



CELSION CORPORATION (NASDAQGM: CLSN)

MEANINGFUL PROGRESS ON ALL FRONTS:

- **ThermoDox[®] Pivotal Phase III trial in primary liver cancer making excellent progress; Yakult (Celsion's Japanese partner) has initiated its preclinical program to support entry into the global liver cancer study; and Orphan Drug designation entitles Celsion to seven years of market exclusivity following FDA approval;**
- **Enrollment commences in ThermoDox Pivotal DIGNITY Trial for recurrent chest wall breast cancer;**
- **Celsion forms a Scientific Advisory Board to optimize R&D priorities;**
- **Phillips Medical / Celsion joint development project makes significant headway;**
- **R&D pipeline advancing. New liposomal technology has potentially large commercial applications with novel drugs;**
- **\$15 million payment from Boston Scientific secures necessary resources to complete patient enrollment of liver and breast ThermoDox trials; and,**
- **A new pharmaceutical partnership is under negotiation to expand the marketing support for ThermoDox to more, large regions.**

Celsion Corporation (NasdaqGM: CLSN) is a biopharmaceutical company with a proprietary platform utilizing heat-sensitive nanoparticles to deliver encapsulated chemotherapeutic agents to solid tumors. Its 3rd-generation liposomes are suitable for numerous drugs and have a wide range of potential applications, including some outside the Company's area of interest, oncology. The lead product, ThermoDox (doxorubicin), is being developed for two indications, primary liver cancer and recurrent chest wall (RCW) breast cancer. Celsion has licensed ThermoDox to Yakult-Honsha for the Japanese market and has a joint development partnership with Phillips for its technology in combination with high-intensity focused ultrasound (HIFU). Additional projects are also being advanced related to new liposomal technologies.

Share Price (07/07/09)	\$4.30
52-Week Price Low / High	\$1.60 - \$5.05
Mkt. Capitalization (issued)	\$46.7 M
Shares Outstanding (issued)	10.85 M
12-month Target Price	\$10.00
Website	www.celsion.com



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We are updating coverage on Celsion Corporation (NasdaqGM: CLSN) and reiterate our BUY rating with a new 12-month price target of \$10.00 for CLSN shares.

With two clinical trials under way and a marketing partnership signed, Celsion is making significant progress toward commercializing ThermoDox (a heat-sensitive liposomal formulation of doxorubicin) in combination with radiofrequency ablation (RFA) on a global scale. Its partner in Japan, **Yakult Honsha**, is preparing to seek regulatory permission to enter an international, pivotal Phase III clinical trial. An affirmative response would expedite ThermoDox's commercialization in Japan by about two years and reduce Celsion's clinical trial costs. Meanwhile, three more medical centers in the Pacific Rim are preparing to join the international study. Stateside, the FDA has granted Orphan Drug status to ThermoDox for treating primary liver cancer, which ensures seven years of market exclusivity post approval, as well as pricing leverage. Likewise, we expect ThermoDox to receive Orphan Drug designation for recurrent chest wall (RCW) breast cancer. The first phase of a registration study of RCW breast cancer has commenced enrollment of patients, and additional investigational sites are lining up to join the second phase within a few months. Celsion's other important partnership, with **Royal Philips Electronics (NYSE: PHG)**, is generating data to support a clinical trial of ThermoDox in combination with high-intensity focused ultrasound (HIFU). The companies will seek a meeting with the FDA this year to discuss the design of the first clinical study of this unique therapeutic combination. Celsion is also negotiating with potential marketing partners in Europe and Asia that would support ThermoDox in those geographic regions. We believe the agreements will provide upfront licensing fees and double-digit royalties. Investors can also look forward to go/no-go decisions this year on the development of two other liposome projects in the R&D pipeline. Meanwhile, the corporate finances remain sound, with adequate funds available to complete enrollment of both clinical trials. The formation of a Scientific Advisory Board should also provide additional guidance and direction to management for the ongoing development of the Company's technology and products. All told, we believe Celsion is executing on plan. Given the aforementioned progress, our updated valuation model indicates a \$10 per-share price. Accordingly, we reiterate our BUY recommendation on Celsion Corporation (NasdaqGM: CLSN) and raise our 12-month target price to \$10.00 per share.

