Celsion CORP
Form S-1/A
February 13, 2017
As filed with the Securities and Exchange Commission on February 13, 2017

Registration No. 333-215321

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

Pre-Effective Amendment No. 2

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**
(State or other jurisdiction of incorporation or organization)	(Primary Standard Industrial Classification Code Number)	(I.R.S. Employer 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

Jeffrey Fessler, Esq.
Sheppard, Mullin, Richter & Hampton, LLP
30 Rockefeller Plaza
New York, New York 10112
(212) 653-8700

Approximate date of commencement of proposed sale to the public:

As soon as practicable after the effective date of this registration statement.

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 (Do not check if a smaller reporting company)	Smaller reporting company

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CALCULATION OF REGISTRATION FEE

Title of each class of securities to be registered	**Proposed maximum aggregate offering price(1) (2)**	**Amount of registration fee(3)**
Common Stock, $0.01 par value per share	$ 5,900,000	
Warrants to purchase shares of common stock	$ 133,333	
Shares of common stock issuable upon exercise of the Warrants	$ 6,000,000	
Pre-funded Warrants	$ 1,966,667	
Total:	$ 14,000,000	$ 1,622.60

(1) Estimated solely for the purpose of calculating the amount of the registration fee in accordance with Rule 457(o) under the Securities Act of 1933, as amended.

(2) Pursuant to Rule 416, the securities being registered hereunder include such indeterminate number of

additional securities as may be issuable to prevent dilution resulting from stock splits, stock dividends or similar transactions.

(3) The registration fees were previously paid.

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 preliminary prospectus is not complete and may be changed. These securities may not be sold until the registration statement filed with the Securities and Exchange Commission is effective. This preliminary 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 FEBRUARY 13, 2017

Preliminary Prospectus

13,333,334 Shares of Common Stock

4,444,444 Pre-Funded Warrants to Purchase Shares of Common Stock

Base Warrants to Purchase 13,333,333 Shares of Common Stock

We are offering shares of our common stock and base warrants to purchase shares of our common stock (and the shares of common stock issuable upon the exercise of the base warrants). Each share of our common stock is being sold together with a base warrant to purchase 0.75 of a share of our common stock for a public offering price of $ per share and $0.01 per base warrant. Each base warrant will have an exercise price per share equal to $, will be immediately exercisable and will expire on the fifth anniversary of the original issuance date. The shares of our common stock and base warrants are immediately separable and will be issued separately, but will be purchased together in this offering.

We are also offering to those purchasers whose purchase of shares of our common stock in this offering would result in the purchaser, together with its affiliates and certain related parties, beneficially owning more than 4.99% of our outstanding common stock following the consummation of this offering, the opportunity to purchase, if they so choose, up to 4,444,444 pre-funded warrants (and the shares of common stock issuable upon the exercise of the pre-funded warrants), in lieu of the shares of our common stock that would result in ownership in excess of 4.99%, pre-funded warrants to purchase shares of our common stock and base warrants to purchase shares of our common stock. Each pre-funded warrant is being sold together with the same base warrant described above being sold with each share of common stock. Each pre-funded warrant will have an exercise price of $0.01 per share and will be immediately exercisable until the pre-funded warrant is exercised in full. The pre-funded warrants and base warrants are immediately separable and will be issued separately, but will be purchased together in this offering. There can be

no assurance that we will sell any of the pre-funded warrants being offered. For each pre-funded warrant sold, the number of shares of common stock we are offering will be decreased on a one-for-one basis. Because a base warrant to purchase 0.75 of a share of our common stock is being sold together in this offering with each share of common stock and, in the alternative, each pre-funded warrant, the number of base warrants sold in this offering will not change as a result of a change in the mix of the shares of our common stock and pre-funded warrants sold.

Our common stock is listed on The NASDAQ Capital Market ("NASDAQ") under the symbol "CLSN." On February 10, 2017, the last reported closing sale price of our common stock on NASDAQ was $0.45 per share. There is no established trading market for the base warrants or the pre-funded warrants. We do not plan on applying to list the base warrants or the pre-funded warrants on NASDAQ, any national securities exchange or any other nationally recognized trading system. Without an active trading market, the liquidity of the base warrants and the pre-funded warrants will be limited.

Investing in our securities involves a high degree of risk. Before making an investment decision, please read "Risk Factors" on page 14 of this prospectus.

Neither the Securities and Exchange Commission (the "SEC") 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.

	Per Share and Related Base Warrant	Per Pre-funded Warrant and Related Base Warrant	Total
Public offering price[1]	$	$	$
Placement agents' fees	$	$	$
Proceeds, before expenses, to us[2]	$	$	$

(1) The public offering price is $ per share of common stock and $0.01 per base warrant to purchase a share of common stock.

(2) We estimate the total expenses of this offering payable by us, excluding the placement agents' fees, will be approximately $350,000. See “Plan of Distribution” on page 50 of this prospectus for a description of the compensation payable to the placement agent.

We have retained H.C. Wainwright & Co., LLC as our exclusive lead placement agent and Maxim Group LLC as co-placement agent to use their reasonable best efforts to solicit offers to purchase the securities in this offering. The placement agents have no obligation to buy any of the securities from us or to arrange for the purchase or sale of any specific number or dollar amount of the securities. Because there is no minimum offering amount required as a condition to closing in this offering, the actual public offering amount, placement agent fees, and proceeds to us, if any, are not presently determinable and may be substantially less than the total maximum offering amounts set forth above.

We anticipate that delivery of the shares and warrants against payment will be made on or about , 2017.

Lead Placement Agent

Rodman & Renshaw

a unit of H.C. Wainwright & Co.

Co-Placement Agent

Maxim Group LLC

The date of this prospectus is , 2017.

