Celsion Corporation Reports Second Quarter 2020 Financial Results and Provides Business Update

August 14, 2020

Initiates Promising Phase II Study of GEN-1 in Advanced Ovarian Cancer

Will Continue Following Patients in Phase III OPTIMA Study for Overall Survival; Data Maturity at Issue

Conference Call Begins Today at 11:00 a.m. Eastern Time

LAWRENCEVILLE, N.J, Aug. 14, 2020 (GLOBE NEWSWIRE) -- Celsion Corporation (NASDAQ: CLSN), an oncology drug development company, today announced financial results for the three and six months ended June 30, 2020, and provided an update on clinical development programs with GEN-1, its DNA-mediated IL-12 immunotherapy currently in Phase II development for the treatment of advanced stage ovarian cancer, and ThermoDox®, its proprietary heat-activated liposomal encapsulation of doxorubicin currently in Phase III development for the treatment of hepatocellular carcinoma, or primary liver cancer.

"GEN-1, our oncology-focused immunotherapy, continues to show encouraging results at the 100 mg/m² dose cohort in the OVATION 2 Study, which is consistent with the results reported from our earlier Phase Ib trial (the OVATION 1 Study) in advanced-stage ovarian cancer. In June 2020, the Data Safety Monitoring Board (DSMB) for the OVATION 2 Study recommended that the Phase II portion of the OVATION Study proceed with the dose of 100 mg/m^2," reported Michael H. Tardugno, Celsion's chairman, president and chief executive officer. "These findings were reinforced by strong progression-free survival (PFS) when comparing study patients to a statistically validated synthetic control arm (SCA) of matched patients from prior studies. In July 2020, we announced the randomization of the first two patients in the Phase II OVATION 2 Study. This milestone was achieved approximately five months ahead of our previously announced schedule. We have a very aggressive recruitment program and anticipate completing enrollment of 105 patients in the second quarter of 2021. Importantly, as an open-label study, clinical updates will be provided throughout the course of treatment including response rates and surgical resection scores," Mr. Tardugno added.

Continuing his comments, Mr. Tardugno noted, "In early July, Celsion received a wholly unexpected recommendation from the independent Data Monitoring Committee (DMC) to consider stopping the global Phase III OPTIMA Study. This recommendation was made following the DMC's second pre-planned interim safety and efficacy analysis of the OPTIMA Study on July 9, 2020. The DMC's analysis found that the pre-specified boundary for stopping the trial for futility of 0.900 was crossed with an actual value of 0.903. However, the p-value of 0.524 for this analysis provides a high level of uncertainty as to the actual hazard ratio value, therefore, the DMC left the final decision of whether to stop the OPTIMA Study to the Company.

Mr. Tardugno further stated, "This development had never been anticipated by the Company or our advisors, nor would it have been forecasted by the first pre-planned efficacy analysis. Further, blinded data available to the Company appeared to be tracking well against the sub-group analysis of the Company's earlier HEAT Study, upon which the OPTIMA Study is based."

In early August, after conducting additional analyses of the unblinded data from the second pre-planned interim analysis, the Company announced plans to continue following patients for overall survival (OS), noting that the unexpected and marginally crossed futility boundary, suggested by the Kaplan-Meier analysis at the second interim analysis, may be associated with a data maturity issue. Additionally, Celsion reported that it is sending all clinical trial data, including Chemistry, Manufacturing and Controls (CMC) data, to the National Institutes of Health (NIH) for independent analysis, including computed tomography (CT) scans for NIH's evaluation of PFS. Depending on the trends noted during the OS follow-up period, Celsion may choose to discontinue the Study at any time. The Company also notes that the vast majority of expenses related to the OPTIMA Study already have been incurred.

Recent Developments

GEN-1 Immunotherapy

Initiation of Phase II OVATION 2 Study in Advanced Ovarian Cancer. In July 2020, the Company announced the randomization of the first two patients in the Phase II portion of the OVATION 2 Study with GEN-1 in advanced ovarian cancer. The Company anticipates completing enrollment of up to 118 patients in the second quarter of 2021. Because this is an open-label study, clinical updates will be provided throughout the course of treatment including response rates and surgical resection scores.