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CELSION EXPANDS ITS INTERNATIONAL LIVER CANCER TRIAL

The pivotal Phase III trial of ThermoDox for primary liver cancer, which is also known as hepatocellular carcinoma, is enrolling patients at 33 medical centers around the globe. Five sites in Italy began enrolling patients in February, and U.S. medical centers have been recruiting patients since late last year. Three more locations, in Thailand, Malaysia, and the Philippines, will enter the global liver cancer trial in the fourth quarter to help to ensure that the full allotment of 600 patients is reached as planned by the first quarter of 2010. Celsion expects 40 to 50 locations to be treating patients by August out of a possible 60 to 70, depending on China's participation in the study. (Regulators in China have sought new information that Celsion has provided, though further delays are possible.) Progress to date in the Phase III study is on target with corporate plans to complete the study in 2010.

- **Yakult, Celsion's partner in Japan, is seeking regulatory permission to enter the international Phase III trial.** The Pharmaceuticals and Medical Devices Agency of Japan has required data showing that a drug's safety profile is appropriate for the local population. But criticism that this has prevented the country's populace from receiving new medicines for two or more years after they've launched elsewhere has led to a shift in the political environment. Among the programs being given priority are anticancer therapies. This initiative complements an effort to speed up the general review process for all drugs. Hence, Yakult and Celsion are in a position to benefit from an improved regulatory environment.
- **Yakult has agreed to fund all clinical trials that support ThermoDox's entry into the local market,** which means that its involvement would save Celsion both time and money. A submission seeking the Pharmaceuticals and Medical Devices Agency's approval is expected to be filed soon, and a decision could be forthcoming later this summer. That timeframe probably would enable Yakult to enroll 25% of the 600 patients in the trial and, thus, cut Celsion's costs by an equal proportion. Note, however, that our estimates do not reflect the involvement of Yakult in the international study, because of the ground-breaking nature of the regulatory decision. Accordingly, we have included the \$18 million milestone payment due upon receipt of regulatory approval in Japan in our estimates for 2013.
- **The Phase III trial is randomized, double-blind, placebo-controlled multi-center study of patients with unresectable hepatocellular carcinoma.**¹ The patients can have no more than four lesions with at least one ≥ 3 cm and none ≥ 7 cm in maximum diameter. If a patient has a large lesion (5-7 cm), all other lesions must be less than 5 cm. RFA may be performed percutaneously, laparoscopically, or surgically. Patients in the combination arm will receive ThermoDox via a single 30-minute iv infusion at a dose of 50 mg/m², starting 15 minutes prior to RFA. The RFA-only patients will receive a dummy infusion. Progression-free survival is the primary endpoint, and secondary endpoints include overall survival, time to local recurrence, and time to a clinically significant deterioration in the patient's self-reported symptoms. The patients will be stratified into the two arms to eliminate confounding effects of tumor size and RFA technique.
- **A technology transfer is in process to establish a second manufacturing site.** This is important to ensure an adequate commercial supply of ThermoDox. We believe the timing is also noteworthy, for it illustrates Celsion's care in planning, since the second site will provide drug for the global liver cancer study and will thereby gain regulatory approval as part of the NDA process. Another plus is that the second location will further optimize the Company's cost structure.

¹ Poon, RTP and Borys, N. Lyso-thermosensitive liposomal doxorubicin: a novel approach to enhance efficacy of thermal ablation of liver cancer. *Expert Opin Pharmacother* (2009); 10(2): 333.

RATIONALE OF CELSION'S DEVELOPMENT & PARTNERING STRATEGIES

The agreement with Yakult is just the first to garner a development partner and marketing support for ThermoDox outside of the United States. Future plans reflect the burden that primary liver cancer poses to humanity. The American Cancer Society estimated that more than 474,000 people worldwide succumbed to liver cancer in 2007, and that 711,000 new cases were diagnosed.² While the most common etiologic factors for primary liver cancer are chronic hepatitis B or C virus infections, the distributions of these viruses differ globally. Chronic hepatitis B infection afflicts an estimated 300 million individuals, with the highest prevalence found in southeastern and eastern Asia. Hence, it is not surprising that China has the highest age-adjusted incidence of primary liver cancer globally and accounts for more than 50% of the cases in the world.³ In contrast, the prevalence of chronic hepatitis C is greater in Japan, Europe, and North America. And within Europe, Italy is noteworthy, as it has an endemic population, particularly in the south where the disease prevalence is 12.6% (versus 3.2% in the north).⁴

