1 Play, 3 Partnerships: The Stock With the Technology Big Pharma Wants

Biotech Gems

Investors Alley
Halozymer Therapeutics: A Solid Bet

Halozymer Therapeutics (NASDAQ: HALO) took off like a rocket for my readers when I recommended it in mid-December of 2014. At that time, I felt that the stock’s 50% decline from its highs nine months before was unwarranted and the company was being unfairly punished. (Tip: this is a common theme with biotech stocks and one that investors should use to their fullest advantage.)

The stock made it back to previous highs and more after that recommendation eventually tripling in price to over $24.00 a share. However, the biggest bear market in the biotech sector since the financial crisis has brought this potentially great stock down to levels slightly above the entry price of $8.65 when I first recommended the trade in mid-December 2014 and now the stock has begun to move higher again.

My readers who bought the stock on my original recommendation and used my “Jensen’s Rules” for culling profits are in a great position to buy back into this stock at these even better prices.

If you aren’t yet familiar with my “Jensen’s Rules,” here it is below:

If you own 1,000 shares in a small cap biotech stock, after a 50% gain sell 100 shares.

If the stock doubles, sell another 200 shares.

If you are lucky enough to get a triple, sell an additional 200 shares.

Now you have locked in a guaranteed profit and can let half the original position ride on the ‘house's money’. This way you can lock in some profits while ensuring you are not cashing out entirely of the next biotech juggernaut.
Halozyme is a San Diego-based biopharma company that develops human enzymes to enable or enhance subcutaneous drug delivery of biological drugs. The value proposition for Halozyme consists of a successful platform that has delivered successful candidates in partnerships with major pharma players and an early stage candidate to treat pancreatic cancer. Let’s take a look at both parts of Halozyme’s potential catalyst.

**Enhanze® Platform:**

Halozyme has a hyaluronidase enzyme platform whose trademark name is Enhanze®. This platform has delivered four drugs to market as of this time. One product (Hylenex) is wholly owned and marketed by Halozyme. The other three products are marketed by their partners. These include Herceptin SC and MabThera SC which is marketed by partner Roche (OTCQX: RHHBY) and HyQVia which is distributed by Baxter (NYSE: BAX). All of these partnered compounds are currently being distributed in Europe only while Hylenex is being distributed in the United States.

This platform should deliver many more drugs with partners over the next few years. Roche’s agreement with Halozyme calls for up to eight products and the company has an agreement with Pfizer (NYSE: PFE) to develop up to 6 drug candidates for potential commercialization over the next few years. The company has collaborations with AbbVie (NYSE: ABBV) – 9 potential indications and Janssen – 5 potential indications, that are in the pre-clinical phases and not as relevant or visible as its programs with other partners.

Halozyme receives milestone payments, license fees, and mid-single digit royalties on these types of partnered drugs. You may recall from my “Biotech Takeover” presentation that partnerships with industry heavyweights are one of the key criteria I look for with any biotech stock.

Herceptin and Rituxan (known as MabThera in Europe) are widely used in cancer therapies with annual sales each in the $7 to $8 billion range. Both therapies are administered by intravenous infusion over several hours. The patent in Europe for MabThera expired in late 2013 and the Herceptin patent expired in 2014 in Europe. By partnering with Halozyme’s Enhanze® platform Roche is using life cycle management to extend these blockbusters. Halozyme has been able to formulate both drugs for subcutaneous delivery rather than IV. If Roche can use this method to capture just $1 billion in sales for each drug in Europe alone, Halozyme’s mid-single digit royalty could easily amount to over $100 million annually with further upside as distribution moves on to other major markets such as Latin America. There is less urgency to garner approval in the United States for these drugs since the patent expiry here for Rituxan is 2018 and 2019 for Herceptin.

The FDA approved HyQvia in the summer of 2014. This is Baxter’s subcutaneous treatment for adult patients with a primary immune deficiency. HyQvia consists of immunoglobulin with Halozyme’s recombinant human hyaluronidase. Peak sales are projected to come in just under $1 billion a year annually. Given the royalty structure, Halozyme could garner between $30 million and $50 million a year as these sales expand.

As noted above the company also entered into an agreement with AbbVie (NASDAQ: ABBV) in June of 2015. This global collaboration and license deal with AbbVie will allow development and commercialization of AbbVie compounds combined with Halozyme’s ENHANZE drug delivery
platform. Under the terms of the agreement, Halozyme received a $23 million upfront payment and could receive milestones up to $130 million for each of nine collaboration targets and tiered royalties on commercial sales. The first fruits of this deal happened in January of this year as the first patient was dosed with that company’s blockbuster drug Humira using Halozyme’s ENHANZE delivery system in early trials. This triggered a $5 million milestone payment to Halozyme. Humira currently does just under $15 billion in sales annually. This biosimilar will start to come off patent later in 2016 and will be fully off patent sometime between 2018 through 2022 depending on how patent challenges work their way through the court system.

Given the growth prospects, pipeline and partnerships around this platform, Enhanze® will be a core driver of revenues and earnings in the years ahead as the platform is now well established and beginning to generate real revenue.

**PEGPH2O:**

Another potential major catalyst that investors are basically getting for free at these price levels is PEGPH20 which is a drug targeted at pancreatic cancer. This very lethal form of cancer is diagnosed in just over 45,000 people in the United States annually with almost 40,000 deaths caused by pancreatic cancer in any given year. A person’s chances of developing this form of cancer over their lifetime are around 1 in 70.

PEGPH20 is Halozyme’s pegylated hyaluronidase drug candidate administered with gemcitabine. The early data showed remarkable efficacy in the small cohort of patients. Pancreatic cancer is just the first target for this potential blockbuster. Halozyme has received Fast Track and Orphan Drug designations from the FDA for PEGPH20 for the treatment of pancreatic cancer which is promising. The company signed a collaboration deal with Japanese pharma concern Eisai for the development of Eribulin in combination with PEGPH20 for women with first line HER2-negative metastatic breast cancer in late July.

A Phase 2 trial evaluating evaluate PEGPH20 in patients with metastatic pancreatic cancer the combination of PEGPH20 with Abraxane and gemcitabine in pancreatic cancer, Study 202, showed doubling in median survival rate compared to Abraxane and gemcitabine alone (9.2 months vs. 4.3 months). A phase III trial evaluating the same combination should begin in the first half of 2016.

**Summary:**

As can be seen above, Halozyme has plenty of possible catalysts and potential “shots on goal”. The company should garner more than $120 million via royalty payments, license fees, and milestone payouts in 2015. These revenue streams should do nothing but increase in the years ahead as sales ramp up from existing products and as new compounds are developed and come on line. Halozyme also entered into a $150 million debt deal in January of this year that was collateralized by future royalty streams. This was a smart way to raise needed development funding without diluting shareholders via a secondary offering as unfavorable prices. This takes funding needs off the table for the foreseeable future.

I expect the company to post small losses over the next year or so but given its pipeline profits
should be forthcoming in the years ahead. With the recent debt raise and the net cash Halozyme already had on hand, this should get Halozyme through to the point the company produces positive free cash flow.

Given its pipeline, increasing revenue streams and partnerships with several major players within the pharma space I would not be surprised at all if the company receives a lucrative buyout offer at some point in the foreseeable future. The median analyst price target by the eight analysts that currently cover the stock is $22.00 a share. This would be more than 150% upside from the stock’s current price levels and still be below the highs the shares hit as recently as July of last year.

**Recommendation: Buy HALO up to $12.00 a share**

Position: Long HALO