
STRAYING FROM THE PATH: FOUR BIOTECH'S LINING UP FOR BREAKOUTS

Biotech Sector – Catalyst Driven to New highs

Though investors are growing more nervous about the biotech sector, there exist opportunities that may separate some from the overall trend to lead their own course. Newly listed biotech's come with significant risks; weak financials, high burn rates, and weak balance sheets. Companies that have potential to do well are those that have overcome several obstacles of developing drugs and are in stages near FDA approval and marketability. This report focuses on four such companies with upcoming catalysts that provide opportunities for investors.

Verastem Inc. – One Catalyst, Huge Upside

Summary

Verastem, Inc. is a biopharmaceutical company. The Company is focused on discovering and developing drugs to treat cancer by the targeted killing of cancer stem cells. The Company's programs target the Focal Adhesion Kinase (FAK) and the PI3K/mTOR signaling pathways. As of December 31, 2014, the Company had received orphan drug designation for the use of VS-6063 and VS-5584 in mesothelioma in the European Union and in the United States. The Company's FAK inhibitor VS-4718 and its dual mTORC1/2 and PI3K inhibitor VS-5584 are in Phase I clinical trials in patients with cancers. The Company has technology to create a stable population of cancer stem cells that it uses to screen for and identify small molecule compounds that target cancer stem cells. The Company's solution includes the discovery and development of oncology therapeutics targeting cancer stem cells (CSCs). The Company is engaged in running clinical trials in cancers where CSCs were implicated in disease progression, including mesothelioma, ovarian, non-small cell lung and other cancers, such as breast cancer.

Recent News and Analysis

According to analysts, Verastem, Inc. is expected to report earnings per share for the current fiscal quarter of \$-0.45. This is the consensus mean estimate based on the individual covering sell-side analysts' reported numbers. The company last reported earnings for the period ending on 2015-03-31 of \$-0.46. The reported number was -0.05 away from the consensus estimate, or a surprise factor of -12.2. Should Verastem report with a positive surprise factor, share price will certainly reflect this with a significant push upwards. Without a doubt, Verastem's biggest catalyst is a clinical trial called Command, testing VS-6063 in patients with mesothelioma, a form of lung cancer. The 350 to 400 patients expected to enroll in the trial have already responded to a combination of Eli Lilly's (NYSE: [LLY](#)) Alimta and a platinum-based chemotherapy but haven't yet progressed following treatment. The estimated completion date for this study is December 2016 while the estimated primary completion is July 2016. Given the patients positive response to other drugs, Verastem has high hopes of positive results coming from this study. Should this be the case, shares of Verastem will experience a massive raise both leading up to the study completion in December and result release in July 2016.

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Verdict

Of the four stock presented in this report, Verastem certainly has the most significant upcoming catalyst accompanied by huge upside potential. The stock is currently trading near the 2016 low and should see a reversal into the positive direction shortly. It is difficult to estimate how high this stock can go given positive results come from ongoing trials, but surely the upside is favorable. For long term investors that participate in the oncology and hematology space, this is certainly one for your portfolio.

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Spectrum – Short Term Winner

Summary

Spectrum Pharmaceuticals, Inc. is a biotechnology company. The Company is engaged in commercial and drug development operations with a focus on hematology and oncology. The Company is engaged in acquiring, developing and commercializing the pipeline of late-stage clinical and commercial drug compounds. The Company market five drugs for the treatment of cancer, which includes FUSILEV injection for patients with advanced metastatic colorectal cancer and to counteract certain effects of methotrexate therapy; ZEVALIN injection for patients with follicular non-Hodgkin's lymphoma; FOLOTYN injection for patients with relapsed or refractory peripheral T-cell lymphoma (PTCL); MARQIBO injection for patients with Philadelphia chromosome–negative acute lymphoblastic leukemia, and BELEODAQ injection for patients with relapsed or refractory PTCL.

