

Seeking Alpha

3 Cancer Immunotherapy Biotechs With Catalysts For 2012

by: Chemistfrog November 16, 2011

With 2011 drawing to a close, biotech investors reflect on a year witnessing cataclysmic events such as the rise of Medivation ([MDVN](#)) from January's \$14 a share market cap of \$489 million to Tuesday's close of \$41.65 and market cap of \$1.45 billion as well as the demise of the mighty Dendreon ([DNDN](#)) falling from April's \$43 a share with a market cap \$6.55 billion to Tuesday's close of \$7.21 with a market cap of \$1.07 billion.

Investing in the biotech industry has its rewards along with its risks. Entrances into MDVN or DNDN at the proper times along with wise exits would have reaped phenomenal rewards. However, gains would have been minimal for the former with devastating losses for the latter if long entrances and exits were improper.

Upcoming catalysts for three relatively unknown biotechs can lead to huge gains for investors with the savvy to open positions before trials complete and data are reported. Even though modest gains are possible and even likely for those awaiting late stage entry into the companies' common stock, early entry before the attention of the masses could mean the difference between ten to fifty percent gains versus several hundred percent gains. Of the three biotechs, one is a recent and another an upcoming IPO for biotech companies with cancer drugs just beginning to garner the attention of investors. Although the medical community and regulatory agencies are familiar with these formerly private industry companies, they are currently well off the radar for the investment community. The three biotechs have novel approaches to attacking cancer and may help redefine how we approach cancer treatments in the future with immunotherapy approaches defining their platforms instead of the historical chemotherapy, radiotherapy and surgery that has defined the treatment protocol in the past.

With a market cap of about \$41 million and currently trading in the \$1.40's, ImmunoCellular Therapeutics ([IMUC.OB](#)) is an early stage biotech with a focus on the immunotherapy approach to fighting cancer. Its most advanced candidate is in Phase II trials and is termed ICT-107. It is a dendritic cell based cancer vaccine designed to fight cancer stem cells with the current indication targeting Glioblastoma multiforme, a common and aggressive form of brain cancer. The Phase I trial included sixteen newly diagnosed patients with Glioblastoma. Trial data indicated six out of sixteen patients treated with ICT-107 were disease-free after more than three years, with one of those patients remaining disease-free after almost five years (data is still be accumulated on the patient set). Median survival was increased almost two years (38.4 vs. 14.8 months) in patients treated with ICT-107 along with the standard of care relative to patients on the current standard of care of radiotherapy and Temozolomide only. The three-year survival

rate was 55% for ICT-107 patients versus 16% for historical data. No treatment-related serious adverse events have been reported to date.

Updates on the original Phase I patients are still forthcoming and are likely to be the next catalyst for the company's common stock. However, investors will also be eyeing enrollment completion for the Phase II trial in Q2 2012 with interim data analysis in Q3 or Q4 2012. If the Phase II data yield comparable results to the Phase I trial, ImmunoCellular Therapeutics will instantly be thrown into the spotlight not only for its novel approach of attacking Glioblastoma via its cancer stem cells, but also ensuring progression free survival and overall survival in patients with GBM. Their novel dendritic cell based cancer vaccine approach attacking CSC's (for more information on cancer stem cells please see [this article](#)) will be further legitimized and likely used to target other types of cancers. CSC's have been identified in cancers of the brain, breast, colon, ovary, pancreas, prostate, melanoma and multiple myeloma and will all be viable possibilities for this platform. Not a "one trick pony", ImmunoCellular is additionally working on other drugs with a dendritic cell vaccine targeting CSC's in ovarian cancer using ICT-140 with a likely Phase I study in 1H 2012 and ICT-121, an "off-the-shelf" cancer vaccine for recurrent GBM with a likely Phase I trial likely in 2012 as well. Success in any of these cancers would be tremendous for the company's product line as it expands, obtains partnership agreements and licensing or even becomes the target of Big Pharma looking to add a cancer vaccine division rather than creating a new one from scratch.

