Healthcare

AVEO Pharmaceuticals: Making Its Mark In Cancer Treatment

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About this article

Ticker	Author rating	Price at publication	Last price	Change since publication	S&P 500
AVEO	Buy	$5.16	$15.00	190.70%	

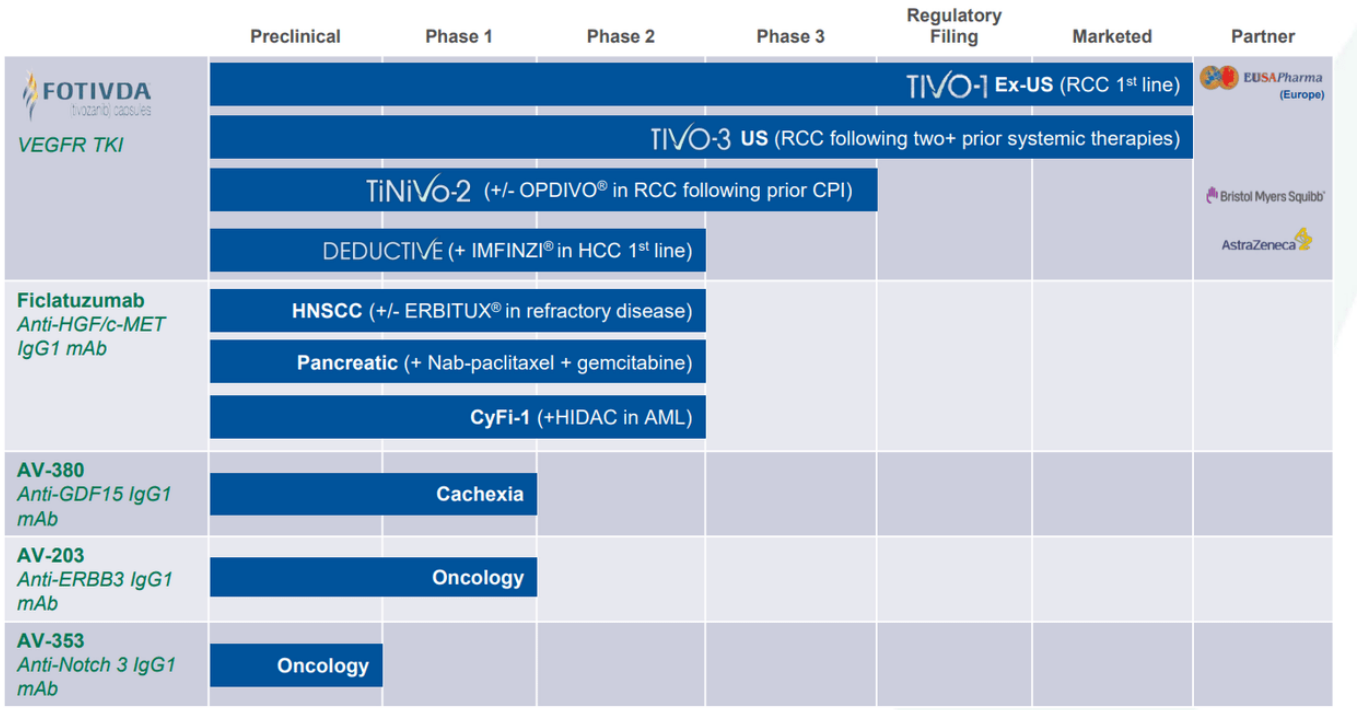
Summary

- AVEO's lead drug candidate, Tivozanib, recently got U.S. FDA approval for treatment of Renal Cell Carcinoma. It clocked in revenue of $1.1 Million within just nine days of getting approved.
- Besides Tivozanib, AVEO is working on four other major drug candidates that will help in the treatment of head and neck cancer (HNSCC), cachexia, breast, pancreatic, and lung cancers.
- AVEO has a comprehensive portfolio of intellectual property and multiple tiers of patents that protects all of its drug candidates.
- The company has a strong balance sheet with adequate cash to support the research and development of its drug candidates.
- AVEO trades at a forward P/S ratio of 4, making it relatively undervalued when compared to the U.S. Biotechnology and Drug industry P/S ratio of ~6.5. By performing a high-level relative valuation, I arrived at an intrinsic per share value of $13.1, indicating an upside of 130% over the current share price.

