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Cytosorbents: Revenue Could Decline 70%+ In 2022

The CytoSorb obtained CE Mark in Europe by reducing the concentration of the inflammatory cytokine IL-6. Subsequent research indicates that the health benefits are ambiguous at best. The EU tightened the regulations for medical device approvals and the CytoSorb will need to be recertified by May 2022. There is a significant chance it fails to get re-approved. The YoY revenue growth rate is likely to be single digits in FY 2019 vs nearly 50% in 2018, which should lead to multiple compression on an unprofitable company. With concerns mounting about theCytoSorb, management is talking up Hemodefend, but the company has a 7-yearhistory of failing to make progress on this product.

Company History

Cytosorbants has a rather unusual origin story. In June 2006, Glider Enterprises Inc acquired the assets of MedaSorb Corporation via a reverse merger. Ownership filings show that Margie Chassman, wife of convicted securities felon David Blech, was the largest shareholder of Glider Enterprises at the time of the reverse merger. David Blech and his brother Isaac Blech have a long history of association with Healthcare companies that have lost nearly all their value and became famous enough to become the subject of a documentary.

Another noteworthy early investor in MedaSorb (at that time known as RenalTech) was Ms. Guillermina Vega Montiel, a citizen of Mexico with a registered address in Ciudad Altamirano, a small town (~25,000 people) in the Mexican state of Guerrero. In a 13D filing, Ms. Vega Montiel is listed as a ‘housewife.’

Source: Exhibit 10.6 to the CTSO 2014 10-K

To this day, Cytosorbants pays Ms. Vega Montiel royalties equal to 3% of gross revenues due to her 2003 investment in RenalTech. The 2018 10-K discloses the arrangement.

In August 2003, in order to induce Guillermina Vega Montiel, a principal member of RenalTech International, LLC at the time, to make a $4 million investment in RenalTech International, LLC, Ms. Montiel was granted a perpetual royalty equal to three percent of all gross revenues received by us from sales of CytoSorb in the applications of sepsis, cardiopulmonary bypass surgery, organ donor, chemotherapy and inflammation control. In addition, for her investment, Ms. Montiel received 1,230,770 membership units of RenalTech International, LLC. Such membership units ultimately were converted into and became 7,420 shares of our common stock following our June 30, 2006 merger. For the year ended December 31, 2018 we have recorded royalty costs of approximately $600,000.

Here's a snap from Google Streetview of the area around Ms. Montiel’s listed address from the filings. It certainly looks where you find the smart money for a medtech startup!

Source: Google Streetview

MedaSorb’s 10QSB filings show that the company had completed development of the CytoSorb as far back as August of 2006 (before the reverse merger), and the 10KSB filing for FY 2006 discloses that the company had submitted a trial design to the FDA and hoped to begin sales in the US in 2009.

We have developed and will seek to commercialize a blood purification technology that we believe will be able to efficiently remove middle molecular weight toxins from circulating blood. We will be required to obtain required approvals from the United States Food and Drug Administration before we can sell our products. In December 2006, we submitted a proposed pilot study for approval to the FDA with respect to CytoSorb™, the first device we intend to bring to market. If we obtain FDA approval, we anticipate commencing clinical studies for CytoSorb™ by the third quarter of

2007. If these studies are successful and we obtain FDA approval to proceed with our follow-up pivotal study, we anticipate that we will be able to begin sales of CytoSorb™ by mid-to-late 2009, at the earliest, assuming a successful pivotal study. However, there can be no assurance we will ever obtain FDA approval for CytoSorb™ or any other device.

Nearly 12 years later, the FDA has yet to approve the CytoSorb, though as I will discuss momentarily, the product did win approval in the European Union.

If the CytoSorb was a valuable piece of technology, it would have been purchased by a major health care company. Instead, it was bought through a reverse merger with a shell company owned by the wife of a convicted felon.