NewLink Genetics' ([NLNK](#)) IPO on Friday, November 11th raised \$43.4 million for the company and its advancing pipeline. Like ImmunoCellular, the company is primarily focused on immunotherapy treatment of cancers. Its lead product candidate is HyperAcute Pancreas cancer immunotherapy for surgically resected pancreas cancer that is well into a Phase III trial that is performed under the FDA's Special Protocol Assessment (SPA). The drug contains two non-patient specific cell lines engineered to express the enzyme a-Gal. The enzyme is not naturally present in the human pancreatic cancer cells, but the engineered cells do contain a similar molecular signature as the cancer cells. The company believes that the body will attack the engineered cells and by doing so will learn to fight the naturally occurring cancer cells found in the pancreas. The 70-patient Phase II trial met its primary endpoint with a median disease free survival of 14.2 months according to a recent [SEC filing](#). A recent analysis of the secondary endpoint indicated a one-year overall survival of 86%. Additional analysis on a 26-patient set receiving high-dose HyperAcute Pancreas immunotherapy demonstrated a median disease-free survival of 15.3 months and a one-year survival of 96%. These data were astounding and are likely attracting the attention of the medical community and Big Pharma as the American Cancer Society stated in 2010 that the mortality rate for pancreas cancer is 96% with one-year survival rates of 24%. NewLink has also indicated a positive safety profile for the drug to date.

The Phase III trial is expected to fully enroll by 2013, however interim data is expected well before then. Investors are urged to watch this company closely as multiple catalysts are possible any of which could drive the share price tremendously. NewLink presented

the Phase II data June 3-7 at ASCO 2011. Interim Phase III and follow up of the Phase II patient set could certainly be likely at [ASCO 2012](#) on June 1-5. In addition to the HyperAcute Pancreas trials underway, the company and its collaborators have also completed enrollment in a Phase I/II trial for HyperAcute Lung for non-small cell lung cancer (NSCLC) and a Phase II trial of HyperAcute Melanoma for Melanoma. In the Phase II arm of the HyperAcute Lung trial, interim analysis in December 2010 indicated median overall survival of 11.3 months and a one-year survival rate of 46%. According to the company, comparable precedent clinical trials of similar patients would have indicated a median overall survival of approximately 8 months. The company anticipates initiating a Phase IIB/III clinical trial in advanced NSCLC patients in the first half of 2012 and completing the first interim analysis in 2013. NewLink anticipates announcing their results from the HyperAcute Melanoma trial in the second half of 2011. The Phase IIB clinical trial in melanoma would likely initiate in 1H 2012. NewLink Genetics is a company for biotech investors to be watching 4Q 2011, 2012 and 2013 with multiple price-per-share-moving catalysts ensuing. Additional positive data from any of these three trials will legitimize the company's HyperAcute Immunotherapy pipeline and drive the company's value. More information on the HyperAcute platform and its working mechanisms is on the [company website](#).

The third company to key in on should be Verastem, Incorporated which is planning an IPO according to a [press release](#) on November 3rd. A timeframe or pricing has not been revealed yet, but this company should provide investors with multiple catalysts as it completes its IPO and starts its publicly traded future. Much like ImmunoCellular's ICT-107, Verastem's pipeline focuses on fighting cancer through cancer stem cells. Although still in pre-clinical development, investors, potential partners and even merger/acquisition candidates will be watching the company closely to ascertain what types of positions they should take in this fledging but exciting biotech.

Dr. Christoph Westphal is the company's CEO/Chairman and Verastem's largest shareholder with 20% ownership. He was also CEO and founder of Sirtris Pharmaceuticals, which was acquired by GlaxoSmithKline ([GSK](#)) in 2008 for \$720 million and cofounder/CEO of Alnylam ([ALNY](#)) of which Novartis AG ([NVS](#)) is 13.1% owner per the [company's website](#). Former Genzyme Corporation's long-time CEO [Henri Termeer](#) sits on Verastem's board of directors and provides invaluable insight and influence in the industry. Upon joining the board he was quoted as stating "I am delighted to join Verastem's Board of Directors and to work closely with this world-class scientific and entrepreneurial team. I believe Verastem's breakthrough work targeting cancer stem cells with novel small molecule drugs has the potential to revolutionize the treatment of breast and other major cancers." Verastem's future looks bright with a novel pipeline and phenomenal leadership.

At a time when many biotechs and other privately owned companies are wary of the IPO process with economic uncertainty dominating the headlines, novel cancer immunotherapy companies are confident enough in their platforms and potential marketability to assure investors of their successful and profitable futures as demonstrated by these latter two IPO's. 2012 will likely be an exciting and potentially

profitable year for those taking early, wise and justifiable positions in ImmunoCellular Therapeutics, NewLink Genetics and Verastem, Incorporated common stock. Investors should always utilize risk assessment as they make entrances, increase and reduce positions and interpret data and company financials. These three companies are in different stages of pipeline development and are at different levels of public maturity. Together, they represent good investment diversity for the immunotherapeutic approach to attacking one of man's most deadly enemies.

Disclosure: I have no positions in any stocks mentioned, and no plans to initiate any positions within the next 72 hours.