Primary liver cancer is not typically detected at an early stage, as the symptoms often consist of a lack of appetite, weight loss, stomach pain, and eventually a mass in the area of the liver. This limits the treatment options, which are determined largely by the stage at which the disease is detected and the general health of the organ. Liver resection, local ablation (e.g., via RFA or ethanol injection), and liver transplantation are commonly used, with varying degrees of success. For instance, liver resection appears to be more effective in the West, with median survival rates of 31.9 months and 6.1 months for stage I and II patients, respectively, versus 5.1 months and 2.7 months for patients in Asia. (The differences may be related to the underlying causes of the disease.) Even transplantation, which is considered curative, is only partially successful, with a three-year survival rate of 60%.³ Better alternatives are badly needed, because today hepatocellular carcinoma is the third leading cause of death by all malignancies worldwide.²

The FDA has granted ThermoDox Orphan Drug status for primary liver cancer, which augurs well for its regulatory treatment, based on historical approval rates granted to therapies given this designation. It also gives the company seven years of market exclusivity, thereby bolstering Celsion's competitive position. Just as important, the approval will likely result in an off-label use, since metastatic colorectal cancer in the liver is also treated by RFA and because doxorubicin is commonly used to treat primary colorectal cancers. Overall, approximately 20% of patients diagnosed with colorectal adenocarcinoma develop liver metastases, and although many are treated via liver resection, 50%-60% develop recurrent disease.⁵ Thus, the patient population for ThermoDox may well include more than 30,000 metastatic colorectal cancer patients annually in the United States alone.

Celsion's plan to conduct its international study in countries with sizable patient populations and respected medical centers should facilitate the acceptance of ThermoDox upon approval by regulatory authorities. We believe future marketing agreements will result in upfront licensing fees and double-digit royalties, similar to the Yakult deal. Our estimates are based on an assumption that one such marketing pact is completed this year.

² Global Cancer Facts & Figures 2007.

³ De Villa, V. and Lo C.M. Liver transplantation for hepatocellular carcinoma in Asia. *Oncologist* 2007; 12: 1321.

⁴ Lugoboni, F. et al. Hepatitis C virus infections: prevalence, predictor variables and prevention opportunities among drug users in Italy. *J Viral Hepat* 2003; 10(5): 394.

⁵ Assumpcao, L. et al. Patterns of recurrence following liver resection for colorectal metastases. *Arch Surg* 2008; 143(8): 743.

DATA IDENTIFIES A NOVEL THERMO DOX ADVANTAGE

Celsion has believed that the high doses of doxorubicin achieved only with its heat-sensitive liposomes have had an effect beyond simply killing malignant liver cells. That hypothesis was proven true recently via a study of the effect of ThermoDox on the vasculature of a tumor. Using a xenograft model, scientists at Duke University, where heat-sensitive liposomes were first developed, followed the release, localized distribution, and uptake of doxorubicin with hyperspectral imaging upon exposure to hyperthermic conditions. The results demonstrate for the first time that ThermoDox delivery dramatically alters the drug delivery kinetics, by reducing its efflux from the tumor tissue. As a consequence, the high local doxorubicin concentrations achieved (up to 30-fold greater than that attained with free drug) extend the time the tumor is exposed to maximum levels and cause uptake of the drug by pericytes and endothelial cells of nearby blood vessels. Thus, ThermoDox has a direct, cytotoxic effect on malignant cells and an indirect effect by disrupting oxygen supply to a tumor.

RCW BREAST CANCER STUDY ENROLLING PATIENTS

Two medical centers, in New York and Florida, began enrolling patients in Celsion's pivotal Phase II trial in February, and two more hospitals are expected to start up shortly. The study, which was designed under a special protocol assessment with the FDA, will assess the benefit of ThermoDox and microwave hyperthermia to women with advanced breast cancer. The first portion of the 100-patient trial will determine the maximum tolerated dose (either 40 or 50 mg/m² per treatment). In the second phase, patients will receive six courses of therapy at 21-day intervals and will be monitored to determine the durable (lasting \geq 3 months) complete local response rate. Celsion should have the data analyzed in the second quarter of next year, which could lead to a commercial launch in late 2010 or early 2011. This market, though smaller than the primary liver cancer population, is important because it is one with few alternatives. (An estimated 13,000 patients will be diagnosed with RCW breast cancer in 2009.) Moreover, it may set the stage for use of ThermoDox and microwave hyperthermia for a larger population, the more than 14,000 patients who are estimated to be diagnosed with advanced lung cancer. In the meantime, we believe the Company will seek Orphan Drug status for treating RCW breast cancer.

