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Zacks Small-Cap Research

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CytoSorbents Corporation (CTSO-NASDAQ)

Strengthened Balance Sheet Supports Growth Initiatives As Demand For CytoSorb Continues to Surge

CTSO has expanded manufacturing to meet rising demand generated, in part, by demand to treat COVID-19 cases. Quarterly revenue reached another record level in 3Q20, coming in at $10.5M, which represents a 73% y/y advance and record high, further supporting CTSO's need to expand production capacity.

Current Price (08/05/20)	$8.03
Valuation	**$15.00**

OUTLOOK

We continue to see upside for CTSO shares. Demand is rising for CytoSorb for a number of applications. To meet demand, CTSO has implemented initiatives to expand sales, manufacturing and distribution. We believe there are opportunities to accelerate the path to FDA approval in the U.S., where sales continue under EUA for COVID-19 treatment. Concurrently, CTSO is also moving HemoDefend forward with the assistance of grants from the U.S. Army Medical Research and Development Command.

SUMMARY DATA

52-Week High	**$11.74**
52-Week Low	**$3.49**
One-Year Return (%)	**81.67**
Beta	**0.39**
Average Daily Volume (sh)	**332,175**
Shares Outstanding (mil)	**43**
Market Capitalization ($mil)	**$347**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**26**
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
($M)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2019	$5.2 A	$6.2 A	$6.1 A	$7.4 A	$25.0A
2020	$8.7 A	$9.8 A	$10.2 A	$10.8 E	$39.8E
2021					$46.8E
2022					$57.4E

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	-$0.02 A	-$0.03 E	-$0.22 E
2021					-$0.08 E
2022					$0.11 E

Quarters might not sum due to rounding & share count.

Disclosures on page 10.

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KEY POINTS

- CytoSorbents reported 3Q20 total revenue of $10.5 million last week, up 73% year-over-year and representing a quarterly record. Of this, $10.2 million or 97% was product revenue, which we believe mirrors the growing demand for CytoSorb for a range of applications, including the treatment of COVID-19 cases.

- CTSO has had to increase manufacturing to meet demand. The company has accomplished this by adding a production line and adding labor and work shifts. These measures have pressured quarterly gross margins. Product gross margins in 3Q20 of about 74% were below the 77% margin in 3Q19, but rebounded somewhat from about 70% in 2Q20.

- Rising demand supports the need for CTSO to expand production capacity. CTSO has delivered more than 110,000 CytoSorb cartridges globally to-date and has treated tens of thousands of patients.

- The company is well-capitalized to support its growth and also continues to strengthen its balance sheet. CTSO ended 3Q20 with a cash balance of about $88.0 million, up from about $35.1 million at the end of 2Q20 following an equity offering during the quarter.

- After obtaining FDA EUA approval for CytoSorb for use in patients with COVID-19 in April, an estimated roughly $2.7 million of 3Q20 product sales came from demand for CytoSorb to treat COVID-19 patients. CTSO began enrolling patients in its CytoSorb Therapy in COVID-19 ICU Patient (CTC) Registry. *New data on the use of CytoSorb in treating critically-ill COVID-19 patients on mechanical ventilation indicates overall positive outcomes.*

- The company also continues to move forward to resume its REFRESH 2-AKI study and to advance research on the HemoDefend adsorber 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 to further this research. We believe the addressable market for HemoDefend could be sizable.

