



UPDATE REPORT

Pharmaceutical Industry • March 2, 2010

CELSION CORPORATION (NASDAQGM:CLSN)

- The ThermoDox[®] primary liver cancer trial is nearly 50% enrolled, as medical centers in China, Japan, and the Asia Pacific region are now participating.
- Celsion aims to expand the market for ThermoDox with a metastatic colorectal cancer study.
- The pivotal recurrent chest wall breast cancer trial is scheduled to end in 2011.
- Celsion and partner Royal Philips will file plans for a clinical trial of ThermoDox and HIFU later this year.
- We reiterate our BUY recommendation on Celsion shares, with a \$10.00 per share price.

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[®] (liposomal doxorubicin), is being tested clinically in conjunction with radio frequency ablation (RFA) for primary liver cancer and with therapeutic microwave energy for recurrent chest wall (RCW) breast cancer. Celsion has licensed ThermoDox to Yakult-Honsha for the Japanese market, and it is engaged in negotiations to secure promotional support in other markets. Two additional clinical trials are scheduled to commence in the months ahead. One will test the combination of ThermoDox and RFA against colorectal cancer liver metastases, while the other will evaluate ThermoDox in conjunction with a newer energy source, high-intensity focused ultrasound (HIFU), via a partnership with Royal Philips Electronics.

Share Price (02/18/10)	\$3.14
52-Week Price Low / High	\$1.60 - \$5.25
Mkt. Capitalization (issued)	\$38.1 MM
Shares Outstanding (issued)	12.13 MM
12-month Target Price	\$10.00
Website	www.celsion.com



Celsion's R&D pipeline includes other drugs suitable for delivery with its proprietary heat-sensitive liposomes. But the primary focus is on establishing the validity of its technology with the commercialization of ThermoDox.

Based on the well-known therapeutic effects of doxorubicin and ThermoDox's commercial potential, we believe Celsion shares are a compelling investment on a risk-adjusted basis.

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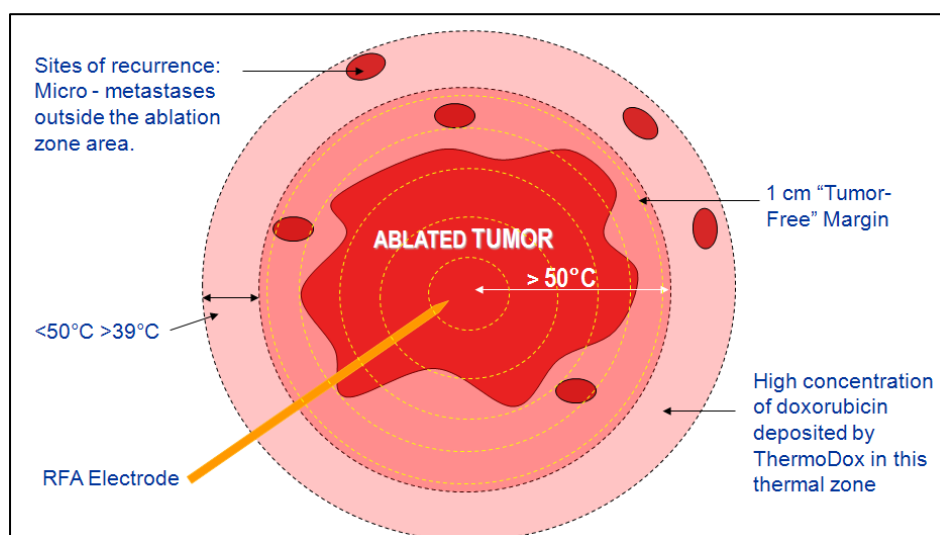
Recent & Near-Term Milestones

- ✓H1, '09 Establish a Scientific Advisory Board to aid in defining scientific and medical priorities.
- ✓H2,'09 Gain regulatory approval to conduct the HEAT trial (the pivotal study of ThermoDox and radio frequency ablation therapy for primary liver cancer) in Japan via a partnership with a local pharmaceutical company, Yakult Honsha.
- ✓H2,'09 Expand the number of medical centers participating in the HEAT trial and significantly increase the number of patients enrolled.
- ✓H2,'09 Initiate enrollment in the recurrent chest wall (RCW) breast cancer study of ThermoDox.
- ✓2009 Expand patent portfolio related to heat-sensitive liposomes.
- ✓2009 Launch Continuing Medical Education accredited program in partnership with the American Liver Foundation to educate physicians of advances in the treatment of primary liver cancer.
- ✓Q1,'10 Obtain interim safety data of HEAT trial from the study's Data Monitoring Committee.
- H1,'10 Partner ThermoDox in China or Europe.
- H1,'10 Present data from the Phase I primary liver cancer trial of ThermoDox and RFA at the 9th World Congress of the International Hepato- Pancreato- Biliary Association.
- H1,'10 Submit IND for a ThermoDox-HIFU clinical trial with partner Royal Philips Electronics.
- Q3,'10 Complete the enrollment in the HEAT trial of ThermoDox.
- Q4,'10 Report follow-up data from the first phase of the pivotal RCW breast cancer trial.
- H2,'10 Obtain interim efficacy data from the HEAT trial from the study's Data Monitoring Committee, once 190 events have occurred.
- H2,'10 Initiate a clinical study of ThermoDox and radio frequency ablation against metastatic colorectal cancer.
- Q1,'11 Submit an NDA for ThermoDox against primary liver cancer, based on the HEAT trial data.
- H2,'11 Complete patient enrollment in the pivotal RCW breast cancer trial.

