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An Industry Outlook With Analyst Vernon Bernardino

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| about: [NBS](#), includes: [AGEN](#), [AMGN](#), [DNDN](#), [GERN](#), [GSK](#), [IMUC](#), [MI](#), [OSIR](#), [PLX](#), [PSTI](#), [TEVA](#), [UTHR](#)**Disclosure:** I am long [NBS](#), [IMUC](#). (More...)

A couple of weeks ago I spoke with Brinson Patrick Securities analyst, Vernon Bernardino, after reading his analyst report on **NeoStem Inc** ([NBS](#)). The analyst offers a very bullish outlook, but also backs up his opinions with solid fundamental and macro analysis in a project that took him many months to complete. After more than a month since his call, I finally had the opportunity to speak with him, and below is a transcript of the key points taken from that conversation.

Brian Nichols

Last year has been quite bullish for biotech companies. Do you feel the biotech space will continue its positive momentum through 2013?

Vernon Bernardino

Correct! Biotech was a huge outperformer in 2012, up 41.7% as measured by the BTK (NYSE Arca Biotechnology Index). However, last year's gains were primarily driven by gains in large-cap, and most of the gains had been seen by the end of April. So far, the BTK is up 16.9% YTD vs. up 28.6% by this date in 2012. We (Brinson Patrick Securities) believe the biotech space will continue its positive momentum in 2013, but with high P/E ratios pointing to large-cap stocks as expensive, the rest of 2013 will be more of a stock picker's market in small-cap and mid-cap stocks.

Brian Nichols

I 100% agree with your outlook for the sector. With the sector's strong performance, it is interesting to see the correlation between now and last April. Perhaps we will see a continued trend? Anyways, one space within biotechnology that you have held highly is cell therapy/regenerative medicine. If you could explain why your outlook is so high including transitions that you've seen in recent quarters/years?

Vernon Bernardino

Our bullish stance on the stem cell space is driven by our analysis of how current players have emerged with lessons learned from past mistakes, such as with clinical trial design and manufacturing. We've seen **Dendreon Corp.** ([DNDN](#)) (Not Rated) blaze a trail in the space with the successful advancement of its cancer vaccine, *Provenge* (sipuleucel-T). However, the company's mistakes with its commercial manufacturing strategy make it almost unfeasible to realize margins that would lead to profitability. Our previous work (not published) shows that Dendreon has to sell almost \$500MM of Provenge to break even.

Whereas some of these mistakes were unique to the product, such as with Provenge, which requires a patient-specific manufacturing process, some of these mistakes resulted from the state-of-the-art technology being too early, especially when the regulatory path to approval was in evolution. Much groundwork still needed to be established and validated. As a result, some players, such as **Geron Corp.** ([GERN](#)) (Not Rated), were initial victims in the changing

environment. Geron had to burn significant amounts of capital to play catch-up with evolving FDA guidelines that required the company to establish assays that would demonstrate the batch-to-batch consistency of its investigational cell-based therapies. I believe more players will fall. However, several players, such as NeoStem, have figured out the hurdles and are implementing strategies. Keep in mind that these therapies won't benefit any patients if the company is under-capitalized to make them.

Brian Nichols

I recently read your research report on NeoStem and found it to be quite detailed. You put a \$6.00 price target on NeoStem; what catalysts do you foresee over the next 12 months that will propel the share price to that level?

Vernon Bernardino

Our \$6.00 price target is the result of a synthesis of several valuation methodologies and is admittedly speculative. However, we would remind investors that, when using a comparable company enterprise valuation analysis of stem cell companies, we derived a per share value of \$0.92 to \$1.00. We believe this result takes into account the current "wait and see" investor view in the space, but also highlights NeoStem's relative value vs. other stem cell companies. Our view has rewarded early investors, as the stock's already up 28% since our initiation of coverage.

In answer to your question, catalysts we believe have potential to propel the shares to \$6.00, which takes into account a 12-month time frame, include announcement of topline 6-month outcome data from the AMR-001 PreSERVE-AMI Phase II study in patients with post-acute myocardial infarction (MI) later this year. These are the sickest patients, at significant risk for major adverse clinical outcomes including sudden death, and where therapeutic advancements do not treat the underlying cause of disease progression, resulting in a recurrent risk of another MI down the road.