SolStock/E+ via Getty Images

Introduction

AVEO (NASDAQ:AVEO) is bringing together its partnerships and resources to develop drugs and commercialize them in North America in addition to other geographies. AVEO has multiple products in the pipeline, with the leading product being FOTIVDA® (Tivozanib). It has received U.S. FDA approval for Renal Cell Carcinoma (RCC) in 2021 and similar EUSA approval in 2017. In preclinical models, Tivozanib is known to substantially reduce regulatory T-cell production. Currently, two models, TIVO-1 and TIVO-3, are being marketed, while Tivozanib (HCC), and TiNivo are in phase 2 of development. Other than Tivozanib, there are four more products in the pipeline, namely, Ficlatuzumab (phase 2), AV-203 (phase 1), AV-380 (phase 1), and AV-353 (pre-clinical).

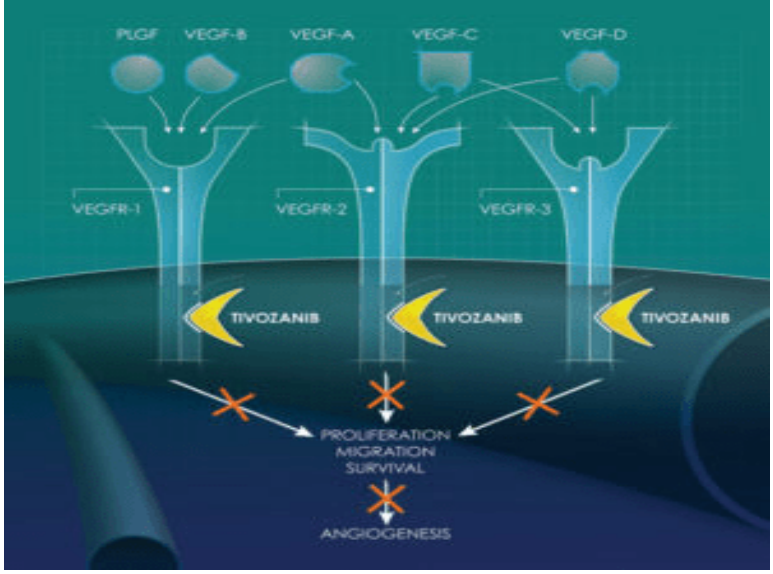


Source: AVEO Investor Presentation

Tivozanib

Tivozanib, marketed in the name of FOTIVDA, is a prescription medicine used for the treatment of adults with kidney cancer (RCC - advanced Renal Cell Carcinoma) that are already treated with 2 or more medicines but the disease has come back and doesn't respond to treatment. It is a once-a-day, oral, differentiated vascular endothelial growth receptor (VEGFR) tyrosine kinase inhibitor (TKI), with a long half-life aimed to improve efficacy and tolerability. "Tivozanib has been shown to significantly reduce regulatory T-cell production in preclinical models."