3Q20 REVENUE REACHES A NEW RECORD

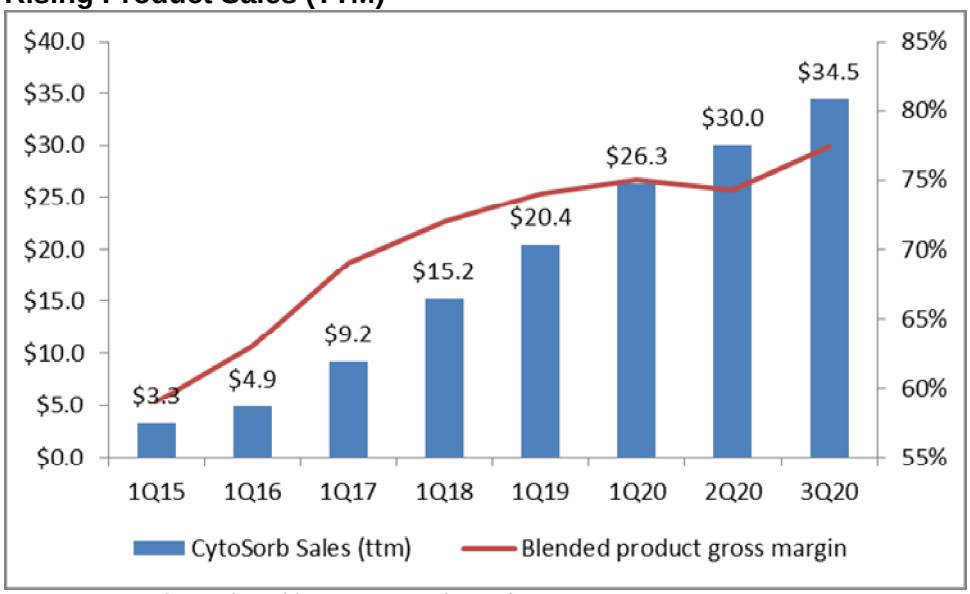
CytoSorbents (NASDAQ-CTSO) reported 3Q20 total revenue of $10.5 million. This represents a 73% year-over-year advance and a quarterly record. Most of this, $10.2 million or 97%, was product revenue. We believe this mirrors the growing demand for CytoSorb. Product revenue for the last 12 months was roughly $34.5 million (see figure below). In 3Q20, CTSO's gross margin was 72.6%, which represents an upward trend back to prior quarterly levels after a short-term decline in 2Q20. Specifically, in 2Q20 CTSO had to stretch its manufacturing capabilities in order to produce enough product to meet demand. It did this by adding a new production line (to three lines currently) and by adding labor and work shifts. These measures, in turn, pressured the quarterly gross margin to roughly 70%. Product gross margins in 3Q20 were about 74%. This is below the 77% product gross margin registered in 3Q19, but above the prior quarter's level. Margins were also negatively impacted primarily by lower margin distributor sales and ongoing need to ramp production and thus offer COVID-19 incentive payments to staff.

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 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 is generating data supporting its efficacy for a growing range of indications.

CTSO has delivered more than 110,000 CytoSorb cartridges globally and has treated tens of thousands of patients. This has translated into product revenue of about $34.5 million over the past 12 months. Moreover, given CTSO's view that COVID-19 is expected to continue to boost revenue in 4Q20 and possibly into 2021, we have adjusted our 4Q20 forecast.

Rising Product Sales (TTM)



2Q-3Q20 margins reduced by COVID-19 incentive payments
Source: www.cytosorbents.com

Balance Sheet

The company is well-capitalized to support its growth and also continues to strengthen its balance sheet. CTSO ended 3Q20 with a cash balance of about $88.0 million, up from about $35.1 million at the end of 2Q20, following an equity offering during 3Q20. Specifically, CTSO completed a $57.5 million equity financing. CTSO also amended its loan agreement, extending terms and expanding the amount to further improve liquidity. The company continues to evaluate other opportunities to refinance and/or restructure its debt balance.

COVID-19: POTENTIAL CATALYST TO BROADEN ADDRESSABLE MARKET

In April, CTSO 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.

CTSO has formed U.S. collaborations with partners including Terumo Cardiovascular, InvoSurg Inc., and Surgical Partners in order to commercialize CytoSorb in a total of 25 states under the above-noted FDA

EUA. Thus, in addition to demand from established applications, CTSO now also sees growing product demand for the treatment of COVID-19.

An estimated roughly $2.7 million of 3Q20 product sales came from demand for CytoSorb to treat COVID-19 patients. In addition, CTSO began enrolling patients in its *CytoSorb Therapy in COVID-19 ICU Patient (CTC) Registry.* The registry is being opened up internationally, with the goal of consolidating data from the more than 30 countries around the world. To-date, an estimated 2,800 COVID-19 patients have been treated with CytoSorb, further providing data and proof-of-concept on the efficacy of the treatment.

As cases of COVID-19 spike in many global markets, 1) a higher percentage of patients are young people who have less severe symptoms and 2) mortality rates are also declining as treatment options have improved. CTSO expects COVID-19 to continue to impact its revenue during the balance of 2020 and possibly into early 2021, depending on the numbers and trends of new cases. *New data on the use of CytoSorb in treating critically-ill COVID-19 patients on mechanical ventilation indicates overall positive outcomes.*

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.