AMR-001 is NeoStem's proprietary preparation of autologous bone marrow-derived CD34+ cells and employs a novel ischemia-targeting strategy that would break the cycle of cardiac muscle damage and recurrent MI. Therefore, positive results with AMR-001 would represent a breakthrough in MI treatment strategy, and with almost 1MM people suffering MI in the US annually, the treatment of even just small numbers of post-acute MI patients represents a blockbuster market opportunity. We also believe announcement of 12-month data, anticipated in early 2014, would be another significant driver of the stock.

Brian Nichols

What's interesting about NeoStem is that aside from its clinical segment it also has a well-established manufacturing business. The cell product-manufacturing segment is a business that has always captured my curiosity especially as a number of companies, including **ImmunoCellular Therapeutics (IMUC)**, have made virtual business models. With PCT, NBS's manufacturing subsidiary, being part of several Phase II and III developments, what would you say is the near term potential for this one segment, based on your research? Are there other contract manufacturing companies with similar scope and expertise in cell therapy?

Vernon Bernardino

We believe Progenitor Cell Therapy (PCT) has unique exposure to the cell product manufacturing landscape. PCT recorded \$14MM in revenues in 2012 or 42.6% year-over-year (YOY) growth. This was partly driven by a change in accounting for revenue recognition implemented last year. As a result, we anticipate that 2013 cell therapy services revenues will only grow 8% YOY in 2013, as some revenue recognition was then shifted forward into 2012. As you point out, PCT stands to benefit from the advancement of its clients' clinical programs and contract needs. Therefore, we project cell therapy services revenue growth for PCT will re-accelerate to >50% annually, amounting for \$27MM in 2014 and growing to \$100MM by 2018.

By giving PCT revenues a 4-times multiple, this values NeoStem at \$108MM alone - its current market cap value. We believe NeoStem stock is currently ascribed value from the company's contract cell products development and manufacturing services subsidiary only. We believe this value recognizes the company's initial strategy of acquiring PCT, which critically positioned the company at the forefront of several emerging technologies. We, of course, believe this valuation discounts any contribution from AMR-001, which represents near-term upside potential.

Brian Nichols

What about the industry as a whole? Do you see 2013 as being a breakout year for all companies in the stem cell space? And what are the most significant milestones on the horizon?

Vernon Bernardino

Although we believe investor sentiment in the stem cell space will continue to be positive and grow in 2013, we believe only select companies will break out in 2013. Companies like NeoStem and another covered company, **Pluristem Therapeutics Inc. (PSTI)** (Market Outperform), are only now realizing positive results with their business strategy. For example, instead of developing its own cell therapy production process internally, NeoStem's transition began with acquiring PCT in January 2011. By focusing first on growing PCT's revenues, the company lowered the initial risk of investing in its own internal development programs, the company's strategy to transform itself into a cell therapy products development company.

Similarly, Pluristem began with a thorough characterization of its PLacental eXpanded (PLX) cells, which are maternal-side mesenchymal stem cells sourced from donated placental afterbirth. They also focused on the optimization of growth conditions for high-yield production of PLX cells prior to the initiation of mid-stage clinical studies and expansion into more than the initial target therapeutic area. We believe Pluristem has a competitive stem cell production technology with potential for application to treat multiple diseases.

Brian Nichols

With so much upside and developmental progress, what factors have kept the companies in the space at the relatively undervalued prices they are at now?

Vernon Bernardino

We believe current prices take into account the current "wait and see" investor view in the space, as some companies like Geron decided to de-emphasize the stem cell part of its product pipeline, or get out of the space altogether. As a result, stem cell companies remain undervalued because of the hurdles faced by the first movers we mentioned above. The space is also undervalued because it is difficult for would-be partners to assess what stem cell assets are worth. Hence, partnership announcements have been slow.

Companies with significant capital to invest, such as big pharma and large cap biotech, for example, would venture well away from their core technology expertise in leaping toward a view that cell-based therapies have pharmacological properties, which we believe they have. Both NeoStem and Pluristem, however, have shown that their stem cells can be targeted and have dose-response properties in a way similar to dosing with antibodies and even small molecule drugs. Results are also still relatively early (i.e., few are in Phase 3), as are refinements to the approach and the technology supporting them. With some exceptions, we anticipate the value of announced partnerships will be small at first.