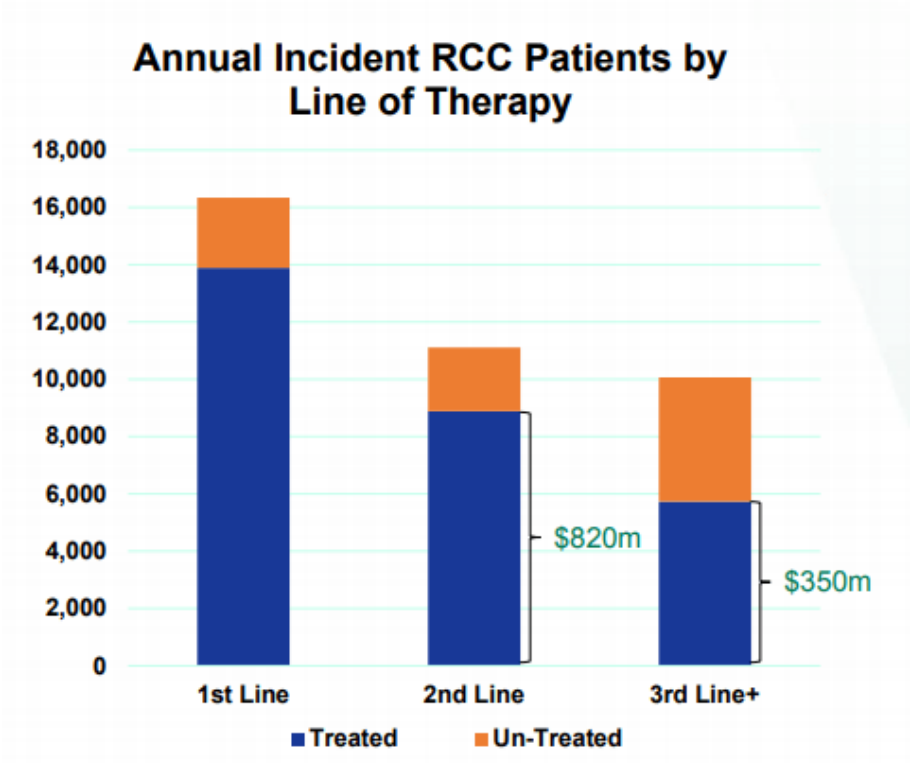
The VEGF pathway plays a substantial role in angiogenesis, which is crucial in cancer. Angiogenesis is responsible for the formation of new blood vessels, endothelial cell proliferation, migration, and survival. There are three VEGF receptors, each of which is important in angiogenesis, so it is important to block all three VEGF receptors.



Source: AVEO Investor Presentation

Commercialization

The United States presents a significant opportunity for FOTIVDA, as the U.S. market for relapsed or refractory RCC is around $1 Billion, that is $700 Million in the second line and $300 Million in the third and fourth lines. The TIVO-3 study is the very first study to be Phase 3 positive in RCC patients who had a relapse or in which the disease became refractory to 2 or 3 systemic therapies before FOTIVDA. The TIVO-3 study is also the first positive Phase 3 study of a population that had already received predominant standard lines of therapy. Thus, it is believed that FOTIVDA could be the standard of care in this scenario of relapse or refractory towards other lines of care.



Source: AVEO Investor Presentation

In reaction to COVID, the commercial strategy was optimized to include more digital marketing strategies and improve remote consumer engagement capabilities, and by March of 2021, the marketing, sales, medical affairs teams, and distribution capabilities were all in place. A recent oncologist survey indicated that 83% of doctors would be expected to prescribe FOTIVDA within 6 months of its availability to RCC patients.

