These are Aeterna Zentaris (NASDAQ: AEZS), Synthetic Biologics (NYSE: SYN) and CytRx Corporation (NASDAQ: CYTR). All three have promising drug pipelines with at least five candidate drugs in various stages of testing and

trials. Financially, each company is similar in that they are not yet profitable, however potential for each exists.

Aeterna Zentaris is certainly the Speculator

Summary

Aeterna Zentaris is a specialty biopharmaceutical company, engaged in the development and commercialization of novel treatments in oncology, endocrinology, and women's health. The company's product pipeline includes MACRILEN, which completed the Phase 2 trial for use in the diagnosis of adult growth hormone deficiency; and zoptarelin doxorubicin, which is in Phase 3 clinical study in endometrial cancer (ZoptEC) of the compound in women with advanced, recurrent, or metastatic endometrial cancer. It is also developing two oncology compounds, including an Erk inhibitor and luteinizing hormone-releasing hormone-disorazol Z product candidates, which are in pre-clinical development.

Recent News and Analysis

The company recently announced it has reached its goal of recruiting 500 patients for its pivotal Phase 3 ZoptEC (Zoptarelin Doxorubicin in Endometrial Cancer) clinical study with zoptarelin doxorubicin in women with advanced, recurrent or metastatic endometrial cancer. The trial is being conducted in over 120 sites in North America, Europe and Israel. The primary efficacy endpoint is improvement in overall survival. Following its first pre-specified interim analysis last April, a Data and Safety Monitoring Board recommended that the ZoptEC Phase 3 study continue as planned. A second interim analysis is expected during Q4, 2015 at approximately 192 events, with the final analysis planned at an anticipated 384 events. The trial is expected to be completed by the end of 2016. In addition to the developments in ZoptEC, the company has three drug candidates in pre-clinical studies, and has moved Macrilen into Phase 3 trials for the evaluation of adult growth hormone deficiency.

Shares of AEZS have retreated dramatically over the past year, falling from a high of $1.54 to as low as $0.20. The drop started when Aeterna Zentaris' Macrilen drug was not approved by the FDA in Nov 2014. Shares of AEZS have been falling ever since. It is believed the company has reached a bottom and should begin an upward trend. This, of course, is with the assumption that the ZoptEC trials are successful and obtain approval in the future. Chances of this appear higher as it was last reported that the analysis of the drug by the FDA recommended continuing with the next set of trials.

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AEZS is certainly the speculator in this trio of companies. It is trading at a significant discount to the 52 – week high and certainly has the potential to reach those levels again. However, success rides heavily on the success of the Phase 3 trials for ZoptEC. If unsuccessful in Phase 3 trials, the company does have several more drug candidates which it can continue to develop and hope for a home run.

CytRx; the runner up

Summary

CytRx Corporation operates as a biopharmaceutical research and development company specializing in oncology. The company's product candidate is aldoxorubicin, which is in Phase III clinical trial as a therapy for patients with soft tissue sarcomas (STS) whose tumors have progressed following treatment with chemotherapy; in Phase IIb clinical trial in small cell lung cancer; in Phase II clinical trial in HIV-related Kaposi's sarcoma; in Phase II clinical trial in patients with late-stage glioblastoma (brain cancer); in Phase Ib trial in combination with ifosfamide in patients with soft tissue sarcoma; and in Phase Ib trial in combination with gemcitabine in subjects with metastatic solid tumors. It also has completed Phase 2b and Phase 1b/2 clinical trials with aldoxorubicin as a first-line therapy for STS; a Phase 1b clinical trial of aldoxorubicin in combination with doxorubicin in patients with advanced solid tumors; and a Phase 1b pharmacokinetics clinical trial in patients with metastatic solid tumors.

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Recent News

The company recently announced the pricing of its previously announced underwritten public offering. CytRx is offering 9,100,000 shares of common stock at a public offering price of $2.75 per share for gross proceeds of approximately $25.0 million, prior to deducting underwriting discounts and commissions and estimated offering expenses payable by CytRx. CytRx intends to use the net proceeds of the offering to fund clinical trials of its drug candidate aldoxorubicin and its drug discovery activities and for general corporate purposes, which may include pre-commercialization activities relating to aldoxorubicin, working capital, capital expenditures, research and development and other commercial expenditures. CytRx has granted the underwriters a 30-day option to purchase up to an additional 1,365,000 shares of common stock. The offering is expected to close on or about July 24, 2015, subject to the satisfaction of customary closing conditions.

