

Celsion CORP

Form 424B5

October 30, 2017

**Filed Pursuant to Rule 424(b)(5)**

**Registration Statement No. 333-206789**

**PROSPECTUS SUPPLEMENT**

**(To Prospectus dated September 25, 2015)**

**2,640,000 Shares of Common Stock**

**Warrants to Purchase up to 1,320,000 Shares of Common Stock**

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Pursuant to this prospectus supplement and the accompanying prospectus (the “accompanying prospectus”), we are offering 2,640,000 shares of our common stock, par value \$0.01 per share, and warrants to purchase up to 1,320,000 shares of our common stock. Each share of our common stock is being sold together with 0.5 warrants (the “Warrants”) at a combined offering price of \$2.50 per unit, with each whole Warrant being exercisable to purchase one share of our common stock. The Warrants will have an exercise price of \$3.00 per share and will be exercisable for a five-year period commencing on April 30, 2018.

Our common stock is listed on The NASDAQ Capital Market under the symbol “CLSN.” On October 26, 2017, the last reported sale price of our common stock on The NASDAQ Capital Market was \$2.86 per share.

As of the date of this prospectus supplement, an aggregate of approximately \$61.6 million of shares of common stock and other securities remain unsold under the registration statement on Form S-3 (File No. 333-206789) filed with the Securities and Exchange Commission on September 4, 2015 and declared effective on September 25, 2015.

Pursuant to the Controlled Equity Offering Sales Agreement dated as of February 1, 2013 (the “Sales Agreement”), by and between Cantor Fitzgerald & Co. and us, we may offer and sell, from time to time through “at-the-market” offerings, up to an aggregate of \$25.0 million of shares of our common stock. We filed with the Securities and Exchange Commission a prospectus supplement dated October 2, 2015 to the accompanying prospectus, covering the sales of shares of our common stock under the Sales Agreement. We have sold shares of our common stock under the Sales Agreement generating total gross proceeds of approximately \$7.6 million and have up to approximately \$17.4 million available for future sale under the Sales Agreement. In connection with this offering, we have agreed not to sell any additional shares under the Sales Agreement for a period of two months after the closing date of this offering.

**Investing in our securities involves a high degree of risk. Before making an investment decision, please read “Risk Factors” beginning on page S-13 of this prospectus supplement, page 9 of the accompanying prospectus and in the documents incorporated by reference into this prospectus supplement and the accompanying prospectus.**

**Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus supplement or the accompanying prospectus is truthful or complete. Any representation to the contrary is a criminal offense.**

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	<b>Per Share and Related</b>	
	<b>Warrants</b>	<b>Total</b>
Public offering price	\$ 2.500	\$6,600,000
Underwriting discount <sup>(1)</sup>	\$ 0.175	\$462,000
Proceeds, before expenses, to us	\$ 2.325	\$6,138,000

We have also agreed to issue to Oppenheimer & Co. Inc. warrants to purchase up to 66,000 shares of our common <sup>(1)</sup>stock, which equates to 2.5% of the number of shares of common stock to be issued and sold in this offering. In addition, we have agreed to reimburse the underwriters for certain expenses. See “*Underwriting.*”

Delivery of the shares of common stock and related Warrants will take place against payment on or about October 31, 2017 subject to the satisfaction of certain conditions.

**Oppenheimer & Co.**

The date of this prospectus supplement is October 27, 2017

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**TABLE OF CONTENTS****Page****Prospectus Supplement**

About This Prospectus Supplement	S-1
Prospectus Supplement Summary	S-2
The Offering	S-11
Risk Factors	S-13
Special Note Regarding Forward-Looking Statements	S-18
Use of Proceeds	S-20
Dividend Policy	S-21
Dilution	S-22
Price Range of Our Common Stock	S-23
Description of the Securities We Are Offering	S-24
Underwriting	S-25
Legal Matters	S-31
Experts	S-31
Changes In Certifying Accountants	S-31
Where You Can Find More Information	S-32
Incorporation of Certain Documents by Reference	S-32

**Prospectus**

Prospectus	
About This Prospectus	1
Where You Can Find Additional Information	1
Information Incorporated by Reference	2
Forward-Looking Statements	3
Prospectus Summary	5
Risk Factors	9
Ratio of Earnings to Fixed Charges	10
Use of Proceeds	10
Dividend Policy	10
General Description of Securities	11
Description of Capital Stock	12
Description of Debt Securities	16
Description of Warrants, Other Rights and Units	22
Plan of Distribution	23
Legal Matters	25
Experts	25



## About This Prospectus Supplement

This prospectus supplement and the accompanying prospectus are part of a “shelf” registration statement on Form S-3 (File No. 333-206789) that we filed with the Securities and Exchange Commission on September 4, 2015 and declared effective on September 25, 2015.

This document is in two parts. The first part is this prospectus supplement, which describes the terms of this offering and also adds to and updates information contained in the accompanying prospectus and the documents incorporated by reference into this prospectus supplement and the accompanying prospectus. The second part is the accompanying prospectus, which gives more general information about the shares of our common stock and other securities we may offer from time to time under our shelf registration statement, some of which does not apply to the securities offered by this prospectus supplement. To the extent there is a conflict between the information contained in this prospectus supplement, on the one hand, and the information contained in the accompanying prospectus or any document incorporated by reference herein or therein, on the other hand, you should rely on the information in this prospectus supplement.

