Zacks Small-Cap Research

January 14, 2016

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# CytoSorbents Cp (CTSO- NASDAQ)

## CTSO: Strong Recovery in Product Sales Following Sales Force Restructuring

| | |
|---|---|
| **Current Recommendation** | **Buy** |
| Prior Recommendation | N/A |
| Date of Last Change | 06/04/2012 |
| Current Price (01/14/16) | $4.42 |
| **Target Price** | **$11.50** |

## OUTLOOK

CTSO continues to generate clinical outcomes data which is being used to accelerate adoption and utilization. CTSO now also focused in U.S. regulatory approval – either with a cardiac surgery and/or sepsis indication. Just received notice from FDA that EAP for critical care illness in U.S. not feasible. CTSO now looking at IDE/PMA study for U.S. approval for sepsis. Will conduct pilot studies to flesh out ideal enrollment/inclusion/exclusion criteria for pivotal trial design purposes.

Recent restructuring of sales force caused a hiccup in sales but looks like was only a short-term issue. Product sales expected to grow ~35% yoy in 2H 2015. Add'l distributors, including Fresenius and add'l geographic territories to come online shortly should further accelerate product sales, as should a more productive sales force. Interest in and use of CytoSorb from hospitals and physicians continues to increase.

## SUMMARY DATA

| | |
|---|---|
| **52-Week High** | **$15.24** |
| **52-Week Low** | **$5.17** |
| **One-Year Return (%)** | **-38.99** |
| **Beta** | **-0.22** |
| **Average Daily Volume (sh)** | **79,448** |
| **Shares Outstanding (mil)** | **25** |
| **Market Capitalization ($mil)** | **$154** |
| **Short Interest Ratio (days)** | **5.43** |
| **Institutional Ownership (%)** | **5** |
| **Insider Ownership (%)** | **26** |
| **Annual Cash Dividend** | **$0.00** |
| **Dividend Yield (%)** | **0.00** |
| **5-Yr. Historical Growth Rates** | |
| **Sales (%)** | **63.5** |
| **Earnings Per Share (%)** | **N/A** |
| **Dividend (%)** | **N/A** |
| **P/E using TTM EPS** | **N/A** |
| **P/E using 2015 Estimate** | **N/A** |
| **P/E using 2016 Estimate** | **N/A** |
| **Zacks Rank** | **N/A** |

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

## ZACKS ESTIMATES

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

| | Q1 (Mar) | Q2 (Jun) | Q3 (Sep) | Q4 (Dec) | Year (Dec) |
|---|---|---|---|---|---|
| 2014 | 1062 A | 1025 A | 1162 A | 874 A | 4123 A |
| 2015 | 723 A | 964 A | 1344 A | 1617 E | 4647 E |
| 2016 | | | | | 11843 E |
| 2017 | | | | | 20245 E |

**Earnings per Share**

| | Q1 (Mar) | Q2 (Jun) | Q3 (Sep) | Q4 (Dec) | Year (Dec) |
|---|---|---|---|---|---|
| 2014 | -0.20 A | -0.27 A | -0.22 A | -0.47 A | -1.29 A |
| 2015 | -0.19 A | 0.06 A | -0.11 A | -0.10 E | -0.34 E |
| 2016 | | | | | -0.27 E |
| 2017 | | | | | -0.21 E |

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

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**Q4 Revenue Preannouncement**

CytoSorbents preannounced expected CytoSorb Q4 revenue in the range of $1.4M - $1.6M. Assuming product sales of $1.5M in Q4, this would represent sequential and yoy growth of 40% and 72% for the quarter and 29% yoy growth for the full year. The guidance is also well ahead of the $1.25M product sales that we had modeled for Q4. And perhaps even more telling of the recent strength in CytoSorb revenue is 2H 2015 will show growth of between 30% and 40%, with both Q3 and Q4 setting new product sales records. So while restructuring of the sales force resulted in a disappointing first half of the year with product sales dropping 22% from the second half of 2014 (i.e. sequentially), it appears that that disruption may now have dissipated.

The Euro/U.S. dollar exchange rate has also been a (non-fundamental) headwind – adjusted for forex, Q4 product sales would have been approximately $1.6M - $1.8M, resulting in yoy growth (using guidance mid-points) of ~95% and 50% for the quarter and full year 2015, respectively.

CTSO notes in the preannouncement that the recent higher growth of product revenue is being driven by greater direct (as opposed to distributor) sales – anecdotally, a sign that the sales force (including newly hired reps) is becoming more productive. Direct sales more than tripled from 2014. This is represented in the product margin – which remains very healthy and is expected to come in at better than 60% for the full year. Reorders from existing customers and new orders from expansion of the customer base are both contributing to the revenue growth.

