Celsion CORP
Form S-1/A
November 16, 2016

As filed with the Securities and Exchange Commission on November 16, 2016

Registration No. 333-214353

**UNITED STATES** 

SECURITIES AND EXCHANGE COMMISSION

**WASHINGTON, D.C. 20549** 

**Pre-Effective Amendment No.1** 

to

FORM S-1

REGISTRATION STATEMENT

**UNDER** 

THE SECURITIES ACT OF 1933

### **CELSION CORPORATION**

(Exact name of registrant as specified in its charter)

**Delaware** 2834 52-1256615

or organization)

(State or other jurisdiction of incorporation (Primary Standard Industrial Classification (I.R.S. Employer Code Number) Identification No.)

997 Lenox Drive, Suite 100

Lawrenceville, New Jersey 08648

(609) 896-9100

(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

#### Michael H. Tardugno

### **President and Chief Executive Officer**

997 Lenox Drive, Suite 100

Lawrenceville, New Jersey 08648

(609) 896-9100

(Name, address, including zip code, and telephone number, including area code, of agent for service)

Copies to:

### Sam Zucker, Esq.

Sidley Austin LLP

1001 Page Mill Road

Building 1

Palo Alto, California 94304

(650) 565-7000

#### Approximate date of commencement of proposed sale to the public:

From time to time after this registration statement is declared effective.

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, check the following box.

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

If this Form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (Check one):

Large Accelerated filer Accelerated filer Non-accelerated Filer Smaller reporting company
(Do not check if a smaller reporting company)

The registrant hereby amends this registration statement on such date or dates as may be necessary to delay its effective date until the registrant shall file a further amendment which specifically states that this registration statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933, as amended, or until the registration statement shall become effective on such date as the Securities and Exchange Commission, acting pursuant to said Section 8(a), may determine.

The information in this prospectus is not complete and may be changed. The selling stockholders may not sell these securities pursuant to this prospectus until the registration statement filed with the Securities and Exchange Commission is effective. This prospectus is not an offer to sell these securities and is not soliciting offers to buy these securities in any jurisdiction where the offer or sale is not permitted.

**SUBJECT TO COMPLETION, DATED NOVEMBER 16, 2016** 

**PROSPECTUS** 

8,823,528 Shares of Common Stock

**Issuable upon Exercise of Outstanding Warrants** 

This prospectus relates to the resale, from time to time, by the selling stockholders identified in this prospectus under the caption "Selling Stockholders," of up to 8,823,528 shares of our common stock, par value \$0.01 per share, issuable upon exercise of certain outstanding common stock purchase warrants. We are not selling any shares of common stock under this prospectus and will not receive any proceeds from the sale of shares of common stock by the selling stockholders. We will receive proceeds from cash exercise of the warrants which, if exercised in cash with respect to all of the 8,823,528 shares of common stock, would result in gross proceeds of approximately \$12,352,939 to us. The selling stockholders will bear all commissions and discounts, if any, attributable to the sale of the shares.

The selling stockholders may sell the shares of our common stock offered by this prospectus from time to time on terms to be determined at the time of sale through ordinary brokerage transactions or through any other means described in this prospectus under the caption "Plan of Distribution." The shares of common stock may be sold at fixed prices, at market prices prevailing at the time of sale, at prices related to prevailing market price or at negotiated prices.

Our common stock is listed on The NASDAQ Capital Market under the symbol "CLSN." November 15, 2016, the last reported closing sale price of our common stock on The NASDAQ Capital Market was \$0.815 per share.

Investing in our common stock involves a high degree of risk. Before making an investment decision, please read "Risk Factors" on page 11 of this prospectus.						
Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.						
The date of this prospectus is	, 2016.					

# TABLE OF CONTENTS

	Page
ABOUT THIS PROSPECTUS	1
WHERE YOU CAN FIND ADDITIONAL INFORMATION	1
INFORMATION INCORPORATED BY REFERENCE	1
FORWARD-LOOKING STATEMENTS	3
PROSPECTUS SUMMARY	4
RISK FACTORS	11
USE OF PROCEEDS	12
DIVIDEND POLICY	12
DESCRIPTION OF CAPITAL STOCK	13
SELLING STOCKHOLDERS	16
PLAN OF DISTRIBUTION	17
LEGAL MATTERS	19
EXPERTS	19

#### **ABOUT THIS PROSPECTUS**

This prospectus relates to the resale by the selling stockholders identified in this prospectus under the caption "Selling Stockholders," from time to time, of up to 8,823,528 shares of our comment stock, par value \$0.01 per share, issuable upon exercise of certain outstanding common stock purchase warrants. On December 17, 2016, (i) 6,617,646 shares of common stock will become exercisable by the selling stockholders and (ii) an additional 2,205,882 shares of common stock will become exercisable by the selling stockholders ratably upon the exercise of certain of the aforementioned shares of common stock in each case as described below under "Description of the Private Placement." We are not selling any shares of common stock under this prospectus and will not receive any proceeds from the sale of shares of common stock by the selling stockholders.

This prospectus is part of a registration statement on Form S-1 that we filed with the Securities and Exchange Commission (SEC). It omits some of the information contained in the registration statement and reference is made to the registration statement for further information with regard to us and the securities being offered by the selling stockholders. Any statement contained in the prospectus concerning the provisions of any document filed as an exhibit to the registration statement or otherwise filed with the SEC is not necessarily complete, and in each instance, reference is made to the copy of the document filed.

You should read this prospectus, any documents that we incorporate by reference in this prospectus and the additional information described below under "Where You Can Find Additional Information" and "Information Incorporated By Reference" before making an investment decision. You should rely only on the information contained or incorporated by reference in this prospectus. We have not authorized any other person to provide you with different information. If anyone provides you with additional, different or inconsistent information, you should not rely on it. This prospectus is not an offer to sell these securities and it is not soliciting an offer to buy these securities in any jurisdiction where the offer or sale is not permitted.

You should not assume that the information in this prospectus or any documents we incorporate by reference herein is accurate as of any date other than the date on the front of those documents. Our business, financial condition, results of operations and prospects may have changed since those dates.

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®, ThermoDox®, EGEN®, TheraPlas<sup>TM</sup> and TheraSilence<sup>TM</sup> 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.

#### WHERE YOU CAN FIND MORE INFORMATION

We are subject to the information requirements of the Securities Exchange Act of 1934, as amended (the Exchange Act). In accordance with the Exchange Act, we file annual, quarterly and current reports, proxy statements and other information with the SEC. Such reports, proxy statements and other information filed by us are available to the public free of charge at www.sec.gov. You may also read and copy any document we file with the SEC at the public reference facilities maintained by the SEC at 100 F Street, N.E., Washington, D.C. 20549. You may obtain information on the operation of the public reference facilities by calling the SEC at 1-800-SEC-0330. Copies of certain information filed by us with the SEC are also available on our website at www.celsion.com. The information available on or through our website is not part of this prospectus and should not be relied upon.

This prospectus is part of a registration statement that we filed with the SEC. This prospectus omits some information contained in the registration statement in accordance with SEC rules and regulations. You should review the information and exhibits in the registration statement for further information about us and the securities being offered hereby. Statements in this prospectus concerning any document we filed as an exhibit to the registration statement or that we otherwise filed with the SEC are not intended to be comprehensive and are qualified by reference to the filings. You should review the complete document to evaluate these statements.