You should read this prospectus supplement, the accompanying prospectus, the documents incorporated by reference in this prospectus supplement and the accompanying prospectus and any free writing prospectus that we have authorized for use in connection with this offering before making an investment decision. You should also read and consider the information in the documents referred to in the sections of this prospectus supplement entitled “Where You Can Find More Information” and “Incorporation of Certain Documents by Reference.”

You should rely only on the information contained or incorporated by reference in this prospectus supplement, the accompanying prospectus and any free writing prospectus that we have authorized for use in connection with this offering. We have not authorized anyone to provide you with different information. If anyone provides you with different or inconsistent information, you should not rely on it.

We are not making an offer to sell the securities covered by this prospectus supplement in any jurisdiction where the offer or sale is not permitted.

The information appearing in this prospectus supplement, the accompanying prospectus, the documents incorporated by reference in this prospectus supplement and the accompanying prospectus and any free writing prospectus that we have authorized for use in connection with this offering is accurate only as of its respective date, regardless of the time of delivery of the respective document or of any sale of securities covered by this prospectus supplement. You should not assume that the information contained in or incorporated by reference in this prospectus supplement or the accompanying prospectus, or in any free writing prospectus that we have authorized for use in connection with this

offering, is accurate as of any date other than the respective dates thereof.

Unless the context indicates otherwise, as used in this prospectus, the terms “Celsion,” “the Company,” “we,” “us” and “our” refer to Celsion Corporation, a Delaware corporation, and its wholly-owned subsidiary CLSN Laboratories, Inc., also a Delaware corporation. The Celsion brand and product names, including but not limited to Celsion® and ThermoDox® contained in this prospectus are trademarks, registered trademarks or service marks of Celsion Corporation or its subsidiary in the United States and certain other countries. This document may also contain references to trademarks and service marks of other companies that are the property of their respective owners.

S-1

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## Prospectus Supplement Summary

*This summary highlights certain information about us, this offering and selected information contained elsewhere in or incorporated by reference into this prospectus supplement and the accompanying prospectus. This summary is not complete and does not contain all of the information that you should consider before deciding whether to invest in the securities covered by this prospectus supplement and the accompanying prospectus. For a more complete understanding of Celsion and this offering, we encourage you to read and consider carefully the more detailed information in this prospectus supplement and the accompanying prospectus, including the information incorporated by reference in this prospectus supplement and the accompanying prospectus and the information included in any free writing prospectus that we have authorized for use in connection with this offering, including the information set forth in the section titled “Risk Factors” in this prospectus supplement beginning on page S-13.*

## Overview

Celsion is a fully-integrated development stage oncology drug company focused on advancing a portfolio of innovative cancer treatments, including directed chemotherapies, DNA-mediated immunotherapy and RNA based therapies. Our lead product candidate is ThermoDox<sup>®</sup>, a proprietary heat-activated liposomal encapsulation of doxorubicin, currently in a Phase III clinical trial for the treatment of primary liver cancer (the “OPTIMA Study”), and a Phase II clinical trial for the treatment of recurrent chest wall breast cancer (the “DIGNITY Study”). Second in our pipeline is GEN-1, a DNA-mediated immunotherapy for the localized treatment of ovarian and brain cancers. We have two platform technologies providing the basis for the future development of a range of therapeutics for difficult-to-treat forms of cancer including: Lysolipid Thermally Sensitive Liposomes, a heat sensitive liposomal based dosage form that targets disease with known therapeutics in the presence of mild heat and TheraPlas, a novel nucleic acid-based treatment for local transfection of therapeutic plasmids. With these technologies we are working to develop and commercialize more efficient, effective and targeted oncology therapies that maximize efficacy while minimizing side-effects common to cancer treatments.

## ThermoDox<sup>®</sup>

ThermoDox<sup>®</sup> is being evaluated in a Phase III clinical trial for primary liver cancer, which we call the OPTIMA Study, which was initiated in 2014, and a Phase II clinical trial for recurrent chest wall breast cancer, which we call the DIGNITY Study. ThermoDox<sup>®</sup> is a liposomal encapsulation of doxorubicin, an approved and frequently used oncology drug for the treatment of a wide range of cancers. Localized heat at hyperthermia temperatures (greater than 40° Celsius) releases the encapsulated doxorubicin from the liposome enabling high concentrations of doxorubicin to be deposited preferentially in and around the targeted tumor.

**The OPTIMA Study.** The OPTIMA Study represents an evaluation of ThermoDox<sup>®</sup> in combination with a first line therapy, radiofrequency ablation (“RFA”), for newly diagnosed, intermediate stage HCC patients. HCC incidence globally is approximately 850,000 new cases per year and is the third largest cancer indication globally. Approximately 30% of newly diagnosed patients can be addressed with RFA alone.

On February 24, 2014, we announced that the United States Food and Drug Administration (the “FDA”), after its customary 30-day review period, provided clearance for the OPTIMA Study, which is a pivotal, double-blind, placebo-controlled Phase III trial of ThermoDox<sup>®</sup>, in combination with standardized RFA, for the treatment of primary liver cancer. The trial design of the OPTIMA Study is based on the comprehensive analysis of data from an earlier clinical trial called the HEAT Study, which is described below. The OPTIMA Study is supported by a hypothesis developed from an overall survival analysis of a large subgroup of patients from the HEAT Study.

