



UPDATE REPORT

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CELSION CORPORATION (NASDAQCM: CLSN)

- **The HEAT Study is now fully enrolled and an interim data analysis is under way.** The 600-patient study is testing ThermoDox[®], which is a formulation of heat-labile liposomes containing doxorubicin, in combination with radiofrequency ablation for treating primary liver tumors. The interim analysis began upon full enrollment and once a minimum of 190 of 380 “progression free survival events” (i.e., largely, disease progression) occurred.
- **Investors should expect the HEAT Study to continue into 2012.** That would indicate data is sufficiently mature to conclude that ThermoDox is providing a survival benefit. (The primary endpoint is progression free survival and the secondary endpoint is overall survival.)
- **A Special Protocol Assessment reduces the regulatory risk** by providing a clear path to FDA approval. Celsion has also taken measures to expedite the review by securing “fast-track” status for ThermoDox, which is deemed an Orphan Drug in the U.S. and Europe.
- **Partnering for ex-U.S. territories should provide additional capital** in the form of upfront payments for marketing rights to Asia and Europe, as well as attractive royalty rates.

We reiterate our BUY recommendation and our 12-month target price of \$10 per share.

Share Price (10/11/2011)	\$2.93
52-Week Price Low / High	\$1.98-\$4.37
Mkt. Capitalization (issued)	\$77.0 million
Shares Outstanding (issued)	26.28 million
12-month Target Price	\$10.00
Average Daily Volume (3 mos.)	602,891
Website	www.celsion.com
Est'd 2011 Earn's (Loss)/shr	(\$1.17)



Celsion Corporation (NasdaqCM: CLSN) is a clinical-stage pharmaceutical company specializing in the development of cancer therapies based on thermosensitive liposome delivery technology. The leading drug candidate, ThermoDox[®], releases its active chemotherapeutic agent, doxorubicin, upon localized heating achieved with radiofrequency ablation (RFA), microwave radiation, or high-frequency ultrasound (HIFU). An international Phase III study of its efficacy against primary liver cancer, will likely deliver final results in the second half

of 2012. ThermoDox has been designated an Orphan Drug in the United States and Europe, and will receive a fast-track review by the FDA. A follow-up trial involving metastatic liver cancer, which is set to start later this year, will greatly expand the market in the U.S. and EU. Partnering talks with overseas marketers are under way. Meanwhile, Celsion and Royal Phillips Electronics plan to initiate a study of ThermoDox and HIFU for treating metastatic bone cancer, and the Company is preparing liposomal formulations of other chemotherapeutic agents.

THE HEAT STUDY WILL LIKELY CONTINUE ON PLAN

The trial is being conducted under a Special Protocol Assessment that was negotiated with the FDA to gain a clear path to approval. The agreement includes a provision for an interim analysis upon completion of enrollment and once 190 of the 380 “events” required for termination of the study have been recorded. (The term “events” refers largely to disease recurrence/progression, and the cumulative tally is being used to define a point at which a significant benefit in progression-free survival from ThermoDox should be seen.) The two criteria were satisfied in the September quarter, and accordingly, an analysis of the interim data is ongoing by the study’s independent Data Monitoring Committee. Three alternatives will be considered based on the results: (i) halt the study due to a lack of efficacy, (ii) end the trial because the results are so much better than expected that it would be unconscionable to delay the drug’s use by the medical community at large, or (iii) continue to follow the progress of the patients until the 380 events have been recorded and then conduct a final analysis for the primary endpoint, progression-free survival, and the secondary endpoint, overall survival, to gain regulatory approvals worldwide. Note that if Celsion were to break the data blind and the results were not deemed to be exceptionally good by the FDA, the study would have to be repeated at great expense in both time and money.

We believe the outcome will be in favor of continuing the trial. Our view is based on two smaller, Phase I studies that provided a glimpse of what to expect in the global Phase III trial and on decisions made by the HEAT Data Monitoring Committee since the study’s inception. The Phase I data suggested that the half-way point in the Phase III trial’s “events” would be reached at about the time the trial was fully enrolled, which is what has happened. In addition, the Data Monitoring Committee’s conclusions from analyses that have been conducted every four months or approximately every 100 patients indicate that no unusual events have been occurring – ThermoDox treated patients are probably benefiting from the therapy. Hence, the HEAT Study appears to be on track for completion in the second half of 2012, much as Celsion predicted.