### INFORMATION INCORPORATED BY REFERENCE

SEC rules allow us to "incorporate by reference" into this prospectus much of the information we file with the SEC, which means that we can disclose important information to you by referring you to those publicly available documents. The information that we incorporate by reference into this prospectus is considered to be part of this prospectus. These documents may include Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q and Current Reports on Form 8-K, as well as proxy statements. You should read the information incorporated by reference because it is an important part of this prospectus.

This prospectus incorporates by reference the documents listed below, other than those documents or the portions of those documents deemed to be furnished and not filed in accordance with SEC rules:

our Annual Report on Form 10-K and Amendment No. 1 on Form 10-K/A for the fiscal year ended December 31, 2015, filed with the SEC on March 30, 2016 and April 29, 2016, respectively;

our Quarterly Report on Form 10-Q for the fiscal quarter ended March 31, 2016, filed with the SEC on May 16, 2016;

our Quarterly Report on Form 10-Q for the fiscal quarter ended June 30, 2016, filed with the SEC on August 15, 2016;

our Quarterly Report on Form 10-Q for the fiscal quarter ended September 30, 2016, filed with the SEC on November 10, 2016;

our Current Reports on Form 8-K filed with the SEC on June 1, 2016, June 13, 2016, June 15, 2016, June 17, 2016 and September 8, 2016;

our Definitive Proxy Statement on Schedule 14A filed with the SEC on May 5, 2016; and

the description of our common stock contained in our registration statement on Form 8-A filed with the SEC on May 26, 2000, as amended by a Form 8-A/A dated February 7, 2008, and any amendments or reports filed for the purpose of updating such description.

Any statement contained in any document incorporated by reference herein shall be deemed to be modified or superseded for purposes of this prospectus to the extent that a statement contained in this prospectus or any prospectus modifies or supersedes such statement. Any statement so modified or superseded shall not be deemed, except as so modified or superseded, to constitute a part of this prospectus.

We also incorporate by reference any future filings, other than current reports furnished under Item 2.02 or Item 7.01 of Form 8-K and exhibits filed on such form that are related to such items, made with the SEC pursuant to Sections 13(a), 13(c), 14 or 15(d) of the Exchange Act, in each case, other than those documents or the portions of those documents deemed to be furnished and not filed in accordance with SEC rules, until the offering of the securities under the registration statement of which this prospectus forms a part is terminated or completed. Information in such future filings updates and supplements the information provided in this prospectus. Any statements in any such future filings will be deemed to modify and supersede any information in any document we previously filed with the SEC that is incorporated or deemed to be incorporated herein by reference to the extent that statements in the later filed

document modify or replace such earlier statements.

Because we are incorporating by reference future filings with the SEC, this prospectus is continually updated and later information filed with the SEC may update and supersede some of the information included or incorporated by reference in this prospectus. This means that you must look at all of the SEC filings that we incorporate by reference to determine if any of the statements in this prospectus or in any document previously incorporated by reference have been modified or superseded.

We will provide without charge to each person, including any beneficial owners, to whom this prospectus is delivered, upon his or her written or oral request, a copy of any or all reports or documents referred to above which have been or may be incorporated by reference into this prospectus but not delivered with this prospectus, excluding exhibits to those reports or documents unless they are specifically incorporated by reference into those documents. You may request a copy of these documents by writing or telephoning us at the following address.

Celsion Corporation

997 Lenox Drive, Suite 100

Lawrenceville, New Jersey 08648

(609) 896-9100

Attention: Jeffrey W. Church

Senior Vice President, Chief Financial Officer and Corporate Secretary

#### FORWARD-LOOKING STATEMENTS

Certain statements contained or incorporated by reference in this prospectus, in any applicable prospectus and in any related free writing prospectus constitute forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 and releases issued by the SEC and within the meaning of Section 27A of the Securities Act of 1933, as amended (the Securities Act), and Section 21E of the Exchange Act. From time to time, we publish forward-looking statements relating to matters such as anticipated financial performance, business prospects, technological developments, new products, research and development activities, mergers, acquisitions or other strategic transactions and other aspects of our present and future business operations and similar matters that also constitute such forward-looking statements. These statements involve known and unknown risks, uncertainties and other factors that may cause our or our industry's actual results, levels of activity, performance or achievements to be materially different from any future results, levels of activity, performance or achievements expressed or implied by such forward-looking statements. Such statements include, without limitation:

any statements regarding future operations, plans, regulatory filings or approvals, including the plans and objectives of management for future operations or programs or proposed new products or services;

any statements regarding the performance, or likely performance, or outcomes or economic benefit of any of our research and development activities, proposed or potential clinical trials or new drug filing strategies or timelines, including whether any of our clinical trials will be completed successfully within any specified time period or at all;

any projections of earnings, cash resources, revenue, expense or other financial terms;

any statements regarding the initiation, timing, progress and results of our research and development programs, preclinical studies, any clinical trials and Investigational New Drug application, New Drug Application and other regulatory submissions;

any statements regarding cost and timing of development and testing, capital structure, financial condition, working capital needs and other financial items;

any statements regarding the implementation of our business model and integration of acquired technologies, assets or businesses and existing or future collaborations, mergers, acquisitions or other strategic transactions;

any statements regarding approaches to medical treatment, any introduction of new products by others, any possible licenses or acquisitions of other technologies, assets or businesses, or possible actions by customers, suppliers, strategic partners, potential strategic partners, competitors or regulatory authorities;

any statements regarding development or success of our collaboration arrangements or future payments that may come due to us under these arrangements;

any statements regarding compliance with the listing standards of The NASDAQ Capital Market; and

any statements regarding future economic conditions or performance and any statement of assumptions underlying any of the foregoing.

In some cases, you can identify forward-looking statements by terminology such as "expect," "anticipate," "estimate," "continue," "plan," "believe," "could," "intend," "predict," "project," "potential," "may," "should," "will" or the negative there thereof and words of similar import regarding our expectations. Forward-looking statements are only predictions and actual events or results may differ materially. Although we believe that our expectations are based on reasonable assumptions within the bounds of our current knowledge of our industry, business and operations, we cannot guarantee that actual results will not differ materially from our expectations. In evaluating such forward-looking statements, you should specifically consider various factors, including the risks outlined under the caption "Risk Factors" contained in this prospectus and any related free writing prospectus, and in our most recent Annual Report on Form 10-K and our most recent Quarterly Report on Form 10-Q, as well as any amendments thereto reflected in subsequent filings with the SEC. The discussion of risks and uncertainties set forth in those filings is not necessarily a complete or exhaustive list of all risks facing us at any particular point in time. We operate in a highly competitive, highly regulated and rapidly changing environment, and our business is in a state of evolution. Therefore, it is likely that over time new risks will emerge and the nature and elements of existing risks will change. It is not possible for management to predict all such risk factors or changes therein or to assess either the impact of all such risk factors on our business or the extent to which any individual risk factor, combination of factors or new or altered factors may cause results to differ materially from those contained in any forward-looking statement. Forward-looking statements represent our estimates and assumptions only as of the date such forward-looking statements are made. You should carefully read this prospectus and any related free writing prospectus, together with the information incorporated herein or therein by reference as described under the section titled "Information Incorporated By Reference," and with the understanding that our actual future results may materially differ from what we expect.

Except as required by law, forward-looking statements speak only as of the date they are made, and we assume no obligation to update any forward-looking statements publicly, or to update the reasons why actual results could differ materially from those anticipated in any forward-looking statements, even if new information becomes available.