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We have not, and the placement agents have not, authorized anyone to provide any information or to make any representations other than those contained in this prospectus or in any free writing prospectuses prepared by or on behalf of us or to which we have referred you. We take no responsibility for, and can provide no assurance as to the reliability of, any other information that others may give you. This prospectus is an offer to sell only the shares offered hereby, and only under circumstances and in jurisdictions where it is lawful to do so. The information contained in this prospectus or in any applicable free writing prospectus is current only as of its date, regardless of its time of delivery or any sale of our securities. Our business, financial condition, results of operations and prospects may have changed since that date.

For investors outside the United States: We have not, and the placement agents have not, done anything that would permit this offering or possession or distribution of this prospectus in any jurisdiction where action for that purpose is required, other than in the United States. Persons outside the United States who come into possession of this prospectus must inform themselves about, and observe any restrictions relating to, the offering of the securities and the distribution of this prospectus outside the United States.

ABOUT THIS PROSPECTUS

This prospectus is an offer to sell only the securities offered hereby, but only under circumstances and in jurisdictions where it is lawful to do so. The information contained in or incorporated by reference in this prospectus is accurate only as of its date regardless of the time of delivery of this prospectus or of any sale of common stock, pre-funded warrants or base warrants.

This prospectus is part of a registration statement on Form S-1 that we filed with the Securities and Exchange Commission (the "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. 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 More Information" and "Information Incorporated By Reference" before making an investment decision. You should rely only on the information contained in 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® and ThermoDox® contained in this prospectus are trademarks, registered trademarks or service marks of Celsion Corporation or its subsidiary in the United States and certain other countries. This document may also contain references to trademarks and service marks of other companies that are the property of their respective owners.

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, September 8, 2016, December 20, 2016 and December 23, 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 NASDAQ; 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 dosage form of doxorubicin based on a heat-activated liposomal platform technology, currently in Phase III development for the treatment of primary liver cancer. Our pipeline also includes GEN-1, a DNA-based immunotherapy in clinical development for the localized treatment of ovarian cancer and pre-clinical development for brain cancer. GEN-1 is based on a platform technology for the development of treatments for those suffering with difficult-to-treat forms of cancer, using novel nucleic acid-based immunotherapies and other anti-cancer DNA or RNA therapies. We are working to develop and commercialize more efficient, effective and targeted oncology therapies based on our technologies, with the goal of developing 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 OPTIMA Study

On February 24, 2014, we announced that the United States Food and Drug Administration (the "FDA"), after its customary 30-day review period, provided clearance for the OPTIMA Study, which is a pivotal, double-blind, placebo-controlled Phase III trial of ThermoDox®, in combination with standardized RFA, for the treatment of

primary liver cancer. The trial design of the OPTIMA Study is based on the comprehensive analysis of data from an earlier clinical trial called the HEAT Study, which is described below. We launched the OPTIMA Study in the first half of 2014. The OPTIMA Study was designed with extensive input from globally recognized hepatocellular carcinoma ("HCC") researchers and 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 countries, 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 overall survival ("OS"), and the secondary endpoints are progression free survival and safety. The statistical plan calls for two interim efficacy analyses by an independent Data Monitoring Committee.

On December 16, 2015, we announced that we had received the clinical trial application approval from the China Food and Drug Administration (the "CFDA") to conduct the OPTIMA Study in China. This clinical trial application approval will 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 OPTIMA Study represents an evaluation of ThermoDox® in combination with a first line therapy, RFA, for newly diagnosed, intermediate stage HCC patients. HCC incidence globally is approximately 850,000 new cases. The RFA addressable percentage of newly diagnosed patients is approximately 30%. The OPTIMA Study is supported with a convincing hypothesis developed from an overall survival analysis of a large subgroup of patients from the HEAT Study.

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 progression free survival ("PFS") data from the HEAT Study were announced in January 2013, with each data set demonstrating progressive improvement in clinical benefit and statistical significance. On August 15, 2016, the Company announced updated results from its final retrospective OS analysis of the data from the HEAT Study. These results demonstrated that in a large, well bounded, subgroup of patients with a single lesion (n=285, 41% of the HEAT Study patients), treatment with a combination of ThermoDox® 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 a single lesion (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 intent-to-treat Chinese patient cohort further confirms the importance of RFA heating time as 72% of patients in this large patient cohort in China received an optimized RFA treatment.

While this information should be viewed with caution since it is based on a retrospective analysis of a subgroup, we also conducted additional analyses that further strengthens the evidence for the HEAT Study sub-group. We commissioned an independent computational model at the University of South Carolina Medical School. The results unequivocally indicate that longer RFA heating times correlate with significant increases in doxorubicin concentration around the RFA treated tissue. We conducted a prospective preclinical study in 21 pigs using two different manufacturers of RFA and human equivalent doses of ThermoDox® that clearly support the relationship between increased heating duration and doxorubicin concentrations.

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

The HEAT Study

On January 31, 2013, the Company announced that the HEAT Study, ThermoDox® in combination with RFA, did not meet the primary endpoint, PFS, of a Phase III clinical trial enrolling 701 patients with primary liver cancer. This determination was made after conferring with the HEAT Study independent Data Monitoring Committee, that the HEAT Study did not meet the goal of demonstrating a clinically meaningful improvement in progression free survival. 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 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®.

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 2017 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, pursuant to Section 4(a)(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™ technology acquired from EGEN in the acquisition.

Our obligations to make the earnout payments will terminate on the seventh anniversary of the closing date.

In the acquisition, we purchased GEN-1, a DNA-based immunotherapy for the localized treatment of ovarian and brain cancers, and 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™ 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 OVATION Study at four clinical sites at the University of Alabama at Birmingham, Oklahoma University Medical Center, Washington University in St. Louis and the Medical College of Wisconsin. In February 2017, we announced the completion of enrollment of the first cohort of patients in the OVATION Study. The OVATION Study will continue into 2017 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.