The OVATION 2 Study combines GEN-1 with standard-of-care neoadjuvant chemotherapy (NACT) in patients newly diagnosed with Stage III/IV ovarian cancer. NACT is designed to shrink the cancer as much as possible for optimal surgical removal after three cycles of chemotherapy. Following NACT, patients undergo interval debulking surgery, followed by three adjuvant cycles of chemotherapy and up to nine additional weekly GEN-1 treatments, the goal of which is to delay progression and improve OS. The OVATION 2 Study is an open-label, 1-to-1 randomized trial, 80% powered to show the equivalent of a 33% improvement in PFS (HR=0.75), the primary endpoint, when comparing the treatment arm (standard of care + GEN-1) with the control arm (standard of care alone).

DSMB Recommends GEN-1 to Proceed to Phase II of the OVATION 2 Study in Advanced Ovarian Cancer. In May 2020, the Company announced the final recommendations of the DSMB following completion of the Phase I dose-finding and tolerance portion of the OVATION 2 Study with GEN-1 in advanced (Stage III/IV) ovarian cancer. Based on favorable safety data from 15 randomized patients, the DSMB recommended that the Phase II portion of the OVATION Study proceed with the dose of 100 mg/m^2. The DSMB also determined that safety is satisfactory with an acceptable

risk/benefit, and that patients tolerate up to 17 doses of GEN-1 during a course of treatment that lasts up to six months. No dose limiting toxicities were reported.

In March 2020, the Company announced the following clinical development achievements for GEN-1:

- Highly encouraging initial clinical data from the first 15 patients enrolled in the ongoing Phase I/II OVATION 2 Study for patients newly diagnosed with Stage III and IV ovarian cancer. GEN-1 plus standard NACT produced positive dose-dependent efficacy results, with no dose-limiting toxicities, which correlates well with successful surgical outcomes as summarized below:
  - Of the 15 patients treated in the Phase I portion of the OVATION 2 Study, nine were treated with GEN-1 at a dose of 100 mg/m² plus NACT and six were treated with NACT only. All 15 had successful resections of their tumors, with seven out of nine patients (78%) in the GEN-1 treatment arm having an R0 resection, which indicates a microscopically margin-negative resection in which no gross or microscopic tumor remains in the tumor bed. Only three out of six patients (50%) in the NACT only treatment arm had an R0 resection
  - When combining these results with the surgical resection rates observed in the Company's prior Phase Ib dose-escalation trial (the OVATION 1 Study), a population of patients with inclusion criteria identical to the OVATION 2 Study, the data reflect the strong dose-dependent efficacy of adding GEN-1 to the current standard of care NACT:

		% of Patients with R0 Resections	
0, 36, 47 mg/m² of GEN-1 plus NACT	n=12	42	%
61, 79, 100 mg/m² of GEN-1 plus NACT	n=17	82	%

- Medidata-matched patient data from a SCA compared with results from the Phase Ib dose-escalating OVATION 1 Study with GEN-1 in Stage III/IV ovarian cancer patients showed positive results in PFS. The HR was 0.53 in the intent-to-treat group, showing strong signals of efficacy. Medidata is a globally recognized leader in clinical data management. GEN-1's strong and encouraging treatment effect, evidenced by the SCA, suggests a potentially remarkable improvement in PFS, an FDA-recognized surrogate for OS, and appears to confirm the science behind IL-12's ability to recruit the innate and adaptive elements of the immune system to fight malignancies. The strong PFS trend is supported by previously published translational data that clearly demonstrate the pro-immune changes in the tumor microenvironment associated with loco-regional GEN-1 therapy. PFS data generated from this analysis comparing GEN-1 with SCA showed the following:

GEN-1 Population	**PFS Hazard Ratio (Confidence Interval)**
Intent-to-treat, n=15	0.53 (95% CI 0.16, 1.73); log-rank p = 0.29
Per-protocol, n=14	0.33 (95% CI 0.08, 1.37); log-rank p = 0.11

- The European Medicines Agency (EMA) Committee for Orphan Medicinal Products recommended that GEN-1 be designated as an orphan medicinal product for the treatment of ovarian cancer. As established by the EMA, this designation provides for scientific advice and certain regulatory assistance during the product development phase, direct access to centralized marketing authorization and certain financial incentives for companies developing new therapies intended for the treatment of a life-threatening or chronically debilitating condition that affects no more than five in 10,000 people in the European Union. GEN-1 previously received orphan drug designation from the FDA.

