

# Celsion Corporation Reports Third Quarter 2012 Financial Results and Business Update

# Company to Hold Conference Call on Monday, November 12, 2012 at 11:00 a.m. ET

LAWRENCEVILLE, NJ -- (Marketwire) -- 11/12/12 -- Celsion Corporation (NASDAQ: CLSN), a leading oncology drug development company, today announced financial results for the third quarter ended September 30, 2012 and provided a business update including development progress with ThermoDox®, Celsion's proprietary heat-activated liposomal encapsulation of doxorubicin for the treatment of hepatocellular carcinoma (HCC), commonly referred to as primary liver cancer. ThermoDox® is currently being evaluated under a Special Protocol Assessment with the U.S. Food and Drug Administration (FDA) in a global, multi-center, randomized, pivotal Phase III trial (the HEAT Study) in patients with non-resectable primary liver cancer. The HEAT Study has been designated as a Priority Trial for liver cancer by the National Institutes of Health, has received Fast Track Designation from the FDA and has received Orphan Drug Designation in both the U.S. and Europe. ThermoDox® is also being evaluated in two Phase II trials for patients with recurrent chest wall breast cancer and colorectal liver metastases.

"Celsion stands focused on ThermoDox®'s transformative potential for the largest unmet need remaining in oncology. With positive results from the HEAT Study, we are preparing to introduce the first and most important 1st line drug therapy ever for non-resectable HCC. If successful, we will create substantial value for all of our stakeholders, including the global oncology community, our investors and most importantly HCC patients and their families," said Michael H. Tardugno, Celsion's President and Chief Executive Officer. "Preparedness leading up to this event is paramount. We have worked to ensure that the HEAT Study is robust and well conducted. We have maintained constant communication with our study sites, our manufacturers and with regulators to ensure a clean, consistent and high quality data package for review in markets around the world. Further, we enter this period with a strong balance sheet, including financial resources that will take us well beyond data and into multiple indications where the promise of ThermoDox® will significantly improve treatment outcomes."

Mr. Tardugno added, "The momentum behind ThermoDox® and our technology platform is evident in the growing interest within industry and the medical and academic communities to explore their application in a broad range of cancers and indications. Following the outcome of the HEAT Study, we intend to accelerate our on-going development programs, an effect that will ultimately reveal the significant potential and elegance of our targeted tumor technology."

### Recent Business Developments

In August 2012, the Company and Royal Philips Electronics (Philips) announced FDA clearance to commence a Phase II Study of ThermoDox® and Philip's Sonalleve MR-Guided HIFU technology for the palliation of painful metastases to the bone caused by lung, prostate or breast cancers.

## In September 2012, the Company announced

- The independent Data Monitoring Committee (DMC) for the Company's HEAT Study completed a regularly scheduled review of all 701 patients enrolled in the trial and has unanimously recommended that the HEAT Study continue according to protocol to its final data readout.
- Ronnie T.P. Poon, MD, MS, PhD, FRCS (Edin), FACS, Professor of Surgery at the University of Hong Kong and Lead Asia Pacific Principal Investigator for Celsion's HEAT Study, discussed advancements in thermal-based treatments in cancer, including the use of ThermoDox® in combination with radiofrequency ablation, at the 2012 Annual Congress of the Cardiovascular and Interventional Radiological Society of Europe in Lisbon, Portugal. Professor Poon's presentation, "Combining Thermal Ablation with Thermosensitive Liposomes," emphasized the need to consolidate standards of care in non-resectable liver cancer to improve outcomes. The presentation can be viewed on Celsion's website at http://investor.celsion.com/events.cfm.
- The presentation of Phase I results from the Company's Phase I/II DIGNITY study of ThermoDox® in Breast Cancer Recurrences at the Chest Wall at the ESMO 2012 Congress, the annual conference for the European Society of Medical Oncology held in Vienna, Austria. The presentation, titled "Breast Cancer Recurrences at the Chest Wall (BCRCW) When Standard Treatments (Tx) Have Failed: Lyso-Thermosensitive Liposomal Doxorubicin (LTLD) + Mild

Local Hyperthermia (MLH)," was delivered by Professor Hope S. Rugo, MD, from the UCSF School of Medicine, and provided a clinical update of the Phase I/II DIGNITY trial studying ThermoDox® for breast cancer. A copy of the poster presentation is available at <a href="https://www.celsion.com/docs/pipeline">www.celsion.com/docs/pipeline</a> presentations.