The CytoSorb Obtained CE Mark in 2011

CytoSorbants flagship product, the CytoSorb, is an extracorporeal cytokine blood filter used in the treatment of sepsis and postoperative care. In the medical literature, the use of products like the CytoSorb is known as extracorporeal cytokine adsorption therapy (ECAT). The purpose of the Cytosorb is to remove pro-inflammatory cytokines and thereby prevent organ failure.

While the original business plan was to get the CytoSorb approved in the USA, the company's efforts in that regard were unsuccessful, but CTSO did catch a lucky break in Europe. The company announced that it had received CE Mark (regulatory approval) in the European Union in a press release on March 31, 2011:

The European Sepsis Trial has successfully demonstrated CytoSorb™'s robust ability to reduce circulating plasma cytokine levels during the extracorporeal treatment of critically-ill patients with sepsis and respiratory failure. CytoSorb™ has achieved its primary endpoint of IL-6 (interleukin-6) reduction with statistical significance based on an interim analysis of the trial. The data demonstrates that CytoSorb™ plus standard of care therapy reduced IL-6 levels by an average of 49.1% (p=0.01) during the CytoSorb™ treatment period compared to standard of care therapy alone. The treatment was well-tolerated, with no serious device related adverse events reported to date in more than 300 treatments in septic patients.

The bolded text here is very important – the primary end point of the study was a reduction in IL-6, an inflammatory cytokine, not a specific health outcome like a reduction in mortality or improved time to recovery. Nonetheless, the reduction in IL-6 was enough to win approval under EU regulations in 2011, and CE Mark allowed CTSO to commercially launch the CytoSorb in Europe. Since then, the EU medical device regulations have been overhauled to require more specific evidence of improved patient outcomes.

The CytoSorb was approved under a set of EU regulations known as the Medical Device Directive (NYSEARCA: MDD), which is presently being phased out and replaced with more stringent regulations, known as the Medical Device Regulation (NYSE: MDR). The change in regulations in Europe was brought about by, among other things, a scandal involving breast implants, and the new regulatory framework intended to reduce the risk to the public by requiring more robust evidence of efficacy and safety. In a later section, I will explain why I believe that the EU is unlikely to approve the CytoSorb just like the FDA hasn't it in the United States for the last decade, but first I will cover the company's financial results and the medical evidence on CytoSorb.

Slowing Growth, Channel Stuffing, Negative Operating Margins, and Insider Sales

The primary driver of revenue for Cytosorbants has been sales of the CytoSorb, but there have been some minimal revenues from research grants. The chart below shows the product sales, other revenue (research grants), and operating income for CTSO from 2012 to 2018, sourced from Capital IQ. CTSO was able to grow revenue quickly off an extremely small base, but this has not been enough for the company to reach profitability.

Rational stock pickers would probably not be very excited to own a company with results like this, but in the current growth bubble in which investors have been excited to overpay for any medtech

company with a rising top line, Cytosorbants reached a peak valuation of $465 million, or 24 times trailing sales, in September of 2018 according to data from S&P Xpressfeed. The excitement was supported by a peak 61% year over year growth rate in revenue in Q2 of 2018.

Cytosorbantes hit the skids on May 7, 2019 when it reported a 17% sequential decline in revenues for the first quarter of 2019. On the earnings call, CEO Philip Chan attributed the slowdown to inventory issues at 3 distributors:

Distributor sales were affected by what we anticipate to be short-term issues from 3 distributors.

Fresenius Medical Care is transitioning to new exclusive sales territories in Mexico, South Korea and the Czech Republic and did not order in Q1 of 2019, as it sells through non-transferable European inventory. Once we achieve registration of CytoSorb in Mexico and South Korea or once European inventories are sold through, we expect new CytoSorb orders. Two other distributors temporarily paused from ordering to rebalance inventory, but have strong and growing end-user demand for CytoSorb.

We believe the factors impacting distributor sales in the first quarter of 2019 are short term and specific to these 3 distributors and expect a resumption of ordering from all 3 over the next several quarters.

