Zacks Small-Cap Research

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# Cytosorbents Cp (CTSO-OTCBB)

## CTSO: *Busy and Productive Last Few Months*

| | |
|---|---|
| **Current Recommendation** | **Outperform** |
| Prior Recommendation | N/A |
| Date of Last Change | 06/04/2012 |
| Current Price (08/13/13) | $0.10 |
| **Target Price** | **$0.50** |

## OUTLOOK

CytoSorb was CE Marked in March 2011 and subsequently commenced its initial commercialization. Near-term game-plan is to build awareness to facilitate broader roll-out in Europe. FDA approval is a longer-term goal, the quest for which is now in the planning stage. $4.8MM worth of gov't contracts/grants that CTSO scored since August 2012 should benefit near-term revenue and cash flow as well as aid their awareness-building efforts, further increase visibility and credibility of the technology, and potentially expand the menu of potential applications of the device. Interest in and use of CytoSorb from key opinion leaders has recently accelerated. Early feedback is positive and encouraging. Investigator-initiated studies and ongoing dosing study will provide add'l data points, facilitate increased uptake, and support quest for U.S.-based study. U.S. pilot study recently approved by FDA.

As near-term revenue and contracts/grants are not expected to be significant enough to fund operations, CTSO will need to continue to raise capital on an ongoing basis which introduces meaningful risk. Despite certain risks, we feel the shares trade cheaper than warranted.

## SUMMARY DATA

| | |
|---|---|
| **52-Week High** | **$0.15** |
| **52-Week Low** | **$0.08** |
| **One-Year Return (%)** | **-31.31** |
| **Beta** | **0.18** |
| **Average Daily Volume (sh)** | **562,116** |
| **Shares Outstanding (mil)** | **231** |
| **Market Capitalization ($mil)** | **$23** |
| **Short Interest Ratio (days)** | **N/A** |
| **Institutional Ownership (%)** | **0** |
| **Insider Ownership (%)** | **N/A** |
| **Annual Cash Dividend** | **$0.00** |
| **Dividend Yield (%)** | **0.00** |
| **5-Yr. Historical Growth Rates** | |
| **Sales (%)** | **N/A** |
| **Earnings Per Share (%)** | **N/A** |
| **Dividend (%)** | **N/A** |
| **P/E using TTM EPS** | **N/A** |
| **P/E using 2013 Estimate** | **N/A** |
| **P/E using 2014 Estimate** | **N/A** |
| **Zacks Rank** | **N/A** |

| | |
|---|---|
| **Risk Level** | **N/A** |
| **Type of Stock** | **N/A** |
| **Industry** | **Med Products** |

## ZACKS ESTIMATES

**Revenue**
(in '000 of $)

| | Q1 (Mar) | Q2 (Jun) | Q3 (Sep) | Q4 (Dec) | Year (Dec) |
|---|---|---|---|---|---|
| 2012 | 17 A | 116 A | 605 A | 604 A | 1343 A |
| 2013 | 371 A | 292 A | 704 E | 858 E | 2225 E |
| 2014 | | | | | 6133 E |
| 2015 | | | | | 15490 E |

**Earnings per Share**

| | Q1 (Mar) | Q2 (Jun) | Q3 (Sep) | Q4 (Dec) | Year (Dec) |
|---|---|---|---|---|---|
| 2012 | -0.01 A | -0.01 A | -0.01 A | -0.01 A | -0.03 A |
| 2013 | -0.01 A | -0.01 A | -0.01 E | -0.01 E | -0.03 E |
| 2014 | | | | | -0.03 E |
| 2015 | | | | | -0.01 E |

Zacks Projected EPS Growth Rate - Next 5 Years % **N/A**

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**Highlights:** U.S. Human Study, Case Study Publication, Increase in KOL's, increased distribution, more….

CytoSorbents reported results for the second quarter ending June 30, 2013 on August 14th. Total revenue was $292k, up 151% from $116k in Q2 2012. CytoSorb sales increased 287% yoy to $128k while grant revenue increased 96% to $164k. While CytoSorb sales fell sequentially and were lower than our number, they remain at levels significantly higher than any quarter in 2012 and we continue to expect product sales to grow throughout the current year, aided by expansion in distribution and awareness building efforts. Operating expenses were $1.5 million, roughly flat from Q1 and in-line with our expectations. Net income and EPS were ($2.0)MM and ($0.01) compared to our ($1.9)MM and ($0.01) estimates.

