August 6, 2020

Zacks Small-Cap Research

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CytoSorbents Corporation (CTSO-NASDAQ)

2Q20 Results Illustrate Surging Demand For CytoSorb

CTSO revenue reached a record $9.8 million in 2Q20, up 58% y/y despite hospital mandates to delay many cardiac surgeries. Strong demand, including for COVID-19 treatment, drove delivery of more than 100,000 CytoSorb treatments to-date.

OUTLOOK

With demand rising for CytoSorb for a number of indications, distribution expanded into 65 markets plus the U.S. under EUA for Covid-19 treatment and HemoDefend advancing towards commercialization, we continue to see upside for CTSO shares.

Current Price (08/05/20)	$9.66
Valuation	**$15.00**

SUMMARY DATA

52-Week High	**$11.74**
52-Week Low	**$3.61**
One-Year Return (%)	**47.71**
Beta	**0.53**
Average Daily Volume (sh)	**625,596**
Shares Outstanding (mil)	**43**
Market Capitalization ($mil)	**$417**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**28**
Insider Ownership (%)	**6**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**55.5**
Earnings Per Share (%)	**N/A**
Dividend (%)	**N/A**
P/E using TTM EPS	**N/A**
P/E using 2020 Estimate	**N/A**
P/E using 2021 Estimate	**N/A**
Zacks Rank	**N/A**

Risk Level	**Above Avg.**
Type of Stock	**Small-Growth**
Industry	**Med Products**

ZACKS ESTIMATES

Revenue
(in 000s of $)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2019	$5,192 A	$6,233 A	$6,095 A	$7,430 A	$24,950A
2020	$8,707 A	$9,795 A	$9,624 E	$9,952 E	$38,080E
2021					$46,791E
2022					$57,400E

EPS

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2019	-$0.15 A	-$0.14 A	-$0.21 A	-$0.16 A	-$0.60 A
2020	-$0.10 A	-$0.08 A	-$0.07 E	-$0.01 E	-$0.25 E
2021					-$0.09 E
2022					$0.11 E

Quarters might not sum due to rounding & share count.

Disclosures on page 9.

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KEY POINTS

- CytoSorbents reported 2Q20 revenue of $9.8 million this week, up 58% y/y and a quarterly record. Of this, $9.5 million was product revenue, which we believe underscores growing demand for CytoSorb as the company continues to generate data supporting the efficacy of CytoSorb for a growing number of indications.

- Reflecting the all-hands-on-deck mode with which CTSO stretched its manufacturing capabilities to meet surging demand, gross margins were roughly 70% versus 76% in 2Q19. We believe the need to incur costs to ramp production quickly in response to COVID-19 and other demand for CytoSorb underscores the need to expand production capacity. On an adjusted basis, gross margins were in-line with recent quarters.

- As the number of indications for CytoSorb use has expanded, CTSO has delivered more than 100,000 CytoSorb cartridges globally and has treated tens of thousands of patients. This has translated into product revenue of about $30 million over the past 12 months.

- Separately, the Data Monitoring Committee (DMC) of the REFRESH 2-AKI trial has completed a comprehensive review of the safety data generated from the study thus far and recommended that the trial resume.

- We believe the potential incremental value of HemoDefend could be significant. CTSO continues to obtain funding to advance HemoDefend and just announced a new $4.4 million contract award from the U.S. Department of Defense to complete HemoDefend-BGA adsorber preclinical development.

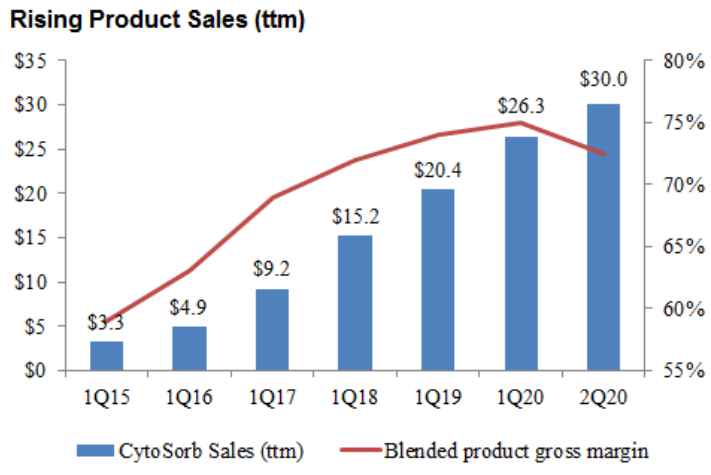
2Q20 RESULTS ILLUSTRATE SURGING DEMAND FOR CYTOSORB

CytoSorbents (NASDAQ-CTSO) reported 2Q20 revenue of $9.8 million. This represents a 58% year-over-year advance and a quarterly record, despite hospital mandates to delay elective cardiac surgeries. The majority of this, $9.5 million, was product revenue, which underscores the growing demand for CytoSorb as the company continues to generate data supporting its efficacy for a growing range of indications. Product revenue for the last 12 months was roughly $30.0 million (see figure below).