ThermoDox®

Patients in Phase III OPTIMA Study Will Continue to be Followed for Overall Survival. In August 2020, the Company provided an update on its ongoing review of unblinded data from the second pre-planned interim analysis of the global Phase III OPTIMA Study. The Company announced it will continue following patients for OS, noting that the unexpected and marginally crossed futility boundary suggested by the Kaplan-Meier analysis at the second interim analysis on July 9, 2020 may be associated with a data maturity issue. The Company further notes that 26 consecutive patient deaths represented exclusively in the second analysis behave far differently from the balance of the patients who have died as of that date. Removing the 26 consecutive patient deaths, which occurred between September 2019 and March 2020, from the pre-planned interim analysis suggests that the OPTIMA Study OS pattern is similar to the prospective HEAT Study subgroup upon which the OPTIMA Study is based, at the approximate comparable point in time. In addition, subsequent to the second interim analysis there were eight patient deaths in a 3:1 ratio of control arm to treatment arm patients, which further supports a concern for data maturity.

It was further noted that OPTIMA Study sites in China and Vietnam, which enrolled over 37% of the subjects, joined the Study approximately 12 and 18 months, respectively, after the trial was initiated. The Kaplan-Meier curves for both geographies demonstrate a potential data maturity issue when compared with the behavior of the HEAT Study subgroup and other OPTIMA Study testing site regions. The China sites, in particular, show a negative Kaplan-Meier curve, yet with a 56% improvement in the treatment arm in the median time to death. The Vietnam sites show a marginal Kaplan-Meier benefit, yet with a 45% improvement in the treatment arm in the median time to death. The Company believes that this dichotomy must be reconciled, most probably with longer follow up, before it can determine the Study's direction.

Recommendation from the Independent DMC to Consider Stopping the Phase III OPTIMA Study of ThermoDox® in Primary Liver Cancer. In July 2020, the Company announced that it received a recommendation from the independent DMC to consider stopping the global Phase III OPTIMA Study. The recommendation was made following the second pre-planned interim safety and efficacy analysis by the DMC on July 9, 2020. The DMC analysis found that the pre-specified boundary for stopping the trial for futility of 0.900 was crossed with an actual value of 0.903. However, the p-value of 0.524 for this analysis provides uncertainty; subsequently, the DMC left the final decision of whether or not to stop the OPTIMA Study to Celsion. There were no safety concerns noted during the interim analysis.

The statistical plan for the OPTIMA Study included two interim efficacy analyses by the DMC. The first interim analysis was announced in November 2019 following data lock in August 2019 after the prescribed minimum number of 128 patient events (deaths) was reached, and the second interim analysis was conducted on July 9, 2020 following data lock in April 2020 after the prescribed minimum number of 158 events was reached.

Corporate Developments

Strengthened Balance Sheet Through a $10 Million Underwritten Offering of Common Stock. In June 2020, the Company entered into an underwriting agreement relating to the sale of 2,666,667 shares of its common stock at an offering price of $3.75 per share. The net proceeds from the offering were $9.3 million, after deducting underwriting discounts and commissions, but before expenses payable by the Company. The shares of common stock were sold to both existing and new institutional investors of the Company. Oppenheimer & Co. Inc. acted as the sole underwriter for the offering.

Received $1.8 Million in Non-Dilutive Funding from the Sale of New Jersey State Net Operating Losses. In April 2020, the Company announced it received $1.8 million of net cash proceeds from the sale of approximately $1.9 million of its unused New Jersey net operating losses (NOLs). The NOL sales cover the tax years 2017 and 2018 and are administered through the New Jersey Economic Development Authority's (NJEDA) Technology Business Tax Certificate Transfer (NOL) Program. An additional sale of $2.0 million of unused New Jersey NOLs anticipated in the second half of 2020 will further increase Celsion's cash reserves on a non-dilutive basis.

Second Quarter Financial Results

For the quarter ended June 30, 2020, Celsion reported a net loss of $5.3 million ($0.18 per share), compared with $5.9 million ($0.29 per share) in the same period of 2019. Operating expenses were $4.9 million in the second quarter of 2020, which represented a $0.8 million (14%) decrease from $5.7 million in the same period of 2019.

The Company ended the second quarter of 2020 with $25.5 million in cash, investment securities and accrued interest receivable. With $25.5 million in cash as of June 30, 2020 coupled with future sales of the Company's New Jersey NOL's, the Company believes it has sufficient capital resources to fund its operations into the fourth quarter of 2021.