CytsoSorbents also continues to make progress on the operational front - including commercialization, awareness building, product development, and government grants - all of which we expect to benefit the early sales efforts but, more importantly, to help validate the technology. Highlights in this regard in just the last few months alone include; beefed up distribution in Europe, FDA approval of the first U.S. based human study in critically ill patients (funded by the U.S. Air Force), initiation of the Phase II Small Business Innovation Research grant from the U.S. Army, presentation on HemoDefend by Dr. Chan at the Military Health System Research Symposium, publication of an important study in the journal Blood Purification detailing intervention with CytoSorb in a critically-ill patient which resulted in a decrease in cytokines, preparation and submission of additional studies for publication, commencement of additional investigator-initiated studies with several more planned, an increase in the number of KOL's interested in CytoSorb, and acceptance of abstracts for presentation at the German Sepsis Society meeting in September.

We remain strong believers in management and the CytoSorb technology and while we continue to expect somewhat of an extended runway until substantial commercialization, believe the company is making meaningful headway in the initial overseas launch, with product development and in awareness-building.

**Operational Update**

Importantly, CytoSorbents and their flagship product CytoSorb have made meaningful progress in 2012 and into 2013. Some recent and ongoing highlights include; CytoSorb is generating sales from recurring orders, CytoSorb sales in the first half of 2013 six times as much as in the first half of 2012 (although remain at a low level), the company is seeing ever-increasing interest and use of CytoSorb for clinical use and in investigator-initiated studies, the range of illnesses and complications that CytoSorb is being used to treat is increasing, early feedback is that CytoSorb appears to be effective in improving outcomes of critically ill patients, and the company is broadening their sales and distribution capabilities.

Of particular significance is growing interest in CytoSorb from clinicians and key opinion leaders. This, along with the ongoing dosing study in Germany, 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. In June the FDA approved the first U.S. based human study of CytoSorb in critically ill patients - which we view as a meaningful milestone towards eventual approval and commencement of larger U.S. studies in support of a regulatory filing.

In a fairly short period of time CTSO has introduced the device to and garnered meaningful interest from some highly influential thought leaders in the field of sepsis and other critical care illnesses. Future recommendations and potentially published manuscripts from some of these thought leaders, including investigators from the German dosing study, could wield meaningful influence - the fruits of which we think may be seen in the short-to-mid term.

Indications are that early feedback relative to safety and efficacy is very encouraging. As an example, the company notes in a recent investor presentation specific instances where CytoSorb was credited with helping save the lives of critically ill patients. Publication of the first CytoSorb case report happened in the journal Blood Purification in July which highlighted how CytoSorb was able to reduce key cytokines in a critically ill patient with septic shock. Also of significance is that while CytoSorb has largely been used in instances where the patient is so critically ill that there's little to lose by trying the device, with the recent additional confidence of its efficacy this is now starting to progress where the device is being introduced at an earlier stage of intervention (another sign of substantial support, in our opinion).

Another particular highlight is progress with CytoSorb in complications from cardiac surgery, a potentially significant market. We had viewed this as more of a back-burner application but with this program moving forward and an unmet need for a clearly effective standard of care, we think this application could potentially begin to bear fruit in the mid-term. This will be something we will keep our eye on.

Recent operational highlights include;

**COMMERCIALIZATION**

- Direct sales of CytoSorb commenced in Germany, Austria and Switzerland
- Agreement penned in May with L.IN.C Medical Systems to distribute CytoSorb in the U.K. and Ireland. In June CTSO signed agreement with Hiti Medical Systems for distribution in Turkey
- Q4 2012, the first quarter that CTSO's sales team was fully active, generated commercial revenue of $88k. Product revenue grew 100% sequentially to $176k in Q1. Q2 product revenue was $128k. Commercial sales are expected to climb, facilitated by a growing sales force, distribution agreements, additional validation studies to further support use of CytoSorb, already established reimbursement in Germany and Austria, and fruits from awareness building efforts, among other catalysts