During 2016, we announced data from the first three 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 2017 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 three cohorts each enrolled three patients. Enrollment in the fourth cohort 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:

Totality of Results in the First Three Cohorts

Of the first nine patients dosed, one patient demonstrated a complete response (“CR”), five patients demonstrated partial response (“PR”) and three patients demonstrated stable disease (“SD”), as measured by RECIST criteria. This translates to a 100% disease control rate (“DCR”) and 66% objective response rate (“ORR”).

Eight patients had successful resections of their tumors, with four 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 had an R2, indicating macroscopic residual tumor. One patient in the second cohort was ineligible for debulking surgery due to a medical complication unrelated to the study or the study drug.

Of the eight surgically treated and evaluable patients, one patient demonstrated a complete pathological response (“cPR”), three patients demonstrated a micro pathological response (“microPR”), and four patients demonstrated a macroPR. These data compare favorably to historical data, which indicate that cPRs are typically seen in less than 7% of patients receiving neoadjuvant chemotherapy followed by surgical resection. cPRs 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 cPR. In addition, microPRs are seen in approximately 30% of patients, and are associated with a median overall survival of 38 months.

Seven patients who completed treatment follow-up experienced a dramatic (greater than 90%) drop in their CA-125 protein levels as of their most recent study visit. CA-125 is used to monitor certain cancers during and after treatment. CA-125 is present in greater concentrations in ovarian cancer cells than in other cells. A 50% reduction in CA-125 levels is considered meaningful. Six patients maintained CA-125 levels below the standard cutoff level of 35 U/mL.

Top Line Translational Data from First Two Cohorts

Celsion also reported initial translational data from the first two cohorts of patients. Tumor and blood samples collected before the start of the neoadjuvant chemotherapy ("NACT") and after the completion of GEN-1 treatment at debulking surgery are being analyzed for immune cell populations. Top line data demonstrates intriguing immunological changes in the tumor that are consistent with the activation of the immune system. Specifically,

- In tumor tissue, there was an increase in cytotoxic CD8+ T-cell density in three out of four evaluable patients at debulking surgery. There was a decrease in immunosuppressive FoxP3+ T-cells in two out of those 4 patients. The ratio of CD8+/FoxP3+ cells was increased in all four evaluable patients. High tumor infiltrating CD8+ T-cell density, low FoxP3+ T-cell density or high CD8+/FoxP3+ ratio demonstrate a potential shift in tumor environment to favoring immune stimulation following NACT + GEN-1 therapy. For the remaining two patients the post-treatment tumor tissue was not available. In one of those two patients there was complete pathological response hence no tumor tissue was present to provide a post-treatment comparison. In the other patient the debulking surgery was not performed due to disease related complications.
- In plasma samples, there was no significant change in T-cell density following the treatment. The density of myeloid derived suppressor cells that are associated with immunosuppression in ovarian cancer were either decreased or did not increase in post-treatment samples.

Additional immune analysis of biological tissue including cytokine ELISA from the first two patient cohorts and a complete analysis of the two higher dose cohorts is in progress.

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 2017 following the completion of the OVATION Study. 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™ Technology Platform

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

TheraSilence™ 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 8, 2016, we signed a 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.

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.

Recent Developments

On December 15, 2016, we received a letter from NASDAQ indicating that the closing bid price of our common stock fell below $1.00 per share for the previous 30 consecutive business days, and that we are therefore not in compliance with the minimum bid price requirement for continued inclusion on The NASDAQ Capital Market and our common stock could be subject to delisting from The NASDAQ Capital Market. We can regain compliance with the $1.00 minimum bid listing requirement if the closing bid price of our common stock is at least $1.00 per share for a minimum of ten consecutive business days over the next 180 calendar days, or until June 13, 2017. If we do not regain compliance during the next 180 calendar days, we may be eligible for additional time to regain compliance.

On December 23, 2016, we issued and sold approximately 5.1 million shares of our common stock to several institutional investors for an aggregate purchase price of approximately $1.8 million in a registered direct offering. In a concurrent private transaction, we sold to each investor warrants, each to purchase one share of our common stock. The warrants are initially exercisable six months following issuance, and terminate five and one-half years following issuance. The warrants have an exercise price of $0.46 per share and are exercisable to purchase an aggregate of approximately 5.1 million shares of our common stock, subject to limited exceptions.

Corporate Information

We were founded in 1982 and are a Delaware corporation. Our shares of common stock trade on NASDAQ 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.

The Offering

Shares of common stock offered:	13,333,334 Shares.
Base warrants offered:	Base warrants to purchase up to 13,333,333 shares of our common stock (and the shares of common stock issuable upon the exercise of the base warrants). Each share of our common stock is being sold together with a base warrant to purchase 0.75 of a share of our common stock. Each base warrant will have an exercise price equal to $, will be immediately exercisable and will expire on the fifth anniversary of the original issuance date.
Pre-funded warrants offered:	We are also offering those purchasers, if any, whose purchase of shares of our common stock in this offering would result in the purchaser, together with its affiliates and certain related parties, beneficially owning more than 4.99% of our outstanding common stock following the consummation of this offering, pre-funded warrants to purchase shares of our common stock (and the shares of common stock issuable upon the exercise of the pre-funded warrants). In lieu of the shares of our common stock that would result in ownership in excess of 4.99%, such purchasers have the opportunity to purchase, if they so choose, up to 4,444,444 pre-funded warrants to purchase such excess shares of our common stock. Each pre-funded warrant is being sold together with the same base warrant described above to purchase 0.75 of a share of common stock. Each pre-funded warrant will have an exercise price of $0.01 per share, will be immediately exercisable until it is exercised in full. There can be no assurance that we will sell any of the pre-funded warrants being offered. For each pre-funded warrant we sell, the number of shares of common stock we are offering will be decreased on a one-for-one basis. Because a base warrant to purchase 0.75 of a share of our common stock is being sold together in this offering with each share of common stock and, in the alternative, each pre-funded warrant, the number of base warrants sold in this offering will not change as a result of a change in the mix of the shares of our common stock and pre-funded warrants sold.
Shares of common stock outstanding after completion of this offering, assuming full exercise of the base warrants:	48,999,435 shares (including common stock underlying the pre-funded warrants), or 62,332,768 shares if the base warrants sold in this offering are exercised in full.
Use of Proceeds:	We estimate that our net proceeds from this offering will be approximately $7.0 million, excluding the proceeds, if any, from the exercise of the base warrants. We intend to use the net proceeds from this offering primarily to continue funding development of OPTIMA, our ongoing Phase III clinical trial of ThermoDox® in patients with primary liver cancer and OVATION, our ongoing Phase I clinical trial of GEN-1 in patients with advanced ovarian cancer and for general corporate purposes, including research and development activities, capital expenditures and working capital.