In November 2012, the Company announced that a minimum of 380 events of progression have been realized in the HEAT Study. According to protocol, 380 events of progression, subject to confirmation by the Study's independent Data Monitoring Committee (DMC), trigger the data collection process, unblinding and final analysis of the results by the DMC. Progression Free Survival (PFS) is the HEAT Study's primary end point which has been granted Special Protocol Assessment by the FDA. Following DMC review, the Company plans to disclose top line results, an announcement that is expected to occur in January 2013.

#### Financial Results

For the quarter ended September 30, 2012, Celsion reported a net loss of \$6.0 million, or \$0.18 per share, compared to a net loss of \$6.4 million, or \$0.25 per share, in the same period of 2011. For the nine months ended September 30, 2012, Celsion reported a net loss of \$18.3 million, or \$0.55 per share, compared to a net loss of \$17.1 million, or \$0.72 per share, in the same period of 2011. For the first nine months of 2012, net cash used in operations was \$16.2 million compared to \$18.3 million in the same period of 2011. The Company reported \$22.7 million in cash and investments (including related accrued interest on these investments) as of September 30, 2012. During the third quarter, the Company received gross proceeds of approximately \$4.0 million from the exercise of warrants and options.

In the third quarter of 2012, the Company recorded an \$881,000 non-cash charge related to the change in the common stock warrant liability compared to a \$375,000 non-cash benefit in the same period of last year. In the first nine months of 2012, Celsion recorded a \$1.3 million non-cash charge related to the change in the common stock warrant liability compared to a non-cash charge of \$42,000 in the same period last year. In the first nine months of 2011, the Company recognized \$2 million in licensing revenue as a result of its Development, Product Supply and Commercialization Agreement for ThermoDox® with Yakult Honsha Co.

Research and development costs decreased by approximately \$1.9 million to \$3.5 million in the third quarter of 2012 compared to \$5.4 million in the same period of 2011. Research and development costs decreased by approximately \$2.4 million to \$12.3 million in the first nine months of 2012 compared to \$14.7 million in the same period of 2011. The decreased costs in each of these periods were primarily due to lower investigator grants and related monitoring activities associated with the HEAT Study. General and administrative expenses remained relatively unchanged at \$1.4 million in the third quarter of 2012 compared to the same period in 2011. General and administrative expenses increased by approximately \$0.7 million to \$4.6 million in the first nine months of 2012, from \$3.9 million for the same period in 2011. This increase is largely the result of an increase in professional fees and personnel costs to support the Company's growth.

# Quarterly Conference Call

The Company is hosting a conference call to provide a business update and discuss the third quarter 2012 results at 11:00 a.m. Eastern Time Monday, November 12, 2012. To participate in the call, interested parties may dial 1-888-364-3108 (Toll-Free/North America) or 1-719-457-2628 (International/Toll) and ask for the Celsion Corporation Third Quarter 2012 Earnings Conference Call approximately ten minutes before the call is scheduled to begin. The call will also be broadcast live on the internet at <a href="http://www.celsion.com">http://www.celsion.com</a>.

The call will be archived for replay on November 12, 2012 at 2:00 p.m. ET and will remain available until November 26, 2012. The replay can be accessed at 1-877-870-5176 (Toll-Free/North America) or 1-858-384-5517 (International/Toll) using Conference ID: 8948347. An audio replay of the call will also be available on the Company's website, <a href="http://www.celsion.com">http://www.celsion.com</a>, for 30 days after 2:00 p.m. ET Monday, November 12, 2012.