CELSION'S PROPRIETARY DRUG DELIVERY PLATFORM

The Company's drug delivery technology is based on a change in the physical state of lipids comprising liposomes that occurs at mild hyperthermic temperatures (39° to 40° C).¹ The increased membrane fluidity that takes place at these temperatures triggers the rapid release of drugs from the liposomes resulting in high, localized drug concentrations. Celsion first applied this technology to the administration of a widely used chemotherapeutic agent, doxorubicin, for the treatment of tumors in conjunction with another common therapeutic intervention, radio frequency ablation (RFA). Studies of ThermoDox have demonstrated that it effectively increases the treated area without destroying all normal tissue in the marginal zone around the tumor. Moreover, ThermoDox not only contributes to the elimination of malignant cells, but also helps to destroy blood vessels providing oxygen and nutrients to the tumor.^{2,3} As shown in Figure 1, this is particularly important in preventing the recurrence of tumors in regions adjacent to the ablation.

Figure 1. Synergistic effect of heat-sensitive liposomal drug delivery & tumor ablation



Source: Celsion

The source of heat is not crucial to the delivery of a drug from heat-sensitive liposomes. Indeed, the Company has successfully used clinical microwave radiation to deliver doxorubicin locally to treat advanced recurrent chest wall (RCW) breast cancer. As with RFA, the advantage of this application is the avoidance of high systemic doses of the drug and therefore the severe side effects that accompany normal, intravenous drug administration. More recently, Celsion has been collaborating with **Royal Philips Electronics (NYSE: PHG)** on the use of ThermoDox with another heat source, high-intensity focused ultrasound (HIFU). This combination has special appeal for applications in which surgical intervention may be avoided, since HIFU can be focused onto a tumor without damaging normal tissue between the energy source and the area that is being targeted. In essence, the combination creates a “smart bomb” that has been shown to release drug rapidly *in vitro* and inhibit tumor growth *in vivo*.⁴

¹ Needham, D, et al. A new temperature-sensitive liposome for use with mild hyperthermia: characterization and testing in a human tumor xenograft model. *Cancer Res* (2000); 60: 1197.

² Chen, Q, et al. Targeting tumor microvessels using doxorubicin encapsulated in a novel thermosensitive liposome. *Mol Cancer Ther* (2004); 3(10): 1311.

³ Chen, Q, et al. Tumor microvascular permeability is a key determinant for antivasular effects of doxorubicin encapsulated in a temperature sensitive liposome. *Int J Hyperthermia* (2008); 24(6): 475.

⁴ Dromi, S, et al. Pulsed-high intensity focused ultrasound and low temperature-sensitive liposomes for enhanced targeted drug delivery and antitumor effect. *Clin Cancer Res* (2007); 13(9): 2722.

Celsion's heat-sensitive liposomes may also be used to deliver other anticancer drugs. Research has already begun to investigate their use with docetaxel and carboplatin in preclinical disease models. However, the Company's focus presently is to commercialize ThermoDox as rapidly as possible.

Heat-sensitive liposomal drugs have a unique competitive position, since they are designed for use only during the application of a therapeutic energy source. Hence, Celsion's drugs may be employed each time a procedure is performed, but they would not prevent the use of an adjuvant medicine. Accordingly, ThermoDox will not alter current medical practice. Moreover, we believe new therapies targeting cancers that are addressable with RFA or HIFU, for instance, pose only a limited competitive threat to the Company's heat-sensitive liposome formulations.

THERMODOX MAKES PROGRESS AGAINST LIVER CANCER

Celsion is conducting a pivotal Phase III clinical study, dubbed the HEAT trial, of ThermoDox with RFA that will involve 600 patients who will receive either RFA + ThermoDox (50 mg/m²) or RFA alone. (Dexamethasone and antihistamines may be administered to prevent anaphylactic reactions seen with other liposomal drugs, such as Doxil®, and injection-site allergic reactions.) This is the largest single study ever conducted involving RFA therapy. To enter the trial, the patients must have a life expectancy greater than 4 months and no more than 4 primary liver tumors, with at least one \geq 3 cm and none > 7 cm as detected via computed tomography (CT scan). Re-treatment within each arm is permitted upon disease progression although the study's primary endpoint is progression-free survival. Other endpoints include overall survival, quality of life, and time to local recurrence. Note that under a Special Protocol Assessment with the FDA, Celsion will be able to file an NDA after 385 events (patients showing signs of progression, regardless of study arm) have occurred.