	See the section titled “Use of Proceeds” in this prospectus.
NASDAQ Capital Market symbol:	CLSN.

Trading:	Our shares of common stock currently trade on NASDAQ. We do not plan on applying to list the base warrants or the pre-funded warrants on NASDAQ, any national securities exchange or any other nationally recognized trading system. Without an active trading market, the liquidity of the base warrants and the pre-funded warrants will be limited.
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 31,221,657 shares outstanding as of February 10, 2017, and excludes, as of such date:

- 2,837,108 shares of our common stock subject to outstanding options having a weighted average exercise price of $4.09 per share, and 67,000 shares of common stock subject to outstanding non-vested restricted stock awards with a weighted average grant date fair value of $2.67;

- 534,089 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;

- 18,981,883 shares of our common stock issuable upon exercise of warrants outstanding, having a weighted average exercise price of $2.06 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

- 4,679 shares of our common stock held as treasury stock.

Unless otherwise indicated, the numbers in this prospectus exclude the shares of common stock issuable upon the exercise of the base warrants and pre-funded warrants to be issued in this offering.

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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.

Risks Related to this Offering

The market price of our common stock has been, and may continue to be volatile and fluctuate significantly, which could result in substantial losses for investors and subject us to securities class action litigation.

The trading price for our common stock has been, and we expect it to continue to be, volatile. Our January 31, 2013 announcement that the HEAT Study failed to meet its primary endpoint has resulted in significant volatility and a steep decline in the price of our common stock, a level of decline that could result in securities litigation. Plaintiffs' securities litigation firms have publicly announced that they are investigating potential securities fraud claims that they may wish to make against us. The price at which our common stock trades depends upon a number of factors, including our historical and anticipated operating results, our financial situation, announcements of technological innovations or new products by us or our competitors, our ability or inability to raise the additional capital we may need and the terms on which we raise it, and general market and economic conditions. Some of these factors are beyond our control. Broad market fluctuations may lower the market price of our common stock and affect the volume of trading in our stock, regardless of our financial condition, results of operations, business or prospect. The closing price of our common stock as reported on The NASDAQ Capital Market had a high price of $1.93 and a low price of $0.30 in the 52-week period ended December 31, 2016 and a high price of $0.51 and a low price of $0.31 from January 3, 2017 through February 10, 2017. Among the factors that may cause the market price of our common stock to fluctuate are the risks described in this "Risk Factors" section and other factors, including:

- results of preclinical and clinical studies of our product candidates or those of our competitors;
- regulatory or legal developments in the U.S. and other countries, especially changes in laws and regulations applicable to our product candidates;
- actions taken by regulatory agencies with respect to our product candidates, clinical studies, manufacturing process or sales and marketing terms;

introductions and announcements of new products by us or our competitors, and the timing of these introductions or announcements;
announcements by us or our competitors of significant acquisitions or other strategic transactions or capital commitments;
fluctuations in our quarterly operating results or the operating results of our competitors;
variance in our financial performance from the expectations of investors;
changes in the estimation of the future size and growth rate of our markets;
changes in accounting principles or changes in interpretations of existing principles, which could affect our financial results;
failure of our products to achieve or maintain market acceptance or commercial success;
conditions and trends in the markets we serve;
changes in general economic, industry and market conditions;
success of competitive products and services;
changes in market valuations or earnings of our competitors;
changes in our pricing policies or the pricing policies of our competitors;
changes in legislation or regulatory policies, practices or actions;
the commencement or outcome of litigation involving our company, our general industry or both;
recruitment or departure of key personnel;
changes in our capital structure, such as future issuances of securities or the incurrence of additional debt;
actual or anticipated changes in earnings estimates or changes in stock market analyst recommendations regarding our common stock, other comparable companies or our industry generally;
actual or expected sales of our common stock by our stockholders;
acquisitions and financings, including the EGEN acquisition; and
the trading volume of our common stock.

In addition, the stock markets, in general, The NASDAQ Capital Market and the market for pharmaceutical companies in particular, may experience a loss of investor confidence. Such loss of investor confidence may result in extreme price and volume fluctuations in our common stock that are unrelated or disproportionate to the operating performance of our business, financial condition or results of operations. These broad market and industry factors may materially harm the market price of our common stock and expose us to securities class action litigation. Such litigation, even if unsuccessful, could be costly to defend and divert management's attention and resources, which could further materially harm our financial condition and results of operations.

Management will have broad discretion as to the use of the net proceeds from this offering, and we may not use these proceeds effectively.