While delayed from earlier expectations, Fresenius has now come online and contributed to revenue in Q4 – which may have included some initial stocking. And while we think initial roll-out through this channel, the game plan for which will largely follow CTSO's direct sales strategy of targeting KOLs, may be somewhat muted on the front-end, this relationship has the potential to be a meaningful contributor to revenue in 2016 and beyond. CTSO notes that Fresenius, which will distribute in Denmark, Finland, France, Norway, Poland and Sweden, is now making preparations for official launch in Europe.

We have updated our Q4 revenue estimate for the preannouncement. We continue to model accelerating product sales growth in 2016 driven by increasing productivity from newly hired reps, incremental ordering from existing distributors (such as Biocon), initial launch of Fresenius, regulatory approvals in additional territories and further build-out of the direct team. CTSO has also had interest from an (unnamed) cardiac surgery partner (top four cardiac surgery company) which recently completed their evaluation of the device. While CTSO noted recently that the evaluation "went as good as expected", they did not provide an update in the revenue preannouncement. They did, however, note in their January Biotech Showcase presentation that they "are currently having discussions with multiple players in this space." This potentially represents another growth opportunity for 2016 and beyond. And CTSO expects data from several ongoing studies to be announced and published in the coming year which should further support the utility of CytoSorb in several critical care applications and during and post-cardiac surgery.

## FINANCIAL MODEL

CytoSorbents Inc.

| | 2014 A | Q1A | Q2A | Q3A | Q4E | 2015 E | 2016 E | 2017 E | 2018 E |
|---|---|---|---|---|---|---|---|---|---|
| **CytoSorb Sales** | $3,135.4 | $703.7 | $773.1 | $1,071.5 | $1,489.0 | $4,037.2 | $11,030.0 | $19,580.0 | $28,010.0 |
| *y-o-y growth* | *281.5%* | *23.6%* | *16.6%* | *3.8%* | *70.9%* | *28.8%* | *173.2%* | *77.5%* | *43.1%* |
| **Total Royalties/Grants/Other** | $987.5 | $19.4 | $190.8 | $272.2 | $127.6 | $610.0 | $813.0 | $665.0 | $0.0 |
| *y-o-y growth* | *-38.3%* | *-96.1%* | *-47.2%* | *108.4%* | *4927.6%* | *-38.2%* | *33.3%* | *-18.2%* | *-100.0%* |
| Revenue | $4,122.9 | $723.1 | $963.9 | $1,343.6 | $1,616.6 | $4,647.2 | $11,843.0 | $20,245.0 | $28,010.0 |
| *YOY Growth* | *70.2%* | *-31.9%* | *-5.9%* | *15.6%* | *85.0%* | *12.7%* | *154.8%* | *70.9%* | *38.4%* |
| Cost of Goods Sold | $2,133.9 | $304.5 | $465.4 | $638.8 | $692.7 | $2,101.4 | $4,911.9 | $8,005.7 | $10,643.8 |
| Gross Income | $1,989.0 | $418.6 | $498.5 | $704.8 | $924.0 | $2,545.8 | $6,931.1 | $12,239.4 | $17,366.2 |
| *Gross Margin* | *48.2%* | *57.9%* | *51.7%* | *52.5%* | *57.2%* | *54.8%* | *58.5%* | *60.5%* | *62.0%* |
| SG&A | $6,836.2 | $2,179.2 | $1,924.3 | $1,988.8 | $2,334.0 | $8,426.3 | $9,654.0 | $13,237.0 | $14,341.1 |
| *% SG&A* | *165.8%* | *301.4%* | *199.6%* | *148.0%* | *144.4%* | *181.3%* | *81.5%* | *65.4%* | *51.2%* |
| R&D | $2,431.7 | $951.0 | $801.7 | $866.3 | $1,035.0 | $3,654.0 | $4,694.0 | $4,902.0 | $4,915.0 |
| *% R&D* | *59.0%* | *131.5%* | *83.2%* | *64.5%* | *64.0%* | *78.6%* | *39.6%* | *24.2%* | *17.5%* |
| Operating Income | ($7,278.9) | ($2,711.6) | ($2,227.5) | ($2,150.3) | ($2,445.1) | ($9,534.4) | ($7,416.9) | ($5,899.7) | ($1,889.9) |
| *Operating Margin* | - | - | - | - | - | - | - | - | - |
| Total Other Expense | $2,428.5 | $2,005.3 | ($3,661.8) | $697.1 | ($3.0) | ($962.3) | $0.0 | $0.0 | $0.0 |
| Pre-Tax Income | ($9,707.4) | ($4,716.9) | $1,434.3 | ($2,847.4) | ($2,442.1) | ($8,572.1) | ($7,416.9) | ($5,899.7) | ($1,889.9) |
| Taxes (benefit) | ($385.6) | $0.0 | $0.0 | $0.0 | $0.0 | $0.0 | $0.0 | $0.0 | $0.0 |
| *Tax Rate* | *4.0%* | *0.0%* | *0.0%* | *0.0%* | *0.0%* | *0.0%* | *0.0%* | *0.0%* | *0.0%* |
| Preferred Dividend | $9,266.7 | $0.0 | $0.0 | $0.0 | $0.0 | $0.0 | $0.0 | $0.0 | $0.0 |
| Net Income | ($18,588.4) | ($4,716.9) | $1,434.3 | ($2,847.4) | ($2,442.1) | ($8,572.1) | ($7,416.9) | ($5,899.7) | ($1,889.9) |
| *Net Margin* | - | *-652.3%* | *148.8%* | *-211.9%* | *-151.1%* | *-184.5%* | *-62.6%* | *-29.1%* | *-6.7%* |
| EPS | ($1.29) | ($0.19) | $0.06 | ($0.11) | ($0.10) | ($0.34) | ($0.27) | ($0.21) | ($0.07) |
| *YOY Growth* | - | - | - | - | - | - | | | |
| Diluted Shares O/S | 14,441 | 24,394 | 24,769 | 25,038 | 25,350 | 24,888 | 27,000 | 27,700 | 28,200 |

