Progenics Pharmaceuticals (Nasdaq: PGNX)

Following on the success of Avanir and recent success with Eagle Pharmaceuticals (Nasdaq: EGRX) I've added another small biotech play to our Small Cap Gems portfolio. There are a couple of reasons for this addition in this volatile sector. The biotech sector had a deep and quick sell-off in early March this year. The vast majority of the big biotech stocks like Gilead Sciences (Nasdaq: GILD) and Celgene (Nasdaq: CELG) have fully recovered from that pull back and are at or near 52 week highs. Small caps had much deeper pullbacks from that air pocket and are still way under their highs earlier in the year for the most part.

That is starting to change as sentiment has improved on the space recently. Part of this could be “risk on” money fleeing the small cap energy sector which has been decimated on the plunge in oil prices since last summer. In addition, myriad small biotech companies have reported encouraging trial results recently and shot higher. Our own Avanir Pharmaceuticals soared 215% before closing out based on news that it was an acquisition target by a Japanese firm and one of other biotech/pharma holdings, Eagle Pharmaceuticals (Nasdaq: EGRX) popped 20% on the day it announced a deal with Teva.

With PGNX I also want to further diversify our Small Cap Gems portfolio within the small biotech area. Simply put, investing in the small biotech space is different than investing in other sectors. Some hedge funds employ PhDs in biochemistry but still get it wrong as much as they get it right. How drugs and drug compounds perform in actual trials is next to impossible to predict consistently. These stocks can soar or crater on every trial result. Diversification mitigates the volatility of holding only one or two stocks in the sector.

The small biotech sector calls for a different investing strategy. My philosophy is to take much smaller positions in a larger number of selections than in other sectors. One must realize that there will be many misses within the biotech portion of your portfolio. However, this should be compensated for by the occasional five or ten bagger. Avanir has us off to a good start having more than doubled since we tagged it as a good prospect in July then closed out our position in December.

Company Overview:

Our first small cap biotech recommendation in this report is Progenics Pharmaceuticals (Nasdaq: PGNX). This company has a market capitalization of just under $500 million. Progenics is developing a stable of products consisting of imaging and therapeutic agents to better detect and treat various forms of cancer and its associated effects. The stock of Progenics sold for just north of $7 a share prior to the big biotech sell-off in March. As I write this shares currently go for just under $7 after being added to our portfolio at $4.86.

The company’s lead product is called Relistor which was just approved to treat opioid-induced constipation (OIC) in patients with chronic non-cancer pain. This drug has been developed in partnership with Salix Pharmaceuticals (Nasdaq: SLXP) and the approval for the injectable form of this drug for this new indication triggered a $40 million milestone
payment to Progenics which will also get another $50 million milestone payment if an oral form of the drug is approved.

Progenics originally partnered with Wyeth to develop Relistor in 2005. By 2008, Relistor had earned FDA approval for a narrow patient population, those suffering OIC in palliative care. The sales from this small indication total more than $40 million a year currently. By 2010, Wyeth was in the midst of being acquired by Pfizer (NYSE:PFE) and jettisoned several partnerships as the result of the merger including that to develop Relistor. Progenics started to partner with Salix in 2011 to develop Relistor for additional indications as well as to get the oral form of this treatment approved.

This approval could take six to 18 months depending on what additional data the FDA will require, up to and including a 52 week trial of the oral form of this medication. The regulatory agency could also approve this version of treatment without any further trial results which would provide a substantial instant positive catalyst for the stock. The oral version of Relistor will have a much bigger customer base than that of the injectable version due to ease of use.

In addition to the milestone payments, the company will receive 15% to 19% of the overall revenues on Relistor as royalties from the commercialization of the drug which Salix believes will eventually have over $1 billion in annual peak sales just in the United States alone. If and when approved, it would be very easy to envision Salix from just buying Progenics outright for a substantial premium to keep all of Relistor’s revenue to itself and pick up Progenics’ drug pipeline as well.