With sales rising, the company intends to expand production capacity to meet growing demand. In fact, demand has grown so rapidly that the company has had to stretch its manufacturing capabilities by adding labor and shifts, which pressured 2Q20 gross margins to roughly 70% versus 76% in the prior year 2Q. On an adjusted basis excluding the added costs of increasing production, gross margins were in-line with recent quarters.

The need to ramp production quickly in response to COVID-19 and other treatments underscores growing demand for CytoSorb for a variety of conditions. CytoSorb has been used to treat an estimated more than 1,200 COVID-19 patients thus far. Use of CytoSorb has expanded with the company's growing database to support its efficacy treating a number of conditions, including trauma, refractory shock, acute respiratory distress syndrome (ARDS) and complications from the SARS-CoV-2 (COVID-19) infection, among many other conditions,

CTSO has delivered more than 100,000 CytoSorb cartridges globally and has treated tens of thousands of patients. This has translated into product revenue of about $30 million over the past 12 months. The company also indicated that 3Q20 is tracking for strong revenue, despite the usual seasonal quarterly downtick in prior years. We have revised our 3Q20 estimate.



2Q20 margin reflects higher costs to accelerate production

Source: Cytosorbents.com

In April, the company obtained FDA approval for CytoSorb for use in patients with COVID-19 infection pursuant to the FDA's EUA (Emergency Use Authorization) process. The EUA process enables the FDA to move rapidly in an emergency situation such as the coronavirus pandemic and authorize unapproved medical products or new uses of approved medical products to diagnose, treat or prevent serious diseases in an emergency situation when no approved alternatives are available. The EUA allows CytoSorb to be sold commercially to hospitals in the U.S. and used on patients with acute lung injury or acute respiratory distress syndrome (ARDS) or life-threatening illness resulting in respiratory failure, septic shock, and/or multiple organ dysfunction or failure.

Strong demand has come from established applications and now also reflects treatment of COVID-19 patients. An estimated roughly $2.4 to $2.6 million of 2Q20 product sales came from demand for CytoSorb to treat COVID-19 patients, with roughly $667,000, or about 7% of total 2Q20 sales, deliveries to U.S. hospitals following receipt of FDA EUA. Prior to receiving emergency approval, the company had donated some CytoSorb units to U.S. hospitals, which also helps boost awareness of CytoSorb, in our view.

As CytoSorb continues to gain approval in various markets and as awareness of its efficacy grows, CTSO also intends to expand its commercial sales team. For example, CTSO has grown its sales force in Germany to 19 people since late 2019. In addition, in June 2020, the company launched CytoSorb in nine Latin American markets: Colombia, Argentina, Perú, Guatemala, Ecuador, Bolivia, the Dominican Republic, El Salvador, and Costa Rica. CytoSorb is now distributed in 65 markets globally.

CYTOSORB FOR COVID-19 & OTHER

CytoSorb to Treat COVID-19 & Combat Cytokine Shock

COVID-19, caused by the SARS-CoV-2 novel coronavirus, causes cytokine storms where the immune system releases an excess of cytokines that cause systemic inflammatory response syndrome. This can often result in organ failure and death. Cytosorbents' CytoSorb aims to reduce inflammatory toxins and reduce the cytokine storm by filtering the blood of potentially lethal substances.

Cytokine storms cause the lungs to accumulate fluid and inflammatory mediators such as cytokines. CytoSorb is designed to prevent this and potentially help reduce the need for mechanical ventilation and/or enable patients to wean more quickly from mechanical ventilators.

Several of the 65 countries where CTSO operates have been impacted by COVID-19, including Italy, Iran, Germany, France, Spain, Hong Kong, among many others. As economies reopen, many markets are beginning to see an uptick in COVID-19 cases. As CytoSorb has proven effective in helping patients fight cytokine shock, or lung failure produced by cytokine storms, we believe COVID-19 has boosted awareness of CytoSorb.

In February 2020, CytoSorb was added to coronavirus treatment guidelines in Italy and Panama. Cytosorbents also signed an agreement with China Medical System Holdings Limited to treat COVID-19 patients using CytoSorb. CytoSorb's use for COVID-19 patients began in March 2020 and initial preliminary feedback has been positive.