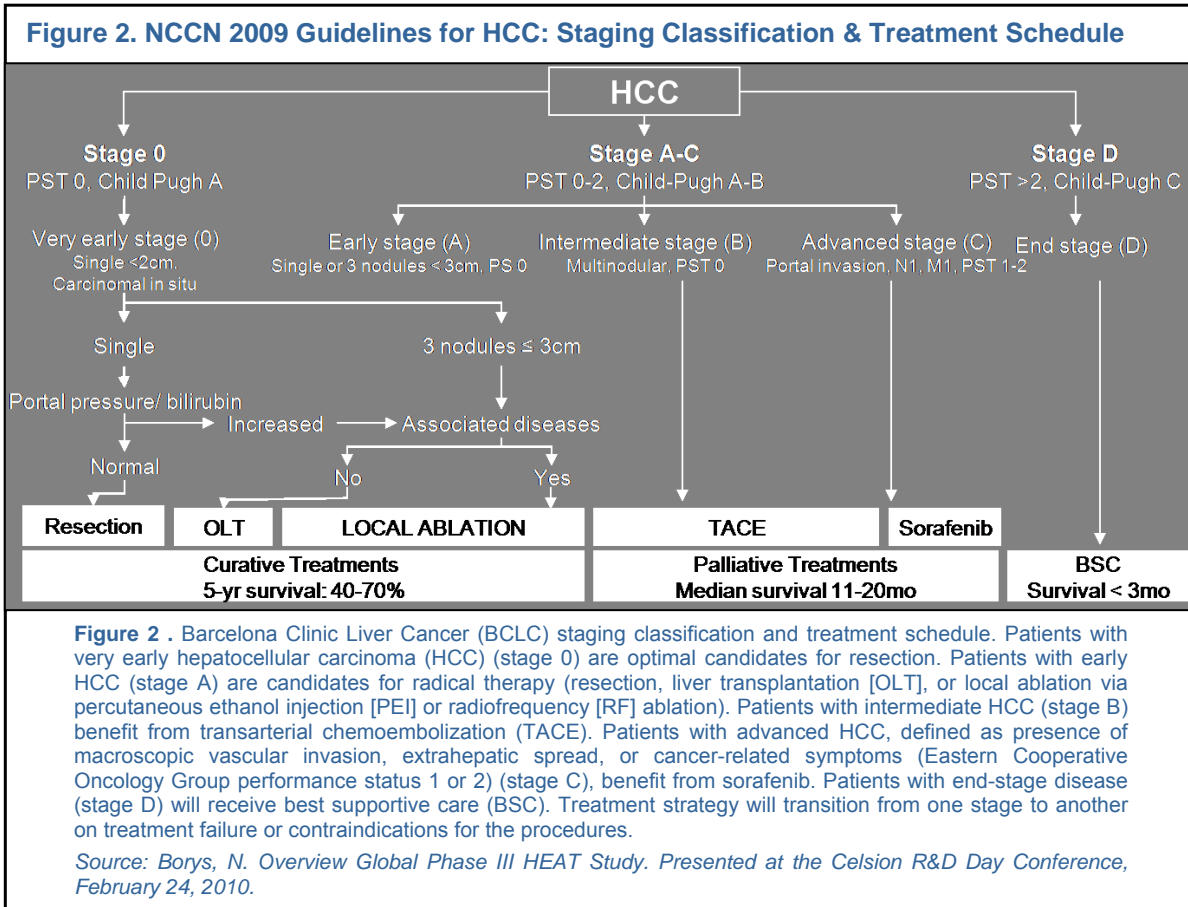
The HEAT trial is being conducted in eleven countries that constitute important potential markets for the drug. The countries are: the United States, Canada, Italy, China, Japan (via a partnership with **Yakult Honsha**), Taiwan, Hong Kong, Korea, Malaysia, the Philippines, and Thailand. Enrollment accelerated with the involvement of a new contract research organization last summer, and stood close to the half-way mark, with 274 of 600 patients treated as of mid-February (about 20% in North America and Europe, and roughly 80% in Asia). In addition, 62 medical centers, including about 30 in the Asia/Pacific region, are now participating. The latest to join, located in China, Malaysia, and the Philippines, are particularly important, since hepatitis is endemic to the region. (See a detailed discussion of primary liver cancer and its causes in the blue area below.) Another eight medical centers, including three in Italy, are expected to begin enrolling patients in the near future, which should help Celsion to complete enrollment during the September quarter.

Primary liver cancer, or hepatocellular carcinoma, is caused largely by chronic hepatitis B and C infections and is often associated with cirrhosis. These related viral infections have different geographic distributions, with hepatitis B found primarily in China, Southeast Asia, and the Pacific Rim and the prevalence of hepatitis C greatest in Japan, the United States, and Europe. In some areas, viral hepatitis is a disease that is passed on from generation to generation. For instance, hepatitis B is endemic to certain parts of China, which accounts for 55% of all primary liver cancer cases, and hepatitis C, to southern Italy. Overall, hepatocellular carcinoma is the third leading cause of cancer death worldwide. In the United States, the incidence of primary liver cancer is still relatively low, amounting to less than 27,000 patients this year, but concern is rising along with the incidence.⁵ The disease is deadly, as the number of deaths per annum has historically approximated 80% of the new cases. That's partly because few patients (approximately 30%) are diagnosed sufficiently early for a curative treatment.