**VALIDATION / REGULATORY**

- In June the FDA approved the first U.S. based human study of CytoSorb in critically ill patients - a significant milestone in our opinion
- CTSO recently noted that about 100 (up from 60 in just the last few months) key opinion leaders (KOL) are either using CytoSorb, want to use it or are planning to use it in clinical trials. CTSO is also in the planning stage for several more investigator initiated studies. CytoSorb studies include those for both sepsis-related (which encompasses severely ill patients with acute lung injury, trauma, and complications from flu) as well as cardiac surgery patients. Human sepsis studies have been ongoing. Relative to cardiac surgery, preliminary testing has been completed and human pilot studies are expected to be initiated in the near-term. CTSO is also making presentations on some of these investigator-led studies at key conferences
- Dosing study (Europe) ongoing with more patients being enrolled. CytoSorb has been used for up to 24 hours over 7 days with no serious device related events reported. CTSO will expand the study to ten leading hospitals in Germany. Data from the study is expected to be used to further supplement the data from the European Sepsis trial as well as support to shape protocol for a U.S. study. We think data from this dosing study could be available in 2013
- CTSO recently noted that a number of case study reports have been borne from ongoing studies. The first published in Blood Purification in July. Others are being prepared and expected to be published in near-term
- Initial feedback from physicians using CytoSorb in clinical practice with critically ill patients, including those with septic shock and multiple organ failure (which includes the initial indications addressed by CytoSorb), have been encouraging with outcomes including a dramatic reduction in IL-6 levels (which was also an endpoint in the European Sepsis Trial), stabilized organ failure, and patient recovery
- Continuing to pursue U.S. regulatory approval pathway
- Initiation of work under the Phase II Small Business Innovation Research grant from the U.S. Army, worth up to $1 million

**AWARENESS-BUILDING**

- Presentations, exhibitions and research talks at several scientific meetings. Anticipate this will continue and will also be supplemented by presentations by key opinion leaders which are using CytoSorb
- Two abstracts were accepted for presentation at the German Sepsis Society meeting in September. One, from the University of Ulm, Germany related to the first successful fungal sepsis case treated and, the other,, from Trauma Hospital in Linz, Austria for the treatment of a septic shock patient with liver cirrhosis.
- In March CTSO exhibited at the International Symposium on Intensive Care and Emergency Medicine in Brussels, Belgium which attracted 6k participants. CTSO noted feedback and interest in CytoSorb from clinicians and potential new customers and distributors was overwhelmingly positive. In addition, there were two presentations related to CytoSorb;
    - Dr. Kellum (University of Pittsburgh Medical Center) presented on his findings from his recently published article in the journal, Molecular Medicine. His presentation, entitled "Reversing sepsis-induced immune suppression" was attended by more than 300 people
    - Dr. Schadler (Kiel University) presented his poster titled, "A multicenter randomized controlled study of an extracorporeal cytokine hemoadsorption device in septic patients"

- **PIPELINE**
    - HemoDefend: refined the filter which now allows a unit of blood to flow through in under a half-hour, within the requirements for blood transfusions. CTSO now working to reduce unit production costs including optimizing packaging

- In August Dr. Chan made a presentation on HemoDefend at the Military Health System Research Symposium
- Beads in a Bag: progress continues towards eventual commercialization. Beads in a Bag technology was the subject of CTSO's poster presentation at the 2012 American Association of Blood Banks conference
- ContrastSorb: CTSO's most recent pipeline candidate is being designed to prevent contrast-induced nephropathy (CIN), a condition that patients with compromised kidney function are susceptible to when undergoing procedures that require use of a contrast agent such as image-guided cardiology and certain radiology procedures. CIN has been estimated to be a ~$500 million/yr market. Current standard of care to address CIN, which is essentially indiscriminately flushes the contrast agent from the body, is often times ineffective. CTSO believes their ContrastSorb technology may be a more effective option to remove contrast agents from these high risk patients

## OUTLOOK / RECOMMENDATION / VALUATION

Following its debut introduction at industry conferences in Europe during Q3 2011, the company began an incremental roll-out of CytoSorb in Germany targeting early adopters and looking to build greater awareness through investigator-led studies. While the device is now generating revenue, sales are expected to remain modest over the course of 2013 as CytoSorbents focuses the roll-out with their initial sales team, bringing on distribution partners, and increasing visibility of the device to influential industry leaders. Initial success of CytoSorb in Germany and throughout Europe will hinge on a number of factors, including sufficient reimbursement, the company's ability to drive awareness and, ultimately, interest from hospitals and critical care units.

We model very modest yet sequentially growing sales of CytoSorb in Germany and other parts of Europe during 2013, reflecting measured progress with implementation of the sales/marketing strategy. We model revenue in 2013 to come from a combination of government contracts (i.e. DARPA / US Army SBIR phase II) and product sales. We assume increased awareness and visibility of CytoSorb results in a greater rate of burgeoning interest materializing during the year.

Our modeled revenue in 2014 and beyond includes mostly sales of CytoSorb (with a relatively small % contribution from contracts/grants). Assuming positive results from company-sponsored and investigator-led studies as well as supportive feedback from hospitals and critical care professionals, we think 2014 could be more of an inflection point for CytoSorb and mark the beginning of a significantly greater ramp in commercial sales.