We initiated the OPTIMA Study in the first half of 2014. The OPTIMA Study was designed with extensive input from globally recognized hepatocellular carcinoma (“HCC”) researchers and expert clinicians and after receiving formal written consultation from the FDA. The OPTIMA Study is expected to enroll up to 550 patients globally at up to 65 sites in the United States, Canada, Europe Union, China and other countries in the Asia-Pacific region, and will evaluate ThermoDox<sup>®</sup> in combination with standardized RFA, which will require a minimum of 45 minutes across all investigators and clinical sites for treating lesions three to seven centimeters, versus standardized RFA alone. The primary endpoint for this clinical trial is overall survival (“OS”), and the secondary endpoints are progression free survival and safety. The statistical plan calls for two interim efficacy analyses by an independent Data Monitoring Committee (“DMC”).

On December 16, 2015, we announced that we had received the clinical trial application approval from the China Food and Drug Administration (the “CFDA”) to conduct the OPTIMA Study in China. This clinical trial application approval will allow Celsion to enroll patients at up to 20 clinical sites in China. On April 26, 2016, we announced that the first patient in China had been enrolled in the OPTIMA Study. Results from the OPTIMA Study, if successful, will provide the basis for a global registration filing and marketing approval.

On August 7, 2017, the Company announced that the independent Data Monitoring Committee (DMC) for the Company's OPTIMA Study completed a regularly scheduled review of the first 50% of patients enrolled in the trial and has unanimously recommended that the OPTIMA Study continue according to protocol to its final data readout. The DMC reviewed study data at regular intervals, with the primary responsibilities of ensuring the safety of all patients enrolled in the study, the quality of the data collected, and the continued scientific validity of the study design. As part of its review of the first 275 patients, the DMC monitored a quality matrix relating to the total clinical data set, confirming the timely collection of data, that all data are current as well as other data collection and quality criteria.

The Company hosted an Investigators Meeting with physicians in South East Asia and key opinion leaders on July 22-23, 2017 in Bangkok, Thailand. A second Investigators Meeting was held on September 23, 2017 with physicians in China. The Company has initiated approximately 70 clinical sites in 14 countries with plans to activate up to 8 additional clinical trial sites in China or Vietnam by the end of 2017. In addition, the Company announced that patient enrollment in the 550 patient Phase III global study has reached over 67%. Based on current enrollment rates, the Company expects to complete enrollment of the study by mid-2018.

Post-hoc data analysis from the Company's earlier Phase III HEAT Study suggest that ThermoDox<sup>®</sup> may substantially improve OS, when compared to the control group, in patients if their lesions undergo a 45 minute RFA procedure standardized for a lesion greater than 3 cm in diameter. Data from nine OS sweeps have been conducted since the top line progression free survival (“PFS”) data from the HEAT Study were announced in January 2013, with each data set demonstrating substantial improvement in clinical benefit over the control group with statistical significance. On August 15, 2016, the Company announced updated results from its final retrospective OS analysis of the data from the HEAT Study. These results demonstrated that in a large, well bounded, subgroup of patients with a single lesion (n=285, 41% of the HEAT Study patients), treatment with a combination of ThermoDox<sup>®</sup> and optimized RFA provided an average 54% risk improvement in OS compared to optimized RFA alone. The Hazard Ratio (“HR”) at this analysis is 0.65 (95% CI 0.45 - 0.94) with a p-value of 0.02. Median OS for the ThermoDox<sup>®</sup> group has been reached which translates into a two year survival benefit over the optimized RFA group (projected to be greater than 80 months for the ThermoDox<sup>®</sup> plus optimized RFA group compared to less than 60 months projection for the optimized RFA only group). Additional findings from this most recent analysis specific to the Chinese patient cohort of 223 patients are summarized below:

In the population of 154 patients with a single lesion who received optimized RFA treatment for 45 minutes or more showed a 53% risk improvement in OS (HR = 0.66) when treated with ThermoDox<sup>®</sup> plus optimized RFA.

These data continue to support and further strengthen ThermoDox<sup>®</sup>'s potential to significantly improve OS compared to an RFA control in patients with lesions that undergo optimized RFA treatment for 45 minutes or more. The clinical benefit seen in the intent-to-treat Chinese patient cohort further confirms the importance of RFA heating time as 72% of patients in this large patient cohort in China received an optimized RFA treatment.

While this information should be viewed with caution since it is based on a retrospective analysis of a subgroup, we also conducted additional analyses that further strengthen the evidence for the HEAT Study sub-group. We commissioned an independent computational model at the University of South Carolina Medical School. The results indicate that longer RFA heating times correlate with significant increases in doxorubicin concentration around the RFA treated tissue. In addition, we conducted a prospective preclinical study in 22 pigs using two different manufacturers of RFA and human equivalent doses of ThermoDox<sup>®</sup> that clearly support the relationship between increased heating duration and doxorubicin concentrations.

S-3

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On November 29, 2016, the Company announced the results of an independent analysis conducted by the National Institutes of Health (the "NIH") from the HEAT Study which reaffirmed the correlation between increased RFA burn time per tumor volume and improvements in overall survival. The NIH analysis, which sought to evaluate the correlation between RFA burn time per tumor volume (min/ml) and clinical outcome, concluded that increased burn time per tumor volume significantly improved overall survival in patients treated with RFA plus ThermoDox<sup>®</sup> compared to patients treated with RFA alone. For all patients with single lesions treated with RFA plus ThermoDox<sup>®</sup>:

One unit increase in RFA duration per tumor volume improved overall survival by 20% (p=0.017; n=227);

More significant differences in subgroup of patients with RFA burn times per tumor volume greater than 2.5 minutes per ml;

Cox multiple covariate analysis showed overall survival to be significant (p=0.038; Hazard Ratio = 0.85); and

Burn time per tumor volume did not have a significant effect on overall survival in single lesion patients treated with RFA only.