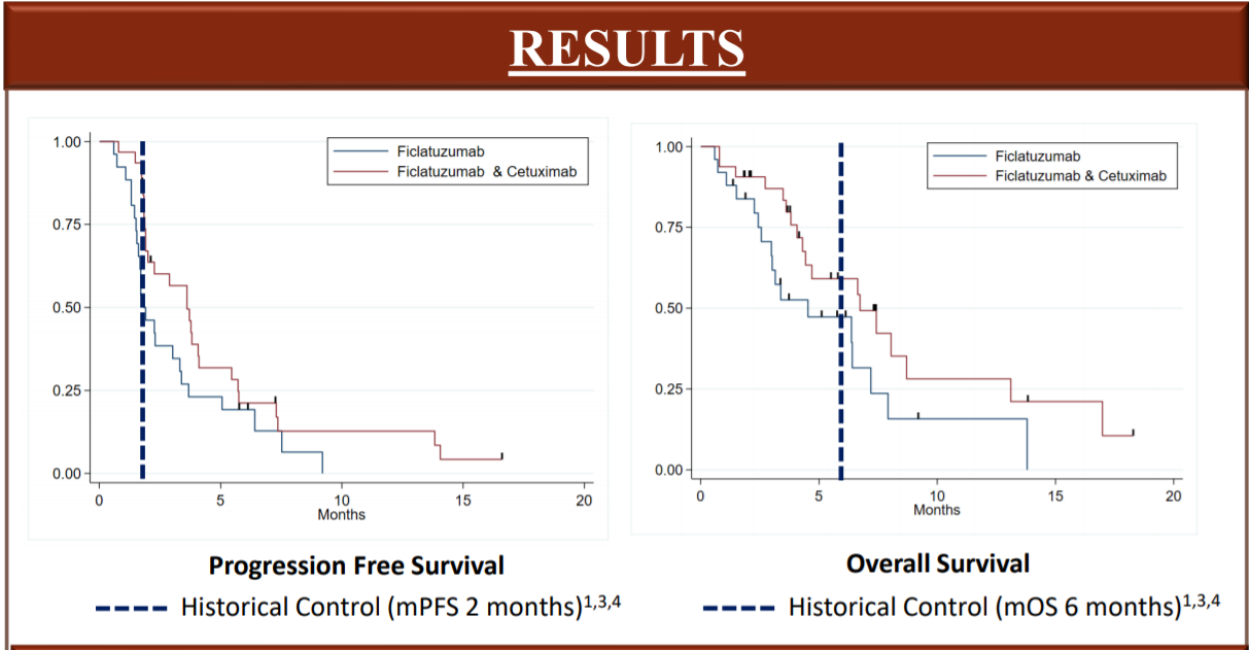
Apart from the United States, FOTIVDA has also commercially launched in Germany, the United Kingdom, Spain, and Italy. According to the company's latest con call, through April 30th 2021, a total of 49 commercial prescriptions have been filled. In addition, 75 free one-month patient experience starter kits samples were requested and delivered.

Ficlatuzumab

Ficlatuzumab is an investigational drug that is yet to be approved by the FDA for commercial use. It is in the second phase of the study, just a step short of regulatory filing and two steps short of being released into the market.

Ficlatuzumab is a humanized IgG1 monoclonal antibody that is capable of blocking the cMET receptors or the natural ligand of cMET (HGF), which is believed to be a trigger to many activities involved in the development of cancer and metastasis. The second phase of the study of Ficlatuzumab is conducted as a combination with cetuximab, as well as a single agent. The study was performed on patients suffering from metastatic head and neck squamous cell carcinoma (HNSCC) where there was a relapse or a refractory towards prior immunotherapy, chemotherapy.

The combination met the primary PFS endpoint in advanced, pan-refractory HNSCC, as there was notable activity, especially in HPV-disease pan-refractory; these results warranted the next phase of the study (Phase 3), and the combination was well tolerated with anticipated levels of toxicity from the cMET/HGF Inhibitors.



Source: AVEO Oncology

The company announced positive results from its Phase 2 study of Ficlatuzumab as a single agent or as a combination with Cetuximab. AVEO is currently waiting for feedback from the FDA to take the decision regarding the initiation of the Phase 3 study of Ficlatuzumab. After considering the annual new cases in the United States of head and neck cancer (57,600), and pancreatic cancer (53,260), the company invested in extra clinical manufacturing for Ficlatuzumab for the phase 3 study.

AV-380

AV-380 is a humanized inhibitory IgG1 antibody; it aims to inhibit the growth of differentiating factor 15 (GDF15), a pro-inflammatory cytokine. The elevated circulating levels of GDF15 have been correlated with cachexia patients suffering from cachectic cancer; AV-380 is currently in a phase 1 study.