MANAGEMENT HAS TAKEN STEPS TO EXPEDITE THERMODOX’S LAUNCH

The first strategic move that was taken was to skip the traditional Phase II trial and go directly from two Phase I studies to a pivotal Phase III trial. That cut at least two years from the development timeline without significantly changing the risk, since primary liver cancer is already known to respond to doxorubicin. (Note that in the first Phase I study, there was a strong trend between drug dose and progression-free survival that the Company used to plan the Phase III trial.¹) We expect the large, international study will satisfy the objectives of the special protocol assessment that management negotiated with the FDA to define an approvable clinical outcome. In addition, Celsion is using a rolling submission to file its data, which should minimize the time between the recording of the 380th event (signifying the official end of the trial) and completion of the NDA. For instance, the Company is preparing to submit a manufacturing-related portion of the document, after it’s received a positive recommendation from the Data Monitoring Committee and completed certain requirements, including the manufacture of registrational batches at its contract manufacturing facility. Also, the filing will probably be made under the 505(b)(2) registration process. (This type of submission enables a company to refer to information developed on a drug that was filed originally by another corporation. It is appropriate for doxorubicin, since the chemotherapeutic agent has already been approved.) We also point out that FDA granted management’s request for “fast-track” status, which means the agency considers ThermoDox important for fulfilling an unmet medical need and has agreed to render a decision within 6 months of completion of the NDA filing. Separately, the agency granted Orphan Drug designation to ThermoDox as a treatment for primary liver cancer, which ensures 7 years of market exclusivity. (European regulators have also provided Orphan Drug protection, but under their laws, exclusivity lasts for 10 years.)

¹ Poon, RT and Borys, N. Lyso-thermosensitive liposomal doxorubicin: an adjuvant to increase the cure rate of radiofrequency ablation in liver cancer. *Future Oncol* 2011; 7(8): 937.

COLORECTAL CANCER – AN IMPORTANT THERMO DOX MARKET

True, hepatocellular carcinoma is the focus of the pivotal trial that should win the drug access to the market. But a Phase II trial that Celsion will initiate before year end should play a key role in determining its commercial value. That study will examine the use of ThermoDox in combination with RFA against liver colorectal metastases, another malignancy known to be treated with RFA and chemotherapeutic agents. Favorable results will therefore expand the drug's U.S. potential market by 3.4 fold, from 26,190 hepatocellular carcinoma patients predicted for 2011 to 65,545 including those with metastatic colorectal cancer.² (Note that approximately 45% of colorectal cancer patients develop metastatic disease.³) Metastatic colorectal cancer may also become an important indication for ThermoDox on a global basis, although its impact outside of the United States is not as dramatic, since causative factors behind primary liver cancer (i.e., hepatitis B and C) are far more prevalent abroad. We do not believe Celsion will seek FDA approval for the metastatic liver cancer indication, but rather, may use the data from the Phase II trial for marketing purposes.

THERMO DOX OFFERS AN AVENUE INTO DEVELOPING MARKETS

One of the most attractive characteristics of the drug is the distribution of the primary liver cancer population worldwide. This malignancy is a concern in the United States and much of Europe, but it is far more common in China, Taiwan, Southeast Asia, and Korea, where hepatitis B virus infections can reach epidemic proportions. Approximately 10% of the population in this region is a hepatitis B carrier. As a result, we believe ThermoDox has special appeal to international pharmaceutical corporations that are trying to gain or expand a presence in the Far East. Celsion has already signed a Japanese marketing partner, Yakult Honsha, that has provided \$4.5 million in licensing/milestone fees to date and will fund clinical development costs in Japan. (The partnering agreement includes additional milestone payments of up to \$12 million and tiered royalty fees on Yakult's sales.) We believe another deal(s) will yield even more attractive terms, since the clinical development risk and much of the regulatory risk may well be eliminated before negotiations are finalized.