Based on the current ambiguity relative to what the FDA will be looking for to support a potential future PMA submission and the real risk of delays (from a best-case-scenario launch in 2016), we do not incorporate any contribution from sales of CytoSorb in the U.S. until an assumed soft-launch sometime in 2017. We will update our assumptions if appropriate when there is more clarity on the U.S. regulatory strategy and related timelines.

Based on our 10-year DCF model, which uses a 15% discount rate to account for certain risks and uncertainties that CytoSorbents faces (several of which we detailed in our initiation report), the shares are valued at approximately $0.50. Our model and assumptions will be updated commensurate with news flow which could also influence the valuation. As it is now, we value the company at $0.50/share, implying upside to the current share price and reflecting our Outperform rating.

## FINANCIAL MODEL

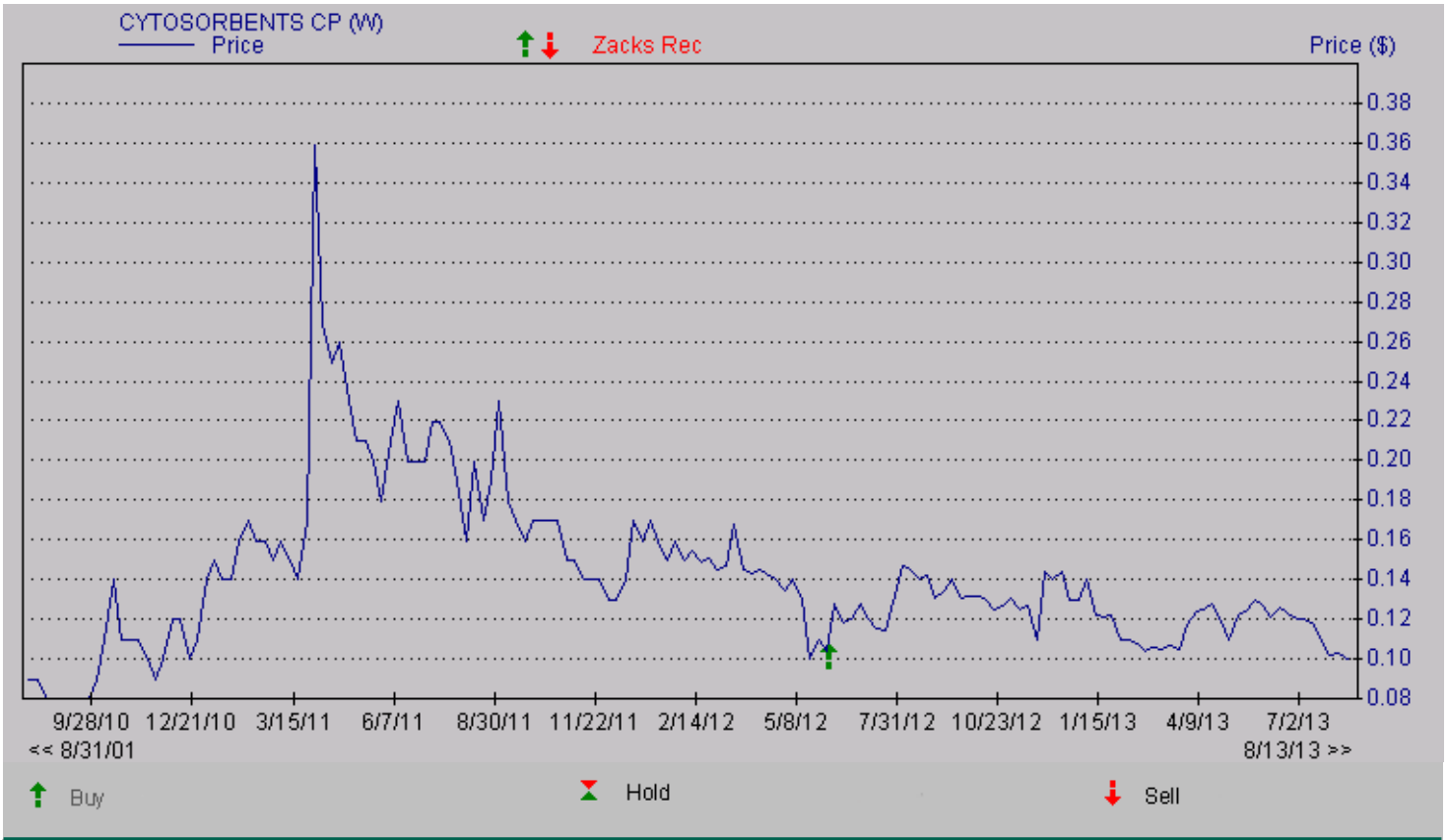
CytoSorbents Inc.