Chan was eager to assure everyone that the issue was temporary and that revenues would soon resume their upward trajectory:

We expect that the second quarter 2019 product sales to return to our historical growth trajectory and are anticipated to be the highest quarterly product sales reported in our history. We are not relying on orders from these distributors to achieve this guidance…We continue to forecast strong 2019 revenue growth driven by organic sales growth

On the second quarter call, Phillip Chan sounded a lot more tepid:

In terms of guidance, CytoSorbents has not historically given specific financial guidance on quarterly results until the quarter has been completed. However, we expect that the third quarter 2019 product sales will exceed third quarter 2018 product sales, and we also expect that the second half of 2019 product sales will exceed the first half of 2019 product sales.

Some simple arithmetic reveals that if CTSO hits its minimum guidance per Chan’s comments on the call, full year product revenues will be just over $20.7 million, which will represent only 3% year over year growth. Typically, when an exciting growth company sees its top line flatten out before it achieves profitability, the valuation declines dramatically.

To me, the revenue situation looks like a classic hangover from channel stuffing. The growth rate accelerated in the first half of 2018. This got naïve investors excited, and they bid the stock price up significantly. It stayed elevated until it was caught up in the broad market selloff in the 4 th Quarter of 2018.

Insiders took advantage of the rising stock price to exercise their stock options and cash out. The table below shows insider transactions for 2018. Transactions labeled as ‘acquired’ without a price represent share awards.

Source: J3SG Insider Trading Data

In aggregate, insiders sold $2.05 million in equity and there were no discretionary purchases among the executives and directors in 2018, only share awards and option exercises. A summary table is below:

Cynics, a group that includes all experienced small cap investors, should see a clear link between the final year of rapid sales growth in 2018, the insider selling, and the subsequent deceleration in sales in 2019. Insiders cashed out while the getting was good. From here, the road will get a lot bumpier.

Clinical Evidence on the CytoSorb Blood Filter

The CytoSorb has clearly benefited company insiders but the data regarding its benefits for patients is a lot less clear. In fact, after numerous trials attempting to demonstrate efficacy and safety, there is consensus among researchers that there no convincing evidence that the CytoSorb significantly improves patient outcomes. Here are excerpts of recently published research on the CytoSorb, with links to the relevant documents. Text in quotes comes directly from the linked articles, and I have added italics for emphasis where I thought it was appropriate.

April 9, 2016 - Effect of hemoadsorption during cardiopulmonary bypass surgery - a blinded, randomized, controlled pilot study using a novel adsorbent : “We did not observe significantly relevant changes in the evolution of pro-inflammatory cytokines in patients treated with the CytoSorb absorber device during CPB. However, we did not find any effects on our patients’ clinical outcomes, although future studies should endeavor to increase the sample size.” In fact, the median IL-6 level was slightly higher in the CytoSorb group compared to the control.

March 27, 2017 - Hemoadsorption by CytoSorb in septic patients: a case series : This was a case series in which 21 of the 26 cases evaluated resulted in hospital mortality. Of these, 19 died in the ICU, and 16 died within 28 days. There was no clear improvement in SOFA scores. The purpose of this study was to evaluate the impact of CytoSorb used as an adjunctive therapy on hemodynamics and clinically relevant outcome parameters. Despite improvements in some clinical measurements, 21 of 26 patients in the series still died, though the predicted / baseline mortality rate was high. The study concluded that “ randomized controlled trials are urgently needed to define the potential benefits of this new treatment option. ”

October 30, 2017 - The Effect of a novel extracorporeal cytokine hemoadsorption device on IL-6 elimination in septic patients: a randomized controlled trial : “97 of the 100 randomized patients were analyzed. We were not able to detect differences in systemic plasma IL-6 levels between the two groups ($n = 75$; $p = 0.15$).