Around 9 million people in Japan, Europe, and North America are affected by cachexia. It is a serious but common complication among patients suffering from advanced cancer and other chronic diseases. In the preclinical data, AV-380 inhibiting the GDF15 led to GDF12 switching from catabolism to anabolism which can potentially reverse cachexia's effects.

AV-203

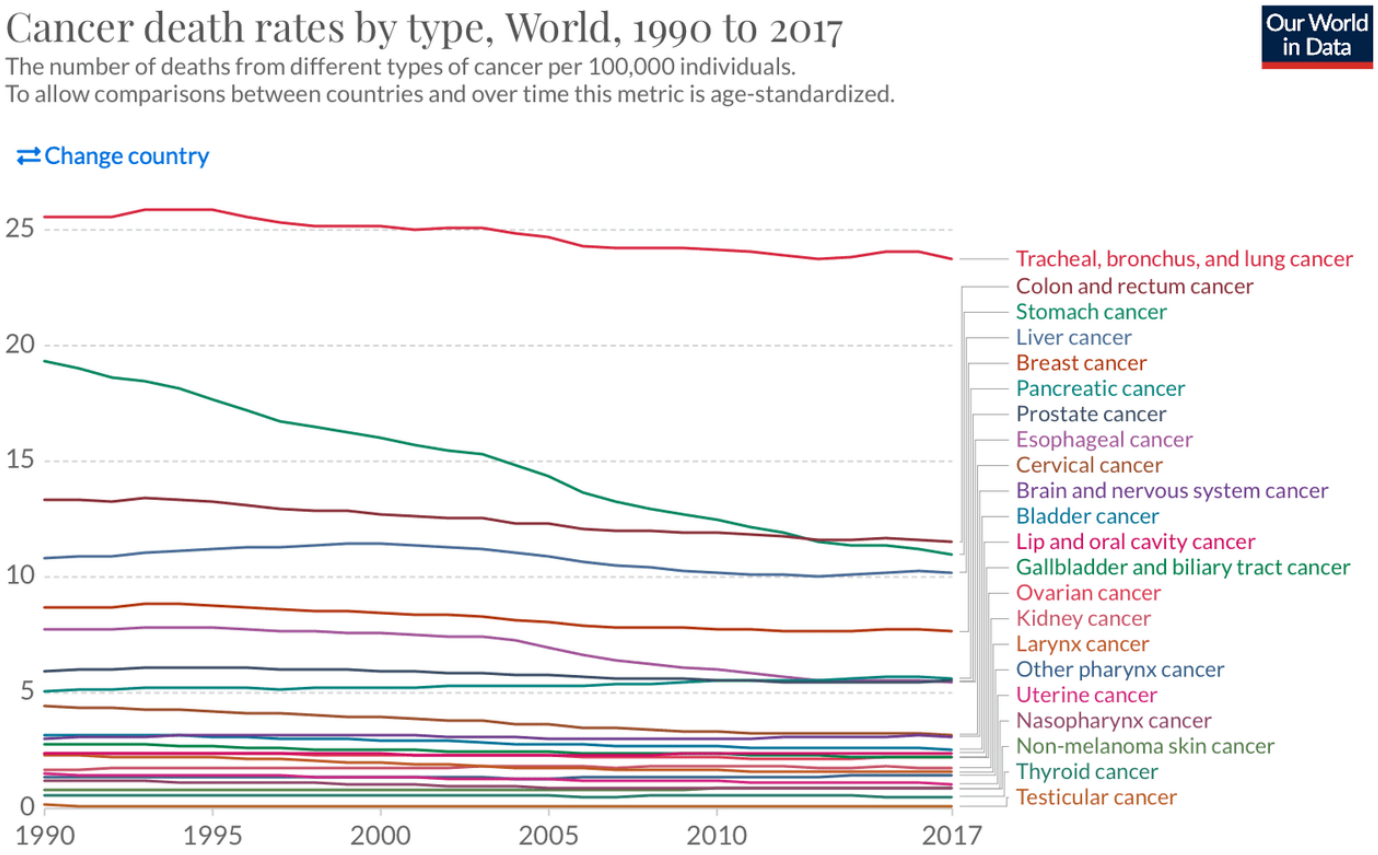
AV-203 is a humanized IgG1 monoclonal antibody that aims to inhibit ligand-dependent and ligand-independent signaling by ErbB3. The drug (AV-203) has shown preclinical activity in various tumor models such as breast, head and neck, pancreatic, lung, and ovarian cancers.