The choice of therapeutic intervention depends on the stage of the patient's disease, as well as the size(s) and location of the tumors, plus the availability of medical equipment. Another important consideration is the health of the liver, since most patients suffer from both cirrhosis and cancer. Surveillance of the at-risk population (i.e., those with cirrhosis and/or chronic hepatitis B or C infections)

⁵ Cancer Facts & Figures 2009. American Cancer Society, 2009.

using α -fetoprotein measurements and ultrasound imaging of the liver can lead to an early diagnosis, but that requires proactive steps by both the patient and physician. Unless the initial treatment yields a cure, most patients undergo more than one type of therapy over the course of their disease. As shown in Figure 2, this may involve surgical resection initially, followed by multiple tissue ablation procedures (e.g., RFA), systemic sorafenib, and eventually hospice care. A large medical center in Italy reportedly uses RFA for 50%-60% of its patients, transarterial chemoembolization for roughly 35%-65%, systemic drugs for about 12%-18%, and surgical resection for approximately 5%-10%.⁶



EXPERTS RECOMMEND A CONTINUATION OF THE HEAT TRIAL

The HEAT trial’s Data Monitoring Committee, which is composed of outside medical and scientific experts, reviewed safety and efficacy data from the first 120 patients treated and recommended that the study continue. The results are not surprising, in our opinion, given the advantages of the ThermoDox and RFA combination discussed above and the fact that doxorubicin alone has shown the most activity against primary liver tumors (though it’s efficacy is still low – less than 20%).⁷ The Committee’s recommendation indicates that both the safety and efficacy of the ThermoDox-RFA combination therapy are within expected ranges.

⁶ Lencioni, R. Current and future role of interventional radiology in the treatment of liver cancer: expected impact of RFA-ThermoDox. Presented at the Celsion R&D Day Conference, February 24, 2010.

⁷ Yeo, W, et al. A randomized phase III study of doxorubicin versus cisplatin/interferon α -2b/doxorubicin/fluorouracil (PIAF) combination chemotherapy for unresectable hepatocellular carcinoma. J Natl Cancer Inst (2005); 97(20): 1532.

EFFICACY DATA SHOULD SUPPORT AN NDA FILING IN EARLY 2011

An interim analysis of the HEAT trial is scheduled for the closing six months of this year to provide an interim analysis of the efficacy. Assuming that the trial is fully enrolled by the end of September, we believe Celsion will have the evidence it needs to gain FDA approval of its first drug. A small Phase I/II study found that the combination of ThermoDox and RFA reduced the incidence of local tumor recurrence to just 4.5% (versus about 20% with RFA alone). Based on that trial, Celsion should have sufficient data within 12 months of completing the Phase III study's enrollment to file for regulatory approval. Thus, the Company is on target for filing the NDA in early 2011 and a possible U.S. launch later that year.

A NEW TARGET: METASTATIC COLORECTAL CANCER

Celsion intends to investigate the effectiveness of ThermoDox and RFA for treating colorectal cancer (CRC) metastases in the liver. This is a direct extension of current medical practice, in which the liver tumors are treated with RFA alone. As discussed in the blue area below, CRC strikes a large number of patients and often metastasizes to the liver.

Metastatic colorectal cancer is commonly found in the liver (35%-55% all CRC patients develop liver metastases during the course of the disease),⁸ perhaps because of the proximity of these organs, but also because the liver provides a favorable environment for CRC cells to populate. Indeed, research suggests that stromal fibroblasts of the liver create an inflammatory environment that favors the settlement and proliferation of colorectal cancer cells.⁹ The American Cancer Society estimated that 147,000 patients would be diagnosed with cancer of the colon or rectum in 2009 and that 50,000 would die from the disease.⁴ These figures compare with an estimated 1.17 billion new cases of colorectal cancer globally in 2007 and 602,967 deaths.¹⁰ Only a fraction of these patients would be considered suitable candidates for RFA therapy, however, since a large proportion are not detected at a sufficiently early stage to be treated with existing electrode designs. Instead, RFA tends to be used for patients with tumors adjacent to critical vascular structures in the liver and for those with multiple tumors, not all of which can be addressed surgically. The differences between the tumors targeted with RFA and those treated with alternative interventions make it difficult to compare the efficacies of ablative therapy and surgical resection. However, disease recurrence with RFA as a monotherapy is high, exceeding 80% (including new hepatic and extra-hepatic CRC metastases), and 3- and 5-year survival is about 45% and 25%, respectively.¹¹ Five-year survival is much better (as high as 40%) in patients with fewer and smaller tumors (<4 cm in diameter), and these results compare well with those obtained with systemic chemotherapy alone.¹¹ Overall, roughly 15% of all colorectal liver metastases may be eligible for RFA therapy today, though many are also candidates for resection.¹²

We believe Celsion's colorectal cancer study is not intended for registrational purposes, but may be used to market ThermoDox. Use of the drug after it has gained regulatory approval will hinge partly on a physician's judgment, and having clinical evidence demonstrating a survival benefit of RFA with ThermoDox would facilitate acceptance. Then, too, such data would likely increase healthcare payers' willingness to reimburse for RFA treatment of colorectal liver metastases with the drug. (At this juncture, RFA is considered a standard of care for treating a variety of cancers, including primary liver, colorectal liver metastases, and lung, as a monotherapy.)

⁸ Gleisner, AL, et al. Colorectal liver metastases. Arch Surg (2008); 143(12): 1204.

⁹ Mueller, L., et al. Stromal fibroblasts in colorectal liver metastases originate from resident fibroblasts and generate an inflammatory microenvironment. Am J Pathol (2007); 171(5): 1608.

¹⁰ Global Cancer Facts & Figures 2007. American Cancer Society, 2007.

¹¹ Crocetti, L, et al. Quality improvement guidelines for radiofrequency ablation of liver tumours. Cardiovasc Intervent Radiol (2010); 33(1): 11.

¹² Lin, SM. Recent advances in radiofrequency ablation in the treatment of hepatocellular carcinoma and metastatic liver cancers. Chang Gung Med J (2009); 32(1): 22.