CELSION HAS FORMED A SCIENTIFIC ADVISORY BOARD

The board will help evaluate new commercial opportunities for ThermoDox, as well as additional ways in which the Company may leverage its expertise in liposomal drug delivery and oncology. Members of the board, who meet monthly, include:

David Cheresh, PhD

- Serves as Professor and Vice Chairman of Pathology at Moores UCSD Cancer Center, University of California, San Diego and as an advisor to several companies on angiogenesis.
- Has received international acclaim for his research of adhesion molecules and tumor angiogenesis.

Peter Corry, PhD

- Holds the position of Vice Chairman, Department of Radiation Oncology, University of Arkansas for Medical Sciences.
- Is an expert in hyperthermia physics, tumor biology and clinical trials.

Mark M Dewhirst, DVM, PhD

- Serves as Professor of Radiation Oncology, Duke University Medical Center, Program Director of the Hyperthermia Treatment Program, and Editor-in-Chief of the journal Hyperthermia
- Has contributed to more than 400 scientific publications in the fields of tumor microcirculation, hyperthermia treatment, and veterinary radiotherapy, which have resulted in numerous awards.

Wafik El-Deiry, MD, PhD

- Serves as a Professor in the Departments of Medicine, Genetics and Pharmacology at the University of Pennsylvania School of Medicine and as Editor-in-Chief of the journal Cancer Biology & Therapy.
- Conducts research into the tumor suppressor p53, hypoxia, and stem cell composition in the tumor microenvironment in an effort to use information about tumor suppressor genes and cell death signaling to develop novel cancer therapies.

Jerry Glickson, PhD

- Serves as a Research Professor of Radiology, University of Pennsylvania School of Medicine and as a member of the Institute for Translational Medicine and Therapeutics.
- Conducts research on molecular imaging and the development of magnetic resonance and optical imaging methods for the prediction, early detection and management of human cancer.

Michael E. Weinblatt, MD

- Serves as the Co-Director, Clinical Rheumatology, Brigham and Women's Hospital, and Professor of Medicine, Harvard Medical School.
- Is an expert in therapeutic interventions in rheumatoid arthritis, an area in which he has received several awards.

R&D PIPELINE INCLUDES NEW LIPOSOMAL TECHNOLOGY WITH LARGE COMMERCIAL POTENTIAL

The new Scientific Advisory Board will play an important role in evaluating current and future commercial opportunities. The R&D pipeline presently includes a few preclinical development programs that aim to expand the applicability of Celsion's liposome technology. Research on these product candidates should provide management with sufficient information to determine their feasibility and, thus, the merit of further investments:

- **Thermolabile docetaxel liposomes appear to have an improved therapeutic index.** Studies to date have found that this formulation of the widely used anticancer drug has significantly greater tumor inhibitory effect than the free drug and a non-heat sensitive liposome formulation. Celsion manufactured a batch of the new therapy in September and has been performing studies to better understand its properties. Against negative controls, the heat sensitive liposomal formulation showed tumor inhibition at all doses tested, though a positive control was more effective against three human cancer cell lines. Experiments that are slated for completion in the near future will evaluate the docetaxel liposomes against a broader range of cell lines.
- **Targeted liposomes have intriguing potential.** The Company has added a peptide that binds to epidermal growth factor (EGF) receptors to create a molecularly targeted liposome. The goal is to use the high binding specificity of the peptide to deliver a large payload of anticancer medicine to cancer cells that overexpress this type of receptor. Heat generated via RFA, medicinal microwave radiation, or high intensity focused ultrasound (HIFU) may then be used to release the active agent to destroy the malignancy. Thus, the targeted liposome probably would achieve the desired effect at a low dose of chemotherapy, resulting in an improved safety profile relative to the free drug.
- **Celsion and Philips Electronics are preparing to advance ThermoDox and HIFU into a clinical trial.** The partners are conducting preclinical studies that will support a meeting later this year with the FDA to discuss the design of the first trial of this unique combination therapy in humans. The first such data, which were recently presented at a medical symposium, indicate that pulsed HIFU increased drug delivery by two fold over levels achieved with free drug and that this treatment regimen resulted in significant growth delay, versus controls. The combination of the heat-sensitive liposomal drug formulation with a non-invasive heat source will constitute the first delivery of a "smart bomb" to a tumor. A successful clinical development program would likely facilitate the adoption of both Celsion's thermosensitive liposomal drug formulations and Philips's HIFU for purposes well beyond the initial indication.

