Zacks Small-Cap Research

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# CytoSorbents Cp (CTSO- NASDAQ)

## CTSO: FDA Requests Add'l Info for EAP Designation

| | |
|---|---|
| **Current Recommendation** | **Outperform** |
| Prior Recommendation | N/A |
| Date of Last Change | 06/04/2012 |
| Current Price (12/01/15) | $7.43 |
| **Target Price** | **$12.50** |

## 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 critical care indication (such as sepsis). Just filed for EAP designation for U.S. which could speed time to market at lower cost.

Recent restructuring of sales force caused a hiccup in sales but looks like was only a short-term issue. Product sales grew 39% from Q2 to Q3. CTSO already made replacements to sales force with 2 add'l hires expected by current year-end. Add'l distributors, including Fresenius and add'l geographic territories to come online shortly should further accelerate product sales. Interest in and use of CytoSorb from hospitals and physicians continues to increase.

## SUMMARY DATA

| | |
|---|---|
| **52-Week High** | **$15.24** |
| **52-Week Low** | **$4.40** |
| **One-Year Return (%)** | **32.18** |
| **Beta** | **-0.22** |
| **Average Daily Volume (sh)** | **91,111** |
| **Shares Outstanding (mil)** | **25** |
| **Market Capitalization ($mil)** | **$188** |
| **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 | 1454 E | 4484 E |
| 2016 | | | | | 12212 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 | -0.35 E |
| 2016 | | | | | -0.27 E |
| 2017 | | | | | -0.21 E |

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

**FDA Requests Additional Data for EAP Application**

In an 8K filed November 30th CTSO reported that FDA responded to their Expedited Access Pathway application for sepsis notifying the company on November 23rd that additional information is required to meet eligibility for EAP designation. The filing further notes that CTSO is in the process of scheduling a teleconference with the agency to discuss the scope of data required and that "Although the company is confident that additional data are available, there can be no assurances that such data are sufficient to obtain EAP designation…".

Part of the application is a draft *Data Development Plan* which must include (per FDA, Centers for Devices and Radiological Health http://1.usa.gov/1fo55NP);

(1) An explanation and justification for the proposed balance of premarket and postmarket data collection, if a premarket-postmarket data shift is proposed and applicable;
(2) A description and summary of the data collection plan, including study synopses and study design; and,
(3) A timeline for the development and marketing of the device as well as for the postmarket data collection.

While the 8K did not specifically state the additional data request relates to the Data Development Plan, that may be the case. The EAP Guidance document notes that "FDA recognizes that the sponsor may not have all the information listed below [see detailed description in the guidance document, pages 42 – 44] at the time of EAP Designation request. FDA's feedback on the draft Data Development Plan represents our best advice in accordance with the information provided and known at the time of review. FDA intends that feedback will not change, provided the information submitted in a future IDE or marketing application is consistent with what was provided in the Data Development Plan and that the data in future submissions do not raise important new issues that affect safety or effectiveness."

Additionally, "If there is insufficient information for FDA to make a decision about EAP designation, FDA may request the sponsor submit additional information. If FDA requests additional information from the sponsor, FDA will notify the sponsor in writing whether or not EAP designation is granted within 30 days of the date of the request for additional information. If FDA has not received enough information in time to make a decision by 30 days after a request for additional information is sent, FDA intends to deny the EAP designation. If the sponsor submits additional information, it should be as a supplement to their Pre-Sub"

CTSO notes that in the event that they do not receive EAP designation at this time that they will request feedback from FDA on their draft development plan and clinical trial design with plans to either 1) resubmit the EAP application when appropriate data are available or 2) file an IDE for approval to conduct a PMA-supporting U.S.-based sepsis study.

