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CytRx is worth $20 per share based on under-appreciated GBM opportunity combined with STS

Last Friday, CytRx Corp (CYTR) raised $75 million in an offering priced at $6.50 per share. The offering was priced at roughly 25% below the closing price of the previous trading day, leading some less sophisticated investors to gripe that they somehow had the rug pulled out from under them.

The reality is that in early December, CytRx was just barely a $2 stock. The entire company was worth just over $80 million. The fact that the company is in a position to raise $75 million in a 1 day offering at $6.50 per share should be a delight for those who have a holding period of longer than one day.

Wall St. has one simple rule: take the money when you can get it (don't wait until you need it). And CytRx now finds itself incredibly well financed, having an extra $75 million in the bank. The high share price of $6.50 in the offering helped to ensure that overall dilution to shareholders was minimized, despite the fact that the company was able to pull in a large nominal amount of cash.

Those with a longer term interest in CytRx are immediately aware that when a stock has run up substantially, investors in the deal will always require a bigger discount. In the case of CytRx, the stock had nearly quadrupled since early January. The other factor which necessitates a decent sized discount is the fact that CytRx was offering an amount of nearly 25% of its market cap at the time. The compares to average deal sizes which seldom exceed ~~10~~20%. As a result, the discount was certainly within market guidelines.

Following the financing, CytRx is currently one of the best risk/rewards in the biotech sector. Despite the recent catalyst-driven spike in the share price, there is currently minimal downside risk in the near term, while the stock still has the potential to triple on the upside.

Momentum and excitement about the stock has ~~ds~~ only begun to build as the stock ~~recently~~ passed the five dollar mark in December 2013. The key catalyst for ~~this~~ that price move was the December 11,2013,announcement of strong, highly statistically significant results in its global phase IIb clinical trial with aldoxorubicin (Aldox) as a front line treatment for soft tissue sarcoma (STS).

Immediately following the announcement the share price more than doubled from $2.39 per share to over $6.00 per share. The incredible excitement over the results of this trial is understandable as convincing results in a phase IIb trial make it more likely that aldoxorubicincould ultimately receive FDA approval. If the drug does receive approval, CytRx will likely be extremely valuable.

For obvious reasons, the STS opportunity is what has grabbed the headlines of late and has therefore been the primary focus of investors at this point. However, CytRx may also be headed towards a compelling opportunity in treating glioblastomamultiforme (GBM), the most prevalent form of primary brain cancer. In fact, my research leads me to conclude that CytRx's GBM opportunity is actually much more valuable than the market is giving it credit for. A proper evaluation of this underappreciated opportunity reveals that CytRx could very quickly command a market cap of roughly $1 billion – or approximately $20 per share. For the sake of clarification, this estimated valuation is based on the combined market opportunity in both STS and GBM.

As shown by the recent surge in the share price, investors are now beginning to appreciate the STS opportunity. But a compelling investment opportunity with CytRx lies in the fact that the GBM opportunity is totally underappreciated. There is vastly more upside to the stock than the market is pricing in.

However, in order to best convey the investment case, I will present this analysis in the following order:

First I will provide some background information on the company. Second, I will outline its platform technology for Aldoxand its application to STS. Third, I will go into detail about the application of Aldoxto GBM and discuss how CytRx's prospects in STS and GBM should be valued. Finally I'll discuss possible risks the company faces.

Company Background

CytRx is a biopharma company concentrating on high value oncology compounds. Thecompany's key platform technology isbased on linker technologies to enhance the efficacy of chemotherapeutic drugs. Aldoxorubicin is the first drug in the pipeline and consists of an acid-sensitive linker attached to the chemotherapy drug doxorubicin.The linker allows 3.5 times the standard dose of doxorubicin to be given to the patient at each cycle. .

CytRx is currently in the clinical development stage with Aldox for multiple indications. The most advanced is a 400 patient pivotal phase III trial as a second line treatment for STS which will begin this quarter. The company received a "Special Protocol Assessment" from the FDA which means there is agreement that this trial can be used to file for marketing approval.Aldox is wrapping up a 123 patient phase IIb trial as a first line treatment for STS., Last week,CytRx announced the start of a 30 patient phase IIb study for AIDS related kaposi's sarcoma with Aldox..

Finally, the company is also enrolling patients in a 28 patient phase II trial as a second line treatment for GBM. Once again, I believe the prospects for aldox in GBM are under appreciated by the market.

Aldoxorubicin

Aldox is a tumor-targeted albumin binding doxorubicin conjugate. For most non-scientists, this description is quite a mouthful. But what it means is that it is the same thing as doxorubicin but with an additional "linker" molecule that makes it therapeutically superior. This molecule binds almost completely to albumin (free doxorubicin in the blood is <1% of the total), the major protein in human blood plasma, and thereby makes its way to the site of the tumor as tumors feed on albumin.