### PROSPECTUS SUMMARY

The following summary highlights information contained elsewhere or incorporated by reference in this prospectus. This summary does not contain all of the information you should consider before investing in the securities. Before making an investment decision, you should read the entire prospectus carefully, including the matters discussed under the heading "Risk Factors" in this prospectus.

#### Overview

Celsion is a fully-integrated oncology drug development stage company focused on developing a portfolio of innovative cancer treatments, including directed chemotherapies, DNA-mediated immunotherapy and RNA based therapies. Our lead product candidate is ThermoDox®, a proprietary heat-activated liposomal encapsulation of doxorubicin, currently in Phase III development for the treatment of primary liver cancer. Our pipeline also includes GEN-1 (formerly known as EGEN-001), a DNA-based immunotherapy for the localized treatment of ovarian and brain cancers. We have three platform technologies for the development of treatments for those suffering with difficult-to-treat forms of cancer, novel nucleic acid-based immunotherapies and other anti-cancer DNA or RNA therapies, including TheraPlasTM and TheraSilenceTM. We are working to develop and commercialize more efficient, effective and targeted oncology therapies based on our technologies, with the goal to develop novel therapeutics that maximize efficacy while minimizing side-effects common to cancer treatments.

### **ThermoDox**®

ThermoDox®, is being evaluated in a Phase III clinical trial, in combination with a standardized radiofrequency ablation (RFA), for primary liver cancer (the OPTIMA Study) and a Phase II clinical trial for recurrent chest wall breast cancer (the DIGNITY study). ThermoDox® 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 degrees Celsius) releases the encapsulated doxorubicin from the liposome enabling high concentrations of doxorubicin to be deposited preferentially in and around the targeted tumor.

The HEAT Study

On January 31, 2013, we announced that ThermoDox® in combination with RFA did not meet the primary endpoint, progression free survival (PFS), of a Phase III clinical trial enrolling 701 patients with primary liver cancer, which we called the HEAT Study. We determined, after conferring with the HEAT Study independent Data Monitoring

Committee, that the HEAT Study did not meet the goal of demonstrating persuasive evidence of clinical effectiveness, that being a clinically meaningful improvement in progression free survival, that could form the basis for regulatory approval in the population chosen for the HEAT Study. In the trial, ThermoDox® was well-tolerated with no unexpected serious adverse events. Following the announcement of the HEAT Study results, we followed patients for overall survival (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®.

Findings from the HEAT Study post-hoc data analysis suggest that ThermoDox ® 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 PFS data from the HEAT Study were announced in January 2013, with each data set showing progressive improvement in 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 (n=285, 41% of the HEAT Study patients), treatment with a combination of ThermoDox ® 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® 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® 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 single lesions (70% of the HEAT Study Chinese patient cohort) who received optimized RFA treatment for 45 minutes or more showed a 53% risk improvement in OS (HR = 0.66) when treated with ThermoDox® plus optimized RFA.

These data continue to support and further strengthen ThermoDox®'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 ITT 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.

This information should be viewed with caution since it is based on a retrospective analysis of a subgroup. We may choose to end this analysis of OS once the median is reached for both arms of the study. We also completed computational modeling with supplementary preclinical animal studies supporting the relationship between heating duration and clinical outcomes.

The OPTIMA Study

On February 24, 2014, we announced that the United States Food and Drug Administration (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®, 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 the HEAT Study. We launched the OPTIMA Study in the first half of 2014. The OPTIMA Study was designed with extensive input from globally recognized HCC researchers and 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 75 sites in the United States, Canada, Europe, China and other Asia Pacific regions, and will evaluate ThermoDox® 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 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.

On December 16, 2015, we announced that we had received the clinical trial application approval from the CFDA to conduct the OPTIMA Study in China. This clinical trial application approval will now allow Celsion to enroll patients at up to 20 additional clinical sites in China. With the addition of these Chinese clinical sites, the Company expects to complete enrollment in the OPTIMA Study during the first half of 2018. On April 26, 2016, we announced that the first patient in China has 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.

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® in patients with recurrent chest wall (RCW) breast cancer. The DIGNITY Study is designed to establish a safe therapeutic dose in Phase I, and in Phase II to demonstrate local control, including complete and partial responses, and stable disease as its primary endpoint. The DIGNITY Study is also planned to evaluate kinetics in ThermoDox® produced from more than one manufacturing site. Of the 28 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.

### The Euro-DIGNITY Study

We anticipate that a Phase II study of RadioTherapy, HyperThermia and ThermoDox® to treat patients with local-regional recurrent chest wall breast cancer will be initiated by four to five clinical sites located in Italy, Israel, Poland and the Czech Republic (the Euro-DIGNITY Study). The Euro-DIGNITY Study is expected to commence in the second half of 2016 and should enroll up to 70 patients affected by recurrent breast adenocarcinoma on the chest wall with/without nodes over a period of two years.

The primary objectives of the Euro-DIGNITY Study will be (i) to evaluate efficacy in patients after 3 cycles of ThermoDox® plus Hyperthermia measuring tumor diameter as a response to therapy and (ii) to evaluate loco-regional breast tumor control in patients who undergo ThermoDox®/hyperthermia/radiotherapy as measured by target lesion clinical response rate combining a RECIST criteria with digital photography to gauge response.

Secondary objectives of the Euro-DIGNITY Study will be (i) to evaluate the safety of the combination of ThermoDox/Hyperthermia/Radiotherapy among patients with local-regional recurrence (LRR) breast cancer, (ii) to evaluate the duration of local control complete response, partial response and stable disease following treatment with ThermoDox/Hyperthermia/Radiotherapy up to 24 months among patients with LRR breast cancer and (iii) to assess Patient Reported Quality of Life using the FACT-B and Brief Pain Inventory following treatment with ThermoDox/Hyperthermia/Radiotherapy among patients with LRR breast cancer.

### **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 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 purchase agreement. At the closing, we paid approximately \$3.0 million in cash after the expense adjustment and issued 2,712,188 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 of 1933, pursuant to Section 4(2) thereof. In addition, 670,070 shares of common stock were held back by us at the closing and are issuable to EGEN on or after August 2, 2016 pending certain potential adjustments for expenses or in relation to EGEN's indemnification obligations under the purchase agreement.

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, 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<sup>TM</sup> 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 (formerly known as EGEN-001), a DNA-based immunotherapy for the localized treatment of ovarian and brain cancers, and three platform technologies for the development of treatments for those suffering with difficult-to-treat forms of cancer, novel nucleic acid-based immunotherapies and other anti-cancer DNA or RNA therapies, including TheraPlasTM and TheraSilenceTM.

### 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<sup>TM</sup> 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.

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 have initiated the 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. In February 2016, we announced the completion of enrollment of the first cohort of patients in the OVATION Study. The OVATION Study will continue into 2016 at higher doses of GEN-1 with the goal to identify a safe, tolerable and therapeutically active dose of GEN-1 by recruiting and maximizing an immune response.