### About ThermoDox® and the Phase III HEAT Study

ThermoDox® is a proprietary heat-activated liposomal encapsulation of doxorubicin, an approved and frequently used oncology drug for the treatment of a wide range of cancers. In the HEAT Study, ThermoDox® is administered intravenously in combination with Radio Frequency Ablation (RFA). Localized mild hyperthermia (39.5 - 42 degrees Celsius) created by the RFA releases the entrapped doxorubicin from the liposome. This delivery technology enables high concentrations of doxorubicin to be deposited preferentially in a targeted tumor.

For primary liver cancer, ThermoDox® is being evaluated in a global, multi-center, randomized, pivotal Phase III HEAT Study at 79 clinical sites under an FDA Special Protocol Assessment. The study is designed to evaluate the efficacy of ThermoDox® in combination with RFA when compared to patients who receive RFA alone as the control. The primary endpoint for the study is progression-free survival with a secondary confirmatory endpoint of overall survival.

Additional information on the Company's ThermoDox® clinical studies may be found at www.clinicaltrials.gov.

### About Celsion Corporation

Celsion is a leading oncology company dedicated to the development and commercialization of innovative cancer drugs including tumor-targeting treatments using focused heat energy in combination with heat-activated liposomal drug technology. Celsion has research, license, or commercialization agreements with leading institutions including the National Institutes of Health, Duke University Medical Center, University of Hong Kong, the University of Pisa, the UCLA Department of Medicine, the Kyungpook National University Hospital and the Beijing Cancer Hospital.

For more information on Celsion, visit our website: <a href="http://www.celsion.com">http://www.celsion.com</a>.

Celsion wishes to inform readers that forward-looking statements in this release are made pursuant to the "safe harbor" provisions of the Private Securities Litigation Reform Act of 1995. Readers are cautioned that such forward-looking statements involve risks and uncertainties including, without limitation, unforeseen changes in the course of research and development activities and in clinical trials; FDA and regulatory risks; the need to raise funds for planned drug development; the Company's history of losses and its expectation of continuing to incur such losses; possible acquisitions of other technologies, assets or businesses; possible actions by customers, suppliers, competitors, regulatory authorities; and other risks detailed from time to time in the Company's periodic reports filed with the Securities and Exchange Commission.

Celsion Corporation

Condensed Statements of Operations

(in thousands except per share amounts)

(unaudited)

|                            | Three Mon | ths Ended | Nine Months | Ended  |
|----------------------------|-----------|-----------|-------------|--------|
|                            | Septem    | ber 30,   | September   | 30,    |
|                            | 2012      | 2011      | 2012        | 2011   |
| Licensing revenue          | \$ -      | \$ -      | \$ - \$     | 2,000  |
| Operating expenses:        |           |           |             |        |
| Research and development   | 3,540     | 5,414     | 12,345      | 14,727 |
| General and administrative | 1,420     | 1,409     | 4,586       | 3,906  |
|                            |           |           |             |        |
| Total operating expenses   | 4,960     | 6,823     | 16,931      | 18,633 |