CELSION MOVES TO NEW JERSEY & RAISES ADDITIONAL CAPITAL

The Company moved its headquarters from Maryland with the support of a grant from the New Jersey Economic Development Authority and attractive terms on a 66 month lease for 10,870 square feet of office space. Indeed, the cost of the move was fully offset by lease incentives and the state development grant.

Celsion also raised \$23 million in late July through the issuance of 6.42 million common shares and warrants to purchase another 2.06 million shares at exercise prices of \$3.13 (628,668 shares) and \$4.22 (1.43 million shares). The funds should support the conclusion of the HEAT Study, final development of its commercial manufacturing process, an expansion of the corporate infrastructure in preparation for ThermoDox's launch, and substantial progress of the metastatic colorectal cancer trial. The balance sheet as of June 30th, which is presented in Figure 1, does not reflect the equity financings completed after the quarter ended.

² Cancer Facts & Figures 2011, Publ. by American Cancer Society.

³ Gleisner, AI, et al. Colorectal liver metastases. Arch Surg (2008); 143(12): 1204.

Figure 1. Celsion's Balance Sheet as of June 30, 2011[#][#] Fiscal year ends December 31st. Balance sheet does not reflect the July equity financings.

ASSETS	June 30, 2011 (unaudited)	December 31, 2010
Current assets:		
Cash and cash equivalents	\$ 5,380,068	\$ 1,138,916
Short-term investments	133,842	395,556
Prepaid expenses and other current assets	693,440	492,184
Total current assets	6,207,350	2,026,656
Property and equipment (at cost, less accumulated depreciation of \$1,129,498 and \$1,046,758, respectively)	479,422	378,672
Other assets:		
Deferred financing fees	85,918	-
Deposits and other assets	76,796	76,796
Patent licensing fees, net	39,375	43,125
Total other assets	202,089	119,921
Total assets	\$ 6,888,861	\$ 2,525,249
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)		
Current liabilities:		
Accounts payable	\$ 3,327,553	\$ 4,548,586
Other accrued liabilities	1,688,009	2,124,189
Note payable - current portion	120,152	123,465
Total current liabilities	5,135,714	6,796,240
Common stock warrant liability	665,991	248,131
Note payable - non-current portion	-	56,403
8% Series A Redeemable Convertible Preferred Stock, 100,000 shares authorized, 5,000 issued and 864 outstanding at June 30, 2011 (aggregate liquidation preference of \$864,000 as of June 30, 2011)	597,744	-
Total liabilities	6,399,449	7,100,774
Stockholders' equity (deficit):		
Common stock, \$0.01 par value; 75,000,000 shares authorized; 20,451,321 and 14,091,370 shares issued and 19,705,091 and 13,331,096 shares outstanding at June 30, 2011 and December 31, 2010, respectively	204,513	140,914
Additional paid-in capital	114,957,958	99,316,859
Accumulated other comprehensive income (loss)	21,551	(18,367)
Accumulated deficit	(111,674,818)	(100,938,261)
Subtotal	3,509,204	(1,498,855)
Treasury stock, at cost (746,230 and 760,274 shares at June 30, 2011 and December 31, 2010, respectively)	(3,019,792)	(3,076,670)
Total stockholders' equity (deficit)	489,412	(4,575,525)
Total liabilities and stockholders' equity (deficit)	\$ 6,888,861	\$ 2,525,249

Source: Celsion 10Q for the quarter ended June 30, 2011

CELSION NEWS TO STIMULATE INVESTOR INTEREST

In November, Celsion will probably report its decision to continue or halt the HEAT Study based on the interim data analysis. Since the trial will likely be continued, we believe that news will have little effect on the share price. However, other news may well arouse the investment community's interest. First, Celsion should announce the initiation of the metastatic colorectal cancer trial, followed soon afterward by the commencement of a Royal Philips Electronics-sponsored metastatic bone cancer trial. Then, it's probably a toss-up of which will come first – the signing of a marketing partner for Asia and/or Europe or the top-line results of the HEAT Study. Regardless, we think these will be the two most important announcements for the corporate valuation over the next 12 months.

The expected news flow in 2012 and 2013 should resonate within the investment community, leading to greater excitement over CLSN stock. Recent trading activity indicates that interest in these shares has already begun to rise, as the daily volume traded has been markedly higher since July 1st. We are therefore maintaining our BUY recommendation and our target price of \$10 per share, which was derived by multiplying our projected 2016 share earnings of \$1.15 by a P/E ratio of 25.0 and discounting the future price of \$28.75 back four years, to 2012, at an annual rate of 30%.