On May 2, 2016 and July 25, 2016, we announced data from the first and second cohorts of patients in the OVATION Study, respectively. The OVATION Study is designed to enroll three to six patients per dose cohort and will continue into 2016 at higher doses of GEN-1 with the goal to identify a safe, tolerable and therapeutically active dose of GEN-1 by recruiting and maximizing an immune response. The first two cohorts each enrolled three patients. Enrollment in the third and fourth cohorts is ongoing, and Celsion expects to complete the OVATION Study in the first half of 2017. Future studies of GEN-1 will include a Phase I/II study combining GEN-1 with Avastin® and Doxil®. The results of the OVATION Study to date are as follows:

Of the first six patients dosed, one patient demonstrated a complete response (CR), two patients demonstrated a partial response (PR) and three patients demonstrated stable disease (SD), as measured by RECIST criteria. Five patients had successful resections of their tumors, with two patients having an R0 resection, which indicates a microscopically margin-negative resection in which no gross or microscopic tumor remains in the tumor bed and three patients with a R1 resection, indicating microscopic residual tumor. One patient in the second cohort is currently ineligible for debulking surgery due to a medical complication unrelated to the study or the study drug. Of the five surgically treated and evaluable patients, one patient (20%) demonstrated a pathological complete response (pCR), two patients (40%) demonstrated a micro pathological response (microPR), and two patients (40%) demonstrated a macroPR. These data compare favorably to historical data, which indicate that pCRs are typically seen in less than 7% of patients receiving neoadjuvant chemotherapy followed by surgical resection. pCRs have been associated with a median overall survival of 72 months, which is more than three years longer than those who do not experience a pCR. In addition, microPRs are seen in approximately 30% of patients, and are associated with a median overall survival of 38 months.

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. We expect to enroll patients beginning in the first half of 2017. 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. 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) makes a sound 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 remarkable synergy between GEN-1 and Avastin® and potentially addresses the VEGF escape mechanisms associated with resistance to Avastin® therapy.

TheraPlas<sup>TM</sup> Technology Platform

TheraPlas<sup>TM</sup> 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<sup>TM</sup> 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<sup>TM</sup> by chemically modifying the low molecular weight polymer to improve its gene transfer activity without increasing toxicity. We believe that TheraPlas<sup>TM</sup> 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.

TheraSilence<sup>TM</sup> Technology Platform

TheraSilenceTM is a technology platform for the delivery of synthetically-generated inhibitory RNA (RNAi), such as small inhibitory RNAs (siRNAs), microRNAs, anti- microRNA mimics, microRNA mimics, and related molecules that can regulate protein expression at the transcript level by exploiting endogenous cell mechanisms. Inhibitory RNA-based therapies have the potential for targeting the disease-related genes with a high degree of specificity, including the target genes that have been widely identified as "non-druggable." The TheraSilence™ technology seeks to address the primary obstacle to nucleic acid-based therapeutics, which is the efficient delivery of RNAs to target cells. Specifically, a delivery system needs to be able to protect the RNAi from nuclease degredation, transfer the molecule across the cellular membranes and release the material so that it can be available to the endogenous RNA silencing machinery. We have developed proprietary, novel structures that we believe are able to interact with the RNAi molecules forming protective nanoparticles that can be readily taken up into cells. In addition, these systems are chemically flexible and amenable to attachment of tissue-targeted ligands, in-vivo stabilizing agents and other functional moieties which can tailor a formulation for a particular application and delivery modality. We believe that these features can provide high specificity for RNAi delivery to select tissue, enhance stability and reduce in-vivo toxicity. In-vivo proof-of-concept studies of our most advanced system have shown the ability to deliver RNAi molecules specifically to the pulmonary vascular following intravenous administration. Using this delivery system we have been able to show in mice that delivery of a siRNA molecule that targets anti-vascular endothelial receptor 2 (VEGF2), a protein that is critical for the growth of new blood vessels in tumors, can significantly inhibit lung tumor growth. Additionally, delivery of an anti-micro RNA molecule into rats with experimentally induced pulmonary arterial hypertension was able to normalize vascular remodeling that occurs in the lung and restore cardiac function that is compromised as a result of the disease. This suggests that this delivery system can effective deliver numerous potentially therapeutic molecular targets and may have application for the treatment of numerous lung diseases.

### Technology Development and Licensing Agreements

On August 9, 2016, we signed a long-term Technology Transfer, Manufacturing and Commercial Supply Agreement (the GEN-1 Agreement) with 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 in effect. 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.

Key provisions of the GEN-1 Agreement are as follows:

the GEN-1 Agreement has targeted unit costs for clinical supplies of GEN-1 that are substantially competitive with the Company's current suppliers;

once approved, the cost structure for GEN-1 will support rapid market adoption and significant gross margins across global markets;

Celsion will provide Hisun a certain percentage of China's commercial unit demand, and separately of global commercial unit demand, subject to regulatory approval;

Hisun and Celsion will commence technology transfer activities relating to the manufacture of GEN-1, including all studies required by CFDA for site approval; and

Hisun will collaborate with Celsion around the regulatory approval activities for GEN-1 with the CFDA. A local China partner affords Celsion access to accelerated CFDA review and potential regulatory exclusivity for the approved indication.

In June 2012, Celsion and Hisun signed a long-term commercial supply agreement for the production of ThermoDox®, Celsion's proprietary heat-activated liposomal encapsulation of doxorubicin. Hisun is one the largest manufacturers of chemotherapy agents globally, including doxorubicin. In July 2013, the ThermoDox® 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® and has obtained regulatory approvals to supply ThermoDox® 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®. 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® in primary liver cancer and other indications.

#### **Business Strategy**

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 product pipeline. This is intended to allow us to diversify the risks associated with our research and development expenditures. However, there can be no assurance that we will be able to develop and maintain a broad range of product candidates. 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 will assess our product pipeline and research and development priorities. 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 is extremely difficult to predict. Clinical development successes and failures can have a disproportionate positive or negative impact on our scientific and medical prospects, financial prospects, financial condition 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 a result of the uncertainties discussed above, 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 our research and development projects in a timely manner or to obtain positive results in our clinical trials, as well as any 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 and clinical trials or whether we are in a position to pursue manufacturing or commercialization activities, it is clear we will need significant additional capital to develop our product candidates through clinical development, manufacturing and commercialization. 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.

### **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. The information available on or through our website is not part of or incorporated by reference into, this prospectus and should not be relied upon.

### **Description of the Private Placement**

On June 13, 2016, we entered into a Securities Purchase Agreement, which was amended on June 20, 2016, (the Purchase Agreement) with certain investors, who are the selling stockholders identified in this prospectus under the caption "Selling Stockholders," pursuant to which we agreed to sell and issue, in a registered direct offering, an aggregate of 2,311,764 shares of our common stock at an offering price of \$1.36 per share. In addition, pursuant to the Purchase Agreement, we agreed to sell and issue Series B warrants (the "Pre-Funded Series B Warrants") to purchase 2,100,000 shares of our common stock (and the shares of common stock issuable upon exercise of the Pre-Funded Series B Warrants), in lieu of shares of common stock to the extent that the purchase of common stock would cause

the beneficial ownership of a purchaser, together with its affiliates and certain related parties, to exceed 9.99% of our common stock. In a concurrent private placement, we agreed to issue each purchaser, for each share of common stock and pre-funded warrant purchased in the registered direct offering, a Series A warrant to purchase 0.5 share of common stock, a Series C warrant to purchase one share of common stock and a Series D warrant to purchase 0.5 share of common stock. The Series D warrants will only become exercisable ratably upon the exercise of the Series C warrants. Upon the full exercise of each of the Series A, Series C and Series D warrants, an aggregate of 8,823,528 shares of common stock will be issued. The closing of the registered direct offering and the concurrent private placement occurred on June 16, 2016, in connection with which we received net proceeds of approximately \$5.5 million after deducting placement agent fees and other expenses payable by us.