THERMODOX EXPECTED TO SHIFT THE TREATMENT PARADIGM

Celsion's drug has the potential to alter the preferred approach to treating primary liver cancer and metastatic disease of the liver. By effectively increasing the volume of the ablation area created with RFA, ThermoDox may expand the use of this interventional therapy to include smaller tumors, based on recurrence seen with surgical resection, and to larger tumors that are now treated with transarterial chemoembolization. (Note that the probability of disease recurrence with RFA today jumps from 10%-20% for tumors less than 3 cm in diameter to 40% for tumors larger than 3 cm.) Accordingly, as shown in Figure 2, ThermoDox would probably increase the number of RFA-treated tumors to approximately 40% of the total patient population.

However, the drug's impact may well extend beyond simply expanding the size range of tumors being treated with RFA. ThermoDox-RFA therapy has the potential to alter the medical approach to liver cancer. An important trend is emerging in the way cancer is viewed, from an acute disease that must be eradicated to a chronic condition that should be managed. This shift in philosophy reflects the availability of multiple therapeutic regimens that can be employed at various disease stages, much as those depicted in Figure 2. Commercialization of ThermoDox will expand the alternatives even further and importantly add a relatively safe treatment that can be employed multiple times to manage the disease. In the extreme, ThermoDox-RFA therapy might be used to treat virtually all patients, since it could be used as a bridge to a liver transplant and since even the most advanced cases might benefit from a reduction in the tumor's mass. Indeed, RFA has been shown to increase the response to subsequent chemotherapy in patients with very large tumors.¹³

The financial implications to Celsion are potentially huge. Accordingly, we have adjusted our financial model to reflect the broader use of ThermoDox-RFA to include both primary liver cancer and metastatic liver disease.

UPDATE ON THE RCW BREAST CANCER TRIAL

ThermoDox is in the first stage of a pivotal trial, called DIGNITY, that is examining its efficacy in extending the lives of women with an advanced form of cancer, recurrent chest wall breast cancer. No therapeutic options exist for this disease, but Celsion believes that its drug affords a life-extending benefit and improved quality of life for these patients. The first stage of the trial, which is being conducted at a small number of U.S. medical centers, is identifying the maximal dosage strength that will be used in the second stage of the trial. (A 40 mg. cohort has been fully enrolled, and dosing with 50 mg. should begin in March.) Patient enrollment has been progressing slower than initially expected, but additional hospitals have agreed to join the study once the second stage commences. As the trial is currently designed, the Company now estimates that the trial will be completed in the second half of 2011, about a year later than initially planned. If enrollment does not accelerate sufficiently, Celsion will discuss the option of redesigning the trial to include patients with other superficial cancers, including melanoma and soft tissue sarcoma. This would accelerate enrollment to determine the maximum tolerated dose in preparation for the second phase of the RCW breast cancer trial. Alternatively, the Company may choose not to go forward with the second phase, but to investigate the use of ThermoDox and microwave therapy for another indication(s).

We have made adjustments to our financial model to allow for the change in commercialization for RCW breast cancer to early 2013 and have reduced the probability of commercialization to take into consideration the potential change in clinical development to focus on other malignancies.

¹³ Hirooka, M, et al. Mass reduction by radiofrequency ablation before hepatic arterial infusion chemotherapy improved prognosis for patients with huge hepatocellular carcinoma and portal vein thrombus. Am J Roentgenol (2010); 194(2): W221.

DEVELOPMENT OF A THERMODOX AND HIFU COMBINATION THERAPY

Celsion has been working with Philips Electronics to optimize the combination of ThermoDox and HIFU therapy as a cancer treatment. The international electronics giant has been funding the preclinical research and the collaborators are currently negotiating terms of a clinical development program. The tumors being considered for the trial include bone metastases, which afflict approximately 300,000 patients, and pancreatic cancer, which was expected to claim the lives of more than 35,000 patients in the United States alone last year. Celsion will have the responsibility to manage the clinical trial.

Since the two companies began their partnership, we believe Philips has been design changes to optimize the use of HIFU release ThermoDox's active ingredient. As a monotherapy, HIFU has been used to ablate prostate, breast, liver, and pancreatic cancers, as well as uterine fibroids. Pulsed ultrasound waves, insufficient to ablate tissues, have generated low-level hyperthermia and caused the release of doxorubicin from Celsion's ThermoDox *in vivo*.¹⁴ More recently, the development of a split focus transducer with a larger effective beam width was able to release more doxorubicin in a larger treatment volume than the conventional single focus transducer.¹⁵ As one of the leading suppliers of HIFU equipment globally, Philips is an ideal partner for Celsion, in our opinion.

The two companies aim to file this summer for FDA approval to conduct a clinical study of ThermoDox and HIFU. However, until they have filed the IND, we will not include this combination therapy in our financial analysis.

CELSION CONTINUES TO INVEST ITS RESOURCES CAREFULLY

The Company kept tight control over its expenditures throughout 2009, as evidenced by its \$13.7 million outlay for drug development (largely for the ThermoDox clinical trials) and by the \$3.3 million spent for general and administrative activities. These amounts compared with \$12.0 and \$2.0 million, respectively, that was expended in 2008.