***The HEAT Study.*** On January 31, 2013, the Company announced that the HEAT Study, ThermoDox<sup>®</sup> in combination with RFA, did not meet the primary endpoint, PFS, of a Phase III clinical trial enrolling 701 patients with primary liver cancer. This determination was made after conferring with the HEAT Study independent DMC, that the HEAT Study did not meet the goal of demonstrating a clinically meaningful improvement in progression free survival. In the trial, ThermoDox<sup>®</sup> was well-tolerated with no unexpected serious adverse events. Following the announcement of the HEAT Study results, we continued to follow patients for OS, the secondary endpoint of the HEAT Study. We have conducted a comprehensive analysis of the data from the HEAT Study to assess the future strategic value and development strategy for ThermoDox<sup>®</sup>.

***The DIGNITY Study.*** On December 14, 2015, we announced final data from our ongoing DIGNITY study, which is an open-label, dose-escalating Phase II trial of ThermoDox<sup>®</sup> in patients with recurrent chest wall ("RCW") breast cancer. The DIGNITY Study was designed to establish a safe therapeutic dose in Phase I, and to demonstrate local control in Phase II, including complete and partial responses, and stable disease as its primary endpoint. The DIGNITY Study was also designed to evaluate kinetics in ThermoDox<sup>®</sup> produced from more than one manufacturing site. Of the 29 patients enrolled and treated, 21 patients were eligible for evaluation of efficacy. Approximately 62% of evaluable patients experienced a local response, including six complete responses and seven partial responses.

## **Acquisition of EGEN Assets**

On June 20, 2014, we completed the acquisition of substantially all of the assets of Egen, Inc., an Alabama corporation, which has changed its company name to EGWU, Inc. after the closing of the acquisition (“EGEN”), pursuant to an asset purchase agreement dated as of June 6, 2014, by and between EGEN and Celsion (the “Asset Purchase Agreement”). We acquired all of EGEN’s right, title and interest in and to substantially all of the assets of EGEN, including cash and cash equivalents, patents, trademarks and other intellectual property rights, clinical data, certain contracts, licenses and permits, equipment, furniture, office equipment, furnishings, supplies and other tangible personal property. In addition, CLSN Laboratories assumed certain specified liabilities of EGEN, including the liabilities arising out of the acquired contracts and other assets relating to periods after the closing date.

The total purchase price for the asset acquisition is up to \$44.4 million, including potential future earnout payments of up to \$30.4 million contingent upon achievement of certain earnout milestones set forth in the Asset Purchase Agreement. At the closing, we paid approximately \$3.0 million in cash after the expense adjustment and issued 193,728 shares of our common stock to EGEN. The shares of common stock were issued in a private transaction exempt from registration under the Securities Act, pursuant to Section 4(2) thereof. In addition, 47,862 shares of common stock were held back by us at the closing and are issuable to EGEN pending satisfactory resolution of any post-closing adjustments for expenses or in relation to EGEN’s indemnification obligations under the Asset Purchase Agreement. These shares were issued on June 16, 2017.

The earnout payments of up to \$30.4 million will become payable, in cash, shares of our common stock or a combination thereof, at our option upon achievement of three major milestone events as follows:

\$12.4 million will become payable upon achieving certain specified development milestones relating to an ovarian cancer study of GEN-1 (formerly known as EGEN-001) to be conducted by us or our subsidiary;

\$12.0 million will become payable upon achieving certain specified development milestones relating to a GEN-1 glioblastoma multiforme brain cancer study to be conducted by us or our subsidiary; and

up to \$6.0 million will become payable upon achieving certain specified milestones relating to the TheraSilence technology acquired from EGEN in the acquisition.

Our obligations to make the earnout payments will terminate on the seventh anniversary of the closing date. In the acquisition, we purchased GEN-1, a DNA-based immunotherapy for the localized treatment of ovarian and brain cancers, and two platform technologies for the development of treatments for those suffering with difficult-to-treat forms of cancer, novel nucleic acid-based immunotherapies and other anticancer DNA or RNA therapies, including TheraPlas and TheraSilence.

## **GEN-1**

GEN-1 is a DNA-based immunotherapeutic product for the localized treatment of ovarian and brain cancers by intraperitoneally administering an Interleukin-12 (“IL-12”) plasmid formulated with our proprietary TheraPlas delivery system. In this DNA-based approach, the immunotherapy is combined with a standard chemotherapy drug, which can potentially achieve better clinical outcomes than with chemotherapy alone. We believe that increases in IL-12 concentrations at tumor sites for several days after a single administration could create a potent immune environment against tumor activity and that a direct killing of the tumor with concomitant use of cytotoxic chemotherapy could result in a more robust and durable antitumor response than chemotherapy alone. We believe the rationale for local therapy with GEN-1 are based on the following:

Loco-regional production of the potent cytokine IL-12 avoids toxicities and poor pharmacokinetics associated with systemic delivery of recombinant IL-12

Persistent local delivery of IL-12 lasts up to one week and dosing can be repeated