The warrants have an exercise price of \$1.40 per share of our common stock. The Series A warrants may be exercised from time to time beginning on December 17, 2016 and expire on December 17, 2021. The Series C warrants may be exercised from time to time beginning on December 17, 2016 and expire on June 17, 2017. The Series D warrants only become exercisable ratably upon the exercise of the Series C warrants, may be exercised from time to time beginning on December 17, 2016 and expire on December 17, 2021. Subject to limited exceptions, a holder of a 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 4.99% of the number of shares of our common stock outstanding immediately after giving effect to such exercise; provided, however, that upon 61 days' prior notice to us, the holder may increase or decrease such beneficial ownership limitation not to exceed 9.99%.

We filed the registration statement on Form S-1, of which this prospectus is a part, to fulfill our contractual obligations under the Purchase Agreement to provide for the resale by these investors of up to 8,823,528 shares of common stock issuable upon exercise of the warrants. We agree to use commercially reasonable efforts to cause such registration to become effective 181 days following the date of issuance of the warrants and to keep such registration statement effective at all times until (a) the warrant shares are sold under such registration statement or pursuant to Rule 144 under the Securities Act, (b) the warrant shares may be sold without volume or manner-of-sale restrictions pursuant to Rule 144 under the Securities Act, and (c) the five-year anniversary of the date of the issuance of the warrants, whichever is the earliest to occur.

### The Offering

Shares of common stock offered by the selling stockholders:

8,823,528 shares of common stock issuable upon exercise of the outstanding common stock purchase warrants.

Shares of common stock outstanding before this offering:

26,060,573

Shares of common stock outstanding after completion of this offering, assuming full exercise of the common stock purchase warrants:

34,884,101

### **Terms of the Offering:**

The selling stockholders, including their transferees, donees, pledgees, assignees and successors-in-interest, may sell, transfer or otherwise dispose of any or all of the shares of common stock offered by this prospectus from time to time on The NASDAQ Capital Market or any other stock exchange, market or trading facility on which the shares are traded or in private transactions. The shares of common stock may be sold at fixed prices, at market prices prevailing at the time of sale, at prices related to prevailing market price or at negotiated prices.

Use of Proceeds:

All proceeds from the sale of shares of common stock issuable upon exercise of the outstanding common stock purchase warrants will be for the account of the selling stockholders. We will not receive any proceeds from the sale of common stock offered pursuant to this prospectus. However, we will receive proceeds upon any cash exercise of the common stock purchase warrants. See the section titled "Use of Proceeds" in this prospectus.

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 common stock purchase warrants and we do not intend to list the common stock purchase warrants on any exchange or other trading system.

**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 the other information included elsewhere in this prospectus for a discussion of factors you should carefully consider before deciding to invest in our securities.

The number of shares of our common stock shown above to be outstanding immediately before and after this offering is based on 26,060,573 shares outstanding as of October 27, 2016, and excludes, as of such date:

2,932,827 shares of our common stock subject to outstanding options having a weighted average exercise price of \$4.27 per share, and 65,000 shares of common stock subject to outstanding non-vested restricted stock awards with a weighted average grant date fair value of \$2.72;

535,925 shares of our common stock reserved for future issuance pursuant to our existing stock incentive plans;

1,850,000 shares of our common stock issuable upon the exercise of the Pre-Paid Series B Warrants, having an exercise price at \$0.01 per share, which were issued in connection with the registered direct offering that closed on June 16, 2016;

5,275,016 shares of our common stock issuable upon exercise of warrants outstanding as of October 27, 2016, having a weighted average exercise price of \$5.15 per share;

up to 670,070 shares of common stock held back by us at the closing of 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), and shares of common stock that we may be required to issue in the future, subject to the requisite approval of our stockholders, for earnout payments of up to \$30.4 million upon achievement, if any, of the earnout milestones set forth in the asset purchase agreement dated as of June 6, 2014, by and between EGEN and us; and

22,920 shares of our common stock held as treasury stock.

### **RISK FACTORS**

Investing in our securities involves a high degree of risk. You should carefully consider and evaluate all of the information contained in this prospectus and in the documents incorporated by reference in this prospectus before you decide to purchase our securities. In particular, you should carefully consider and evaluate the risks and uncertainties described in "Part I — Item 1A. Risk Factors" of our most recent Annual Report on Form 10-K, as updated by the additional risks and uncertainties set forth in our most recent Quarterly Report on Form 10-Q and in other filings we make with the SEC, as well as the risks and uncertainties described under the heading "Risk Factors" contained in the applicable prospectus or in any other document incorporated by reference into this prospectus. Any of the risks and uncertainties set forth therein could materially and adversely affect our business, results of operations and financial condition, which in turn could materially and adversely affect the trading price or value of our securities. As a result, you could lose all or part of your investment.

#### **USE OF PROCEEDS**

All shares of our common stock offered by this prospectus are being registered for the account of the selling stockholders. We will not receive any of the proceeds from the sale of these shares. We will receive proceeds from the cash exercise of the warrants which, if exercised in cash with respect to all of the 8,823,528 shares of common stock, would result in gross proceeds of \$12,352,939 to us. We will use any proceeds received by us from the cash exercise of the warrants for general corporate purposes, including research and development activities, capital expenditures and working capital. We may also use all or a portion of such proceeds to fund possible investments in, or acquisitions of, complementary businesses, technologies or products, but we currently have no agreements or commitments with respect to any investment or acquisition. We cannot predict when or if the warrants will be exercised, and it is possible that the warrants may expire and never be exercised.

#### MARKET INFORMATION FOR OUR COMMON STOCK

The following table sets forth the high and low reported closing sale prices on the NASDAQ Global Select Market for the periods indicated:

	High	Low
<b>2016 (THROUGH NOVEMBER 15, 2016)</b>		
First Quarter (January 1 – March 31, 2016)	\$ 1.93	\$ 1.08
Second Quarter (April 1 – June 30, 2016)	\$ 1.73	\$ 1.25
Third Quarter (July 1 – September 30, 2016)	\$ 1.34	\$ 1.20
Fourth Quarter (October 1 – November 15, 2016)	\$ 1.20	\$ 0.815

### **Dividend Policy**

We have never declared or paid any cash dividends on our common stock and do not currently anticipate declaring or paying cash dividends on our common stock in the foreseeable future. We currently intend to retain all of our future earnings, if any, to finance operations. Any future determination relating to our dividend policy will be made at the discretion of our board of directors and will depend on a number of factors, including future earnings, capital requirements, financial conditions, future prospects, contractual restrictions and other factors that our board of directors may deem relevant.

#### **Holders of Record**

As of September 30, 2016, there were approximately 13,600 holders of record of our common stock. The actual number of stockholders is greater than this number of record stockholders and includes stockholders who are beneficial owners but whose shares are held in street name by brokers and other nominees. This number of stockholders of record also does not include stockholders whose shares may be held in trust by other entities.

### DESCRIPTION OF CAPITAL STOCK

#### General

Our authorized capital stock consists of 112,600,000 shares of common stock, \$0.01 par value per share, and 100,000 shares of preferred stock, \$0.01 par value per share. As of October 27, 2016, there were 26,060,573 shares of our common stock outstanding and no shares of preferred stock outstanding.