CytoSorb's Efficacy Treating COVID-19 Could Be a Catalyst to Broaden Addressable Market

As noted, CytoSorbents generated about 7% of total revenue from U.S. hospital sales of CytoSorb to treat critical COVID-19 patients. At this early stage in the COVID-19 pandemic, the outlook for the virus is uncertain. With several domestic and international markets either experiencing a second surge or warning about one, demand for CytoSorb for COVID-19 treatment might remain high. We believe, however, a more important aspect of the pandemic for CTSO is that it has put CytoSorb on the map for treatment of patients with lung disease generally, offering proof of concept about CytoSorb's efficacy that might help broaden the market for CytoSorb. The database of evidence supporting the utility of CytoSorb is, in fact, expanding. We believe this continues to be a key catalyst in driving awareness, adoption and utilization of CytoSorb. CTSO recently conducted a Key Opinion Leader (KOL) webinar to discuss CytoSorb, noting the rapid pace at which CytoSorb adoption is increasing.

CytoSorb Breakthrough Designation

In April 2020, CytoSorb received breakthrough designation from the FDA for use in reducing ticagrelor during urgent or emergent cardiac surgery. There is often a high risk of hemorrhage when patients on ticagrelor need cardiac surgery. The breakthrough designation enables the FDA to accelerate the review and approval process and potentially authorize CytoSorb for the removal of ticagrelor.

REFRESH 2-AKI

CTSO put enrollment in its REFRESH 2-AKI trial on hold in November of 2019 in order to re-monitor existing data and collect and analyze new data with a new contract research organization (CRO) in order to improve patient safety. Following a review of the safety data from the 153 patients included in the trial to-date, the company will make minor modifications and resume the trial.

HEMODEFEND: DEVELOPMENT OF UNIVERSAL PLASMA

Adsorber Removes Anti-A and Anti-B Antibodies from Blood and Plasma for Transfusion

With CytoSorb consuming most of the investor interest in CTSO, the potential incremental value of HemoDefend may be under-realized, in our view. CTSO's program for HemoDefend is intended to remove anti-A and anti-B antibodies from blood and plasma for transfusion in order to create universal plasma that can be administered to a trauma patient regardless of blood type. CTSO is receiving funding from the U.S. Army Medical Research and Development Command. Not surprisingly, the army would like to see the development of universal plasma to treat military trauma patients in the field where blood type testing generally is not viable and transfusions are needed urgently, with delays likely to result in higher mortality rates. CTSO recently was awarded a $4.4 million contract by the U.S. Department of Defense to complete HemoDefend-BGA adsorber preclinical development.

CTSO hopes that its HemoDefend-BGA adsorber will help expand the availability of universal plasma and whole blood for transfusions. Immune hemolytic transfusions reactions happen when the transfused blood products are incompatible with the patient's own blood type. Simply put, patients with blood type A cannot safely be infused with B type blood products and vice versa because the A or B antigens on the surface of their red blood cells will fight the transfused blood, often producing a hemolytic transfusion reaction. Even with Type O whole blood, which generally is the universal donor type, varying levels of anti-A and anti-B antibodies can cause immune hemolytic transfusion reactions.

The HemoDefend-BGA filter removes anti-A and anti-B antibodies from whole blood and plasma to enable these products to be "universal" for safe transfusion in a patient regardless of that patient's blood type, thereby reducing or eliminating hemolytic transfusion reactions.

Broad Market Opportunity

The addressable market for HemoDefend could be sizable, we believe. According to the World Health Organization (WHO), worldwide roughly 118.5 million blood donations are made annually. Blood donation rates vary widely from country to country. Specifically, 40% of annual blood donations are produced in high-income countries that collectively represent some 16% of the global population, according to WHO data.

WHO estimates that hemorrhage is responsible for about 35% of the mortality from traumatic injuries. In non-combat civilian situations, the National Trauma Institute estimates that the percentage of deaths resulting from hemorrhage within the first 24-hours of injury is even higher. HemoDefend-BGA aims to increase the safety of whole blood transfusion of all types of blood to reduce the occurrences of Immune hemolytic transfusions reactions.

VALUATION

COVID-19 Offers CytoSorb Proof-of-Concept/Expands Database

Our valuation of CTSO shares is based on a discounted cash flow (DCF) model. We use a 10% discount rate and a 2% terminal growth rate in our 10-year DCF model, which suggests a valuation of about $15 for CTSO shares.