Significant IL-6 elimination, averaging between 5 and 18% per blood pass throughout the entire treatment period was recorded. In the unadjusted analysis, 60-day-mortality was significantly higher in the treatment group (44.7%) compared to the control group (26.0%; $p = 0.039$). The proportion of patients receiving renal replacement therapy at the time of enrollment was higher in the treatment group (31.9%) when compared to the control group (16.3%). After adjustment for patient morbidity and baseline imbalances, no association of hemoperfusion with mortality was found ($p = 0.19$). ”

September 3, 2018 – Clinical Utility of Extracorporeal Cytokine Hemoadsorption Therapy: A Literature Review : “Extracorporeal blood purification using cytokine hemoadsorption therapy has been shown to normalize serum cytokine levels in patients with sepsis and septic shock, although this has not consistently translated to improved patient outcomes. The jury is still out until larger, RCTs are performed to validate the safety and efficacy of this emerging technology. ”

February 2019 - HemoAdsorption with CytoSorb : “While we wait for more evidence from these RCTs, the use of CytoSorb in clinical practice should take into account the absence of clear evidence for benefit, the potential for adverse effects, and the cost.”

March 18, 2019 - Cytokine clearance with CytoSorb during cardiac surgery: a pilot randomized controlled trial : The primary outcome was the change in blood levels of key cytokines, and it was found that there were no statistically significant differences between the two groups in serum levels of any of the cytokines of interest at any point in time. “Our study shows that, even in patients at high risk of complications, as defined by clinical criteria, CytoSorb HA, during CPG is not associated with a significant decrease in cytokine levels. Together with the trial from Bernardi et al., and despite small sample sizes, we can now conclude that routine application of CytoSorb HA seems not to be justified for elective cardiac procedures. Indeed, given the absence of effect in two well-conducted RCTs in patients with high risk of complications and prolonged

CPB but nevertheless low cytokine levels, it is highly unlikely that a larger or multi-centre trial would demonstrate a benefit. ”

In addition to the studies linked above, I found two publicly available literature reviews that summarize the evidence from trials and publications on the CytoSorb:

March, 2019 - Extracorporeal Cytokine Hemoadsorption Therapy in Patients with Sepsis or SIRS: Systematic Review : “ The current evidence does not suffice to prove that ECAT in patients with sepsis, septic shock and SIRS is effective and safe. Clinical benefits in terms of patient-relevant outcomes in both indications need to be demonstrated in order to introduce ECAT into practice. A re-evaluation is recommended in 2019, if results from RCTs or CT including more than 100 patients are available.” The most frequently reported outcome were changes in IL-6 levels, and inflammatory markers in the blood (CRP, Lactate, Procalcitonin). This paper points out some flaws in the clinical trials: Critical patient related outcomes such as mortality, organ function, days in the ICU and days of hospitalisation were presented as secondary outcomes, and not statistically tested. Long- term patient benefit was not assessed in any study. Potential harms of the technology were only addressed in the discussion and not in the results part of the studies.

March 29, 2019 - What have we learned about the use of Cytosorb adsorption columns? : “We agree with the general consensus, that the evidence to support the use of extracorporeal blood purification techniques (in general) in sepsis/other acute conditions is insufficient at this point. However, the potential benefits of adsorption therapy (control of the exaggerated immune response in particular, which typically translates into hemodynamic stability) cannot be ignored. We often think of this type of therapy as a bridge to stabilize critically ill patients, until more definitive therapies take place. The availability of adsorption devices with different removal capacities as demonstrated in the in vitro study by Malard et al. [22] could enable treatment to be more tailored to patients’ conditions resulting in better response.”

In summary, after 15 years and many trials, there is still no compelling evidence that the CytoSorb actually improves patient outcomes. Some studies report mildly favorable results in a few measured outcomes and others show that patients treated with the CytoSorb fared no better or in some cases even worse than the control groups. The lack of clear-cut evidence on the safety and efficacy of the CytoSorb will present a challenge when the product needs to be recertified under the updated European regulations.

The European Union Has Tightened Regulations, and the CytoSorb May Not Be Reapproved

Europe is a critical market for CTSO. The 10-K filings show that the majority of the product revenue is coming from Germany. The note to this table tells us that the company’s direct sales offices are located in Germany, Switzerland, Austria, Belgium and Luxembourg, so it’s a safe assumption that the “all other countries” direct sales comes from Europe (mostly EU) as well. Only the (stuffed) distributor channel is facilitating sales to other regions.