The following summary description of our capital stock is based on the applicable provisions of the Delaware General Corporation Law, as amended (DGCL), and on the provisions of our certificate of incorporation, as amended (our certificate of incorporation), and our bylaws, as amended (our bylaws). This information is qualified entirely by reference to the applicable provisions of the DGCL, our certificate of incorporation and bylaws. For information on how to obtain copies of our certificate of incorporation and bylaws, which are exhibits to the registration statement of which this prospectus is a part, see the section titled "Where You Can Find Additional Information" in this prospectus.

### **Common Stock**

Holders of common stock to be registered hereunder are entitled to one vote for each share held of record on all matters submitted to a vote of stockholders and do not have cumulative voting rights. Subject to any preferential rights of any outstanding preferred stock, holders of common stock are entitled to receive ratably such dividends, if any, as may be declared from time to time by the board of directors of the Company (our board) out of funds legally available therefor. In the event of a dissolution, liquidation or winding-up of the Company, holders of common stock are entitled to share ratably in all assets remaining after payment of liabilities and any preferential rights of any outstanding preferred stock.

Holders of common stock have no preemptive or conversion rights or other subscription rights. There are no redemption or sinking fund provisions applicable to the common stock. All outstanding shares of common stock are fully paid and non-assessable. The rights, preferences and privileges of the holders of common stock are subject to, and may be adversely affected by, the rights of the holders of shares of any series of preferred stock which may be designated and issued in the future.

### **Preferred Stock**

Pursuant to our certificate of incorporation, our board has the authority, without further action by the stockholders (unless such stockholder action is required by applicable law or NASDAQ rules), to designate and issue shares of preferred stock in one or more series, to establish from time to time the number of shares to be included in each such series, to fix the designations, powers (including voting), privileges, preferences and relative participating, optional or other rights, if any, of the shares of each such series and the qualifications, limitations or restrictions thereof and to increase or decrease the number of shares of any such series, but not below the number of shares of such series then outstanding.

The DGCL provides that the holders of preferred stock will have the right to vote separately as a class or, in some cases, as a series on an amendment to our certificate of incorporation if the amendment would change the par value or, unless our certificate of incorporation provides otherwise, the number of authorized shares of the class or the powers, preferences or special rights of the class or series so as to adversely affect the class or series, as the case may be. This right is in addition to any voting rights that may be provided in the applicable certificate of designation.

Our board may authorize the issuance of preferred stock with voting or conversion rights that could adversely affect the voting power or other rights of the holders of our common stock or other securities. Preferred stock could be issued quickly with terms designed to delay or prevent a change in control of our company or make removal of management more difficult. Additionally, the issuance of preferred stock may have the effect of decreasing the market price of our common stock.

Anti-Takeover Considerations and Special Provisions of Our Certificate of Incorporation, Our Bylaws and the Delaware General Corporation Law

### Certificate of Incorporation and Bylaws

A number of provisions of our certificate of incorporation and bylaws concern matters of corporate governance and the rights of our stockholders. Provisions that grant our board the ability to issue shares of preferred stock and to set the voting rights, preferences and other terms thereof may discourage takeover attempts that are not first approved by our board, including takeovers that may be considered by some stockholders to be in their best interests, such as those attempts that might result in a premium over the market price for the shares held by stockholders. Certain provisions could delay or impede the removal of incumbent directors even if such removal would be beneficial to our stockholders, such as the classification of our board and the lack of cumulative voting. Since our board has the power to retain and discharge our officers, these provisions could also make it more difficult for existing stockholders or another party to effect a change in management.

These provisions may have the effect of deterring hostile takeovers or delaying changes in our control or in our management. These provisions are intended to enhance the likelihood of continued stability in the composition of our board and in the policies they implement and to discourage certain types of transactions that may involve an actual or threatened change of our control. These provisions are designed to reduce our vulnerability to an unsolicited acquisition proposal. The provisions also are intended to discourage certain tactics that may be used in proxy fights. However, such provisions could have the effect of discouraging others from making tender offers for our shares and, as a consequence, they also may inhibit fluctuations in the market price of our shares that could result from actual or rumored takeover attempts.

These provisions also could discourage or make more difficult a merger, tender offer or proxy contest, even if they could be favorable to the interests of stockholders, and could potentially depress the market price of our common stock. Our board believes that these provisions are appropriate to protect our interests and the interests of our stockholders.

Classification of Board; No Cumulative Voting. Our certificate of incorporation and bylaws provide for our board to be divided into three classes, with staggered three-year terms. Only one class of directors is elected at each annual meeting of our stockholders, with the other classes continuing for the remainder of their respective three-year terms. Because our stockholders do not have cumulative voting rights, our stockholders representing a majority of the shares of common stock outstanding will be able to elect all of our directors due to be elected at each annual meeting of our stockholders.

Meetings of and Actions by Stockholders. Our bylaws provide that annual meetings of our stockholders may take place at the time and place designated by our board. A special meeting of our stockholders may be called at any time by our board, the chairman of our board or the president. Our bylaws provide that (i) our board can fix separate record dates for determining stockholders entitled to receive notice of a stockholder meeting and for determining stockholders entitled to vote at the meeting; (ii) we may hold a stockholder meeting by means of remote communications; (iii) any stockholder seeking to have the stockholders authorize or take corporate action by written consent shall, by written notice to the secretary of the Company, request that the board fix a record date and the board shall adopt a resolution fixing the record date in all events within ten calendar days after a request is received; and (iv) a written consent of stockholders shall not be effective unless a written consent signed by a sufficient number of stockholders to take such action is received by us within 60 calendar days of the earliest dated written consent received.

Advance Notice Requirements for Stockholder Proposals and Director Nominations. Our bylaws provide that stockholders seeking to bring business before an annual meeting of stockholders or to nominate candidates for election as directors at an annual meeting of stockholders must provide timely notice in writing. To be timely, a stockholder's notice must be delivered to, or mailed and received by, the secretary of the Company at our principal executive offices not later than the close of business on the 90th calendar day, nor earlier than the close of business on the 120th calendar day in advance of the date specified in the Company's proxy statement released to stockholders in connection with the previous year's annual meeting of stockholders. If the date of the annual meeting is more than 30 calendar days before or after such anniversary date, notice by the stockholder to be timely must be so not earlier than

the close of business on the 120th calendar day in advance of such date of annual meeting and not later than the close of business on the later of the 90th calendar day in advance of such date of annual meeting or the tenth calendar day following the date on which public announcement of the date of the meeting is made. In no event shall the public announcement of an adjournment or postponement of an annual meeting commence a new time period (or extend any time period) for the giving of an advance notice by any stockholder. Any stockholder that proposes director nominations or other business must be a stockholder of record at the time the advance notice is delivered by such stockholder to us and entitled to vote at the meeting. Our bylaws also specify requirements as to the form and content of a stockholder's notice. These provisions may preclude stockholders from bringing matters before an annual meeting of stockholders or from making nominations for the election of directors at an annual meeting of stockholders. Unless otherwise required by law, any director nomination or other business shall not be made or transacted if the stockholder (or a qualified representative of the stockholder) does not appear at the meeting to present the director nominee or other proposed business.