We note, however, that rising interest in CytoSorb for use as part of an integrated program to help COVID-19 patients is likely to expand overall awareness and visibility of CytoSorb as a treatment for patients with lung injuries and/or acute respiratory distress syndrome (ARDS). We believe that COVID-19 and the cytokine storms that often accompany the virus offer proof of concept about the efficacy of the treatment and could accelerate and/or increase demand for CytoSorb. In turn, this could imply upside to our current valuation projection.

RECENT NEWS

- CTSO reported 2Q20 results on August 4, 2020.
- The company announced the REFRESH 2-AKI trial data monitoring committee recommended that the study resume on July 28, 2020.
- CTSO raised about $57.5 million through a public equity offering in July of 2020.
- The company pre-announced certain 2Q20 metrics on July 20, 2020.

- CTSO held a KOL webinar on July 13, 2020.
- On July 21, 2020, CTSO was awarded a $4.4 million award from the U.S. Army Medical Research group to advance HemoDefend.
- CTSO was awarded a $2.9 million Phase III STTR contract to advance HemoDefend on June 9, 2020.
- CytoSorb received E.U. approved to remove rivaroxaban on May 12, 2020.
- On May 5, 2020, CytoSorbents reported record results for 1Q 2020.
- On April 20, 2020, the FDA granted breakthrough designation to CytoSorb for removal of Ticagrelor during cardiopulmonary bypass in emergent and urgent cardiothoracic surgery.
- The company released results of a new study that suggests that CytoSorb improves clinical outcomes in pneumonia patients with septic shock and acute respiratory distress syndrome (ARDS) on April 15, 2020.

FINANCIAL MODEL

CytoSorbents Inc.

CTSO	2019 A	Q1 A	Q2 A	Q3 E	Q4 E	2020 E	2021 E
CytoSorb Sales	$22,765.9	$8,156.0	$9,451.3	$9,186.7	$9,489.1	$36,283.1	$44,520.2
y-o-y growth	*12.4%*	*78.2%*	*61.5%*	*62.6%*	*41.8%*	*59.4%*	*22.7%*
Total Royalties/Grants/Other	$2,183.6	$551.3	$343.6	$437.3	$465.1	$1,797.3	$2,271.0
y-o-y growth	*-3.0%*	*-10.4%*	*-10%*	*-2.1%*	*-37.1%*	*-17.7%*	*26.4%*
Revenue	$24,949.5	$8,707.3	$9,794.9	$9,624.0	$9,954.2	$38,080.4	$46,791.2
YOY Growth	*10.9%*	*67.7%*	*57.2%*	*57.9%*	*34.0%*	*52.6%*	*22.9%*
Cost of Goods Sold	$7,363.9	$2,384.8	$3,249.8	$3,079.7	$2,936.5	$11,650.8	$10,643.1
Gross Income	$17,585.6	$6,322.5	$6,545.1	$6,544.3	$7,017.7	$26,429.7	$36,148.1
Gross Margin	*70.5%*	*72.6%*	*66.8%*	*68.0%*	*70.5%*	*69.4%*	*77.3%*
SG&A	$24,467.8	$6,836.0	$7,436.8	$6,990.6	$6,578.4	$27,841.8	$29,237.4
SG&A %of Prod Sales	*107.5%*	*78.5%*	*78.7%*	*72.6%*	*66.1%*	*73.1%*	*62.5%*
R&D	$12,091.8	$1,965.3	$2,406.0	$2,746.5	$2,844.8	$9,962.6	$9,844.6
R&D %Tot Sales	*48.5%*	*22.6%*	*24.6%*	*28.5%*	*28.6%*	*26.2%*	*21.0%*
Operating Income	($18,974.1)	($2,478.8)	($3,297.7)	($3,192.8)	($2,405.5)	($11,374.7)	($2,933.9)
Operating Margin	-						
Total Other Expense	$1,384.0	($974.0)	$430.7	$345.0	$2,168.6	$1,970.3	$568.7
Pre-Tax Income	($20,358.1)	($3,452.8)	($2,867.0)	($2,847.8)	($236.9)	($9,404.4)	($3,502.6)
Taxes (benefit)	$1,092.4	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Tax Rate	*-5.4%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*
Preferred/Othr Dividend	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Net Income	($19,265.6)	($3,452.8)	($2,867.0)	($2,847.8)	($236.9)	($9,404.4)	($3,502.6)
Net Margin	*-77.2%*	*-39.7%*	*-29.3%*	*-29.6%*	*-2.4%*	*-24.7%*	*-7.5%*
EPS	($0.60)	($0.10)	($0.08)	($0.07)	($0.01)	($0.25)	($0.09)
Diluted Shares O/S	32,255	33,981	36,483	38,880	43,158	38,126	39,500

Source: Zacks

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