CTSO’s access to the European market is at risk. The most recent prospectus for the company, dated July 9, 2019, contains this warning:

We recognize that CytoSorb will have to be re-certified under the Medical Devices Regulation and we are in the process of updating internal procedures to ensure compliance with the new Medical Devices Regulation. Additional steps may include undertaking a gap analysis to determine the additional steps required to comply with this regulation, including determining whether additional clinical trial or post market study data or other regulatory requirements might be required to be obtained.

The European Union is in the process of transitioning from the Medical Device Directive (MDD), which was in place when the CytoSorb obtained CE Mark, to the Medical Device Regulation (MDR). According to an explainer by regulatory solutions company R&Q, the change to the MDR means increased requirements for clinical data supporting the efficacy and safety of medical devices:

Historically, the European Commission’s approach to medical device governance was seen by some as laissez-faire in comparison to its regulatory agency counterparts in countries such the United States, Canada, Japan, Australia, and Brazil. One of the key objectives of the new EU MDR is to ensure a high level of health and safety protection for EU citizens. Making clinical investigation and evaluation requirements more stringent is aimed at improving health and safety through transparency and traceability… The bar has been raised on not just the requirements surrounding clinical evidence, but the level of examination now expected… The EU MDR is setting the stage for busy times ahead and clinical evidence plays a big role. While some requirements of the MDD carried over into the MDR, it is safe to say that the clinical support piece needs to be re-evaluated sooner rather than later.

During the transition period from the MDD to the MDR, currently approved medical devices will remain on the market. Since the CtyoSorb was granted CE Mark in 2011, it will need to be reapproved by May 2022:

Source: Oriel Stat A Matrix, EU MDR Timelines: Common Questions answered about 2017/745 Implementation Dates

A summary of the regulations themselves is available in the Official Journal of European Union, dated May 5, 2017. The Cytosorb is considered a class IIb device since it is intended to treat life threatening conditions. Under the MDR, regulatory approval will be granted after a review from a panel of independent experts. The procedure is described in the Factsheet for manufacturers of medical devices :

For certain Class III and Class IIb devices there is a new clinical evaluation consultation procedure to be carried out by an independent expert panel, based on the clinical evaluation assessment report of the Notified Body.

Please bear with me for a moment – you are about to read the text of European Medical Device Regulations, which are most certainly less entertaining than tales of David Blech, royalties to mysterious Mexican housewives, or exciting stories about blood filters saving (or perhaps taking) lives. However, re-approval of the CytoSorb will be vitally important to CTSO, so this is worth reviewing in detail. The regulation itself states that

For class III implantable devices, and for class IIb active devices intended to administer and/or remove a medicinal product as referred to in Section 6.4. of Annex VIII (Rule 12), the notified body shall, having verified the quality of clinical data supporting the clinical evaluation report of the manufacturer referred to in Article 61(12), prepare a clinical evaluation assessment report which sets out its conclusions concerning the clinical evidence provided by the manufacturer, in particular concerning the benefit-risk determination, the consistency of that evidence with the intended purpose, including the medical indication or indications and the PMCF plan referred to in Article 10(3) and Part B of Annex XIV...

(NYSE: C) The expert panel shall decide, under the supervision of the Commission, on the basis of all of the following criteria:

(NYSE: I) the novelty of the device or of the related clinical procedure involved, and the possible major clinical or health impact thereof ;

(II) a significantly adverse change in the benefit-risk profile of a specific category or group of devices due to scientifically valid health concerns in respect of components or source material or in respect of the impact on health in the case of failure of the device;

(NASDAQ: III) a significantly increased rate of serious incidents reported in accordance with Article 87 in respect of a specific category or group of devices, whether to provide a scientific opinion on the clinical evaluation assessment report of the notified body based on the clinical evidence provided by the manufacturer, in particular concerning the benefit-risk determination, the consistency of that evidence with the medical indication or indications and the PMCF plan.