Other Products in the Pipeline:

Other drugs in early stage development for Progenics include, Azedra and PSMA-ADC. Azedra is an ultra-orphan product in late stage development. It is owned 100% by PGNX without any partnerships, and the company is projecting about $100 million in peak sales from just for one indication. The product contains a radioactive isotope which means the product will never go generic. The company is in the process of restarting a pivotal trial on this compound.

PSMA-ADC is being look at as both from an imaging and therapeutic perspective for prostate cancer. Prostate cancer is the second most common form of cancer affecting men in the United States: an estimated one in six will be diagnosed with prostate cancer in his lifetime. The compound produced encouraging Phase II trials earlier in the year.

The company also has a couple of other compounds in very early stage development that represent additional “shots on goal” at some point in the future. However, given their stage of current development we will not factor them into our valuation on Progenics.

With the recently triggered $40 million milestone payment from Salix for the injectable form of Relistor, Progenics will now have approximately $120 million in cash on hand. This is just under 40% of the company’s overall market capitalization. The company’s burn rate is less
than $10 million per quarter and that is before the additional revenue stream from the injectable form of Relistor to treat OIC in patients with chronic non-cancer pain starts to hit the books. No dilutive capital raises seem likely in the foreseeable future.

Analyst Commentary:
Given the company’s small market capitalization, it receives very little coverage from analysts. Only three analysts have price targets on the shares. They range from $6 to $11 a share. The last ratings change on the stock happened in February when Needham moved the stock of Progenics from a Hold to a Buy.

Big holders of the stock are more enthusiastic. A fund that is a beneficial owner (over 10% of the float) in Progenics, added over $7 million shares in July of this year. Insiders own over 10% of the shares and have been net purchasers of the shares over the past two years.

Outlook:
If we cut Salix’s estimate for peak Relistor annual sales in half and do not assume any sales outside the United States for now, Progenics should easily receive $100 million in annual revenues as Relistor gets approved for oral use and expanded for other indications.

Putting a very conservative 4-6 times that revenue stream provides a value of $7 to $10 a share just for this compound. Add in $2 a share for the net cash on Progenics’ balance sheet which does not include the $50 million milestone payment the company will receive once the oral treatment of Relistor is approved. Finally, throw in a conservative $1 to $2 a share for the value of the other early stage products Progenics has in development. This gives us a sum of the parts valuation for Progenics of $10 to $14 a share for the stock.

Recommendation: Buy PGNX, sell at $14 a share.

Position: Long PGNX
Agenus Inc. (Nasdaq: AGEN)

The biotechs in our Small Caps Gems portfolio have been star performers since they were added to the portfolio. One thing these plays all have in common is they have many “shots on goal” within their pipelines which is a one of the key traits I look for when selecting biotechs for investment.

The simple fact is that most drugs and compounds fail somewhere along the approval process. Therefore it is a good thing to not put all of one’s eggs in one basket. The second recommendation in this report, Agenus Inc. (Nasdaq: AGEN), is no exception to the rule. It is developing compounds in three key areas which we will delve into shortly.

The other thing I like about Agenus is acts likes an arms merchant to major pharma concerns. It supplies various compounds that help their drugs do their jobs successfully. This is a good financial model as their partners fund the development process. If the compound moves through trials successfully on to approval, Agenus gets milestone payments along the way and then a royalty stream as the drug moves through to distribution. The company has an approximate market capitalization of $185 million with around $50 million in cash on the books.

Vaccines:

The company has a compound called QS-21 Stimulon. This is a vaccine adjuvant that enhances the body’s immune system and revs it up to make vaccines more effective. QS-21 is an adjuvant extracted from Quillaja Saponaria, or the "soap bark tree," which exists in abundance in Chile.

This adjuvant is currently being used in over a dozen vaccine trials with partners. Phase III trials involving over 15,000 children concluded this year. The trial showed it helped protect young children from malaria for up to 18 months after vaccination, reducing infections by 46%.