| | 2012 A | Q1A | Q2A | Q3E | Q4E | 2013 E | 2014 E | 2015 E | 2016 E |
|---|---|---|---|---|---|---|---|---|---|
| **CytoSorb Sales** | $151.6 | $176.1 | $128.0 | $175.0 | $200.0 | $679.1 | $4,820.0 | $15,190.0 | $24,260.0 |
| *y-o-y growth* | - | *942.4%* | *287.3%* | *1179.3%* | *127.3%* | *348.0%* | *609.8%* | *215.1%* | *59.7%* |
| **Total Royalties/Grants** | $1,191.4 | $195.2 | $163.5 | $529.0 | $658.0 | $1,545.7 | $1,313.0 | $300.0 | $0.0 |
| *y-o-y growth* | - | - | *96.2%* | *-10.6%* | *27.4%* | *29.7%* | *-15.1%* | *-77.2%* | *-100.0%* |
| Revenue | $1,342.9 | $371.3 | $291.5 | $704.0 | $858.0 | $2,224.8 | $6,133.0 | $15,490.0 | $24,260.0 |
| *YOY Growth* | - | *2098.1%* | *150.5%* | *16.3%* | *42.0%* | *65.7%* | *175.7%* | *152.6%* | *56.6%* |
| Cost of Goods Sold | $319.3 | $253.5 | $199.6 | $461.4 | $516.6 | $1,431.0 | $2,688.7 | $6,036.2 | $8,976.2 |
| Gross Income | $1,023.6 | $117.8 | $91.9 | $242.6 | $341.5 | $793.8 | $3,444.4 | $9,453.8 | $15,283.8 |
| *Gross Margin* | *76.2%* | *31.7%* | *31.5%* | *34.5%* | *39.8%* | *35.7%* | *56.2%* | *61.0%* | *63.0%* |
| SG&A | $1,982.0 | $835.9 | $790.6 | $787.0 | $813.0 | $3,226.5 | $6,062.0 | $10,327.0 | $13,558.0 |
| *% SG&A* | *147.6%* | *225.1%* | *271.2%* | *111.8%* | *94.8%* | *145.0%* | *98.8%* | *66.7%* | *55.9%* |
| R&D | $2,532.4 | $704.1 | $708.2 | $660.0 | $850.0 | $2,922.3 | $5,650.0 | $5,500.0 | $3,800.0 |
| *% R&D* | *188.6%* | *189.6%* | *243.0%* | *93.8%* | *99.1%* | *131.4%* | *92.1%* | *35.5%* | *15.7%* |
| Operating Income | ($3,490.8) | ($1,422.2) | ($1,406.8) | ($1,204.4) | ($1,321.6) | ($5,355.0) | ($8,267.7) | ($6,373.2) | ($2,074.2) |
| *Operating Margin* | - | - | - | - | - | - | - | - | - |
| Total Other Expense | $564.4 | $206.7 | $8.1 | $22.0 | $22.0 | $258.9 | $12.0 | $0.0 | $0.0 |
| Pre-Tax Income | ($4,055.2) | ($1,628.9) | ($1,415.0) | ($1,226.4) | ($1,343.6) | ($5,613.9) | ($8,279.7) | ($6,373.2) | ($2,074.2) |
| Taxes (benefit) | ($391.8) | $0.0 | $0.0 | $0.0 | $0.0 | $0.0 | $0.0 | $0.0 | $0.0 |
| *Tax Rate* | *0.0%* | *0.0%* | *0.0%* | *0.0%* | *0.0%* | *0.0%* | *0.0%* | *0.0%* | *0.0%* |
| Preferred Dividend | $2,511.5 | $586.4 | $616.5 | $645.0 | $645.0 | $2,492.9 | $1,500.0 | $0.0 | $0.0 |
| Net Income | ($6,174.9) | ($2,215.4) | ($2,031.5) | ($1,871.4) | ($1,988.6) | ($8,106.8) | ($9,779.7) | ($6,373.2) | ($2,074.2) |
| *Net Margin* | - | *-596.6%* | *-696.9%* | *-265.8%* | *-231.8%* | - | - | *-41.1%* | *-8.5%* |
| EPS | ($0.03) | ($0.01) | ($0.01) | ($0.01) | ($0.01) | ($0.03) | ($0.03) | ($0.01) | ($0.00) |
| *YOY Growth* | - | - | - | - | - | - | - | - | |
| Diluted Shares O/S | 198,228 | 222,969 | 231,583 | 242,000 | 250,000 | 236,638 | 363,000 | 505,000 | 535,000 |

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