2009 FIRST QUARTER ON BUDGET

The company spent \$2.9 million on product development in the March period, virtually unchanged from the year-earlier level, as enrollment in the latest ThermoDox trials ramped up. However, Celsion cut its general and administrative costs by about 42%, to \$688,000, thanks to ongoing efforts to operate efficiently.

The quarter closed with \$4.3 million in cash on hand. In June, an additional \$15.0 million was received from Boston Scientific for the sale for the previously reported sale of Prolieve® assets, providing the necessary funding to support the two clinical trials of ThermoDox through patient enrollment without the need for additional fund raising. Moreover, the balance sheet is debt free.

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 RCW breast cancer, 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. Please see our Initiation Report on Celsion Corporation, dated July 30, 2008, for further details regarding the development program and the assumptions underlying our projections.
- ❑ **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 the Company'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 pharmaceutical 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.

FINANCIAL FORECASTS & VALUATION

Please see our Initiation Report on Celsion Corporation, dated July 30, 2008, for additional information about the product pipeline.

REVENUE SOURCES

ThermoDox: Liver Cancer - U.S.			
Year penetration starts	2011	Incidence	21625
Starting penetration rate	10%	Percent addressable	40%
Years between penetration start and peak	5	Market growth rate	1%
Peak penetration	40%	Price per patient per year	\$9,000
Duration of peak penetration in years	3	Treatment price growth	0%
Retention rate in decline years	90%	Royalty rate	0%
Stage of development	Phase II	Probability of commercialization	40%

ThermoDox: Liver Cancer - Foreign			
Year penetration starts	2011	Incidence	706000
Starting penetration rate	7%	Percent addressable	25%
Years between penetration start and peak	6	Market growth rate	1.5%
Peak penetration	40%	Price per patient per year	\$9,000
Duration of peak penetration in years	2	Treatment price growth	0%
Retention rate in decline years	90%	Royalty rate	21%
Stage of development	Phase II	Probability of commercialization	40%

Assumptions regarding ThermoDox for Primary Liver Cancer:

- Primary liver cancer will be diagnosed in an estimated 21,625 patients in the United States in 2009 and 706,000 in all other countries, based on projections of the American Cancer Society.^{6,7} We expect the number of new diagnoses will continue to increase, at an annual rate of 1% domestically and at a slightly higher rate abroad, particularly in areas in which hepatitis is endemic.
- The addressable market is estimated at 40% in the United States, since most liver cancer patients are diagnosed with advanced disease, which is not treatable with RFA, and 15%-20% of the patients are eligible for surgical resection. Overseas, we estimate the addressable market is 25%, since surgery is more commonly used in certain countries than it is in the United States and more patients present with a later stage of disease.
- ThermoDox clinical trial results demonstrate an improvement in progression-free survival and overall survival, which supports an initial market penetration rate of 12% and a final penetration rate of 40% stateside. Penetration of foreign markets begins with a somewhat lower rate, 8%, because of the multiple regulatory and reimbursement decisions that must be secured. As a result, it takes a little longer to reach the maximum penetration rate of 40% outside the United States.
- The price to treat one tumor is \$6,000, but because many patients have more than one tumor, we've assumed that the therapy costs \$9,000 on average per patient.
- Because of uncertainty over changes in the reimbursement environment for pharmaceutical care, we have not included potential adjustments to the drug's price for inflation.

⁶ Cancer Facts & Figures – 2009. Published by the American Cancer Society.