Recent News

Spectrum has attracted some recent attention from investors with expectations of positive news. Firstly, SPPI has announced it will host a teleconference and webcast on Aug 6, 2015 with management to discuss the second quarter 2015 financial results, provide an update on the Company's business, and discuss expectations for the future. Analysts estimate SPPI will report earnings of \$-0.22 per share according to four analysts polled by Zacks Research. In terms of price targets, sell-side brokerage firms are projecting that the stock will reach the range of \$6-10. The average number taken from the 4 surveyed analysts, often referred to as the consensus price target, stands at \$7.75. Should SPPI meet or exceed expectations, investors will surely reward the company with an increase in share price. This is surely a short term catalysts expected to have significant effect on the company's stock. Secondly, in late December, Spectrum filed a new drug application for a product that has created quite a bit of buzz among the Spectrum faithful, Captisol-enabled (CE) melphalan. While CE melphalan will most certainly be FDA approved, and a preferred drug for multiple myeloma patients prior to stem-cell transplants, it likely won't replace what was lost with Fusilev - profitability. This, a more long term catalyst, is what is casting a shadow over the fate of this tock. Back in 2012, Fusilev had sales over \$200 million, but competition caused sales of Fusilev to fall 70%. The effect of this loss has been quite meaningful to Spectrum's top and bottom line. Spectrum may gain some lost revenue with the launch of CE melphalan, but like all new launches, its peak sales won't be achieved instantly. It might take Spectrum four years to realize \$80 million in sales from the product, and initially, costs are going to be higher as it markets, manufactures, and shares revenue on lower sales of CE melphalan. With CE melphalan being like most of Spectrum's other products, an improved version of an older drug, there is little hope that the company's margins will improve, or that it'll be profitable near-term. Since the Fusilev debacle, Spectrum's operating margin has crumbled.

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Verdict

Near term catalysts for SPPI certainly look and feel more positive than long term. Spectrum experienced a tough loss with the Fusilev drug and recovery from this will be difficult. Though the new drug will bring in revenue, it is unlikely to make up for the losses incurred from Fusilev. It is believed that SPPI will meet analyst expectations and will experience a slight bump in share price over the next several days. Long term, it is believed that the stock price will hover around the current market price and only a significant material change could break that trend. Certainly a short term 'Buy' and a long term 'Hold'.

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BDSI and its Many Catalysts

Summary

BioDelivery Sciences International, Inc. is a specialty pharmaceutical company. The Company develops and commercializes, either on its own or in partnerships with third parties, applications of approved therapeutics to address important unmet medical needs using drug delivery technologies. The Company develops pharmaceutical products aimed principally in the areas of pain management and addiction. The Company's products and certain of its product candidates utilize the BioErodible MucoAdhesive (BEMA) drug delivery technology, a small, erodible polymer film for application to the buccal mucosa (the lining inside the cheek). The Company's United States Food and Drug Administration (FDA) approved product, ONSOLIS (fentanyl buccal soluble film), as well as its approved product BUNAVAIL (buprenorphine and naloxone buccal film) and its product candidate, BELBUCA utilize its BEMA technology.

Recent News and Analysis

Most recently on the news front BDSI announced that Enoch Bortey, Ph.D., has joined the company as Vice President of Clinical Biostatistics and Data Systems. In this capacity, Dr. Bortey will be responsible for overseeing the global design and development of the biostatistics function, translating the development strategies into tactical statistical plans to support product development objectives. Though not very interesting, there are several upcoming catalysts for BDSI that should have a positive effect on the company's share price.

The first catalyst to watch out for will be a regulatory decision slated to take place in the fourth quarter for BDSI's drug Belbuca. Belbuca is indicated for the treatment of moderate to severe chronic pain. The regulatory decision is expected to take place in the fourth quarter of 2015, based on the announcement of the FDA acceptance of the filing. This decision will be very important to Biodelivery shareholders, as the company will be eligible for a milestone payment of up to \$50 million upon FDA approval of the drug. The drug is partnered with Endo International (NASDAQ:[ENDP](#)). The approval of this drug is expected to generate much needed low cost revenue for BDSI, improving margins and profitability. Onsolis is Biodelivery's product for breakthrough cancer pain in opioid-tolerant patients. Biodelivery hopes to file a data package with the FDA soon, which will allow for FDA approval in 2015 followed by market release. After re-acquiring the rights to Onsolis, Biodelivery has been preparing the data package to get the FDA's go-ahead to re-introduce the product. The projected timeline for the FDA decision would probably be at the end of 2015, which should allow for Biodelivery to re-introduce the product in early 2016.

