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Zacks Small-Cap Research

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CytoSorbents Corporation (CTSO-NASDAQ)

CTSO: Positive Implications of $2.9 Million STTR Phase III Contract

Based on our 10-year DCF model, which uses a 10% discount rate and a 2% terminal growth rate, we estimate that CTSO shares are valued at approximately $15.00.

Current Price (06/17/20)	$9.35
Valuation	**$15.00**

OUTLOOK

We believe the STTR contract award validates the potential of the company's technology and will enable CTSO to move HemoDefend-BGA closer to commercialization. Separately, demand for CytoSorb to treat COVID-19 patients contributed to a 78% Y/Y improvement in sales in 1Q20 and $2.7 million sales backlog. Recent FDA EUA approval for CytoSorb for treatment of COVID-19 patients and breakthrough designation for use in reducing ticagrelor during urgent or emergent cardiac surgery could portend continued sales ramp going forward, we believe.

SUMMARY DATA

52-Week High	**$11.24**
52-Week Low	**$3.49**
One-Year Return (%)	**42.53**
Beta	**0.57**
Average Daily Volume (sh)	**889,231**
Shares Outstanding (mil)	**36**
Market Capitalization ($mil)	**$349**
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 (%)	**54.1**
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	$9,348 E	$8,053 E	$8,484 E	$34,592E
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	-$0.06 E	-$0.09 E	-$0.07 E	-$0.33 E
2021					-$0.09 E
2022					$0.11 E

Quarters might not sum due to rounding & share count.

Disclosures on page 10.

KEY POINTS

- Cytosorbents was awarded a Defense Health Agency Small Business Technology Transfer (STTR) Phase III contract valued at up to $2.9 million over a two-year period, enabling CTSO to move HemoDefend-BGA closer to commercialization.

- 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 the patient's blood type, thereby reducing or eliminating the risk of hemolytic transfusion reactions.

- According to the World Health Organization (WHO), roughly 118.5 million blood donations are made annually on a worldwide basis. HemoDefend-BGA aims to increase the safety of transfusions.

- Separately, Cytosorbents' CytoSorb blood purification technology has proven effective in helping patients fight cytokine shock, or lung failure produced by cytokine storms. 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. In turn, this can help medical facilities expand resources to care for a greater number of patients.

- As economies reopen, many markets are beginning to see an uptick in COVID-19 cases. 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. CTSO obtained FDA approval for CytoSorb under the FDA's EUA process in April.

NEW CONTRACT VALIDATES HEMODEFEND POTENTIAL

Earlier this month Cytosorbents (NASDAQ-CTSO) announced that it was awarded a Defense Health Agency Small Business Technology Transfer (STTR) Phase III contract valued at up to $2.9 million over a two-year period. The contract is intended to advance the company's HemoDefend-BGA plasma and whole blood adsorber to human clinical trials.

After successfully completing Phases I and II, companies can apply for Phase III via a competitive process. During the first two phases of STTR, CTSO obtained roughly $1.15 million to work with researchers at Penn State University to advance the HemoDefend-BGA adsorber. Under the prior STTR Phase II program, CTSO and researchers developed an advanced HemoDefend-BGA prototype. In Phase III, CTSO can continue to advance the HemoDefend-BGA adsorber closer to commercialization.

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

CTSO's program for HemoDefend is called *"Development of a Highly Efficient Adsorber to Remove Anti-A and Anti-B Antibodies from Blood and Plasma for Transfusion.*" CTSO is receiving funding from the U.S. Army Medical Research and Development Command.

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.

CTSO has earmarked the STTR money to optimize the HemoDefend-BGA adsorber prototype and scale-up manufacturing to produce commercial-grade materials with the objective of ultimately garnering FDA regulatory approval after clinical testing. The company hopes that its HemoDefend-BGA adsorber will help expand the availability of universal plasma and whole blood for transfusions.

Broad Market Opportunity

The addressable market for HemoDefend could be sizable, we believe. According to the World Health Organization (WHO), roughly 118.5 million blood donations are made annually on a worldwide basis. 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.

COVID-19 TREATMENT BOOSTS MARKET AWARENESS

A New Opportunity For CytoSorb To Combat Cytokine Shock

The company operates in several countries, including Italy, Iran, Germany, France, Spain, Hong Kong, that are affected by COVID-19. COVID-19 is caused by SARS-CoV-2, the novel coronavirus. SARS-CoV-2 causes cytokine storm, where the immune system releases an excess of cytokines that cause systemic inflammatory response syndrome which results in organ failure and eventually death. This feature is typical in patients having respiratory illness, sepsis, burn injury, trauma, liver failure, complications in cardiac surgery, etc. Initially, CytoSorb was specifically added to coronavirus treatment guidelines in Italy and Panama.