Though the news is very similar to that of Synthetic Biologics, the important difference in the discount offered to the market price of the shares. The stock of CTYR peaked at nearly $5.50 per share before falling due to a correction in the price. It is difficult for investors to reward a company for raising cash for advancing projects by offering shares at a significant discount to the market price. It goes back to the question of whether management is losing confidence in the company. Since reaching the 52 – week high in late April, the company has experienced significant retreats in share price and it seems that this trend is here to stay for the long run.

Verdict

CytRx was a darling in the biotech space for the majority of 2015. Shares appreciated significantly since January. In April a correction occurred and shares have not recovered since. This is solely a result of

management raising cash at a significant discount to the market price of the shares indicating to investors the lack of confidence in the company. Though it is believed the company does have an upside, that upside is quite a distance away. The cash CytRx raised will allow it to move several drugs into Phase 2 trials; should those be successful, management might raise their valuation of the company.

Synthetic Biologics – The Clear Winner

Summary

Synthetics Biologics, Inc. is a clinical-stage biotechnology company that develops pathogen-specific therapies for serious infections and diseases with a focus on protecting the microbiome. It is developing an oral biologic to protect the gut microbiome (gastrointestinal (GI) microflora) from intravenous (IV) antibiotics for the prevention of C. difficile infection; an oral statin treatment to reduce the impact of methane producing organisms on irritable bowel syndrome with constipation (IBS-C); and a monoclonal antibody combination for the treatment of Pertussis. The company is also developing a Phase II oral estriol drug for the treatment of relapsing-remitting multiple sclerosis (MS) and cognitive dysfunction in MS. It has collaboration agreements with Intrexon Corporation, The University of Texas at Austin, and Cedars-Sinai Medical Center; sublicense agreement with Meda AB; and license agreements with McLean Hospital and The Regents of University of California.

Recent News and Analysis

Synthetic Biologics recently announced that it has closed the public offering of 15.3 million shares of common stock, including the fully exercised over-allotment option by the underwriters covering 2.0 million shares, at an offering price of $3.00 per share. The total gross proceeds of the offering, including the exercise in full of the over-allotment option, were approximately $46.0 million. Net proceeds to the Company, after deducting the underwriters' discount and other estimated expenses, are expected to be approximately $42.6 million. The Company anticipates using the net proceeds from the offering to fund its clinical programs including Phase 2 clinical candidates, SYN-004 for the prevention of C. difficile and SYN-010 for the treatment of irritable bowel syndrome with constipation (IBS-C), research & development, potential licensing and acquisition of intellectual property, investments in and acquisition of complementary businesses or partnerships, and for general corporate purposes.

This recent equity raise was a disappointment to many investors as shares of SYN were trading well above the $3.00 offering price before this announcement. Shares fell last week on the day of the announcement but have since recovered to approximately $3.45. The raise gives the company enough cash to conduct trials on several of its drug candidates. Given the recent movement in the price, it is expected that the share continue to appreciate as the company continues to deliver on its guidance. Success in Phase 2 trials will surely send this stock flying to its 1 – year target price of $7.50 as reported by Maxim Group via Yahoo Finance.

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SYN has great potential especially after the recent offering suggesting investors are willing to pay up for the story at a hefty $3.00 a share. The company needed the cash and convinced investors that they will be able to profit on their principal. SYN has an extensive pipeline of drugs with four having completed Phase 1 trials and are expected to move on to Phase 2 trials. Synthetic Biologics is the certain winner of the trio, with the most upside potential and least amount of risk involved.

Conclusion

The biotechnology sector has provided investors with spectacular returns over the past several months. Many biotech ETFs and indices have outpaced the overall market in growth and continues to do so. However, not every company is a winner and there are far more losers in the bunch. The trio of companies discussed in this article provides a good summary of the small to mid-cap biotech space with most of those companies not being profitable and only some having low risk and high potential for returns. In the case of CytRx, Aeterna Zentaris and Synthetic Biologics, the clear best choice is Synthetic Biologics given the stages of development its drugs are entering, the diverse pipeline the company possesses and the confidence management has in the company. These are necessary factors for a biotech to be successful even if not every drug candidate receives full FDA approval. SYN will hold its ground and will likely offer the most potential upside with the least amount of risk.

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A complete list of filings including the risk factors for AEZS can be found here: http://www.sec.gov/cgi-bin/browse-edgar?CIK=aezs&Find=Search&owner=exclude&action=getcompany

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