INVESTMENT CONCERNS AND RISKS

For a complete description of risks and uncertainties related to Celsion's business, see the "Risk Factors" section in Celsion's SEC filings, which can be accessed directly from the SEC Edgar filings at www.sec.gov. Potential risks include:

- ❑ **Stock risk and market risk:** There is a limited trading market for the Company's common stock. There can be no assurance that an active and liquid trading market will develop or, if developed, that it will be sustained, which could limit one's ability to buy or sell the Company's common stock at a desired price. Investors should also consider technical risks common to many small-cap or micro-cap stock investments, such as small float, risk of dilution, dependence upon key personnel, and the strength of competitors that may be larger and better capitalized.
- ❑ **New and rapidly changing field:** The pharmaceutical and biotechnological markets are rapidly evolving, and research and development are expected to continue at an accelerated pace with increased frequency. Other companies are also actively engaged in the development of therapies to directly or indirectly treat those disorders being pursued by Celsion. These companies may have substantially greater research and development capabilities, as well as significantly greater marketing, financial, and human resources abilities than Celsion.
- ❑ **Products still in development phases:** Although the Company intends to continue with clinical development of ThermoDox[®] for primary liver cancer and other indications, successful development of this product and others in the R&D pipeline is highly uncertain. Product development costs and timelines can vary significantly for each product candidate and are difficult to accurately predict. In addition, products in development that appear to be promising may not reach commercialization for various reasons, including failure to achieve regulatory approvals, safety concerns, and/or the inability to be manufactured at a reasonable cost.
- ❑ **Funding requirements:** It is difficult to predict the Company's future capital requirements. Celsion may need additional financing to continue funding the research and development of its products and to expand its business. There is no guarantee that it can secure the desired future capital or, if sufficient capital is secured, that current shareholders will not suffer significant dilution.
- ❑ **Regulatory risk:** Various statutes and regulations govern or influence the manufacturing, safety, labeling, storage, recordkeeping and marketing of each product. The lengthy process of seeking approval and the subsequent compliance with applicable statutes and regulations require the expenditure of substantial resources. Any failure to obtain, or any delay in obtaining, regulatory approvals could materially adversely affect Celsion's business. There is no guarantee that Celsion's products will be approved by the U.S. Food and Drug Administration (FDA) or international regulatory bodies for marketing in the U.S. or abroad.
- ❑ **Competitive risk:** The biotechnology industry is extremely competitive, mainly due to its large market potential. Many companies are developing products for the same therapeutic indications targeted by Celsion. These companies may have substantially more resources than Celsion and any potential partners, which could adversely affect the Company's position in the market place.

DISCLOSURES

ANALYST(S) CERTIFICATION: The analyst(s) responsible for covering the securities in this report certify that the views expressed in this research report accurately reflect their personal views about Celsion Corporation (the "Company") and its securities. The analyst(s) responsible for covering the securities in this report certify that no part of their compensation was, is, or will be directly or indirectly related to the specific recommendation or view contained in this research report.

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DISCLOSURES FOR OTHER COMPANIES MENTIONED IN THIS REPORT: To obtain applicable current disclosures in electronic format for the subject companies in this report, please refer to SEC Edgar filings at www.SEC.gov. In particular, for a description of risks and uncertainties related to subject companies' businesses in this report, see the "Risk Factors" section in the SEC filings.

PRICE CHART – 2 Year



Source: BigCharts.com

7/30/2008 – Initiating Coverage: share price: \$3.85; rating: BUY; 12-month price target: \$9.00. **11/21/08** – Updating Coverage: share price: \$2.00; rating: BUY; 12-month price target: \$9.00. **7/7/2009** – Updating Coverage: share price: \$4.36; BUY; 12-month price target: \$10.00. **3/2/2010** – Updating Coverage: share price: \$3.14; BUY; 12-month price target: \$10.00; **10/14/2011** – Updating Coverage: share price: \$2.93; BUY; 12-month price target: \$10.00.

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