For example, the out-license agreement Pluristem has with **United Therapeutics Corp. (UTHR)** (Not Rated) for the development and potential commercialization of PLX cell-based treatments for pulmonary hypertension included an upfront payment of \$7MM and has potential to receive regulatory milestone and other payments totaling \$55MM. On the other hand, **Mesoblast Limited (MSB.ASX)** (Not Rated) received \$320MM from Cephalon, now part of **TEVA Pharmaceuticals Inc. (TEVA)** (Not Rated), in exchange for 20% equity and joint rights for Mesoblast's bone marrow, cardiovascular, and neurological cell-based therapy development projects. The deal has a potential value worth up to \$1.7BN upon the achievement of key regulatory and clinical milestones. We anticipate seeing more of these blockbuster announcements in the next 12-15 months, lifting the stem cell space to higher valuations.

Brian Nichols

With all investments there are risks, but it seems as though you believe risk is priced into the stock; is this a fair assumption and what are the short and long-term risks with NeoStem?

Vernon Bernardino

The collective view of investors regarding risk and value is not consistently accurate. For example, with the value of NeoStem stock primarily driven by the value of PCT revenues, which in our view have a low-risk of missing analyst projections, we do believe risk is priced into the stock. As there is time before NeoStem announces results from a

high-risk event, such as top-line AMR-001 Phase 2 data later this year, the near-term risk for investors is potential dilution from a stock offering. However, with the stock at such low prices, we believe NeoStem management will manage its capital needs efficiently and wait until the proximity of announcing AMR-001 top-line prior to raising capital.

Brian Nichols

Lastly, what other companies or disciplines in the life science space do you feel will have strong returns for investors in 2013?

Vernon Bernardino

Our view of Dendreon notwithstanding, we are still bullish about the cancer immunotherapy space. As you mentioned, I have covered companies in this space in the past, but do not currently. I am restricted from making any recommendations; however, we have favorable views of companies with emerging Phase 2 cancer vaccine candidates.

There are also many late-stage cancer vaccines with data readouts expected in the next 6-9 months that we believe will be positive. One announcement that already occurred came from **Amgen Inc. (AMGN)** (Not Rated), which voted with its balance sheet when it acquired BioVex in March 2011 for \$425MM in cash plus the potential for an additional \$575MM in milestones, and recently announced positive top-line results in melanoma from OncoVEX (talimogene laherparepvec), the oncolytic vaccine initially in development by BioVex.

Another announcement we anticipate will be positive is data from **GlaxoSmithKline plc (GSK)** (Not Rated). GSK has ongoing Phase III studies to evaluate its investigational MAGE-A3 Antigen-Specific Cancer Immunotherapeutic (ASCI) in non-small cell lung cancer (initiated October 2007) and melanoma (initiated December 2008). GSK's vaccines use MAGE-A3, which is a tumor-specific antigen expressed in a large variety of cancers, including melanoma, non-small cell lung cancer (NSCLC), head and neck cancer, and bladder cancer, and contains QS-21, an adjuvant from **Agenus Inc. (AGEN)** (Not Rated) that is being studied in 17 clinical-stage vaccine programs. We believe an announcement of the results will lift sentiment in the space and be positive for valuations.

Conclusion

Although this interview has been shortened for grammar and readability, Vernon Bernardino provided a great assessment of this challenging space. His outlook is bullish and is based on a "trial and error" outlook, but also very precise fundamental and macro analysis. This is an undervalued space in biotechnology, and with good data it will appreciate with large gains; the key words being "with good data".

*On a final note, next Monday/Tuesday I will continue my interview analysis with experts in the space. These interviews have included analysts; [Stephen Potter](#) who was instrumental in the development of **Osiris Therapeutics' (OSIR)** Prochymal; [Dr. Robin Smith](#) who is the CEO of NeoStem; and [Monsignor Trafny](#) from the Vatican regarding the recent partnership with Stem for Life Foundation. Next week I will publish what I consider to be the best yet, and that is from one of the most decorated physicians in the space, Dr. Douglas Losordo who led the development of Baxter's Phase 3 CD34+ cell therapy and is also a leading scientific advisor for both NeoStem and the Stem for Life Foundation. His knowledge, experience, and opinions are priceless for someone considering an investment in the space.*