In February 2020, Cytosorbents inked an agreement with China Medical System Holdings Limited (CMS), a well- established, specialty pharma, to treat critically-ill patients in China with COVID-19 infection using CytoSorb. CytoSorb was introduced to four hospitals in Wuhan, China. The therapy was evaluated in 17 severe COVID-19 coronavirus patients with a systemic inflammatory response who were treated with either continuous renal replacement therapy (CRRT) or extracorporeal membrane oxygenation (ECMO).

To-date, CytoSorb has been used in more than 750 patients infected with COVID-19 in Italy, China, Germany, France and other markets afflicted with the virus. Of these treatments, 25 patients are from the U.S. (under the EUA authorization see below). Preliminary feedback from physicians point to CytoSorb use as generally being associated with a marked reduction in cytokine storm and inflammation, improved lung function, weaning from mechanical ventilation and a reversal of shock. Also based on these preliminary reports, CytoSorb has been specifically recommended in the Italy Brescia Renal COVID Task Force Guidelines to treat patients with severe COVID-19 infection and Stage 3 renal failure on continuous renal replacement therapy. CytoSorb has also been recommended in the National Treatment Guidelines from Panama for Adult COVID-19 patients if they have either refractory shock or severe/refractory respiratory failure requiring either high ventilator support or ECMO.

FDA EUA: *Increased Attention on CytoSorb During Pandemic Could Facilitate & Accelerate Broader Use FDA Approval*

In April 2020, the company also obtained FDA approval for CytoSorb for use in patients with COVID-19 infection pursuant to the FDA's EUA (Emergency Use Authorization) process. In February 2020, FDA issued *Immediately in Effect Guidance* on diagnostics testing for the coronavirus. The EUA process enables the FDA to move rapidly in an emergency situation such as the coronavirus pandemic. Specifically, it allows the FDA to 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 that have 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. The company has recommended the use of four cartridges per patient. Initial feedback from the physicians, based on preliminary clinical evidence, seems to indicate that CytoSorb may be beneficial if utilized in the early acute phase of the COVID-19 infection.

Moreover, as economies reopen, many markets are also beginning to see an uptick in COVID-19 cases. The COVID crisis has thrust the company into the spotlight. In a fairly short period of time CytoSorb has garnered meaningful interest from several geographies to treat COVID-19. CytoSorb s apparent early success in treating COVID-19 patients is encouraging, particularly as it may relate to CytoSorb s effective utility in other critical care illnesses that are associated with cytokine storm.

Future recommendations and potentially published manuscripts from some of these investigator-initiated studies, could wield meaningful influence - the fruits of which we think may be seen in the short-to-mid-term. This growing interest in CytoSorb to treat cytokine storm is what we think will be pivotal in accelerating uptake and interest of CytoSorb for clinical use as well as providing support for initiation of U.S. clinical studies. We view FDA s EUA authorization of CytoSorb as a meaningful milestone towards eventual approval and commencement of larger U.S. studies in support of a regulatory filing.

CytoSorb Breakthrough Designation

Separately, 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.

In addition, we continue to see other catalysts having an initial influence on sales. This includes assignment of reimbursement amount in Switzerland (possibly within the next 12 months), and adoption driven by case studies, investigator-initiated studies, KOL interest and (potentially positive results of) the ongoing REMOVE and REFRESH 2-AKI studies. HemoDefend, a U.S. pivotal study for which could begin in the coming months, represents another potential near-term catalyst.

VALUATION

CytoSorb Demand to Treat COVID-19 Patients Contributed to 1Q 78% Y/Y Sales Improvement

Given rising interest in CytoSorb for use as part of an integrated program to help COVID-19 patients, we assume awareness and visibility of CytoSorb continues to grow. Preliminary feedback about the efficacy of CytoSorb has been positive, as noted, particularly when CytoSorb use occurs early in the patient's treatment. The company achieved 78% y/y improvement in product sales in 1Q20 to $8.2 million, with an estimated roughly $1.5 to $1.7 million (18% to 21%) of that reflecting demand for CytoSorb for COVID-19

patients. We think that if results and feedback from hospitals and critical care professionals remains positive, it bodes well for further commercial sales growth. CytoSorb's use for COVID-19 patients began in March 2020. Primarily reflecting demand for CytoSorb to treat COVID-19 patients, CTSO ended 1Q20 with a sales backlog of about $2.7 million.

At 1Q20, CTSO had $26.4 million in cash and $5.4 million in grants and accounts receivable with which to advance its technologies. As we have noted previously, CTSO also continues to pursue and win grant income to help subsidize R&D, as well as to provide additional validation of its technology, as we believe the recent STTR contract shows.