…The notified body shall give due consideration to the views expressed in the scientific opinion of the expert panel. Where the expert panel finds that the level of clinical evidence is not sufficient or otherwise gives rise to serious concerns about the benefit-risk determination, the consistency of that evidence with the intended purpose, including the medical indication((s)), and with the PMCF plan, the notified body shall, if necessary, advise the manufacturer to restrict the intended purpose of the device to certain groups of patients or certain medical indications and/or to impose a limit on the duration of validity of the certificate, to undertake specific PMCF studies, to adapt the instructions for use or the summary of safety and performance, or to impose other restrictions in its conformity assessment report, as appropriate.

To summarize the text above, the revised regulations will require the CytoSorb to be assessed by an independent panel of experts, who will provide a recommendation to European regulators based on the clinical data and their assessment of the benefit-risk profile of the device. The regulators themselves will need to review the clinical evidence and "the consistency of that evidence with the intended purpose, including the medical indication or indications." The "systematic review" cited above by the Ludwig Boltzmann Institut in Vienna did just that. They concluded "The current evidence does not suffice to prove that ECAT in patients with sepsis, septic shock and SIRS is effective and safe."

To reiterate: it has been over a decade since the CytoSorb was developed, and the evidence that the it is actually beneficial is still inadequate. If the EU regulators and their panel of expert advisors reaches the same conclusion as either of the literature reviews cited above, CTSO will lose access to the markets that represent at least 71% of its revenue in FY 2018. If necessary, new clinical trials would be expensive and there is no guarantee that the outcome would be positive. Losing access to the European market would likely send the stock down to net cash value or below.

HemoDefend – Delay, Delay, and More Delay

With concerns mounting about the company's growth rate and CytoSorb, CEO Philip Chan has talking more about to HemoDefened, another product in the company's pipeline. On the Q2 2018 Earnings call he said

And in terms of HemoDefend, this is a point-of-care filter that rapidly and efficiently removes noninfectious contaminants from transfused packed red blood cells that can cause transfusion reactions. This is a program that is funded up to $4.7 million, by National Heart, Lung and Blood Institute, a division of NIH, as well as U.S. SOCOM or Special Operations Command. This technology is technically compatible with pathogen reduction technologies that are being offered by a number of other companies in this space. We are targeting a total addressable market of 100 million packed red blood cell transfusions administered annually worldwide…

The pivotal trial design is a post-transfusion recovery and survival assay for autologous blood. The goal is to have the FDA IDE submission this year following requisite bench testing for efficacy. Meanwhile, our CRO and clinical trial sites have been selected. Following IDE approval, the clinical trial is expected to be completed within 3 to 6 months.

A TAM of 100 million transfusions? SOCOM? An IDE submission this year, with trial results in 3-6 months? All of that sounds very impressive, unless of course you actually examine the history of this product.

CTSO announced development of Hemodefend in October 2011 and outlined the idea for the device in its 2013 10-K. In the 10-K, it disclosed that the "In September 2013, the National Heart, Lung, and Blood Institute ("NHLBI"), a division of the National Institutes of Health ("NIH"), awarded the Company a Phase I SBIR (Small Business Innovation Research) contract to further advance its HemoDefend™ blood purification technology." This was the first of several research grants from the US Government. In the Q4 2013 earnings call, CEO Phillip Chan highlighted upcoming clinical trails

Now another opportunity for us on the business development side is a HemoDefend. We expect there to be two major trials in 2014 that maybe very important to HemoDefend platform. These are the research trial and the APO trial where in the research trial they are giving old versus new blood to cardiac surgery patients… So again HemoDefend is designed to keep new blood fresh and we're actually supported by a Phase I SBIR alternate from the NHLBI, the National Heart, Lung, and Blood Institute that will use contaminants from transude blood products that accumulates during blood storage as blood gets old the things accumulate that can cause transfusion reactions in adverse events such as organ failure and death and we continue to advance development of a HemoDefend platform towards commercialization increasing at the value while de-risking the assets with the goal of utilizing the technology with a major strategic partner.