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. In addition to Italy and China, many other of the 66 countries where CTSO operates have been impacted by COVID-19, including Iran, Germany, France, Spain and Hong Kong, among many others. Many countries 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.

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.

INFRASTRUTURE & R&D TO SUPPORT GROWTH / EXPAND POTENTIAL

REFRESH 2-AKI Trial

Although COVID-19 has been front and center lately, CTSO has many other applications and treatments that it is pursuing. In November of 2019, CTSO put enrollment in its REFRESH 2-AKI trial on hold so that it could 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.

Targeting Expanded Production & Distribution

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 66 markets globally, including Brazil.

The company also increased headcount to about 175 full-time and part-time employees to support growth, adding over 20 staff members over the course of 2020. As CTSO grows its network, the company remains focused on clinical development, and R&D, as well as manufacturing and commercialization of CytoSorb.

CTSO is also analyzing the best way to expand production in order to support some $300 million to $400 million of annual CytoSorb sales. The company expects to have secured a new building to construction manufacturing lines by early 2021. Once it has installed new capacity and ramped production, CTSO expects to achieve blended product gross margins above the 80% level. With an eye towards commercialization, the company is also looking to fill the position of VP of U.S. Sales to help direct commercial sales of CytoSorb for potential applications such as ticagrelor removal and COVID-19, among other applications.

HemoDefend Development of Universal Plasma
Removal of 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. The U.S. Army Medical Research Acquisition Activity (USAMRAA) also awarded CTSO a two-year contract valued at $1.1 million towards HemoDefend.

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.

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 3Q20 results on November 4, 2020.
- On October 14, 2020, CTSO, along with Aferetica, announced that the EU had approved CTSO's PerSorb™ cartridge in tandem with Aferetica's treatment system for combined perfusion and purification of pre-transplant solid organs.
- The U.S. Department of Defense awarded CTSO $1.1 million for ongoing development of HemoDefend on October 9, 2020.
- 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.
- 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 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.

CytoSorbents Inc.

CTSO	2019 A	Q1A	Q2A	Q3A	Q4E	2020 E	2021 E
CytoSorb Sales	$22,765.9	$8,156.0	$9,451.3	$10,245.6	$10,301.9	$38,154.9	$44,520.2
y-o-y growth	*12.4%*	*78.2%*	*61.5%*	*81.4%*	*54.0%*	*67.6%*	*16.7%*
Total Royalties/Grants/Other	$2,183.6	$551.3	$343.6	$301.0	$465.1	$1,661.0	$2,271.0
y-o-y growth	*-3.0%*	*-10.4%*	*-10%*	*-32.6%*	*-37.1%*	*-23.9%*	*36.7%*
Revenue	$24,949.5	$8,707.3	$9,794.9	$10,546.6	$10,767.0	$39,815.9	$46,791.2
YOY Growth	*10.9%*	*67.7%*	*57.2%*	*73.0%*	*44.9%*	*59.6%*	*17.5%*
Cost of Goods Sold	$7,363.9	$2,384.8	$3,249.8	$2,890.4	$2,907.1	$11,432.1	$10,643.1
Gross Income	$17,585.6	$6,322.5	$6,545.1	$7,656.2	$7,860	$28,384	$36,148.1
Gross Margin	*70.5%*	*72.6%*	*66.8%*	*72.6%*	*73.0%*	*71.3%*	*77.3%*
SG&A	$24,467.8	$6,836.0	$7,436.8	$7,282.4	$6,578.4	$28,133.5	$29,237.4
SG&A %of Prod Sales	*107.5%*	*78.5%*	*78.7%*	*71.1%*	*61.1%*	*70.7%*	*62.5%*
R&D	$12,091.8	$1,965.3	$2,406.0	$1,753.5	$3,087.9	$9,212.6	$9,844.6
R&D %Tot Sales	*48.5%*	*22.6%*	*24.6%*	*16.6%*	*28.7%*	*23.1%*	*21.0%*
Operating Income	($18,974.1)	($2,478.8)	($3,297.7)	($1,379.6)	($1,806.3)	($8,962.3)	($2,933.9)
Operating Margin	-						
Total Other Expense	$1,384.0	($974.0)	$430.7	($539.8)	$550.0	($533.2)	$568.7
Pre-Tax Income	($20,358.1)	($3,452.8)	($2,867.0)	($839.7)	($1,256.3)	($8,415.8)	($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)	($839.7)	($1,256.3)	($8,415.8)	($3,502.6)
Net Margin	*-77.2%*	*-39.7%*	*-29.3%*	*-8.0%*	*-11.7%*	*-21.1%*	*-7.5%*
EPS	($0.60)	($0.10)	($0.08)	($0.02)	($0.03)	($0.22)	($0.08)
Diluted Shares O/S	32,255	33,981	36,483	41,593	43,158	38,804	43,158