As a result of expected sales growth combined with contained R&D spending, we expect CTSO to near breakeven as we move into 2022. 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.

RECENT HIGHLIGHTS

Operational & Financial

- **Record Revenue, Margins**: Q1 set records on product revenue. Achieved guidance on product margins which widened to 80% by Q4 2019, are benefitting from growth in direct sales (proportionally as well as in aggregate) and achieved more product efficiencies
- **CE Mark Renewal:** on August 15th , 2019 CytoSorbents announced that they received renewal of its European Union CE Mark through May 2024 and ISO 13485 to September 2022, ensuring no interruptions to international commercialization
- **REFRESH 2-AKI:** Guiding to reach 50% mark (i.e. 200 patients) by Q4 2020-Q1 2021 and, if all goes to plan, make PMA filing by ~mid-2022. Continued progress in REFRESH 2-AKI is what represents the most significant potential pipeline-related value enhancement in our opinion
- **REMOVE:** rapid enrollment pace continues with 288 patients (of planned 250) through. Data analysis to follow. Guiding for topline data by mid-2020 which we think will represent a potential value-inflection event in CTSO s share price
- **Commercialization Footprint Expanding**: CTSO s footprint continues to grow and now encompasses 58 countries and counting. Regulatory clearances anticipated in S. Korea, a substantial market. CTSO s direct territories recently increased to 10. Direct sales bring enhanced margins, as well as other benefits
- **HemoDefend U.S. Clinical Trial:** CTSO expects to seek U.S. regulatory approval to commence a pivotal study for HemoDefend. Study could begin and finish by mid-next year and, if all goes smoothly, HemoDefend could be on the U.S. market shortly afterwards. Progress on this pursuit also holds value-inflection opportunity in our opinion
- **Extended CytoSorb distribution to 58 countries**: In addition to selling through distributors, the company extended its sales using direct sales force in 10 countries.

Financial Review: CytoSorbents reported 1Q20 financial results and provided a business update

Total revenue from product sales was $8.2M for Q1 which increased 78% yoy and 22% qoq. Sales growth was fueled by strength in core critical care and cardiac surgery markets. As the company had previously guided, Q1 2020 product sales exceeded Q1 2019 product sales driven by strength in direct sales from increased product demand. The record increase in product sales was also fueled by demand for CytoSorb in response to the coronavirus pandemic. In the earnings call, CEO Phillip Chan said the company has ramped up the production of CytoSorb and the manufacturing facility is running at near full capacity. The company had sales back order of approximately $2.7M. The company has rapidly scaled-up manufacturing with a goal to fulfill backorders by the end of Q2 2020. The ~$1.5M incremental revenue related to the surge in CytoSorb demand from the COVID-19 pandemic represents about 20% of the overall $8.2M revenue for Q1. Based on the estimate given by the company, we think that roughly 20-

30% of the Q2 revenues could be directly related to the sales of CytoSorb to treat COVID-19 patients. While CytoSorb demand is likely to remain strong in the second quarter, we think the demand would likely weaken, extending through the rest of 2020, as the pandemic subsides resulting in lower revenues during this time. However, if there is a second and third resurgence from this virus, we could witness demand shooting up again for CytoSorb. Also, noteworthy as it relates to product sales reaching a new record, is that this a foreign exchange headwind negatively affected sales by $237k (or ~3% of product sales). Meanwhile, grant income was $551k in Q1. While we expect additional (and near-term) opportunities to score future grants, we expect overall revenues to soften a bit by decreasing grant revenues as grant-related activities have been suspended temporarily due to quarantine and physical distancing requirements because of COVID-19.

Product gross margins for Q1 were 76%, higher from 74% in Q1 2019 but lower from 80% in Q4 2019 due to increased costs required to rapidly scale-up CytoSorb production. We expect gross margins to widen to 80% and beyond as production efficiencies improve and once the initial costs associated with the increases in production capacity are met with. We currently model full year 2020 product margin of nearly 80%, or ~300 basis points better than 2019.

Meanwhile, grant income continues to help subsidize R&D as well as providing additional validation of CTSO s technology (particularly given the list of contracts has continually grown). We think CTSO will continue to look to monetize the successes of these grant-funded studies with further label extensions and in the development of new technologies (such as HemoDefend). That could provide additional optionality in terms of commercial programs that CTSO could pursue. We think HemoDefend may be a dark horse that is mostly being overlooked by investors and the significance of continued development progress should not be underestimated.