We intend to use the net proceeds from this offering primarily to continue funding development of the OPTIMA Study, our ongoing Phase III clinical trial of ThermoDox® in patients with primary liver cancer and the OVATION Study, our ongoing Phase I clinical trial of GEN-1 in patients with advanced ovarian cancer and for general corporate purposes, including research and development activities, capital expenditures and working capital. As of the date of this prospectus, we cannot specify with certainty all of the particular uses for the net proceeds we will have upon completion of the offering. Accordingly, we will retain broad discretion over the use of these proceeds.

You will experience immediate and substantial dilution as a result of this offering and may experience significant dilution as a result of future equity offerings or issuances and exercise of outstanding options and warrants.

Since the public offering price per share of our common stock and related base warrant being offered is expected to be substantially higher than the net tangible book value per share of our common stock, you will suffer substantial dilution in the net tangible book value of the common stock you purchase in this offering. Our net tangible book value as of September 30, 2016 was approximately $(17.2) million, or $(0.66) per share. After giving effect to the assumed sale of 17,777,778 shares of our common stock (including common stock underlying the pre-funded warrants) and base warrants to purchase 13,333,333 shares of our common stock in this offering at an assumed public offering price of $0.44 per share of our common stock and $0.01 per related base warrant, and after deducting the placement agents' fees and estimated offering expenses payable by us, if you purchase securities in this offering, you will suffer immediate and substantial dilution of $0.53 per share in the net tangible book value of the common stock you acquire. In the event that you exercise your base warrants, you will experience additional dilution to the extent that the exercise price of the base warrants is higher than the tangible book value per share of our common stock. See the section titled "Dilution" below for a more detailed discussion of the dilution you would incur if you purchase shares of our common stock in this offering. The discussion above assumes no sale of pre-funded warrants, which, if sold, would reduce the number of shares of common stock that we are offering on a one-for-one basis.

In addition, we have a significant number of stock options and warrants outstanding. To the extent that outstanding stock options or warrants, including the base warrants and the pre-funded warrants offered in this prospectus, have

been or may be exercised or other shares issued, you may experience further dilution.

In order to raise additional capital or pursue strategic transactions, we may in the future offer, issue or sell additional shares of our common stock or other securities convertible into or exchangeable for our common stock, including the issuance of common stock in relation to the achievement, if any, of milestones triggering our payment of earn-out consideration in connection with the EGEN acquisition. Our stockholders may experience significant dilution as a result of future equity offerings or issuances. Investors purchasing shares or other securities in the future could have rights superior to existing stockholders. As of February 10, 2017, we have a significant number of securities convertible into, or allowing the purchase of, our common stock, including 20,831,883 shares of common stock issuable upon exercise of warrants outstanding, 2,904,108 options to purchase shares of our common stock and restricted stock awards outstanding, and 534,089 shares of common stock reserved for future issuance under our stock incentive plans. Under the Controlled Equity Offering SM Sales Agreement entered into with Cantor Fitzgerald & Co. on February 1, 2013, we may offer and sell, from time to time through “at-the-market” offerings, up to an aggregate of $25 million of shares of our common stock. We had only sold $7.6 million under the Sales Agreement as of February 10, 2017.

Future sales of our common stock in the public market could cause our stock price to fall.

Sales of a substantial number of shares of our common stock in the public market, or the perception that these sales might occur, could depress the market price of our common stock and could impair our ability to raise capital through the sale of additional equity securities. As of February 10, 2017, we had 31,221,657 shares of common stock outstanding, all of which, other than shares held by our directors and certain officers, were eligible for sale in the public market, subject in some cases to compliance with the requirements of Rule 144, including the volume limitations and manner of sale requirements. In addition, all of the shares of common stock issuable upon exercise of warrants will be freely tradable without restriction or further registration upon issuance.

Holders of our warrants will have no rights as a common stockholder until they acquire our common stock.

Until you acquire shares of our common stock upon exercise of your warrants, you will have no rights with respect to shares of our common stock issuable upon exercise of your warrants. Upon exercise of your warrants, you will be entitled to exercise the rights of a common stockholder only as to matters for which the record date occurs after the exercise date.

A large number of shares issued in this offering may be sold in the market following this offering, which may depress the market price of our common stock.

A large number of shares issued in this offering may be sold in the market following this offering, which may depress the market price of our common stock. Sales of a substantial number of shares of our common stock in the public market following this offering could cause the market price of our common stock to decline. If there are more shares of our common stock offered for sale than buyers are willing to purchase, then the market price of our common stock may decline to a market price at which buyers are willing to purchase the offered shares of our common stock and sellers remain willing to sell the shares. All of the securities issued in the offering will be freely tradable without restriction or further registration under the Securities Act.

The base warrants may not have any value.

Each base warrant sold in this offering will have an exercise price equal to $ and will expire on the fifth anniversary of the date they first become exercisable. In the event our common stock price does not exceed the exercise price of the base warrants during the period when the base warrants are exercisable, the base warrants may not have any value.

We may be unable to maintain compliance with The NASDAQ Marketplace Rules which could cause our common stock to be delisted from The NASDAQ Capital Market. This could result in the lack of a market for our common stock, cause a decrease in the value of an investment in us, and adversely affect our business, financial condition and results of operations.

Our common stock is currently listed on The NASDAQ Capital Market. To maintain the listing of our common stock on The NASDAQ Capital Market, we are required to meet certain listing requirements, including, among others, either: (i) a minimum closing bid price of $1.00 per share, a market value of publicly held shares (excluding shares held by our executive officers, directors and 10% or more stockholders) of at least $1 million and stockholders' equity of at least $2.5 million; or (ii) a minimum closing bid price of $1.00 per share, a market value of publicly held shares (excluding shares held by our executive officers, directors and 10% or more stockholders) of at least $1 million and a total market value of listed securities of at least $35 million. As of February 10, 2017, the closing sale price per share of our common stock was $0.45, the total market value of our publicly held shares of our common stock (excluding shares held by our executive officers, directors and 10% or more stockholders) was approximately $13.9 million and the total market value of our listed securities was approximately $14.0 million. There is no assurance that we will continue to meet the minimum closing price requirement and other listing requirements. As of September 30, 2016, we had stockholders' equity of approximately $10.6 million.