This year's budget includes roughly \$8.5 million for the R&D program and about \$3.5 million for general and administrative functions. The decline in R&D expenditures is not an indication that the Company is cutting back on its clinical trials, but rather, it reflects Yakult Honsha's contribution to the trial by financing the investigation in Japan, where approximately 25% of patients in the primary liver cancer trial will be enrolled. We recognize that a portion of this year's expenses may be offset by an upfront payment upon the signing of a marketing partner in Europe or China, but have not included this in our 2010 estimates given the uncertainty over the timing and potential dollar amount involved.

¹⁴ Dromi, S, et al. Pulsed-high intensity focused ultrasound and low temperature-sensitive liposomes for enhanced targeted drug delivery and antitumor effect. *Clin Cancer Res* (2007); 13(9): 2722.

¹⁵ Patel, PR, et al. *In vitro* and *in vivo* evaluations of increased effective beam width for heat deposition using a split focus high intensity ultrasound (HIFU) transducer. *Int J Hyperthermia* (2008); 24(7): 537.

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.
- ❑ **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.

FINANCIAL ANALYSIS

REVENUE SOURCES

We've made several basic assumptions regarding the commercialization of ThermoDox, regardless of the indication: Due to uncertainty over healthcare reform and continuing efforts to limit the cost of medical care worldwide, we've made no provision for price increases. The probability of commercialization is 40%, based on historical success rates for drugs that have entered into, but not yet completed pivotal clinical trials. This may actually underestimate the probability for ThermoDox, since the active ingredient, doxorubicin, is already approved by regulatory agencies worldwide. Finally, our Financial Analysis is based on an assumption that Celsion markets ThermoDox in the United States and relies on partners to sell it abroad.

1. ThermoDox & Primary Liver Cancer

ThermoDox: Liver Cancer - U.S.			
Year penetration starts	2012	Incidence	26,895
Starting penetration rate	7%	Percent addressable	40%
Years between penetration start and peak	5	Market growth rate	1%
Peak penetration	35%	Price per patient per year	\$9,000
Duration of peak penetration in years	2	Treatment price growth	0%
Retention rate in decline years	80%	Royalty rate	0%
Stage of development	Phase II	Probability of commercialization	40%

ThermoDox: Liver Cancer - Foreign, excl China			
Year penetration starts	2012	Incidence	300,840
Starting penetration rate	3%	Percent addressable	40%
Years between penetration start and peak	6	Market growth rate	1.5%
Peak penetration	30%	Price per patient per year	\$6,000
Duration of peak penetration in years	0	Treatment price growth	0%
Retention rate in decline years	80%	Royalty rate	18%
Stage of development	Phase II	Probability of commercialization	40%

ThermoDox: Liver Cancer - China			
Year penetration starts	2012	Incidence	400,563
Starting penetration rate	3%	Percent addressable	40%
Years between penetration start and peak	8	Market growth rate	1.5%
Peak penetration	35%	Price per patient per year	\$9,000
Duration of peak penetration in years	6	Treatment price growth	0%
Retention rate in decline years	80%	Royalty rate	18%
Stage of development	Phase II	Probability of commercialization	40%

Assumptions related to Primary Liver Cancer

- Primary liver cancer will be diagnosed in an estimated 26,895 patients in the United States in 2010 and 701,400 in all other countries, based on projections of the American Cancer Society and worldwide population growth. 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. We have broken out our estimates related to China separately, because of differences the reimbursement and the treatment of intellectual property there versus other countries. Specifically, ThermoDox will be reimbursed by the government's health program five years after its commercial launch, and it will have patent protection that extends to 2024.
- The addressable market is estimated at 40% in the United States and abroad, 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.

- ThermoDox clinical trial results demonstrate an improvement in progression-free survival and overall survival, which supports an initial market penetration rate of 7% in the United States and a final penetration rate of 35%. Penetration of foreign markets, including China, begins with a somewhat lower rate, 3%, 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. We have assumed maximum penetration rates of 35% and 30% for China and other foreign countries, respectively.
- The probability of commercialization is 40%, based on historical success rates for drugs that are in Phase III clinical trials.
- The price to treat one tumor is \$6,000, but because many patients are treated more than once with RFA, we've assumed that the therapy costs \$9,000 on average per patient in the United States and China where reimbursement is more generous. We've assumed only one treatment for other foreign countries as a hedge against lower pricing.

2. ThermoDox & Colorectal Cancer Liver Metastases

ThermoDox: Metastatic CRC - U.S.			
Year penetration starts	2012	Incidence	148,717
Starting penetration rate	7%	Percent addressable	15%
Years between penetration start and peak	5	Market growth rate	1%
Peak penetration	30%	Price per patient per year	\$9,000
Duration of peak penetration in years	2	Treatment price growth	0%
Retention rate in decline years	80%	Royalty rate	0%
Stage of development	Phase II	Probability of commercialization	40%

ThermoDox: Metastatic CRC - Foreign			
Year penetration starts	2012	Incidence	1,143,507
Starting penetration rate	3%	Percent addressable	15%
Years between penetration start and peak	6	Market growth rate	1.5%
Peak penetration	35%	Price per patient per year	\$6,000
Duration of peak penetration in years	0	Treatment price growth	0%
Retention rate in decline years	80%	Royalty rate	18%
Stage of development	Phase II	Probability of commercialization	40%

Assumptions related to Colorectal Cancer Liver Metastases

- Colorectal cancer will be diagnosed in approximately 148,700 individuals in the United States in 2010 and 1.14 billion people abroad, based on estimates from the American Cancer Society for 2009 and 2007, respectively, adjusted for population growth.
- The addressable market consists of 15% of newly diagnosed cases. This is consistent with the number of CRC patients who present with synchronous liver metastases and with the proportion of overall patients who would be candidates for RFA treatment at some point during the course of their disease.¹⁶
- ThermoDox clinical trial results demonstrate an improvement in progression-free survival and overall survival, which supports an initial market penetration rate of 7% in the United States and a final penetration rate of 30%. Penetration of foreign markets begins with a somewhat lower rate, 3%, 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 35% outside the United States.
- The probability of commercialization is 40%, based on historical success rates for drugs that are in Phase III clinical trials.