Source: Zacks

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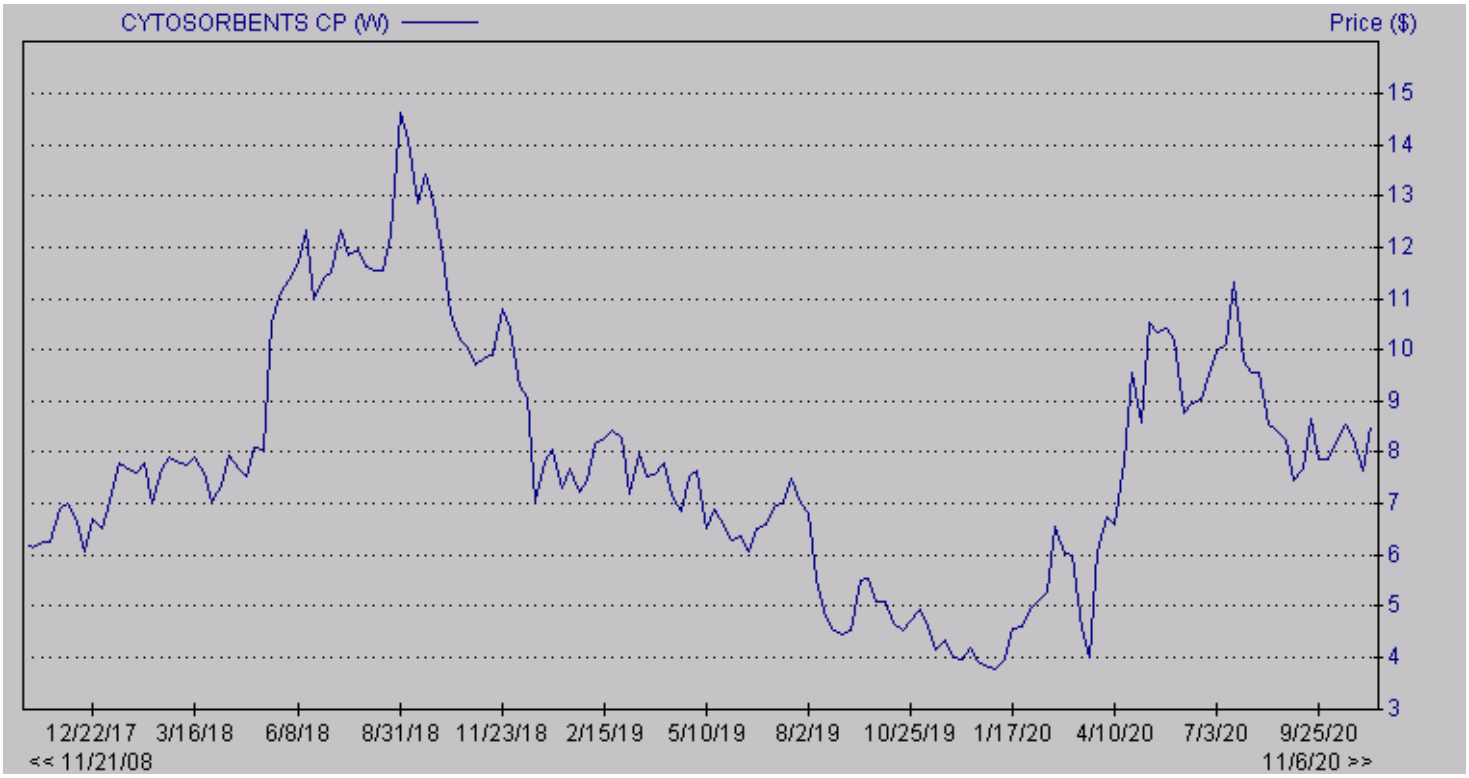
HISTORICAL STOCK PRICE



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