A bit later on, it turned out that the age of the blood was not so important.

Source: a Cytosorbants post on social media

The most relevant text is in the middle of the post: "the overall conclusion, as presented yesterday at the AABB conference, was that the age of the blood had no statistically significant impact on the progression to organ dysfunction… or death… The serious adverse event rate in both new and old blood groups was approximately 50%." Recall that Hemodefend was intended to "keep new blood fresh" and protect patients from contaminants that appear "as blood gets old." It turned out that the problem that Hemodefend was meant to solve did not exist.

At that point, Hemodefend became less frequently mentioned on Cytosorbant's earnings calls, though the company did continue get development grants from the US Government. US SOCOM awarded CTSO $1.5 million in October 2015 and USAMRAA awarded $150,000 in 2016 and another for $959,000 in 2017. Unfortunately, this appears to be a case of the government throwing good money after bad, and the Hemodefend trial seems to keep getting delayed.

In a press release from June 12, 2018, COO Vincent Capponi said "we plan to utilize the current manufacturing facility, leveraging existing assets and infrastructure, to produce HemoDefend clinical devices for the planned HemoDefend U.S. pivotal trial to start in late 2018-early 2019." In the 2018 Q2 earnings call in August 2018, Philip Chan said that the " U.S. pivotal trial for this product is expected to start in the first quarter of 2019." After that, on the Q4 2018 earnings call, COO Vince Capponi revealed that the timeline had been affected by problems with a supplier and the trial was pushed back yet again:

So here is what's happened last several months. We've been experiencing delays from this key part supplier that's responsible for actually all the HemoDefend parts. They were recently required by another company and the results of that acquisition, they actually - as it happens in many M&A activities and number of the key personnel were actually let go that were working on the product and this has impacted the timeline.

So in revising kind of our tables and forecasting we are probably instead of those first half we're looking for a second half submission, I've been in constant contact with these folks and obviously, even in the acquiring company to get them to focus on our project. So just talking to one of the senior engineers today actually, we're hopeful that they will be getting these parts to us shortly to be able to carry the project forward, because it's really, because it's really, the polymer is ready, it's just been matter of getting the parts now. So it's really going to be more of a second half type event with respect to submissions to the FDA.

In Q1, Philip Chan was excited to announce that "the pivotal trial for the U.S. FDA approval is back on track for a second half of 2019 IDE submission." I am quite skeptical – Cytosorbants has been talking about getting this product approved since at least 2013 and in fact has been making similar claims about getting FDA approval for the CytoSorb since 2007.

The ATM Financing

Like many low quality cash burning companies, Cytosorbants frequently needs to raise money, and they have chosen to establish an At-The-Market (ATM) facility with Jeffries and B Riley FBR

for up to $25 million. Unsurprisingly, both Jeffries and B Riley have “buy” ratings on CTSO. As of June 30, 2019, the company had a cash balance of $16.34 million and cash used in operations of $12.76 million over the trailing 12 months, so I expect that they will use the ATM liberally to bolster their cash position. ATM financings have a well-known tendency to put pressure on the stock price and may have been a factor in the stock’s slide since the deal was announced on July 9.

Conclusion

Sales growth is slowing from a torrid 60% to an annual rate of just above 3% per the guidance, the operating profit margin is nearly -70%, the company seems unable to prove that core product provides any clinical benefits, and now it is at risk of losing regulatory approval in Europe, which is by far its largest market. Cytosorbants also has a long history of talking up Hemodefend and the other products in its ‘pipeline’ while failing to accomplish much of anything. I see no reason to think that CTSO will ever generate a profit or get acquired. As such, I would put its value at net cash, which was about 20 cents per share at the end of last quarter.

Disclosure: I am/we are short CTSO. I wrote this article myself, and it expresses my own opinions. I am not receiving compensation for it (other than from Seeking Alpha). I have no business relationship with any company whose stock is mentioned in this article.