Using albumin to deliver an anti-cancer drug to the tumor has already been proven by Abraxane, which generated $447 million of sales in the first nine months of 2013. In other words, CytRx is applying a known approach but with some additional advantages.Aldox requires an acidic environment to release the drug from the linker. This is a key feature since it does not release the drug in healthy,non-acidic tissues. This allows 3.5 times the standard dose of doxorubicin to be given to the patient at each cycle. Further, CytRx has reported that they can treat for longer than six cycles which is the current maximum for doxorubicin due to toxicity. . It stands to reason that we should expect further strong performance in clinical trials,ultimately resulting in FDA approval in the future.

Doxorubicin is a chemotherapy drug used in a wide variety of cancers including breast cancer, ovarian cancer, and bladder cancer, as well as non-Hodgkin's lymphoma and sarcoma. The compound is a topoisomerase II inhibitor, it works by blocking an enzyme, topoisomerase, that causes cancer cells to grow.

Aldox has several properties that give it significant advantages compared to doxorubicin. Most importantly, it dramatically reduces the toxicity of doxorubicin while also improving the efficacy by concentrating the drug on the actual site of the tumor. Doxorubicin is particularly noted for creating cardiotoxicity that can result in significant, even life threatening heart damage. Thelack of cardiotoxicity, therefore, is a key value proposition of Aldox. These properties are generally very useful in a cancer therapy, as the December 11th results, which showed that Aldoxwas superior to doxorubicin in all efficacy endpoints, demonstrated.

Thus far, investors have been focusing on Aldoxas a potential treatment for STS. The drug's value proposition in

STS is very compelling since doxorubicin is the current standard of care.

Analysts are currently modeling roughly 30,000 new STS patients every year in the US and EU (and growing). The price for each atientconservatively should be on the order of $50,000 per year, and quite possibly higher. This is how we arrive at the potential for a "10 figure" (over $1 billion) market for the drug.

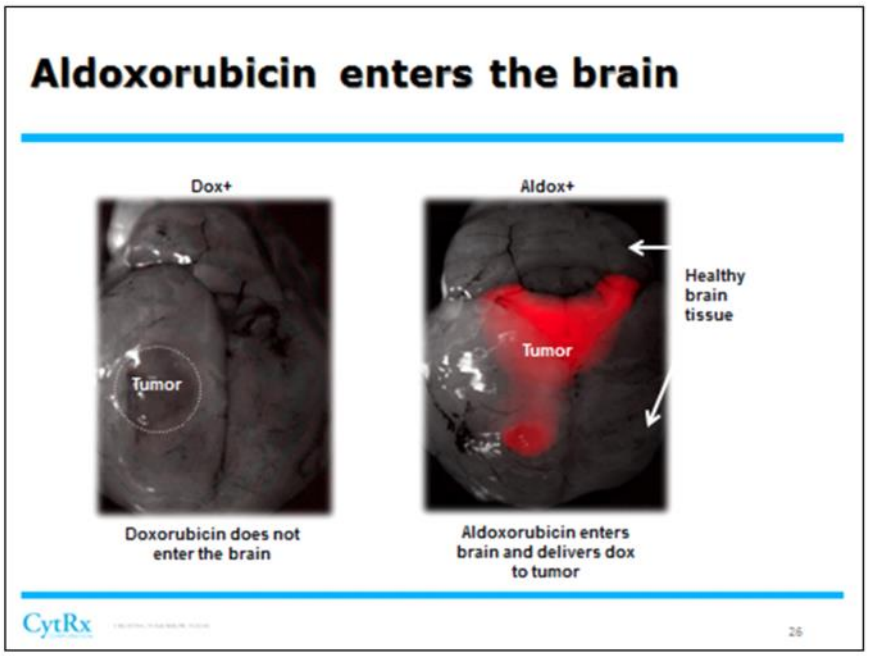
Not only is the market large, but STS is a very deadly form of cancer with poor treatment options available today. The overall relative (accounting for other possible causes of death in a patient population) 5-year survival rate of patients diagnosed with STS is roughly 50% according to the National Cancer Institute (NCI).

Finally, Aldox demonstrates 80-100% superiority over doxorubicin in progression-free survival in 1st-line STS. This is a very compelling value proposition when compared to the comparatively incremental benefits that many new drugs offer. Even more importantly, Aldoxis the first and only agent to ever surpass doxorubicin in STS.

The STS results are very exciting and the market has been very focused on them over the last few weeks, but Aldoxin GBM is extremely exciting as well.

Aldox in GBM

Aldox is particularly useful in GBM because it can cross the blood brain barrier and concentrateat the tumor site in animal models. For a concrete illustration of this property, the picture below shows the difference of uptake of Aldoxvs. doxorubicin in the brain of aGBM animal:



The fact that Aldox has this property is excellent news, as GBM is the most prevalent form of brain tumor and is very deadly.

Roughly 12,000 patients are diagnosed with GBM every year in the United States alone according to the American Brain Tumor Association. The current standard of care is surgery followed by radiotherapy and chemotherapy.