Ideal for long-term maintenance therapy

***GEN-1 OVATION Study.*** In February 2015, we announced that the FDA accepted, without objection, the Phase I dose-escalation clinical trial of GEN-1 in combination with the standard of care in neo-adjuvant ovarian cancer (the “OVATION Study”). On September 30, 2015, we announced enrollment of the first patient in the OVATION Study. The OVATION Study will seek to identify a safe, tolerable and potentially therapeutically active dose of GEN-1 by recruiting and maximizing an immune response and is designed to enroll three to six patients per dose level and will evaluate safety and efficacy and attempt to define an optimal dose for a follow-on Phase I/II study combining GEN-1 with Avastin® and Doxil®. In addition, the OVATION Study establishes a unique opportunity to assess how cytokine-based compounds such as GEN-1, directly affect ovarian cancer cells and the tumor microenvironment in newly diagnosed patients. The study is designed to characterize the nature of the immune response triggered by GEN-1 at various levels of the patients’ immune system, including:

infiltration of cancer fighting T-cell lymphocytes into primary tumor and tumor microenvironment including peritoneal cavity, which is the primary site of metastasis of ovarian cancer;

changes in local and systemic levels of immuno-stimulatory and immunosuppressive cytokines associated with tumor suppression and growth, respectively; and

expression profile of a comprehensive panel of immune related genes in pre-treatment and GEN-1-treated tumor tissue.

We initiated the OVATION Study at four clinical sites at the University of Alabama at Birmingham, Oklahoma University Medical Center, Washington University in St. Louis and the Medical College of Wisconsin. During 2016 and 2017, we announced data from the first fourteen patients in the OVATION Study who completed treatment.

On October 3, 2017, we announced final clinical and translational research data from its OVATION Study, a Phase Ib dose escalating clinical trial combining GEN-1, the Company's DNA-based immunotherapy, with the standard of care for the treatment of newly-diagnosed patients with advanced Stage III/IV ovarian cancer who will undergo neoadjuvant chemotherapy followed by interval debulking surgery.

Key translational research findings from all evaluable patients are consistent with the earlier reports from partial analysis of the data and are summarized below:

The intraperitoneal treatment of GEN-1 in conjunction with neoadjuvant chemotherapy resulted in dose dependent increases in IL-12 and Interferon-gamma (IFN-g) levels that were predominantly in the peritoneal fluid compartment with little to no changes observed in the patients' systemic circulation. These and other post-treatment changes including decreases in VEGF levels in peritoneal fluid are consistent with an IL-12 based immune mechanism. Consistent with the previous partial reports, the effects observed in the IHC analysis were pronounced decreases in the density of immunosuppressive T-cell signals (Foxp3, PD-1, PDL-1, IDO-1) and increases in CD8+ cells in the tumor microenvironment.

The ratio of CD8+ cells to immunosuppressive cells was increased in approximately 75% of patients suggesting an overall shift in the tumor microenvironment from immunosuppressive to pro-immune stimulatory following treatment with GEN-1. An increase in CD8+ to immunosuppressive T-cell populations is a leading indicator and believed to be a good predictor of improved overall survival.

Analysis of peritoneal fluid by cell sorting, not reported before, shows treatment-related decrease in the percentage of immunosuppressive T-cell (Foxp3+), which is consistent with the reduction of Foxp3+ T-cells in the primary tumor tissue, and a shift in tumor naïve CD8+ cell population to more efficient tumor killing memory effector CD8+ cells.

Celsion also reported positive clinical data from the first fourteen patients who have completed treatment in the OVATION Study. GEN-1 plus standard chemotherapy produced positive clinical results, with no dose limiting toxicities and positive dose dependent efficacy signals which correlate well with positive surgical outcomes as summarized below:

Of the fourteen patients treated in the entire study, two patients demonstrated a complete response, ten patients demonstrated a partial response and two patients demonstrated stable disease, as measured by RECIST criteria. This translates to a 100% disease control rate ("DCR") and an 86% objective response rate ("ORR"). Of the five patients treated in the highest dose cohort, there was a 100% objective response rate with one complete response and four partial responses.

Fourteen patients had successful resections of their tumors, with nine patients (64%) having an R0 resection, which indicates a microscopically margin-negative resection in which no gross or microscopic tumor remains in the tumor bed. Seven out of eight (87%) patients in the highest two dose cohorts experienced a R0 surgical resection. All five patients treated at the highest dose cohort experienced a R0 surgical resection.

All patients experienced a clinically significant decrease in their CA-125 protein levels as of their most recent study visit. CA-125 is used to monitor certain cancers during and after treatment. CA-125 is present in greater concentrations in ovarian cancer cells than in other cells.

Of the eight patients who have received GEN-1 treatment over one year prior to the date of this prospectus supplement (cohort 1 - 3) and are being followed; only two patients' cancer has progressed. This compares favorably to the historical median progression free survival (PFS) of 12 months for newly-diagnosed patients with Stage III and IV ovarian cancer that undergo neoadjuvant chemotherapy followed by interval debulking surgery. Of the remaining six patients who have been on the study for over one year, their average PFS as of September 30, 2017 is 18 months with the longest progression-free patient at 24 months.

The Company also held an Advisory Board Meeting on September 27, 2017 with the clinical investigators and scientific experts including those from Roswell Park Cancer Institute, Vanderbilt University Medical School, and M.D. Anderson Cancer Center to review and finalize clinical, translational research and safety data from the OVATION Study in order to determine the next steps forward for our GEN-1 immunotherapy. With the endorsement and recommendations from the Advisory Board, the Company expects to file a next phase protocol with FDA by the end of 2017.