⁷ Global Cancer Facts & Figures – 2007. Published by the American Cancer Society.

- The probability of commercialization is 40%, reflecting the well-established safety and efficacy of doxorubicin against primary liver cancer.
- We assume Celsion retains marketing rights to the drug in the United States, since a relatively small sales force should be adequate. Elsewhere, we believe ThermoDox will have marketing support from such partners as Yakult and that the agreements yield an average royalty rate of 21% to Celsion, as well as upfront and milestone payments.

ThermoDox: RCW Breast Cancer - U.S.			
Year penetration starts	2011	Incidence	13000
Starting penetration rate	8%	Percent addressable	80%
Years between penetration start and peak	4	Market growth rate	1%
Peak penetration	35%	Price per patient per year	\$24,000
Duration of peak penetration in years	4	Treatment price growth	0%
Retention rate in decline years	95%	Royalty rate	0%
Stage of development	Phase I	Probability of commercialization	40%

ThermoDox: RCW Breast Cancer - Foreign			
Year penetration starts	2011	Incidence	64645
Starting penetration rate	3%	Percent addressable	80%
Years between penetration start and peak	6	Market growth rate	2%
Peak penetration	25%	Price per patient per year	\$18,000
Duration of peak penetration in years	3	Treatment price growth	0%
Retention rate in decline years	95%	Royalty rate	21%
Stage of development	Phase I	Probability of commercialization	40%

Assumptions regarding ThermoDox for RCW Breast Cancer:

- Recurrent chest wall breast cancer strikes an estimated 13,000 patients in the United States in 2009, based on data showing that 10%-35% of patients diagnosed with stage I-III breast cancer had locoregional recurrence and that 24% of these had a subsequent relapse.^{8,9} In 2009, 194,280 new patients are expected to be diagnosed with breast cancer, of whom nearly 90% will present with stage I or II disease and more than 5% will present with more advanced disease.^{10,11}
- We expect the number of new diagnoses will increase at an annual rate of 1%-2%.
- The addressable market is 80%, reflecting the severity of the disease, the lack of effective alternative therapies, and the non-invasive nature of the ThermoDox treatment.
- ThermoDox® clinical trial results demonstrate a moderate improvement in progression-free survival with an improved quality of life. This supports an initial market penetration rate of 8% in the United States, limited partly by the availability of clinical microwave instruments, and a final penetration rate of 35%, based on an assumption that HIFU gains wider acceptance. Penetration of foreign markets begins at a lower level (3%) and rises to 25%, reflecting the multiple regulatory and reimbursement hurdles that must be cleared and the availability of the appropriate energy sources.
- We've assumed that the price to treat one cycle is \$6,000 and that the average patient receives four

⁸ Santillan, AA, et al. Outcomes of locoregional recurrence after surgical chest wall resection and reconstruction for breast cancer. *Ann Surg Oncol* (2008); 15(5): 1322.

⁹ Bareggi, C, et al. Pattern of breast cancer presentation at first diagnosis in 2,246 patients from a single Italian institution. *J Clin Oncol* (2008); 26 (May 20 suppl): 22182.

¹⁰ Zaloznik, AJ. Breast cancer stage at diagnosis: Caucasians versus Afro-Americans. *Breast Cancer Res Treat* (1995); 34: 195.

¹¹ Zaloznik, AJ. Breast cancer stage at diagnosis: Caucasians versus Hispanics. *Breast Cancer Res Treat* (1997); 42: 121.

courses of drug therapy, resulting in \$24,000 of ThermoDox sales per patient in the United States. Overseas, the average patient receives three courses of drug therapy.

- Because of uncertainty over changes in the reimbursement environment for pharmaceutical care, we have not included adjustments in the drug's price for inflation.
- The probability of commercialization is 40%. The rate reflects the use of a proven and approved chemotherapeutic agent as the active ingredient in ThermoDox.
- We assume Celsion retains marketing rights to the drug in the United States, since a relatively small sales force should be adequate. In foreign countries, ThermoDox has the support of experienced marketing partners under agreements that generate royalties at a rate of 21% and provide for upfront and milestone payments.

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INCOME STATEMENT (ALL DATA IS IN THOUSANDS, EXCEPT PER-SHARE FIGURES.)(Fiscal year ends on December 31st.)