Filling of Board Vacancies. Our certificate of incorporation and bylaws provide that the authorized size of our board shall be determined by the board by board resolution from time to time and that our board has the exclusive power to fill any vacancies and newly created directorships resulting from any increase in the authorized number of directors and the stockholders do not have the power to fill such vacancies. Vacancies in our board and newly created directorships resulting from any increase in the authorized number of directors on our board may be filled by a majority of the directors remaining in office, even though that number may be less than a quorum of our board, or by a sole remaining director. A director so elected to fill a vacancy shall serve for the remaining term of the predecessor he or she replaced and until his or her successor is elected and has qualified, or until his or her earlier resignation, removal or death.

Amendment of the Certificate of Incorporation. Our certificate of incorporation may be amended, altered, changed or repealed at a meeting of our stockholders entitled to vote thereon by the affirmative vote of a majority of the outstanding stock entitled to vote thereon and a majority of the outstanding stock of each class entitled to vote thereon as a class, in the manner prescribed by the DGCL.

Amendment of the Bylaws. Our bylaws may be amended or repealed, or new bylaws may be adopted, by either our board or the affirmative vote of at least 66 2/3 percent of the voting power of our outstanding shares of capital stock.

#### Section 203 of the Delaware General Corporation Law

We are subject to Section 203 of the DGCL, which prohibits a Delaware corporation from engaging in any business combination with any interested stockholder for a period of three years after the date that such stockholder became an interested stockholder, with the following exceptions:

before such date, the board of directors of the corporation approved either the business combination or the transaction that resulted in the stockholder becoming an interested stockholder;

upon completion of the transaction that resulted in the stockholder becoming an interested stockholder, the interested stockholder owned at least 85 percent of the voting stock of the corporation outstanding at the time the transaction began, excluding for purposes of determining the voting stock outstanding (but not the outstanding voting stock owned by the interested stockholder) those shares owned (i) by persons who are directors and also officers and (ii) pursuant to employee stock plans in which employee participants do not have the right to determine confidentially whether shares held subject to the plan will be tendered in a tender or exchange offer; and

on or after such date, the business combination is approved by the board of directors and authorized at an annual or special meeting of the stockholders, and not by written consent, by the affirmative vote of at least 66 2/3 percent of the outstanding voting stock that is not owned by the interested stockholder.

In general, Section 203 defines a business combination to include the following:

any merger or consolidation involving the corporation and the interested stockholder;

any sale, lease, transfer, pledge or other disposition of ten percent or more of the assets of the corporation to or with the interested stockholder;

subject to certain exceptions, any transaction that results in the issuance or transfer by the corporation of any stock of the corporation to the interested stockholder;

any transaction involving the corporation that has the effect of increasing the proportionate share of the stock or any class or series of the corporation beneficially owned by the interested stockholder; and

the receipt by the interested stockholder of the benefit of any loss, advances, guarantees, pledges or other financial benefits by or through the corporation.

In general, Section 203 of the DGCL defines an "interested stockholder" as an entity or person who, together with the entity's or person's affiliates and associates, beneficially owns, or is an affiliate of the corporation and within three years prior to the time of determination of interested stockholder status did own, 15 percent or more of the outstanding voting stock of the corporation.

A Delaware corporation may "opt out" of these provisions with an express provision in its certificate of incorporation. We have not opted out of these provisions, which may as a result, discourage or prevent mergers or other takeover or change of control attempts of us.

### **Transfer Agent and Registrar**

The transfer agent and registrar for our common stock is American Stock Transfer & Trust Company, LLC (AST), located at 6201 15th Avenue, Brooklyn, New York 11219. AST's phone number is (800) 937-5449.

### **NASDAQ Capital Market Listing**

Our common stock is listed on The NASDAQ Capital Market under the symbol "CLSN."

### SELLING STOCKHOLDERS

This prospectus covers an aggregate of up to 8,823,528 shares of our common stock that may be sold or otherwise disposed of by the selling stockholders. Such shares are issuable to the selling stockholders upon the exercise of the common stock purchase warrants we issued to the selling stockholders in a private placement transaction.

The following table sets forth certain information with respect to each selling stockholder, including (i) the shares of our common stock beneficially owned by the selling stockholder prior to this offering, (ii) the number of shares being offered by the selling stockholder pursuant to this prospectus and (iii) the selling stockholder's beneficial ownership after completion of this offering, assuming that all of the shares covered hereby (but none of the other shares, if any, held by the selling stockholders) are sold. The registration of the shares of common stock issuable to the selling stockholders upon the exercise of the warrants does not necessarily mean that the selling stockholders will sell all or any of such shares.

The table is based on information supplied to us by the selling stockholders, with beneficial ownership and percentage ownership determined in accordance with the rules and regulations of the SEC and include voting or investment power with respect to shares of stock. This information does not necessarily indicate beneficial ownership for any other purpose. In computing the number of shares beneficially owned by a selling stockholder and the percentage ownership of that selling stockholder, shares of common stock subject to warrants held by that selling stockholder that are exercisable as of October 28, 2016, or exercisable within 60 days after October 28, 2016, are deemed outstanding. Such shares, however, are not deemed outstanding for the purposes of computing the percentage ownership of any other person. The percentage of beneficial ownership after this offering is based on 26,060,573 shares outstanding on October 28, 2016.

The registration of these shares of common stock does not mean that the selling stockholders will sell or otherwise dispose of all or any of those securities. The selling stockholders may sell or otherwise dispose of all, a portion or none of such shares from time to time. We do not know the number of shares, if any, that will be offered for sale or other disposition by any of the selling stockholders under this prospectus. Furthermore, the selling stockholders may have sold, transferred or disposed of the shares of common stock covered hereby in transactions exempt from the registration requirements of the Securities Act since the date on which we filed this prospectus.

To our knowledge and except as noted below, none of the selling stockholders has, or within the past three years has had, any position, office or other material relationship with us or any of our predecessors or affiliates.

**Beneficial Ownership Before This Offering** 

**Beneficial Ownership After This Offering** 

Number of Shares Owned	Shares Underlying Warrants Offered Hereby <sup>(5)</sup>	Number of Shares Owned	Percentage of Outstanding Shares
1,901,957	(3)5,882,352	1,901,957	(3)7.29%
704,100	(4)2,941,176	704,100	(4)2.70%
	Owned 1,901,957	Owned  Warrants Offered Hereby <sup>(5)</sup> 1,901,957  (3)5,882,352	Number of Shares Owned  Warrants Offered Hereby <sup>(5)</sup> Number of Shares Owned  1,901,957  (3)5,882,352  1,901,957