Research and development expenses decreased $0.6 million to $3.0 million in the second quarter of 2020, compared with $3.6 million in the second quarter of 2019. Clinical development costs for the Phase III OPTIMA Study decreased $0.6 million to $0.6 million in the second quarter of 2020, compared with $1.2 million in the second quarter of 2019, due to the completion of enrollment in this 556-patient trial in August 2018. Costs associated with the OVATION 2 Study increased to $0.2 million in the second quarter of 2020 compared with $0.1 million in the same period of 2019. Other costs related to clinical supplies and regulatory support for the ThermoDox® and GEN-1 clinical development programs increased to $2.3 million in the current quarter from $2.2 million in the second quarter of 2019 largely driven by higher manufacturing costs for GEN-1 clinical supplies for the Phase II portion of the OVATION 2 Study.

General and administrative expenses were $1.9 million in the second quarter of 2020, compared with $2.1 million in the same period of 2019. The 11% decrease was primarily attributable to lower professional fees incurred during the second quarter of 2020.

In connection with the Company's venture debt facility with Horizon entered in late June 2018, the Company incurred interest expense of $0.3 million during the second quarter of 2020. This compares with interest expense of $0.4 million in the comparable prior-year period.

Six Month Financial Results

For the six months ended June 30, 2020, the Company reported a net loss of $10.4 million ($0.37 per share), compared with $8.3 million ($0.42 per share) in the same period of 2019. Operating expenses were $9.8 million during the first six months of 2020, which represented a $0.9 million (8%) decrease from $10.7 million in the same period of 2019.

Net cash used for operating activities was $7.9 million in the first six months of 2020, compared with $10.2 million in the same period in 2019. This was in line with the Company's projected cash utilization for 2020 of approximately $15 million, or an average of approximately $3.75 million per quarter. Cash provided by financing activities was $18.6 million during the first six months of 2020 resulting from equity offerings in March 2020 and June 2020, and proceeds from the exercise of stock options.

Research and development expenses decreased $0.3 million to $6.0 million in the first half of 2020 from $6.3 million in the first half of 2019. Clinical development costs for the Phase III OPTIMA Study decreased by $0.8 million to 1.3 million in the first half of 2020, compared with $2.1 million in the first half of 2019, due to the completion of enrollment in this 556-patient trial in August 2018. Costs associated with the OVATION 2 Study increased to $0.5 million in the first half of 2020, compared with $0.2 million in the comparable six-month period in 2019. Other costs related to clinical supplies and regulatory support for the ThermoDox® and GEN-1 clinical development programs increased by $0.4 million in the first half of 2020, compared with the same prior-year period due to higher manufacturing costs for GEN-1 clinical supplies for the Phase II portion of the OVATION 2 Study.

Other expenses during the first half of 2020 included a non-cash charge of $0.3 million for the change in valuation of the earn-out milestone liability for the GEN-1 ovarian product candidate, compared with a non-cash gain of $2.7 million, net of charge of $0.4 million for the 200,000 warrant issuance related to an amendment for the potential milestone payments for the GEN-1 ovarian product candidate during the comparable prior-year period. The Company realized $0.1 million of interest income during the first half of 2020 and $0.3 million in the comparable prior-year period. In connection with the Company's venture debt facility with Horizon entered in late June 2018, the Company incurred interest expense of $0.7 million during the first six months of 2020 and 2019.

Second Quarter Conference Call

The Company will host a conference call to provide a business update and discuss its second quarter 2020 financial results at 11:00 a.m. EDT today. To participate in the call, interested parties may dial 1-800-353-6461 (Toll-Free/North America) or 1-334-323-0501 (International/Toll) 10 minutes before the call is scheduled to begin, and ask for the Celsion Corporation Second Quarter 2020 Earnings Call (Conference Code: 4777957). The call will also be broadcast live on the internet at www.celsion.com. The call will be archived for replay through August 28, 2020. The replay can be accessed at 1-719-457-0820 or 1-888-203-1112 using Conference ID: 4777957. An audio replay of the call will also be available on the Company's website, www.celsion.com, for 90 days after 2:00 p.m. EDT Friday, August 14, 2020.