Most positive of these catalysts is the potential in gaining strength in the balance sheet. The company's current burn rate of \$17.6 million quarterly is expected to remain stable for the remainder of the year. The company reported over \$63 million in cash to close the first quarter of 2015 and an injection of \$50

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million is expected given the approval of Belbuca. The milestone payment from Endo should help to stave off any immediate need for dilution; making current shareholders very happy.



Verdict

With many upcoming catalysts, it appears as though BDSI is a very attractive investment given its current share price is hovering near the 52 – week low. The upcoming catalysts have the potential to substantially move the stock higher for the rest of the year, presenting a very good and profitable opportunity for investors.

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Catalyst Pharma – A Gamble for the Risk Averse

Summary

Catalyst Pharmaceuticals, Inc., formerly Catalyst Pharmaceutical Partners, Inc., incorporated on July 7, 2006, is a biopharmaceutical company. The Company is focused on developing and commercializing therapies for people with rare debilitating diseases. The Company has three drugs in development: Firdapse, CPP-109 and CPP-115. The Company's Firdapse consists of the phosphate salt of amifampridine. Firdapse is used for the treatments of Lambert-Eaton myasthenic syndrome (LEMS) and congenital myasthenic syndromes (CMS). The Company is conducting a Phase III trial to determine the safety and efficacy of Firdapse in the treatment of LEMS. The Company's CPP-115 is a gamma-aminobutyric acid (GABA) aminotransferase inhibitor. CPP-115 is used for the treatment of addiction and epilepsy. The Company is evaluating CPP-115 in a Phase 1(b) multi-dose safety and tolerance study. CPP-115 has been granted Orphan Drug Designation by the Food and Drug Administration (FDA) for the treatment of infantile spasms and Orphan Medicinal Product Designation in the European Union, for West syndrome (a form of infantile spasms). The Company's CPP-109 (vigabatrin) is a gamma-aminobutyric acid (GABA) aminotransferase inhibitor. CPP-109 is used to treat addiction.

Recent News and Analysis

Most recently, CPRX announced the initiation of a rolling submission of a NDA to the FDA for Firdapse for the treatment of Lambert-Eaton Myasthenic Syndrome (LEMS). Firdapse has received Breakthrough Therapy Designation from the FDA for the treatment of LEMS, as well as orphan drug designations for LEMS and congenital myasthenic syndromes (CMS). The company expects to complete the submission of the NDA in the fourth quarter of 2015, at which time the company will be requesting a Priority Review of their application.

Thus far the company has spent millions to develop this drug but has yet to recognize any revenue. If all goes well, as the company expects, the drug - whose potential cost to patients could be in the high five figures or even six figures - will receive the go-ahead from the FDA early next year. This is certainly an upcoming catalyst for CPRX and appears to have high potential for marketization. The response from both patients and doctors has been positive; time is the only limiting factor for CPRX to begin generating revenue.

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Verdict

It appears as though the tail wind that has been pushing CPRX's stock ahead is only getting stronger. As we approach the decision from the FDA, investors are becoming more and more excited as reflected by the share price. Though CPRX is trading near its 52-week high, the potential upside given full FDA approval is believed to be significant. It may be a gamble to go long CPRX at this time, but the rewards could be great.

Conclusion

The biotech sector has seen explosive growth in recent times. Analysts are predicting a pullback but investors continue to inject cash into the sector. I too believe the sector has grown too rapidly and will soon experience a decline but the above four stocks, all with upcoming catalysts, are setting up for straying from the expected downward trend of the sector. It is believed that Verastem, BioDelivery

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Sciences and Catalyst Pharmaceuticals are long term winners. Given the positive news coming from each of these companies, it is only a matter of time until these show their true colors. Spectrum on the other hand has short term potential. With upcoming releases of Q2 earnings, the company has some upside, however long term it is believed the stock will not make much of a move and follow the rest of the biotech sector. Always do your due diligence and choose your winners.

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<https://www.sec.gov/edgar/searchedgar/companysearch.html>

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