Operating expenses increased slightly on a yoy basis as compared to Q1 2019. Operating expenses, which included about $150k worth of non-cash stock compensation, were $8.8M (including ~$0.8M in stock comp) in Q1 2020, compared to $7.7M (including ~$2M in stock comp) in Q1 2019. R&D spend decreased by ~$1M as compared to Q1 2019 due to the temporary pause in the REFRESH 2-AKI study that resulted in lower clinical trial costs. This decrease was offset by an increase in expenses related to increase in headcount of the sales and marketing staff. The direct sales force (including support staff) now stands at 79 people. While operating expenses have increased, these investments are expected to result in steepening of the revenue and, eventual, earnings curve.

Cash used in operating activities was $3.2M in Q1 2020 as compared to $4.2M in the comparable prior year period. The company exited the quarter with a strong cash position of approximately $26M. Of this amount, approximately $13M was raised by utilizing the ATM facility. The company also received approximately $1M in cash from the approved sale of NOLs and R&D credits from the State of New Jersey in the Q1 2020. Management has guided that the cash runway is likely to extend well into 2021. As of May 1, 2020, the company had about 41M common shares o/s on a diluted basis.

RECENT COMPANY NEWS

- CTSO was awarded a $2.9 million Phase III STTR contract to advance HemoDefend to clinical trials 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 E	Q3 E	Q4 E	2020 E	2021 E	2022 E
CytoSorb Sales	$22,765.9	$8,156.0	$8,936.0	$7,615.2	$8,018.4	$32,725.6	$44,520.2	$55,128.3
y-o-y growth	*12.4%*	*78.2%*	*52.7%*	*34.8%*	*19.8%*	*43.7%*	*36.0%*	*23.8%*
Total Royalties/Grants/Other	$2,183.6	$551.3	$412.3	$437.3	$465.1	$1,866.0	$2,271.0	$2,272.0
y-o-y growth	*-3.0%*	*-10.4%*	*7.9%*	*-2.1%*	*-37.1%*	*-14.5%*	*21.7%*	*0.0%*
Revenue	$24,949.5	$8,707.3	$9,348.3	$8,052.5	$8,483.5	$34,591.6	$46,791.2	$57,400.3
YOY Growth	*10.9%*	*67.7%*	*50.0%*	*32.1%*	*14.2%*	*38.6%*	*35.3%*	*22.7%*
Cost of Goods Sold	$7,363.9	$2,384.8	$2,168.8	$1,731.3	$1,764.6	$8,049.5	$10,643.1	$12,454.1
Gross Income	$17,585.6	$6,322.5	$7,179.5	$6,321.2	$6,718.9	$26,542.1	$36,148.1	$44,946.2
Gross Margin	*70.5%*	*72.6%*	*76.8%*	*78.5%*	*79.2%*	*76.7%*	*77.3%*	*78.3%*
SG&A	$24,467.8	$6,836.0	$6,998.3	$6,321.0	$5,483.5	$25,638.8	$29,237.4	$31,028.4
SG&A %of Prod Sales	*107.5%*	*78.5%*	*74.9%*	*78.5%*	*64.6%*	*74.1%*	*62.5%*	*54.1%*
R&D	$12,091.8	$1,965.3	$2,000.0	$2,946.5	$3,300.8	$10,212.6	$9,844.6	$9,345.6
R&D %Tot Sales	*48.5%*	*22.6%*	*21.4%*	*36.6%*	*38.9%*	*29.5%*	*21.0%*	*16.3%*
Operating Income	($18,974.1)	($2,478.8)	($1,818.8)	($2,946.3)	($2,065.4)	($9,309.3)	($2,933.9)	$4,572.2
Operating Margin	*-*							*8.0%*
Total Other Expense	$1,384.0	$974.0	$310.0	$345.0	$341.3	$1,970.3	$568.7	$1.0
Pre-Tax Income	($20,358.1)	($3,452.8)	($2,128.8)	($3,291.3)	($2,406.7)	($11,279.6)	($3,502.6)	$4,571.2
Taxes (benefit)	$1,092.4	$0.0	$0.0	$1.0	$2.0	$3.0	$0.0	$1.0
Tax Rate	*-5.4%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*
Preferred/Othr Dividend	$0.0	$0.0	$0.0	$1.0	$2.0	$3.0	$0.0	$1.0
Net Income	($19,265.6)	($3,452.8)	($2,128.8)	($3,293.3)	($2,410.7)	($11,285.6)	($3,502.6)	$4,569.2
Net Margin	*-77.2%*	*-39.7%*	*-22.8%*	*-40.9%*	*-28.4%*	*-32.6%*	*-7.5%*	*8.0%*
EPS	($0.60)	($0.10)	($0.06)	($0.09)	($0.07)	($0.33)	($0.09)	$0.11
Diluted Shares O/S	32,255	33,981	34,385	34,879	35,145	34,598	39,500	42,500

Source: Zacks

HISTORICAL STOCK PRICE

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