In the phase 1 study of AV-203, it was found to be safe and well-tolerated and by September 2021, AVEO is going to get full rights for the AV-203 program.

Oncology Industry - Cancer or not cancer?

The saying "in pharma, cancer is the king" stands true seeing the overwhelming amount of the pharmaceutical industry concentrated in oncology. This in part can be attributed to the unstoppable and ever-changing world focused on the consumption of carcinogens, resulting in more people succumbing to this disease, ergo more demand for resources to combat cancer.

Even though the instances of people diagnosed with cancer have dramatically increased, statistically speaking, a person diagnosed with cancer just a decade ago had a significantly lower survival rate than they would have today.



Source: (ourworldindata)

According to a report by PwC:

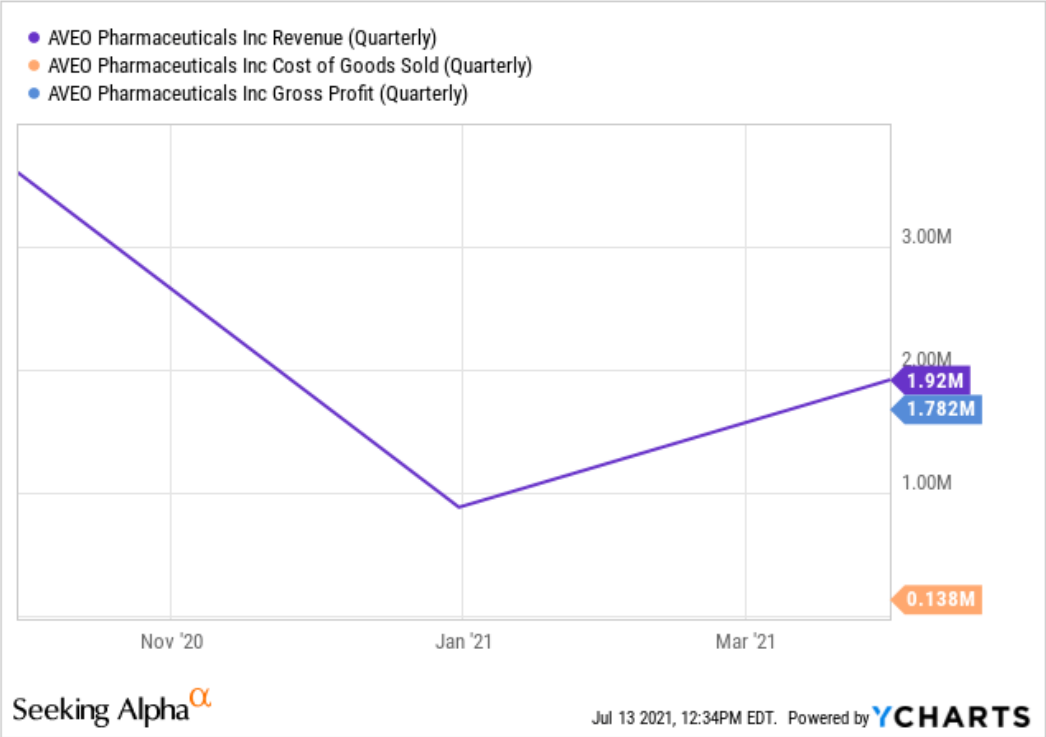
> "Simple projections of demand, as measured by prevalence across tumor types, suggest there will be approximately 18 million patients in the US alone by 2020, a 31% increase from 13.8 million in 2010. Global spending on therapeutic and supportive care for cancer is expected to rise from US$133 Billion in 2017 to as much as $200 Billion in 2022, at which point it will account for roughly 14% of total global medical expenditure."