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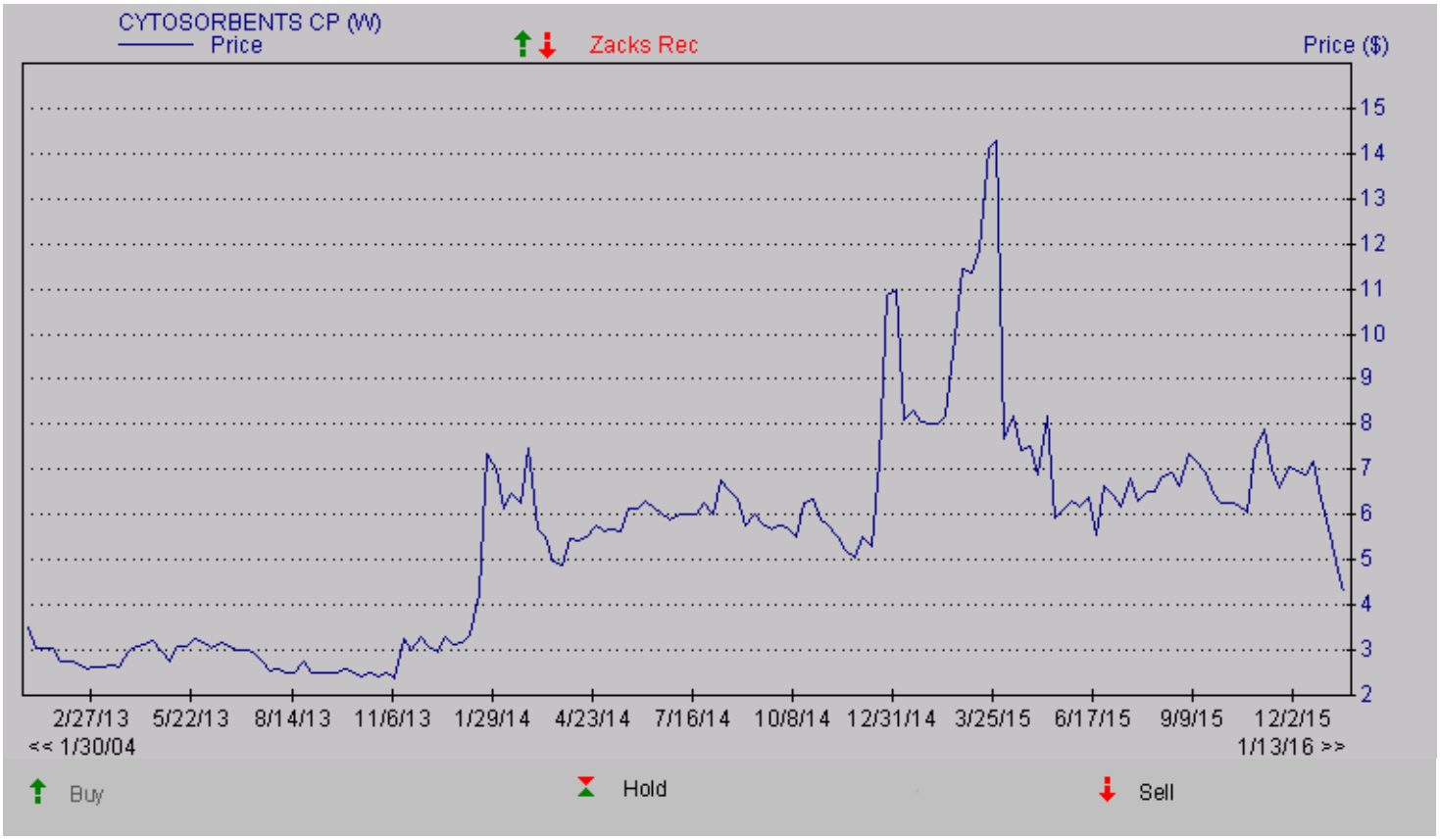


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