This vaccine has been submitted for approval to the European agency that controls approval for use in Africa by GlaxoSmithKline (NYSE: GSK). Approval is expected sometime in the middle of 2015. Agenus received a couple million dollar milestone payment after the successful conclusion of the trial, the company will receive a similar milestone payment upon approval and royalties for 10 years on sales. It will be the first significant recurring revenue stream for Agenus and should be a positive catalyst for the stock when approved as well.

More importantly, this compound could save huge amounts of malaria victims in Africa. Some 600,000 people die of malaria in Africa each year, mostly children. Based on trial results, if fully distributed across the affected parts of the continent, over 250,000 people could be saved on an annual basis.
**Checkpoint Inhibitors:**

Agenus has a platform that has a variety of cancer checkpoint inhibitors for use in conjunction in partnerships with GlaxoSmithKline, Merck (NYSE: MRK) and Johnson & Johnson (NYSE: JNJ). Combining checkpoint inhibitors with other immune therapies for cancer is a developing trend right now. The idea is to develop a vaccine that stimulates the immune system to attack the cancer, plus a checkpoint inhibitor that prevents the cancer from protecting itself against the vaccine.

Agenus signed a deal with Merck in the second quarter of this year that could provide the company with $100 million in milestone payments if trials are successful. We are years away from successful trial results but this is a promising area that Agenus acquired when it bought a small company (4-Antibody) in February of this year. If Agenus starts to see promising results in early stage trials, I would not be surprised if one of the company's partners decides it makes more sense to acquire Agenus at a substantial premium to keep this technology to itself.

**Heat-Shock Protein Platform:**

Finally, the company has a Heat-Shock Protein platform (HSP). HSP expression increases when cells are subjected to stress, such as high temperatures. HSPs produced by cancer cells differ from normal tissue HSPs and can be made to produce an immune response against a patient's cancer profile. If successful, each patient would receive a vaccine that is specific to his or her cancer. This is an example of personalized medicine, a trend that will be a key focus area in biotechnology over the coming decades.

Over the years, the company has a couple of these compounds get successfully through Phase II trials but not through Phase III trials as of yet. A vaccine using this platform produced encouraging results in Phase II trials for genital herpes in June.

The company also had success in a limited phase II trial for GBM (glioblastoma multiforme, a type of brain cancer) with a compound called Prophage. This could have blockbuster potential but is in very preliminary stages and a successful product is years away. Agenus is working with the FDA to discuss a definitive, randomized Phase III trial at some point in the future.

**Summary:**

As can be seen from the details above, Agenus has a lot of development in progress. It also has established partnerships with some of the biggest names in the pharma space. 2015 should see the approval of the malaria vaccine by GlaxoSmithKline using Agenus’ adjuvant which will provide the company with a recurring revenue stream and garner positive press as well. I expect progress in the New Year in both of the company’s other two areas of focus as well. In short, I believe 2015 could be the year that Agenus finally starts to deliver against its long held potential.

I like the risk/reward scenario for this small cap biotech company. If not much happens in 2015, the stock will most likely muddle along as has for many years, just at a higher range...
Biotech Stocks to Light Up 2015

since we added it (See Chart). If one or more of the positive catalysts comes through in the New Year, the stock is heading much higher.

The stock has spiked up to $8 a share in 2010 and to $6 a share in 2012 on hope that products that cleared Phase II trials successfully would do the same thing through Phase III trials, which unfortunately did not occur. Failure in late stage trials is nothing new in the biotech space, which is exactly why we constantly look for firms with multiple shots on goal here at Small Cap Gems.

A few months ago, a four star ranked analyst (according to TipRanks) from Maxim Group reiterated a Buy rating with a $9.00 a share price target on Agenus. Among the reasons the analyst was effusive on the company was the following “we see a paradigm shift taking hold in immune-based therapeutics and believe that Agenus is ideally positioned to create value in this emerging field.” I have made money on this analyst’s calls in the past and we will use his $9.00 a share on AGEN as our bogey for the time being while awaiting for things to play out positively for the company in the coming year.

Recommendation: Buy AGEN. Sell at $9.00 a share

Position: Long AGEN