Biopharma companies are painstakingly directing their funds towards oncolytic R&D, where the competition is fierce. The conversion rate of active research into a blockbuster (a blockbuster drug is one that generates revenue upwards of a billion-dollar for a company) is quite low. According to MIT research, only 3.4% of all cancer drug programs during the 2000-2015 period moved past phase 1 to regulatory approval. AVEO has achieved a huge breakthrough by getting its lead drug candidate FOTIVDA approved.

Company's Financial Position

As of Q1 2021, AVEO has cash and cash equivalents of $121.4 Million. Its management believes that it will spend approximately $40 Million for the year. On top of it, AVEO has started earning revenues on its lead drug candidate FOTIVDA. In an ideal scenario where AVEO continues to generate revenues from FOTIVDA, and decrease its SG&A expenses, I believe that AVEO will not face any liquidity crisis in the future.

Coming to the margins, AVEO got its lead drug candidate FOTIVDA approved on March 22, 2021, and just within nine days of quarter-end, it generated sales of $1.1 Million. The cost of sales was just $0.138 Million. As a result the company exhibited a whopping 93% gross margin for Q1 2021.



Source: YCharts

Valuation Outlook

AVEO has crossed an important milestone with the approval of FOTIVDA. The company is addressing an underserved market where half of the 3rd and 4th line treatment patients are untreated. The current market size of 3rd line treatment is $350 Million which only includes the treated portion. The company launched the drug on March 22, 2021. Aveo generated sales of $1.1 Million in the first quarter which mostly reflected the inventory shipped to the distributor. Since then the company has received multiple reorders from its distributors.

Revenue Estimate	Current Qtr. (Jun 2021)	Next Qtr. (Sep 2021)	Current Year (2021)	Next Year (2022)
No. of Analysts	4	4	4	4
Avg. Estimate	8.94M	15.08M	49.22M	138.55M
Low Estimate	4.6M	10M	32M	86.2M
High Estimate	16.49M	21.97M	76.67M	188.75M
Year Ago Sales	749k	2.77M	6.02M	49.22M
Sales Growth (year/est)	1,093.60%	444.40%	717.70%	181.50%

(Source: Yahoo Finance)

With increased traction and pickup in sales, the market expects the company to post a top line of $49.22 Million for 2021 and $138.55 Million for 2022. This figure is expected to grow even further as the company gains market share. The company currently trades at a forward Price/Sales ratio of 4.0x based on the expected 2021 sales which seem quite reasonable. The wider biotechnology and drug industry P/S ratio is 6.43x.

		Expected 2023 Sales (in $mm)				
		120	150	180	210	240
P/S ratio	3	228.2	285.3	342.3	399.4	456.4
	3.5	266.3	332.8	399.4	465.9	532.5
	4	304.3	380.4	456.4	532.5	608.6
	4.5	342.3	427.9	513.5	599.1	684.7
	5	380.4	475.5	570.5	665.6	760.7

The above sensitivity analysis portrays the company's 2023 expected sales multiplied by the P/S ratio. The resulting value is then discounted at 20% for 2.5 years portraying a rough calculation of the company's intrinsic value. On a base case, the company's intrinsic value is close to $456 Million or a per share value of $13.1, which is 2.3x times the current market value. The expected value creation is highly dependent on the company's ability to expand its market share as well as the progress in its drug pipeline. Overall, the value proposition at the current levels is expected to provide an adequate return over a longer time frame.

Rating: Buy

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