***GEN-1 Plus Doxil® and Avastin® Trial.*** On April 29, 2015, we announced the expansion of our ovarian cancer development program to include a Phase I dose escalating trial to evaluate GEN-1 in combination with Avastin® and Doxil® in platinum-resistant ovarian cancer patients. This new combination study in platinum-resistant ovarian cancer is supported by three preclinical studies indicating that the combination of GEN-1 with Avastin® may result in significant clinical benefit with a favorable safety profile. Specifically:

In two preclinical studies using an animal model of disseminated ovarian cancer, GEN-1 in combination with Avastin® led to a significant reduction in tumor burden and disease progression. The effectiveness of the combined treatment was seen when GEN-1 was combined with various dose levels of Avastin® (low-medium-high). Additionally, it was shown that GEN-1 treatment alone resulted in anti-tumor activity that was as good as or better than Avastin® treatment alone.

The preclinical studies indicated that no obvious overt toxicities were associated with the combined treatments of GEN-1 and Avastin®. The preclinical data are also consistent with the mechanism of action for GEN-1, which exhibits certain anti-angiogenic properties and suggests that combining GEN-1 with lower doses of Avastin® may enhance efficacy and help reduce the known toxicities associated with this anti-VEGF drug.

The distinct biological activities of GEN-1 (immune stimulation) and Avastin® (inhibition of tumor blood vessel formation) also suggest scientific rationale for this combination approach. Additionally, the anti-angiogenic activity of GEN-1 mediated through up regulation of the interferon gamma (“IFN-g”) pathway may help to explain the synergy between GEN-1 and Avastin® and potentially addresses the VEGF escape mechanisms associated with resistance to Avastin® therapy.

***TheraPlas Technology Platform.*** TheraPlas is a technology platform for the delivery of DNA and messenger RNA (“mRNA”) therapeutics via synthetic non-viral carriers and is capable of providing cell transfection for double-stranded DNA plasmids and large therapeutic RNA segments such as mRNA. There are two components of the TheraPlas system, a plasmid DNA or mRNA payload encoding a therapeutic protein and a delivery system. The delivery system is designed to protect the DNA/RNA from degradation and promote trafficking into cells and through intracellular compartments. We designed the delivery system of TheraPlas by chemically modifying the low molecular weight polymer to improve its gene transfer activity without increasing toxicity. We believe TheraPlas is a viable alternative to current approaches to gene delivery due to several distinguishing characteristics, including enhanced molecular versatility that allows for complex modifications to improve activity and safety.

***Technology Development and Licensing Agreements.*** Our current efforts and resources are applied on the development and commercialization of cancer drugs including tumor-targeting chemotherapy treatments using focused heat energy in combination with heat-activated drug delivery systems, immunotherapies and RNA-based therapies. To support our research and development, we raised gross proceeds of approximately \$127.2 million in equity financings and warrant and option exercises in the years 2010 through 2015. During 2016, we raised gross proceeds of \$7.8 million through two registered direct equity financings with several institutional investors. In 2017 thus far, we raised \$10.1 million in gross proceeds from a public offering equity financing and \$22.0 million from the exercise of warrants to purchase common stock. We had cash and cash equivalents totaling \$2.7 million at September 30, 2017. We have one credit facility for a total principle amount of up to \$20 million and have drawn down \$10 million under this credit facility.

S-7

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On August 8, 2016, we signed a Technology Transfer, Manufacturing and Commercial Supply Agreement (the “GEN-1 Agreement”) with Zhejiang Hisun Pharmaceutical Co. Ltd. (“Hisun”) to pursue an expanded partnership for the technology transfer relating to the clinical and commercial manufacture and supply of GEN-1, Celsion’s proprietary gene mediated, IL-12 immunotherapy, for the greater China territory, with the option to expand into other countries in the rest of the world after all necessary regulatory approvals are obtained. The GEN-1 Agreement will help to support supply for both ongoing and planned clinical studies in the United States, and for potential future studies of GEN-1 in China. GEN-1 is currently being evaluated by Celsion in first line ovarian cancer patients.

In June 2012, Celsion and Hisun signed a long-term commercial supply agreement for the production of ThermoDox<sup>®</sup>. Hisun is one the largest manufacturers of chemotherapy agents globally, including doxorubicin. In July 2013, the ThermoDox<sup>®</sup> collaboration was expanded to focus on next generation liposomal formulation development with the goal of creating safer, more efficacious versions of marketed cancer chemotherapeutics. During 2015, Hisun successfully completed the manufacture of three registration batches for ThermoDox<sup>®</sup> and has obtained regulatory approvals to supply ThermoDox<sup>®</sup> to participating clinical trial sites in all of the countries of South East Asia, Europe and North America, as well as to the European Union countries allowing for early access to ThermoDox<sup>®</sup>. The future manufacturing of clinical and commercial supplies by Hisun will result in a cost structure allowing Celsion to profitably access all global markets, including third world countries, and help accelerate the Company’s product development program in China for ThermoDox<sup>®</sup> in primary liver cancer and other approved indications.