On December 15, 2016, we received a letter from NASDAQ indicating that the closing bid price of our common stock fell below $1.00 per share for the previous 30 consecutive business days, and that we are therefore not in compliance with the minimum bid price requirement for continued inclusion on The NASDAQ Capital Market and our common stock could be subject to delisting from The NASDAQ Capital Market. If our common stock is delisted, trading of the stock will most likely take place on an over-the-counter market established for unlisted securities, such as the Pink Sheets or the OTC Bulletin Board. An investor is likely to find it less convenient to sell, or to obtain accurate quotations in seeking to buy, our common stock on an over-the-counter market, and many investors may not buy or sell our common stock due to difficulty in accessing over-the-counter markets, or due to policies preventing them from trading in securities not listed on a national exchange or other reasons. In addition, as a delisted security, our common stock would be subject to SEC rules regarding "penny stock," which impose additional disclosure requirements on broker-dealers. The regulations relating to penny stocks, coupled with the typically higher cost per trade to investors in penny stocks due to factors such as broker commissions generally representing a higher percentage of the price of a penny stock than of a higher priced stock, would further limit the ability and willingness of investors to trade in our common stock. For these reasons and others, delisting would adversely affect the liquidity, trading volume and price of our common stock, causing the value of an investment in us to decrease and having an adverse effect on our business, financial condition and results of operations, including our ability to attract and retain qualified executives and employees and to raise capital.

There is currently no public market for the pre-funded warrants or the base warrants to purchase shares of our common stock being offered in this offering, and we can provide no assurance that an active trading market will develop.

We do not plan on applying to list the base warrants or the pre-funded warrants on NASDAQ, any national securities exchange or any other nationally recognized trading system. Without an active trading market, the liquidity of the base warrants and the pre-funded warrants will be limited.

USE OF PROCEEDS

We estimate that our net proceeds from this offering will be approximately $7.0 million, excluding the proceeds, if any, from the exercise of the base warrants, based on the sale of 17,777,778 shares of our common stock (including common stock underlying the pre-funded warrants) and base warrants to purchase 13,333,333 shares of our common stock in this offering at an assumed public offering price of $0.44 per share of our common stock and $0.01 per base warrant, and after deducting estimated placement agents' fees and estimated offering expenses payable by us.

A $0.05 increase (or decrease) in the assumed public offering price of $0.44 per share of our common stock and $0.01 per related base warrant would increase (or decrease) the expected net cash proceeds of the offering to us by approximately $0.9 million. An increase (or decrease) of 1.0 million in the assumed number of shares sold in this offering would increase (or decrease) the expected net cash proceeds of the offering to us by approximately $0.4 million, assuming the public offering price of $0.44 per share and $0.01 per related base warrant.

We are also offering to those purchasers whose purchase of shares of our common stock in this offering would result in the purchaser, together with its affiliates and certain related parties, owning more than 4.99% of our outstanding common stock following the consummation of this offering, the opportunity to purchase, if they so choose, up to 4,444,444 pre-funded warrants, in lieu of shares of our common stock that would result in ownership in excess of 4.99%, pre-funded warrants to purchase shares of our common stock and base warrants to purchase shares of our common stock. There can be no assurance that we will sell any of the pre-funded warrants being offered. For each pre-funded warrant sold, the number of shares of common stock we are offering will be decreased on a one-for-one basis.

We intend to use the net proceeds from this offering primarily to continue funding development of the OPTIMA Study, our ongoing Phase III clinical trial of ThermoDox® in patients with primary liver cancer and the OVATION Study, our ongoing Phase I clinical trial of GEN-1 in patients with advanced ovarian cancer and for general corporate purposes, including research and development activities, capital expenditures and working capital. As of the date of this prospectus, we cannot specify with certainty all of the particular uses for the net proceeds we will have upon completion of the offering. Accordingly, we will retain broad discretion over the use of these proceeds.

PRICE RANGE OF OUR COMMON STOCK

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

Period	High	Low
Year Ending December 31, 2017		
First Quarter (January 3, 2017 – February 10, 2017)	$ 0.51	$ 0.31
Year Ended December 31, 2016		
First Quarter	$ 1.99	$ 1.04
Second Quarter	$ 1.78	$ 1.30
Third Quarter	$ 1.34	$ 1.20
Fourth Quarter	$ 0.99	$ 0.30
Year Ended December 31, 2015		
First Quarter	$ 3.54	$ 2.15
Second Quarter	$ 3.57	$ 2.42
Third Quarter	$ 2.72	$ 1.63
Fourth Quarter	$ 2.31	$ 1.61

The reported last sale price of our common stock on NASDAQ on February 10, 2017 was $0.45 per share.

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 January 31, 2017, 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.

DILUTION

If you purchase securities in this offering, you will experience dilution to the extent of the difference between the price per share you pay in this offering and the net tangible book value per share of our common stock immediately after this offering assuming no value is attributed to the base warrants, and such base warrants are accounted for and classified as equity. The net tangible book value of our common stock on September 30, 2016 was $(17.2) million, or $(0.66) per share (based upon 26,060,573 shares of our common stock). Net tangible book value per share is equal to the amount of our total tangible assets, less total liabilities, divided by the aggregate number of shares of our common stock outstanding.