¹⁶ Manfredi, S, et al. Epidemiology and management of liver metastases from colorectal cancer. Ann Surg (2006); 244(2): 254.

- The price per treatment is \$6,000, and each patient is treated only once, even though some patients may actually undergo RFA therapy more than once.

3. ThermoDox & Recurrent Chest Wall Breast Cancer

ThermoDox: RCW Breast Cancer - U.S.			
Year penetration starts	2013	Incidence	13,000
Starting penetration rate	4%	Percent addressable	80%
Years between penetration start and peak	4	Market growth rate	0.5%
Peak penetration	25%	Price per patient per year	\$24,000
Duration of peak penetration in years	1	Treatment price growth	0%
Retention rate in decline years	85%	Royalty rate	0%
Stage of development	Phase I	Probability of commercialization	25%

ThermoDox: RCW Breast Cancer - Foreign			
Year penetration starts	2013	Incidence	64,645
Starting penetration rate	2%	Percent addressable	80%
Years between penetration start and peak	4	Market growth rate	2%
Peak penetration	20%	Price per patient per year	\$18,000
Duration of peak penetration in years	1	Treatment price growth	0%
Retention rate in decline years	85%	Royalty rate	18%
Stage of development	Phase I	Probability of commercialization	25%

Assumptions related to RCW Breast Cancer

- Recurrent chest wall breast cancer strikes an estimated 13,000 patients in the United States in 2010, 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.¹⁷ In 2009, 194,280 new patients were 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.^{18,19,20}
- We expect the number of new diagnoses will increase at an annual rate of 0.5%-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 4% in the United States, limited partly by the availability of clinical microwave instruments, and a final penetration rate of 25%, based on an assumption that the technology gains wider acceptance over time. Penetration of foreign markets begins at a lower level (2%) and rises to 20%, reflecting the multiple regulatory and reimbursement hurdles that must be cleared and the availability of the appropriate energy sources.
- The probability of commercialization is 25%, reflecting the possibility that Celsion may decide to pursue a different indication than RCW breast cancer once the initial phase of the current clinical trial is completed.
- We've assumed that the price to treat one cycle is \$6,000 and that the average patient receives four 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.

¹⁷ 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.

¹⁸ 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.

¹⁹ Zaloznik, AJ. Breast cancer stage at diagnosis: Caucasians versus Afro-Americans. *Breast Cancer Res Treat* (1995); 34: 195.

²⁰ Zaloznik, AJ. Breast cancer stage at diagnosis: Caucasians versus Hispanics. *Breast Cancer Res Treat* (1997); 42: 121.

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

	2009(A)	2010	2011	2012	2013	2014
Revenue						
Sales	\$ -	\$ -	\$ -	\$ 21,463	\$ 47,115	\$ 76,375
Royalties & Licensing fees		-	1,000	20,031	51,642	88,858
Total revenue	\$ -	\$ -	\$ 1,000	\$ 41,493	\$ 98,757	\$ 165,233
COGS	-	-	-	2,146	3,693	5,270
Gross profit	\$ -	\$ -	\$ 1,000	\$ 39,347	\$ 95,064	\$ 159,963
Operating expenses						
R&D	\$ 13,681	\$ 8,500	\$ 8,000	\$ 9,000	\$ 16,789	\$ 28,090
Selling & marketing			3,000	15,000	16,789	28,090
General & administrative	3,327	3,500	4,000	7,000	11,000	16,523
Total expense	17,008	12,000	15,000	31,000	44,577	72,703
Operating profit	\$ (17,008)	\$ (12,000)	\$ (14,000)	\$ 8,347	\$ 50,486	\$ 87,260
Non-operating income/expense						
Other income/expense	1009					
Total non-operating	1,009	-	-	-	-	-
Pretax profit	\$ (15,999)	\$ (12,000)	\$ (14,000)	\$ 8,347	\$ 50,486	\$ 87,260
Income tax/(benefit)	(806)			1,002	19,185	33,159
Net income	\$ (15,193)	\$ (12,000)	\$ (14,000)	\$ 7,346	\$ 31,302	\$ 54,101
Earnings (loss) per share	\$ (1.43)	\$ (0.86)	\$ (0.93)	\$ 0.41	\$ 1.74	\$ 2.96
Shares outstanding †	10655	14000	15000	18000	18000	18250

† Shares outstanding are average basic shares in 2009 through 2011 and diluted shares thereafter. **Note: Results for 2009 are actual.**