## **Business Strategy and Development Plan**

We have not generated and do not expect to generate any revenue from product sales in the next several years, if at all. An element of our business strategy has been to pursue, as resources permit, the research and development of a range of product candidates for a variety of indications. We may also evaluate licensing cancer products from third parties for cancer treatments to expand our current product pipeline. This is intended to allow us to diversify the risks associated with our research and development expenditures. To the extent we are unable to maintain a broad range of product candidates, our dependence on the success of one or a few product candidates would increase and results such as those announced in relation to the HEAT study on January 31, 2013 will have a more significant impact on our financial prospects, financial condition and market value. We may also consider and evaluate strategic alternatives, including investment in, or acquisition of, complementary businesses, technologies or products. As demonstrated by the HEAT Study results, drug research and development is an inherently uncertain process and there is a high risk of failure at every stage prior to approval. The timing and the outcome of clinical results are extremely difficult to predict. The success or failure of any preclinical development and clinical trial can have a disproportionately positive or negative impact on our results of operations, financial condition, prospects and market value.

Our current business strategy includes the possibility of entering into collaborative arrangements with third parties to complete the development and commercialization of our product candidates. In the event that third parties take over the clinical trial process for one or more of our product candidates, the estimated completion date would largely be under the control of that third party rather than us. We cannot forecast with any degree of certainty which proprietary products or indications, if any, will be subject to future collaborative arrangements, in whole or in part, and how such

arrangements would affect our development plan or capital requirements. We may also apply for subsidies, grants or government or agency-sponsored studies that could reduce our development costs.

As of June 30, 2017, we have \$3.6 million in cash and cash equivalents. In July 2017, the Company completed a \$5 million registered direct equity offering of shares of common stock, or pre-funded warrants in lieu thereof, and a concurrent private placement of warrants to purchase common stock, with several institutional healthcare investors. In early October 2017, the Company received \$17 million in gross proceeds collectively from certain warrant holders exercising warrants to purchase collectively 5.0 million shares of common stock. Given our development plans, we anticipate cash resources will be sufficient to fund our operations through 2018 and the Company has no committed sources of additional capital. The Company has a Controlled Equity Offering SM Sales Agreement (the “ATM Agreement”) with Cantor Fitzgerald & Co. In connection with this offering, we have agreed not to sell any additional shares under the Sales Agreement for a period of two months after the closing date of this offering. As a result of the risks and uncertainties discussed in our 2016 Annual Report on Form 10-K and Quarterly Report on Form 10-Q for the quarter ended June 30, 2017, among others, we are unable to estimate the duration and completion costs of our research and development projects or when, if ever, and to what extent we will receive cash inflows from the commercialization and sale of a product. Our inability to complete any of our research and development activities, preclinical studies or clinical trials in a timely manner or our failure to enter into collaborative agreements when appropriate could significantly increase our capital requirements and could adversely impact our liquidity. While our estimated future capital requirements are uncertain and could increase or decrease as a result of many factors, including the extent to which we choose to advance our research, development activities, preclinical studies and clinical trials, or if we are in a position to pursue manufacturing or commercialization activities, we will need significant additional capital to develop our product candidates through development and clinical trials, obtain regulatory approvals and manufacture and commercialize approved products, if any. We do not know whether we will be able to access additional capital when needed or on terms favorable to us or our stockholders. Our inability to raise additional capital, or to do so on terms reasonably acceptable to us, would jeopardize the future success of our business. Based on the above, management determined there was substantial doubt regarding our ability to continue as a going concern. As a result, our independent registered accounting firm expressed substantial doubt about our ability to continue as a going concern in their report dated March 24, 2017 included in our 2016 Annual Report on Form 10-K.

## Recent Developments

On May 26, 2017, the Company effected a reverse stock split of our common stock at an exchange ratio of 14-to-1 (the “Reverse Stock Split”) and set the number of authorized shares of common stock outstanding immediately after the split at 112.5 million shares. As a result of the Reverse Stock Split, every fourteen shares of common stock outstanding immediately prior to the effectiveness of the Reverse Stock Split were combined and converted into one share of common stock immediately thereafter without any change in the per share par value. The Company’s common stock started to trade on the post-split basis at the commencement of trading on May 30, 2017 under a new CUSIP number 15117N503 with the same ticker symbol, CLSN. Unless otherwise expressly stated, the share and per share data in this section and elsewhere in this prospectus supplement have been adjusted to reflect the Reverse Stock Split.

During 2017, the Company has issued a total of 11.1 million shares of common stock in the following equity transactions, for an aggregate \$32.1 million in gross proceeds.

On February 14, 2017, the Company entered into a securities purchase agreement whereby it sold, in a public offering (the “February 14, 2017 Public Offering”), an aggregate of 1,384,704 shares of common stock of the Company at an offering price of \$3.22 per share. In addition, the Company sold Series AA Warrants (the Series AA Warrants) to purchase up to 1,177,790 shares of common stock and Pre-Funded Series BB Warrants (the Pre-Funded Series BB Warrants) to purchase up to 185,713 shares of common stock. The Series AA Warrants have an exercise price of \$3.22 per share, have a five year life and are immediately exercisable. The Pre-Funded Series BB Warrants were offered at \$3.08 per share, are immediately exercisable for \$0.01 per share of common stock, do not have an expiration date and were issued in lieu of shares of common stock to the extent that the purchase of common stock would cause the beneficial ownership of the purchaser of such shares, together with its affiliates and certain related parties, to exceed 9.99% of our common stock. The Company received approximately \$5.0 million in gross proceeds before the deduction of the placement agent fees and offering expenses (excluding any proceeds from the exercise of the warrants) in the February 14, 2017 Public Offering. During the first quarter of 2017, all 185,713 of the Series BB Pre-Funded warrants were exercised in full.