About Celsion Corporation

Celsion is a fully integrated oncology company focused on developing a portfolio of innovative cancer treatments, including immunotherapies, DNA-based therapies and directed chemotherapies. The Company's product pipeline includes GEN-1, a DNA-based immunotherapy for the localized treatment of ovarian cancer and ThermoDox®, a proprietary heat-activated liposomal encapsulation of doxorubicin, currently in Phase III development for the treatment of primary liver cancer and in development for other cancer indications. Celsion has two feasibility stage platform technologies for the development of novel nucleic acid-based immunotherapies and other anti-cancer DNA or RNA therapies. Both are novel synthetic, non-viral vectors with demonstrated capability in nucleic acid cellular transfection. For more information on Celsion, visit: http://www.celsion.com. (CLSN-FIN).

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; the uncertainties of and difficulties in analyzing interim clinical data; the significant expense, time, and risk of failure of conducting clinical trials; the need for Celsion to evaluate its future development plans; possible acquisitions or licenses of other technologies, assets or businesses; possible actions by customers, suppliers, competitors, regulatory authorities; and other risks detailed from time to time in Celsion's periodic reports and prospectuses filed with the Securities and Exchange Commission. Celsion assumes no obligation to update or supplement forward-looking statements that become untrue because of subsequent events, new information or otherwise.

Celsion Investor Contact
Jeffrey W. Church
609-482-2455
jchurch@celsion.com

LHA Investor Relations
Kim Sutton Golodetz
212-838-3777
kgolodetz@lhai.com

[Tables to Follow]

Celsion Corporation
Condensed Statements of Operations
(in thousands except per share amounts)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2020	**2019**	**2020**	**2019**
Licensing revenue	$ 125	$ 125	$ 250	$ 250
Operating expenses:				
Research and development	2,991	3,558	6,043	6,326
General and administrative	1,901	2,137	3,740	4,354
Total operating expenses	4,892	5,695	9,783	10,680
Loss from operations	(4,767)	(5,570)	(9,533)	(10,430)
Other income (expense):				
(Loss) gain from change in valuation of earn-out milestone liability	(256)	(127)	(298)	2,600
Fair value of warrants issued in connection with amendment to modify GEN-1 earn-out milestone payment	-	-	-	(400)
Interest expense, investment income and other income (expense), net	(320)	(208)	(569)	(442)
Total other income (expense), net	(576)	(335)	(867)	2,158
Net loss	$ (5,343)	$ (5,904)	$ (10,400)	$ (8,272)
Net loss per common share Basic and diluted	$ (0.18)	$ (0.29)	$ (0.37)	$ (0.42)
Weighted average shares outstanding Basic and diluted	29,887	20,606	27,831	19,713

Celsion Corporation
Selected Balance Sheet Information
(in thousands)

	June 30, 2020 (Unaudited)	**December 31, 2019**

ASSETS		
Current assets		
Cash and cash equivalents	$ 22,654	$ 6,875
Investment securities and interest receivable on investment securities	2,799	8,007
Advances, deposits on clinical programs and other current assets	1,343	1,353
Total current assets	**26,796**	**16,235**
Property and equipment	**339**	**405**
Other assets		
Deferred tax asset	-–	1,820
In-process research and development	15,736	15,736
Goodwill	1,976	1,976
Operating lease right-of-use assets, net	1,245	1,432
Other intangible assets, deposits and other assets	631	674
Total other assets	**19,588**	**21,638**
Total assets	**$ 46,723**	**$ 38,278**
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable and accrued liabilities	$ 3,910	$ 5,166
Notes payable – current portion	4,386	1,840
Operating lease liability – current portion	410	388
Deferred revenue - current portion	500	500
Total current liabilities	**9,206**	**7,894**
Earn-out milestone liability	6,015	5,718
Notes payable	5,611	7,963
Operating lease liability	933	1,144
Deferred revenue and other liabilities	750	1,000
Total liabilities	**22,515**	**23,719**
Stockholders' equity		
Common stock	332	232
Additional paid-in capital	324,870	304,886
Accumulated other comprehensive gain (loss)	8	43
Accumulated deficit	(300,917)	(290,517)
	24,293	14,644
Less: Treasury stock	(85)	(85)
Total stockholders' equity	**24,208**	**14,559**
Total liabilities and stockholders' equity	**$ 46,723**	**$ 38,278**

# # #

Source: Celsion CORP