Unfortunately, median survival for patients receiving standard of care is roughly 15 months, and less than one in twenty patients survives for five years following a diagnosis. There is clearly an enormous unmet need for effective treatments, and one can only hope Aldox will be a powerful new tool oncologists can use to improve outcomes.

That said, the unmet need is not due to lack of economic opportunity or lack of attempts by major pharmaceutical companies. The effectiveness of Roche's Avastinwas recently called into question for its phase III survival results. While Avastin did win FDA approval, it's utility is so equivocal that the European Medicine's Agency (EMA) decided not to approve it. Moreover, Avastin was associated with several significant side effects including hypertension and thrombosis. ImmunoCellular (IMUC) has taken a vaccine based approach to treating GBM. This is a novel approach that quite a few companies are taking including Galena and Northwest Biotherapeutics. Vaccine based approaches, also described as cancer immunotherapy or "immuno-oncology" train the human immune system to identify and kill cancer cells. This is very different from a chemotherapy drug which simply kills cancer cells itself. Also, not only does ImmunoCellular's therapy target tumor's but it also target's cancer stem cells. In short, the vaccine based approach taken by ImmunoCellular and others leverages the human immune system and is therefore more complex.

However, thus far ImmunoCellular recently had disappointing trial results. A quick look at the share price will confirm all this as the stock performance in December speaks for itself. The company's phase II trial for the use of the ICT-107 vaccine in GBM failed to meet its primary endpoint of overall survival. That said, there was a statistically significant improvement in progression free survival compared to placebo. This is still significant despite the overall disappointing trial results because this is the first demonstration of statistically significant improvement in a clinically relevant measure in a placebo-controlled immunotherapy trial in glioblastoma.

Northwest Biotherapeutics (NWBO) had a related approach and has been the subject of a lot of investor attention since the disappointing results of ICT-107. However, investors remain enthusiastic about the company's vaccine DCVax, as it does vary from ICT-107 in several important ways including that it avoids the problem of using synthetic antigens. At the end of the day, shares of Northwest are up roughly 50 % over the last few months, as investors have taken an increasing interest including a significant stake from Capital Ventures, receiving coverage at Oppenheimer, and discussion on several news networks

Celldex's (CLDX) rindopepimut may be the most advanced. Phase III trial results from rindopepimut should be available in the second half of 2016.

While rindopepimut is indeed a promising new drug, it would be a mistake to view it as preventing Aldoxfrom gaining significant market share for two reasons.

First, rindopepimut has an entirely different approach from Aldox. Whereas Aldoxis based on a known chemotherapeutic agent, rindopepimut is a vaccine which limits its use to approximately 20% of GBM patients that have a specific mutation. The objective of rindopepimut is to train the immune system to identify and kill cancer cells. In other words while Aldox itself kills cancer cells, rindopepimut simply trains the immune system to do the same thing. With this in mind, Rindopepimut and Aldox could potentially be used alongside one another.

Second, the current standard of treatment for GBM is so far from effective. The global market isamulti-billion dollar opportunity for an effective drug, that there is plenty of room for several effective drugs in the market, so rindopepimut and Aldoxcould be separately successful on their own.

Valuation

CytRx has several opportunities with Aldox, but for this article I'll just focus on STS and GBM as these are the two

most advanced indications. However, I do intend to pen a follow up article which will go into further detail on CytRx's additional products in the pipeline.

Aldox for second line STS will likely launch in 2017, and it would be reasonable to assume it reaches 30 % market penetration of the almost 10,000 worldwide relapsed patients receiving second line treatment. At $5k per month, or $60k per patient per year, Aldox revenue for second line STS could be $180 million.

Aldox for first line STS will likely launch and hit full market penetration later than second line use. We model first line STS use reaching market penetration of 20 % of the 12,000 worldwide new STS patients receiving first line treatment and having the same price point. This yields another $144 million in worldwide revenue.

Finally with roughly 12,000 new patients diagnosed with GBM every year in the US alone, and a roughly equivalent treatable population in the EU, but higher pricing, second line GBM is almost as large of an opportunity as STS.

Aldox for second line GBM will likely launch in 2018, and can reasonably reach $300 million in sales itself based on a 25 % market penetration and equivalent pricing to STS.

This represents a total of $624 million annual sales. Assuming a 20 % royalty rate, CytRx should have revenue well over $100 million per year. It's difficult to know how much the company would be spending on further R&D at that point, but if it can just earn $50 million per year its worth significantly more than $20 per share on the current share count of 42 million. For example, assuming a price of $20 per share, the stock would be trading at a P/E of 16.8.

Conclusion

In the biotech world, the move from $7 to $20 is actually not that large. We see similar moves in biotech several times each month. The difficulty is simply predicting WHICH biotech company will display a such a move.

In fact, the $20 price target for CytRx may actually prove to be conservative compared to a company like Agios (AGIO) with a market cap close to a billion and no clinical data.

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