| Loss from operations            |     | (4,960) |    | (6,823) |    | (16,931) |    | (16,633) |
|---------------------------------|-----|---------|----|---------|----|----------|----|----------|
| Other (expense) income:         |     |         |    |         |    |          |    |          |
| (Loss) gain from valuation of   |     |         |    |         |    |          |    |          |
| common stock warrant            |     |         |    |         |    |          |    |          |
| liability                       |     | (881)   |    | 375     |    | (1,251)  |    | (42)     |
| Other (expense)income, net      |     | (177)   |    | 55      |    | (127)    |    | (426)    |
|                                 |     |         |    |         |    |          |    |          |
| Total other (expense)           |     |         |    |         |    |          |    |          |
| income, net                     |     | (1,058) |    | 430     |    | (1,378)  |    | (468)    |
|                                 |     |         |    |         |    |          |    |          |
| Net Loss                        | \$  | (6,018) | \$ | (6,393) | \$ | (18,309) | \$ | (17,101) |
|                                 | === | =====   | == | =====   | == | ======   | == | =====    |
| Net loss per common share -     |     |         |    |         |    |          |    |          |
| basic and diluted               | \$  | (0.18)  | \$ | (0.25)  | \$ | (0.55)   | \$ | (0.93)   |
|                                 | === | =====   | == | =====   | == | =====    | == | =====    |
| Weighted average shares         |     |         |    |         |    |          |    |          |
| outstanding - basic and diluted |     | 33,642  |    | 25,150  |    | 33,418   |    | 18,360   |

Celsion Corporation

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Selected Balance Sheet Information

(in thousands)

| September 30 |
|--------------|
|--------------|

|  | 2012        | December 31, |  |  |
|--|-------------|--------------|--|--|
|  | (unaudited) | 2011         |  |  |
|  |             |              |  |  |
| ASSETS                                     |             |              |  |  |
| Current assets:                            |             |              |  |  |
| Cash and cash equivalents                  | \$ 8,318    | \$ 20,146    |  |  |
| Short-term investments                     | 14,229      | 10,157       |  |  |
| Accrued interest on short term investments | 134         | 244          |  |  |
| Other current assets                       | 1,085       | 961          |  |  |
|  |             |              |  |  |
| Total current assets                       | 23,766      | 31,508       |  |  |
|  |             |              |  |  |
|  |             |              |  |  |
| Property and equipment                     | 1,008       | 783          |  |  |
|  |             |              |  |  |
|  |             |              |  |  |
| Other assets:                              |             |              |  |  |
| Deposits, deferred fees and other assets   | 605         | 323          |  |  |
| Patent licensing fees, net                 | 30          | 35           |  |  |
|  |             |              |  |  |
| Total other assets                         | 635         | 358          |  |  |
|  |             |              |  |  |
|  |             |              |  |  |
| Total assets                               | \$ 25,409   | \$ 32,649    |  |  |
|  | ========    | =========    |  |  |

LIABILITIES AND STOCKHOLDERS' EQUITY

Current liabilities:

| Accounts payable and accrued liabilities | \$   | 5,661     | \$   | 6,042     |
|--|------|-----------|------|-----------|
| Notes payable - current portion          |      | 945       |      | 110       |
|  |      |           |      |           |
| Total current liabilities                |      | 6,606     |      | 6,152     |
|  |      |           |      |           |
| Common stock warrant liability           |      | 1,417     |      | 166       |
| Notes payable - non-current portion &    |      |           |      |           |
| other                                    |      | 4,362     |      | 137       |
|  |      |           |      |           |
| Total liabilities                        |      | 12,385    |      | 6,455     |
|  |      |           |      |           |
|  |      |           |      |           |
| Stockholders' equity:                    |      |           |      |           |
| Common stock                             |      | 354       |      | 339       |
| Additional paid-in capital               |      | 158,121   |      | 153,237   |
| Accumulated other comprehensive loss     |      | (131)     |      | (276)     |
| Accumulated deficit                      |      | (142,620) |      | (124,222) |
|  |      |           |      |           |
| Subtotal                                 |      | 15,724    |      | 29,078    |
| Treasury stock                           |      | (2,700)   |      | (2,884)   |
|  |      |           |      |           |
| Total stockholders' equity               |      | 13,024    |      | 26,194    |
|  |      |           |      |           |
|  |      |           |      |           |
| Total liabilities and stockholders'      |      |           |      |           |
| equity                                   | \$   | 25,409    | \$   | 32,649    |
|  | ==== | ======    | ==== |           |

Argot Partners

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Source: Celsion Corporation

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