## 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 | $1,242.7 | $3,790.9 | $11,030.0 | $19,580.0 | $28,010.0 |
| *y-o-y growth* | *281.5%* | *23.6%* | *16.6%* | *3.8%* | *42.6%* | *20.9%* | *191.0%* | *77.5%* | *43.1%* |
| **Total Royalties/Grants/Other** | $987.5 | $19.4 | $190.8 | $272.2 | $211.1 | $693.5 | $1,181.8 | $665.0 | $0.0 |
| *y-o-y growth* | *-38.3%* | *-96.1%* | *-47.2%* | *108.4%* | *8217.6%* | *-29.8%* | *70.4%* | *-43.7%* | *-100.0%* |
| Revenue | $4,122.9 | $723.1 | $963.9 | $1,343.6 | $1,453.8 | $4,484.4 | $12,211.8 | $20,245.0 | $28,010.0 |
| *YOY Growth* | *70.2%* | *-31.9%* | *-5.9%* | *15.6%* | *66.4%* | *8.8%* | *172.3%* | *65.8%* | *38.4%* |
| Cost of Goods Sold | $2,133.9 | $304.5 | $465.4 | $638.8 | $667.6 | $2,076.3 | $5,225.4 | $8,005.7 | $10,643.8 |
| Gross Income | $1,989.0 | $418.6 | $498.5 | $704.8 | $786.2 | $2,408.1 | $6,986.4 | $12,239.4 | $17,366.2 |
| *Gross Margin* | *48.2%* | *57.9%* | *51.7%* | *52.5%* | *54.1%* | *53.7%* | *57.2%* | *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%* | *160.5%* | *187.9%* | *79.1%* | *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%* | *71.2%* | *81.5%* | *38.4%* | *24.2%* | *17.5%* |
| Operating Income | ($7,278.9) | ($2,711.6) | ($2,227.5) | ($2,150.3) | ($2,582.8) | ($9,672.2) | ($7,361.6) | ($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) | ($2,579.8) | ($8,709.8) | ($7,361.6) | ($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) | ($2,579.8) | ($8,709.8) | ($7,361.6) | ($5,899.7) | ($1,889.9) |
| *Net Margin* | - | *-652.3%* | *148.8%* | *-211.9%* | *-177.4%* | *-194.2%* | *-60.3%* | *-29.1%* | *-6.7%* |
| EPS | ($1.29) | ($0.19) | $0.06 | ($0.11) | ($0.10) | ($0.35) | ($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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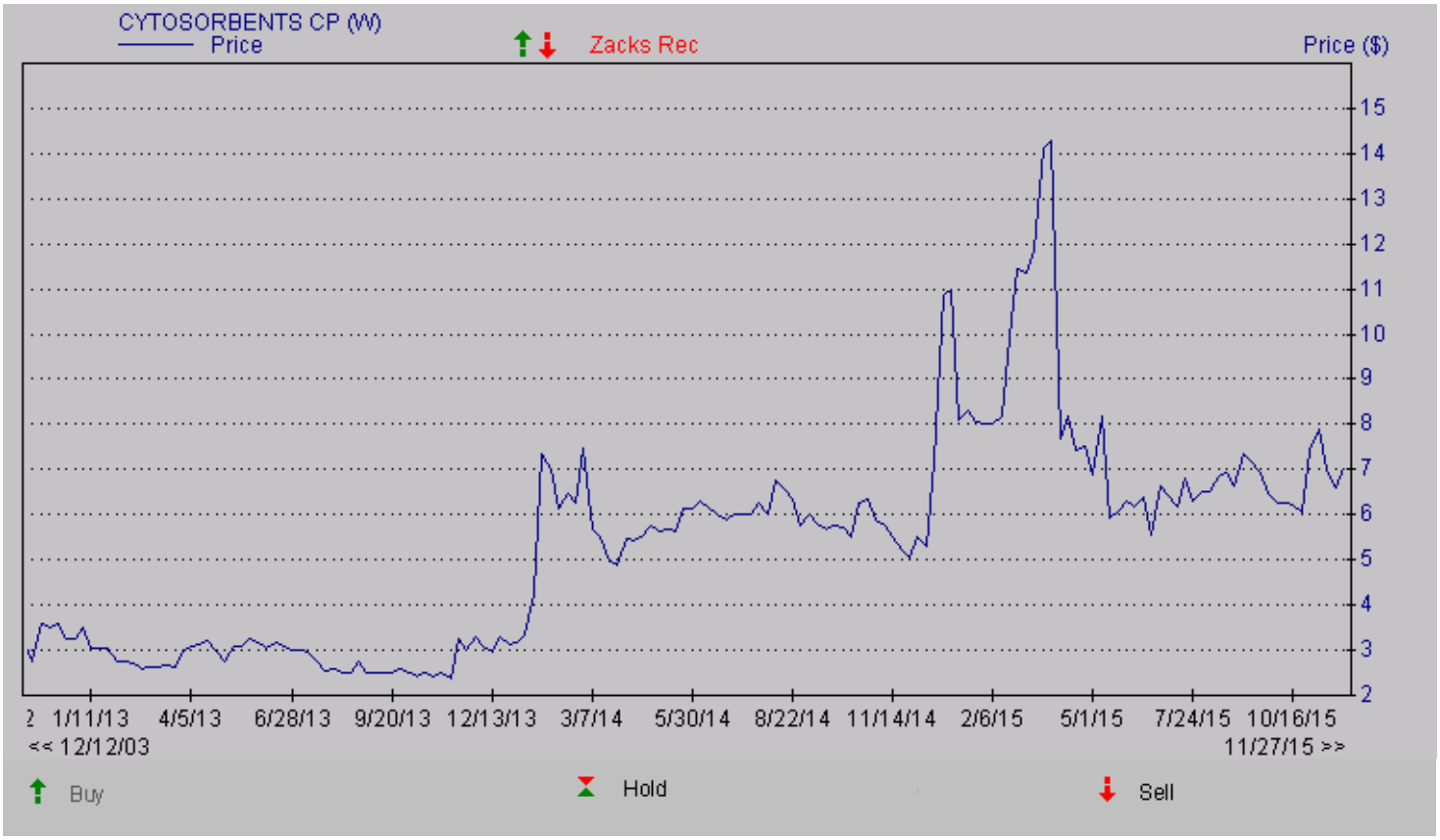
## HISTORICAL ZACKS RECOMMENDATIONS

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