On July 6, 2017, the Company entered into a securities purchase agreement with several investors, pursuant to which the Company agreed to issue and sell, in a registered direct offering, an aggregate of 2,050,000 shares of common stock of the Company at an offering price of \$2.07 per share for gross proceeds of \$4,243,500 before the deduction of the placement agent fee and offering expenses. In addition, the Company sold Pre-Funded Series CCC Warrants to purchase 385,000 shares of common stock (and the shares of common stock issuable upon exercise of the Pre-Funded Series CCC Warrants), in lieu of shares of common stock to the extent that the purchase of common stock would cause the beneficial ownership of the Purchaser, together with its affiliates and certain related parties, to exceed 9.99% of our common stock. The Pre-Funded Series CCC Warrants were sold at an offering price of \$2.06 per share for gross proceeds of \$793,100, are immediately exercisable for \$0.01 per share of common stock and do not have an expiration date. As of August 11, 2017, the Prefunded Series CCC Warrants were fully exercised. In a concurrent private placement, the Company agreed to issue to each investor, for each share of common stock and pre-funded warrant purchased in the offering, a Series AAA Warrant and Series BBB Warrant, each to purchase one share of

common stock. The Series AAA Warrants are initially exercisable six months following issuance, and terminate five and one-half years following issuance. The Series AAA Warrants have an exercise price of \$2.07 per share and are exercisable to purchase an aggregate of 2,435,000 shares of common stock. The Series BBB Warrants are immediately exercisable following issuance, and terminate twelve months following issuance. The Series BBB Warrants have an exercise price of \$4.75 per share and are exercisable to purchase an aggregate of 2,435,000 shares of common stock. Subject to limited exceptions, a holder of a Series AAA and Series BBB Warrant will not have the right to exercise any portion of its warrants if the holder, together with its affiliates, would beneficially own in excess of 9.99% of the number of shares of common stock outstanding immediately after giving effect to such exercise.

S-9

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The Company has received gross proceeds of \$22.0 million from the exercise of warrants to purchase 7,617,147 shares of common stock thus far in 2017.

We are a party to a Controlled Equity Offering SM Sales Agreement (ATM) dated as of February 1, 2013 with Cantor Fitzgerald & Co., pursuant to which we may sell additional shares of our common stock having an aggregate offering price of up to \$25 million through “at-the-market” equity offerings from time to time. From February 1, 2013 through December 31, 2015, the Company sold and issued an aggregate of 105,681 shares of common stock under the ATM, receiving approximately \$7.4 million in net proceeds. The Company did not have any sales under the ATM in 2016 and through September 30, 2017. In connection with this offering, we have agreed not to sell any additional shares under the Sales Agreement for a period of two months after the closing date of this offering.

### **Corporate Information**

We were founded in 1982 and are a Delaware corporation. Our shares of common stock trade on The NASDAQ Capital Market under the symbol “CLSN.” Our principal executive offices are located at 997 Lenox Drive, Suite 100, Lawrenceville, New Jersey 08648. Our telephone number is (609) 896-9100 and our website is [www.celsion.com](http://www.celsion.com). The information available on or through our website is not part of, nor incorporated by reference into, this prospectus supplement or the accompanying prospectus, and should not be relied upon.

## The Offering

**Common stock offered by us:** 2,640,000 shares

**Shares of common stock outstanding before this offering** 8,354,679 shares (as more fully described in the notes following this table)

**Shares of common stock outstanding after completion of this offering:** 10,994,679 shares (as more fully described in the notes following this table)

Warrants to purchase up to 1,320,000 shares of common stock. Each share of our common stock is being sold together with 0.5 Warrants, each whole Warrant being exercisable to purchase one share of our common stock. Each of the Warrants will have an exercise price of \$3.00 per share. The Warrants will be exercisable for a five-year period commencing on April 30, 2018.

### Warrants Offered by Us

This prospectus supplement also relates to the offering of the shares of common stock issuable upon exercise of Warrants. The exercise price of the Warrants and the number of shares into which the Warrants may be exercised are subject to adjustment in certain circumstances. See “*Description of the Securities we are Offering*” on page S-24.

**Use of Proceeds:** We estimate that our net proceeds from this offering will be approximately \$5.8 million. We intend to use the net proceeds from this offering primarily to continue funding development of OPTIMA, our ongoing Phase III clinical trial of ThermoDox® in patients with primary liver cancer and OVATION, our ongoing clinical development program of GEN-1 in patients with advanced ovarian cancer and for general corporate purposes, including research and development activities, capital expenditures and working capital.

See the section titled “Use of Proceeds” in this prospectus supplement.

**NASDAQ Capital Market symbol:** CLSN

**Trading:** Our shares of common stock currently trade on The NASDAQ Capital Market.

There is no established trading market for the Warrants and we do not expect a market to develop. In addition, we do not intend to apply for the listing of the Warrants on any national securities exchange or other trading market. Without an active trading market, the liquidity of

the Warrants will be limited.

S-11

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**Risk Factors:** Investing in our securities involves a high degree of risk and purchasers of our securities may lose their entire investment. See “Risk Factors” below and in our most recent Annual Report on Form 10-K, which is incorporated by reference and the other information included elsewhere in this prospectus supplement and the accompanying prospectus for a discussion of factors you should carefully consider before deciding to invest in our securities.

The number of shares of our