Assumptions related to the Income Statement

- Filing for marketing approval with the primary regulatory authorities in Asia and Europe result in \$5 million of milestones each. For modeling purposes, we assume each milestone is recognized over a five-year period.
- The gross profit margin on ThermoDox sales is 90%, as Celsion relies on contract manufacturers to produce the drug. The company incurs no costs on royalty revenue.
- R&D expenses decrease in 2010 as the primary liver cancer trial in Japan advances, with the financial backing of Yakult. By 2013, investments in the R&D pipeline amount to 17% of total revenues, reflecting the opportunities addressable with the targeted, heat-sensitive liposomes.
- The Company begins to incur marketing costs in 2011 in preparation for the launch of ThermoDox the following year. In 2012, direct marketing expenses in the United States begin to rise markedly, reaching 17% of total revenues in 2013. This is consistent with other specialty drug companies.
- General & administrative costs increase moderately in 2010 as Celsion expands its infrastructure. Expenses rise more significantly in 2011 in preparation for ThermoDox's launch, payment of royalties (5% of income) to Duke University, and a general build-out of the corporate infrastructure. By 2013, 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 2012 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 2015. As of December 31, 2008, Celsion had \$49.2 million of operating loss carryforwards.

- Shares outstanding rise via external financing and the exercise of stock option grants.

BALANCE SHEET (All data is in thousands.)

Fiscal year ends on December 31st.

ASSETS	12/31/2009	12/31/2008
Current Assets		
Cash & equivalents	12,619	7,517
Accounts Receivable †	-	15,000
Other	1,501	306
Total Current Assets	\$ 14,120	\$ 22,823
Property & equipment	\$ 537	\$ 223
Intangible assets	-	-
Other	148	642
Total Assets	\$ 14,805	\$ 23,688
LIABILITIES		
Current Liabilities		
Accounts payable	\$ 2,191	\$ 1,186
Debt due	108	235
Other	1,452	2,514
Total Current Liabilities	\$ 3,751	\$ 3,935
Long-term debt	\$ -	\$ -
Other **	1,019	27
Total Long-Term Liabilities	\$ 1,019	\$ 27
Shareholders Equity		
Common Stock, par value	\$ 129	\$ 108
Additional Paid-In Capital	95,035	89,181
Accumulated Deficit	(82,052)	(66,924)
Treasury Stock	(3,077)	(2,639)
Total Shareholders Equity	\$ 10,035	\$ 19,726
Total liabilities & equity	\$ 14,805	\$ 23,688

† Accounts receivable in 2008 represent the final payment due from Boston Scientific for an asset sold in 2006.

** Other long-term liabilities in 2009 are largely warrant related.

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

	2010	2011	2012	2013	2014
Revenue	\$ -	1000	41493	98757	165233
Operating income	-12000	-14000	8347	50486	87260
Net income	-12000	-14000	7346	31302	54101
Depreciation/amortization	170	170	170	170	180
Stock-based compensation	1,250	1250	1250	1250	1250
Tax loss carryforwards	-	0	1002	19185	33159
Capital expenditures	(125)	-125	-150	-150	-200
Asset acquisitions					
Other					
Total cash flow adjustments	(125)	(125)	852	19,035	32,959
Free cash flow	\$ (12,125)	\$ (14,125)	\$ 8,197	\$ 50,336	\$ 87,060
Risk-adjusted free cash flow	\$ (12,125)	\$ (14,125)	\$ 8,197	\$ 20,135	\$ 32,927

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%	\$191,936.33	\$ 147,591	\$ 182,157	\$ 236,476	\$339,527
10.0%	\$153,840.00	\$ 71,873	\$ 82,946	\$ 97,710	\$225,713	\$236,786	\$251,550
12.5%	\$124,223.96	\$ 39,091	\$ 43,629	\$ 49,235	\$163,315	\$167,853	\$173,459
15.0%	\$100,954.40	\$ 22,706	\$ 24,839	\$ 27,360	\$123,660	\$125,794	\$128,315
17.5%	\$82,488.93	\$ 13,793	\$ 14,888	\$ 16,147	\$96,282	\$97,377	\$98,635

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%	\$ (12,511)	\$352,038	\$386,605	\$440,923	\$ 19.56
10.0%	(12,511)	\$238,224	\$249,297	\$264,061	\$ 13.23	\$ 13.85	\$ 14.67
12.5%	(12,511)	\$175,826	\$180,364	\$185,970	\$ 9.77	\$ 10.02	\$ 10.33
15.0%	(12,511)	\$136,171	\$138,305	\$140,826	\$ 7.57	\$ 7.68	\$ 7.82
17.5%	(12,511)	\$108,793	\$109,888	\$111,146	\$ 6.04	\$ 6.10	\$ 6.17

Discount Rate	Terminal Value as % Enterprise Value			Implied EBITDA Multiple		
	2.0%	3.0%	4.0%	2.0%	3.0%	4.0%
7.5%	43.5%	48.7%	55.2%	11.39	14.06	18.25
10.0%	31.8%	35.0%	38.8%	7.83	9.04	10.65
12.5%	23.9%	26.0%	28.4%	5.97	6.66	7.52
15.0%	18.4%	19.7%	21.3%	4.82	5.27	5.81
17.5%	14.3%	15.3%	16.4%	4.04	4.36	4.73

Assumptions related to the Discounted Cash Flow Analysis:

- The DCF model projects cash flow through 2025, 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 2014, 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 any 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. **3/2/2010** – Updating Coverage: share price: \$3.14; BUY; 12-month price target: \$10.00.

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