	2009	2010	2011	2012	2013
Revenue					
Sales	\$ -	\$ -	\$ 28,290	\$ 50,520	\$ 73,020
Royalties & Licensing fees	2,000	4,000	37,641	68,964	99,189
Total revenue	\$ 2,000	\$ 4,000	\$ 65,931	\$ 119,483	\$ 172,208
COGS	-	-	2,829	4,799	6,572
Gross profit	\$ 2,000	\$ 4,000	\$ 63,102	\$ 114,684	\$ 165,637
Operating expenses					
R&D	\$ 13,000	\$ 11,000	\$ 17,000	\$ 20,312	\$ 29,275
Selling & marketing		6,000	20,000	25,091	36,164
General & administrative	2,500	3,500	10,000	11,948	17,221
Total expense	15,500	20,500	47,000	57,352	82,660
Operating profit	\$ (13,500)	\$ (16,500)	\$ 16,102	\$ 57,332	\$ 82,977
Non-operating income/expense					
Interest expense					
Interest income					
Other					
Total non-operating	-	-	-	-	-
Pretax profit	\$ (13,500)	\$ (16,500)	\$ 16,102	\$ 57,332	\$ 82,977
Income tax			1,932	21,786	31,531
Net income	\$ (13,500)	\$ (16,500)	\$ 14,170	\$ 35,546	\$ 51,445
Earnings (loss) per share	\$ (0.96)	\$ (1.10)	\$ 0.79	\$ 1.97	\$ 2.82
Diluted shares outstanding	14000	15000	18000	18000	18250

Assumptions regarding the Income Statement:

- Out-licensing of ThermoDox generates upfront licensing fees of \$7 – \$15 million for Asia and \$10 million for Europe. Filing for marketing approval with regulatory authorities in China and Italy result in \$10 million of milestones, and obtaining approvals in these markets generates another \$15 million in milestone payments. For modeling purposes, we assume each upfront fee and milestone is recognized over a five-year period.
- The gross profit margin on U.S. ThermoDox sales is 90% initially and gradually rises to 92.5% by 2016.
- R&D expenses increase in 2009 due to the primary liver cancer trial and formulation/manufacturing of additional products. By 2012, investments in the R&D pipeline amount to 17% of total revenues, reflecting the opportunities addressable with the targeted, heat-sensitive liposome technology.

- The Company begins to incur marketing expenses in 2010 in preparation for the launch of ThermoDox the following year. In 2011, direct marketing costs in the United States begin to rise markedly, reaching 21% of total revenues in 2012. This level is consistent with other specialty drug companies.
- General & administrative costs increase through 2010 as Celsion prepares for ThermoDox commercialization. Expenses rise more significantly in 2011 with the drug's launch, payment of royalties (5% of income) to Duke University, and a general build-out of the corporate infrastructure. By 2012, administrative costs stabilize at 10% of total revenue.
- Non-operating income/expenses are nominal.
- Provisions for income taxes are made for financial reporting purposes, starting in 2011 with an effective rate of 12%. Thereafter, the company books tax liabilities at a 38% rate. Note, however, that we expect the use of net operating loss carryforwards will greatly limit the Company's cash tax liabilities until 2014. As of December 31st, Celsion had \$49.2 million of operating loss carryforwards.
- Shares outstanding rise via external financing and the exercise of stock option grants.

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BALANCE SHEET (All data is in thousands.)Fiscal year ends on December 31st.

ASSETS	3/31/2009
Current Assets	
Cash & equivalents **	4,266
Accounts Receivable	-
Other **	15,161
Total Current Assets	<u>\$ 19,427</u>
Property & equipment	\$ 207
Intangible assets	-
Other	624
Total Assets	<u><u>\$ 20,258</u></u>
LIABILITIES	
Current Liabilities	
Accounts payable	\$ 1,861
Debt due	59
Other	1,903
Total Current Liabilities	<u>\$ 3,823</u>
Long-term debt	\$ -
Other	26
Total Long-Term Liabilities	<u>\$ 26</u>
Shareholders Equity	
Common Stock, par value	\$ 108
Additional Paid-In Capital	89,483
Accumulated Deficit	(70,541)
Treasury Stock	(2,641)
Total Shareholders Equity	<u>\$ 16,409</u>
Total liabilities & equity	<u><u>\$ 20,258</u></u>

** "Other assets" includes \$15 million payment that was due from Boston Scientific and paid in the June quarter.

DISCOUNTED CASH FLOW ANALYSIS (All data is in thousands, except per-share figures.)