After giving effect to the assumed sale by us of shares of our common stock and base warrants to purchase 31,111,111 shares of our common stock in this offering at an assumed public offering price of $0.44 per share of common stock and $0.01 per base warrant, and after deducting the placement agents' fees and estimated offering expenses payable by us, our as adjusted net tangible book value as of September 30, 2016 would have been $(3.2) million, or $(0.08) per share of common stock. This represents an immediate increase in net tangible book value of $0.58 per share to existing stockholders and an immediate dilution of $0.53 per share to new investors purchasing shares of our common stock in this offering, attributing none of the assumed combined public offering price to the base warrants offered hereby. The following table illustrates this per share dilution :

Assumed public offering price per share and associated base warrant	$ 0.45
Net tangible book value per share as of September 30, 2016	$ (0.66)
Increase in net tangible book value per share attributable to this offering	$ 0.58
As adjusted net tangible book value per share as of September 30, 2016, after giving effect to this offering	$ (0.08)
Dilution per share to the investor purchasing shares in this offering	$ (0.53)

Each $0.05 increase (or decrease) in the assumed combined public offering price of $0.45 per share and related base warrant would increase (or decrease) our as adjusted net tangible book value after this offering by $1.4 million, or $0.02 per share, and the dilution per share to new investors by $0.05 per share, assuming that the number of shares of common stock and related base warrants offered by us, as set forth above, remains the same and after deducting the placement agents' fees and estimated offering expenses payable by us. We may also increase or decrease the number of shares of common stock and related base warrants we are offering from the assumed number of shares of common stock and related base warrants set forth above. An increase (or decrease) of 1.0 million shares of common stock and related base warrants in the number of shares of common stock and related warrants offered by us from the assumed number of shares of common stock and related base warrants set forth above would increase (or decrease) our as adjusted net tangible book value after this offering by $0.4 million, or $0.01 per share, and the dilution per share to new investors by $(0.01) per share, assuming that the combined public offering price of $0.45 per share and related base warrant remain the same and after deducting the placement agents' fees and estimated offering expenses payable by us.

The information discussed above is illustrative only and will adjust based on the actual public offering price, the actual number of shares, pre-funded warrants and base warrants that we offer in this offering, and other terms of this offering determined at pricing. Additionally, the table and discussion above do not reflect possible adjustments related to the likely derivative treatment of the warrants to be issued in this offering. This table does not take into account further dilution to new investors that could occur upon the exercise of outstanding options and warrants, including the base warrants offered in this offering, having a per share exercise price less than the public offering price per share in this offering.

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 September 30, 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 $4.31 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;

13,839,040 shares of our common stock issuable upon exercise of warrants outstanding, having a weighted average exercise price of $2.80 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.

To the extent that any of our outstanding options or warrants are exercised, new options are issued under our stock incentive plans or we otherwise issue additional shares of common stock in the future, there may be further dilution to the investor participating in this offering.

BUSINESS

Overview

We are 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 dosage form of doxorubicin based on a heat-activated liposomal platform technology, currently in Phase III development for the treatment of primary liver cancer. Our pipeline also includes GEN-1, a DNA-based immunotherapy in clinical development for the localized treatment of ovarian cancer and pre-clinical development for brain cancer. GEN-1 is based on a platform technology for the development of treatments for those suffering with difficult-to-treat forms of cancer, using novel nucleic acid-based immunotherapies and other anti-cancer DNA or RNA therapies. We are working to develop and commercialize more efficient, effective and targeted oncology therapies based on our technologies, with the goal of developing 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 OPTIMA Study

On February 24, 2014, we announced that the United States Food and Drug Administration (the "FDA"), after its customary 30-day review period, provided clearance for the OPTIMA Study, which is a pivotal, double-blind, placebo-controlled Phase III trial of ThermoDox®, in combination with standardized RFA, for the treatment of primary liver cancer. The trial design of the OPTIMA Study is based on the comprehensive analysis of data from an earlier clinical trial called the HEAT Study, which is described below. We launched the OPTIMA Study in the first half of 2014. The OPTIMA Study was designed with extensive input from globally recognized hepatocellular carcinoma ("HCC") researchers and 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 countries, 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 overall survival ("OS"), and the secondary endpoints are progression free survival and safety. The statistical plan calls for two interim efficacy analyses by an independent Data Monitoring Committee.

On December 16, 2015, we announced that we had received the clinical trial application approval from the China Food and Drug Administration (the "CFDA") to conduct the OPTIMA Study in China. This clinical trial application approval will 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 OPTIMA Study represents an evaluation of ThermoDox® in combination with a first line therapy, RFA, for newly diagnosed, intermediate stage HCC patients. HCC incidence globally is approximately 850,000 new cases. The RFA addressable percentage of newly diagnosed patients is approximately 30%. The OPTIMA Study is supported with a convincing hypothesis developed from an overall survival analysis of a large subgroup of patients from the HEAT Study.

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 progression free survival ("PFS") data from the HEAT Study were announced in January 2013, with each data set demonstrating progressive improvement in clinical benefit and statistical significance. On August 15, 2016, the Company announced updated results from its final retrospective OS analysis of the data from the HEAT Study. These results demonstrated that in a large, well bounded, subgroup of patients with a single lesion (n=285, 41% of the HEAT Study patients), treatment with a combination of ThermoDox® 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 a single lesion (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 intent-to-treat Chinese patient cohort further confirms the importance of RFA heating time as 72% of patients in this large patient cohort in China received an optimized RFA treatment.

While this information should be viewed with caution since it is based on a retrospective analysis of a subgroup, we also conducted additional analyses that further strengthens the evidence for the HEAT Study sub-group. We commissioned an independent computational model at the University of South Carolina Medical School. The results unequivocally indicate that longer RFA heating times correlate with significant increases in doxorubicin concentration around the RFA treated tissue. We conducted a prospective preclinical study in 21 pigs using two different manufacturers of RFA and human equivalent doses of ThermoDox® that clearly support the relationship between increased heating duration and doxorubicin concentrations.