- This table and the information in the notes below are based upon information supplied by the selling stockholders, including reports and amendments thereto filed with the SEC on Schedule 13G.
  - Sabby Management, LLC is the investment manager of Sabby Healthcare Master Fund, Ltd. and Sabby Volatility Warrant Master Fund, Ltd. and shares voting and investment power with respect to these shares in this capacity. As manager of Sabby Management, LLC, Hal Mintz also shares voting and investment power on behalf of each selling stockholder. Each of Sabby Management, LLC and Hal Mintz disclaims beneficial ownership over the securities
- (2) listed except to the extent of their pecuniary interest therein. The address of principal business office of each of Sabby Healthcare Master Fund, Ltd., Sabby Volatility Warrant Master Fund, Ltd., Sabby Management, LLC and Hal Mintz is 10 Mountainview Road, Suite 205, Upper Saddle River, New Jersey 07458. Neither Sabby Healthcare Master Fund, Ltd. nor Sabby Volatility Warrant Master Fund, Ltd. is a registered broker-dealer or an affiliate of a registered broker-dealer.
  - Based on information supplied to us on October 28, 2016 and excluding (i) 5,882,352 shares of common stock, issuable upon exercise of the common stock purchase warrants exercisable at \$1.40 per share, being offered for resale pursuant to this prospectus, the terms of which warrants include a blocker provision that restricts exercise to the extent the securities beneficially owned by the selling stockholder and its affiliates would represent beneficial
- ownership in excess of 4.99% of shares of our common stock outstanding immediately after giving effect to such exercise, subject to the holder's option, on 61 days' prior notice to us, to increase or decrease this beneficial ownership limitation not to exceed 9.99% of shares of our common stock and (ii) 142,382 shares of common stock upon exercise of the Pre-Funded Series B Warrants, which may only be exercised to the extent beneficial ownership by Sabby Healthcare Master Fund, Ltd. and Sabby Volatility Warrant Master Fund, Ltd., in the aggregate, does not exceed 9.99% of our common stock. See the section titled "Description of the Private Placement" in this prospectus. Based on information supplied to us on October 28, 2016 and excluding 2,941,176 shares of common stock, issuable upon exercise of the common stock purchase warrants exercisable at \$1.40 per share, being offered for resale pursuant to this prospectus. The terms these warrants include a blocker provision that restricts exercise to the
- (4) extent the securities beneficially owned by the selling stockholder and its affiliates would represent beneficial ownership in excess of 4.99% of shares of our common stock outstanding immediately after giving effect to such exercise, subject to the holder's option, on 61 days' prior notice to us, to increase or decrease this beneficial ownership limitation not to exceed 9.99% of shares of our common stock.
  - The actual number of shares of common stock offered hereby and included in the registration statement of which this prospectus forms a part includes, in accordance with Rule 416 under the Securities Act, such indeterminate
- (5) number of additional shares of our common stock as may become issuable in connection with any proportionate adjustment for any stock splits, stock combinations, stock dividends, recapitalizations or similar events with respect to common stock.

#### PLAN OF DISTRIBUTION

The selling stockholders, including their transferees, donees, pledgees, assignees and successors-in-interest, may sell, transfer or otherwise dispose of any or all of the shares of common stock offered by this prospectus from time to time on The NASDAQ Capital Market or any other stock exchange, market or trading facility on which the shares are traded or in private transactions. These dispositions may be at fixed prices, at market prices prevailing at the time of sale, at prices related to prevailing market price or at negotiated prices. The selling stockholders may use any one or more of the following methods when selling shares:

ordinary brokerage transactions and transactions in which the broker-dealer solicits purchasers;

block trades in which the broker-dealer will attempt to sell the shares as agent but may position and resell a portion of the block as principal to facilitate the transaction;

purchases by a broker-dealer as principal and resale by the broker-dealer for its account;

an exchange distribution in accordance with the rules of the applicable exchange;

privately negotiated transactions;

broker-dealers may agree with the selling shareholder to sell a specified number of such shares at a stipulated price per share;

a combination of any such methods of sale;

through the writing or settlement of options or other hedging transactions, whether through an options exchange or otherwise; or

any other method permitted pursuant to applicable law.

The selling stockholders may also sell shares under Rule 144 under the Securities Act, if available, rather than under this prospectus.

Broker-dealers engaged by the selling stockholders may arrange for other brokers-dealers to participate in sales. Broker-dealers may receive commissions or discounts from the selling stockholders or, if any broker-dealer acts as agent for the purchaser of shares, from the purchaser in amounts to be negotiated. The selling stockholders does not expect these commissions and discounts relating to its sales of shares to exceed what is customary in the types of transactions involved.

The selling stockholder may enter into hedging transactions with broker-dealers or other financial institutions, which may in turn engage in short sales of the common stock in the course of hedging the positions they assume. The selling shareholders may also sell shares of our common stock short and deliver these securities to close out its short positions, or loan or pledge the common stock to broker-dealers that in turn may sell these securities. The selling shareholders may also enter into option or other transactions with broker-dealers or other financial institutions or the creation of one or more derivative securities which require the delivery to such broker-dealer or other financial institution may resell pursuant to this prospectus, as supplemented or amended to reflect such transaction.

The selling stockholders and any broker-dealers or agents that are involved in selling the shares may be deemed to be "underwriters" within the meaning of the Securities Act in connection with such sales. In such event, any commissions received by such broker-dealers or agents and any profit on the resale of the shares purchased by them may be deemed to be underwriting commissions or discounts under the Securities Act. Each selling stockholder has informed us that it does not have any agreement or understanding, directly or indirectly, with any person to distribute the common stock.

Because the selling stockholders may be deemed to be an "underwriter" within the meaning of the Securities Act, it will be subject to the prospectus delivery requirements of the Securities Act. In addition, any securities covered by this prospectus which qualify for sale pursuant to Rule 144 under the Securities Act may be sold under Rule 144 rather than under this prospectus. The selling stockholders have advised us that there is no underwriter or coordinating broker acting in connection with the proposed sale of the resale securities by the selling stockholders.

The shares will be sold only through registered or licensed brokers or dealers if required under applicable state securities laws. In addition, in certain states, the shares may not be sold unless they have been registered or qualified for sale in the applicable state or an exemption from the registration or qualification requirement is available and is complied with.

Under applicable rules and regulations under the Exchange Act, any person engaged in the distribution of the resale shares may not simultaneously engage in market making activities with respect to our common stock for the applicable restricted period, as defined in Regulation M, prior to the commencement of the distribution. In addition, the selling stockholders will be subject to applicable provisions of the Exchange Act and the rules and regulations thereunder, including Regulation M, which may limit the timing of purchases and sales of shares of our common stock by the selling stockholders or any other person. We will make copies of this prospectus available to the selling stockholders and have informed the selling stockholders of the need to deliver a copy of this prospectus to each purchaser at or prior to the time of the sale (including by compliance with Rule 172 under the Securities Act).

We have agreed to use commercially reasonable efforts to keep the registration statement continuously effective at all times until (a) the warrant shares are sold under such registration statement or pursuant to Rule 144 under the Securities Act, (b) the warrant shares may be sold without volume or manner-of-sale restrictions pursuant to Rule 144 under the Securities Act, and (c) the five-year anniversary of the date of the issuance of the warrants, whichever is the earliest to occur. The shares will be sold only through registered or licensed brokers or dealers if required under applicable state securities laws. In addition, in certain states, the shares may not be sold unless they have been registered or qualified for sale in the applicable state or an exemption from the registration or qualification requirement is available and is complied with.

We are required to pay certain fees and expenses in connection with the registration of the shares of common stock issuable upon exercise of the warrant. We have agreed to indemnify the selling stockholders against certain losses, claims, damages and liabilities, including liabilities under the Securities Act.

We will not receive any proceeds from the sale of the shares by the selling stockholders.

### **LEGAL MATTERS**

The validity of the shares of our common stock being offered by this prospectus will be passed upon for us by Sidley Austin LLP, Palo Alto, California.

### **EXPERTS**

Stegman & Company, an independent registered public accounting firm, has audited our financial statements included in our Annual Report on Form 10-K, as amended by Amendment No. 1 on Form 10-K/A, for the year ended December 31, 2015, as set forth in their report, which is incorporated by reference in this prospectus. Our financial statements are incorpor