	2009	2010	2011	2012	2013
Revenue	\$ 2,000	4000	65931	119483	172208
Operating income	-13500	-16500	16102	57332	82977
Net income	-13500	-16500	14170	35546	51445
Depreciation/amortization	170	170	170	170	180
Stock-based compensation	1,250	1250	1250	1250	1250
Tax loss carryforwards	-	0	1932	21786	31531
Capital expenditures	(125)	-125	-150	-150	-200
Asset acquisitions					
Other					
Total cash flow adjustments	(125)	(125)	1,782	21,636	31,331
Free cash flow	\$ (13,625)	\$ (16,625)	\$ 15,952	\$ 57,182	\$ 82,777
Risk-adjusted free cash flow	\$ (13,625)	\$ (16,625)	\$ 6,381	\$ 22,873	\$ 33,111

Discount Rate	Discounted Cash Flows (2009 - 2024)	PV of Terminal Value at a					
		Perpetual growth rate of rFCF			Enterprise Value		
		2.0%	3.0%	4.0%	2.0%	3.0%	4.0%
7.5%	\$195,809.27	\$ 175,208	\$ 216,242	\$ 280,725	\$371,017	\$412,052	\$476,534
10.0%	\$155,472.01	\$ 85,322	\$ 98,467	\$ 115,994	\$240,794	\$253,939	\$271,466
12.5%	\$124,330.38	\$ 46,405	\$ 51,793	\$ 58,448	\$170,736	\$176,123	\$182,778
15.0%	\$100,027.06	\$ 26,955	\$ 29,487	\$ 32,480	\$126,982	\$129,514	\$132,507
17.5%	\$80,867.72	\$ 16,374	\$ 17,674	\$ 19,168	\$97,241	\$98,542	\$100,036

Discount Rate	Net Debt	Total Equity Value			Value per Diluted Share		
		2.0%	3.0%	4.0%	2.0%	3.0%	4.0%
		7.5%	\$ (4,207)	\$375,224	\$416,259	\$480,741	\$ 20.85
10.0%	(4,207)	\$245,001	\$258,146	\$275,673	\$ 13.61	\$ 14.34	\$ 15.32
12.5%	(4,207)	\$174,943	\$180,330	\$186,985	\$ 9.72	\$ 10.02	\$ 10.39
15.0%	(4,207)	\$131,189	\$133,721	\$136,714	\$ 7.29	\$ 7.43	\$ 7.60
17.5%	(4,207)	\$101,448	\$102,749	\$104,243	\$ 5.64	\$ 5.71	\$ 5.79

Discount Rate	Terminal Value as % Enterprise Value			Implied EBITDA Multiple		
	2.0%	3.0%	4.0%	2.0%	3.0%	4.0%
	7.5%	47.2%	52.5%	58.9%	11.40	14.07
10.0%	35.4%	38.8%	42.7%	7.84	9.05	10.66
12.5%	27.2%	29.4%	32.0%	5.97	6.67	7.52
15.0%	21.2%	22.8%	24.5%	4.82	5.28	5.81
17.5%	16.8%	17.9%	19.2%	4.05	4.37	4.74

Assumptions related to the Discounted Cash Flow Analysis:

- The DCF model projects cash flow through 2023, discounted back at multiple annual rates (7.5%, 10.0%, 12.5%, 15.0%, and 17.5%) to demonstrate the potential variability related to this assumption. It also includes three perpetual growth rates (2%, 3%, and 4%) to show the impact on the present value of the company's terminal value. The rates used in calculating the per-share value for Celsion Corporation are a 12.5% annual discount rate and a perpetual growth rate of 3%. The number of fully-diluted shares estimated to be outstanding in 2013, 18.25 million, is used in the per-share calculation.
- The cash flows are risk adjusted, based on the proportional gross profit contribution by each drug/indication on an annual basis and the probability of that drug/indication being commercialized. For years in which we are projecting negative cash flow, the probability is conservatively set at 100%.

Disclosures

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TWO-YEAR PRICE CHART



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.

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