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

The HEAT Study

On January 31, 2013, the Company announced that the HEAT Study, ThermoDox® in combination with RFA, did not meet the primary endpoint, PFS, of a Phase III clinical trial enrolling 701 patients with primary liver cancer. This determination was made after conferring with the HEAT Study independent Data Monitoring Committee, that the HEAT Study did not meet the goal of demonstrating a clinically meaningful improvement in progression free survival. 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 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 have shown to be well balanced and not diminished in anyway by other factors. Supplementary computational modeling and prospective preclinical animal studies have shown additional support the relationship between heating duration and clinical outcomes. These data have been presented, without objection, at multiple scientific and medical conferences in 2013 through 2016 by key HEAT Study investigators and leading liver cancer experts. The presentations include:

World Conference on Interventional Oncology in May 2013;

European Conference on Interventional Oncology in June 2013 and April 2014;

International Liver Cancer Association Annual Conference in September 2013, 2014 and 2015;

American Society of Clinical Oncology 50th Annual Meeting in June 2014;

Asian Conference on Tumor Ablation in October 2015 and October 2016; and

Asia-Pacific Primary Liver Cancer Expert (APPLE) Meeting in July 2016.

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.

These data are consistent with the combined clinical data from two Phase I trials, our Phase I DIGNITY Study and the Duke University sponsored Phase I trial of ThermoDox® plus hyperthermia in RCW breast cancer in December 2013. The two similarly designed Phase I studies enrolled patients with highly resistant tumors found on the chest wall and who had progressed on previous therapy including chemotherapy, radiation therapy and hormone therapy. There were 29 patients treated in the two trials, including 11 patients in the DIGNITY Study and 18 patients in the Duke study. Of the 29 patients treated, 23 were eligible for evaluation of efficacy. A local response rate of over 60 percent was reported in 14 of the 23 evaluable patients with five complete responses and nine 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 2017 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, pursuant to Section 4(a)(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 TheraSilenceTM technology acquired from EGEN in the acquisition.

Our obligations to make the earnout payments will terminate on the seventh anniversary of the closing date.

In the acquisition, we purchased GEN-1, a DNA-based immunotherapy for the localized treatment of ovarian and brain cancers, and 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™ 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 OVATION Study at four clinical sites at the University of Alabama at Birmingham, Oklahoma University Medical Center, Washington University in St. Louis and the Medical College of Wisconsin. 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 2017 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.

During 2016, we announced data from the first three 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 2017 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 three cohorts each enrolled three patients. Following the safety review of the first three patient cohorts conducted by the independent Data Safety Monitoring Board (“DSMB”) in September 2016 and the DSMB’s subsequent recommendation to continue the fourth patient cohort, 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:

Totality of Results in the First Three Cohorts

Of the first nine patients dosed, one patient demonstrated a complete response ("CR"), five patients demonstrated partial response ("PR") and three patients demonstrated stable disease ("SD"), as measured by RECIST criteria. This translates to a 100% disease control rate ("DCR") and 66% objective response rate ("ORR").

Eight patients had successful resections of their tumors, with four 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 had an R2, indicating macroscopic residual tumor. One patient in the second cohort was ineligible for debulking surgery due to a medical complication unrelated to the study or the study drug.

Of the eight surgically treated and evaluable patients, one patient demonstrated a complete pathological response ("cPR"), three patients demonstrated a micro pathological response ("microPR"), and four patients demonstrated a macroPR. These data compare favorably to historical data, which indicate that cPRs are typically seen in less than 7% of patients receiving neoadjuvant chemotherapy followed by surgical resection. cPRs 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 cPR. In addition, microPRs are seen in approximately 30% of patients, and are associated with a median overall survival of 38 months.

Seven patients who completed treatment follow-up experienced a dramatic (greater than 90%) drop in their CA-125 protein levels as of their most recent study visit. CA-125 is used to monitor certain cancers during and after treatment. CA-125 is present in greater concentrations in ovarian cancer cells than in other cells. A 50% reduction in CA-125 levels is considered meaningful. Six patients maintained CA-125 levels below the standard cutoff level of 35 U/mL.

Top Line Translational Data from First Two Cohorts

Celsion also reported initial translational data from the first two cohorts of patients. Tumor and blood samples collected before the start of the neoadjuvant chemotherapy ("NACT") and after the completion of GEN-1 treatment at debulking surgery are being analyzed for immune cell populations. Top line data demonstrates intriguing immunological changes in the tumor that are consistent with the activation of the immune system. Specifically:

In tumor tissue, there was an increase in cytotoxic CD8+ T-cell density in three out of four evaluable patients at debulking surgery. There was a decrease in immunosuppressive FoxP3+ T-cells in two out of those 4 patients. The ratio of CD8+/FoxP3+ cells was increased in all four evaluable patients. High tumor infiltrating CD8+ T-cell density, low FoxP3+ T-cell density or high CD8+/FoxP3+ ratio demonstrate a potential shift in tumor environment to favoring immune stimulation following NACT + GEN-1 therapy. For the remaining two patients the post-treatment tumor tissue was not available. In one of those two patients there was complete pathological response hence no tumor tissue was present to provide a post-treatment comparison. In the other patient the debulking surgery was not performed due to disease related complications.

In plasma samples, there was no significant change in T-cell density following the treatment. The density of myeloid derived suppressor cells that are associated with immunosuppression in ovarian cancer were either decreased or did not increase in post-treatment samples.

Additional immune analysis of biological tissue including cytokine ELISA from the first two patient cohorts and a complete analysis of the two higher dose cohorts is in progress.

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 2017 following the completion of the OVATION Study. 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.

TheraPlasTM Technology Platform

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

TheraSilenceTM 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.

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 risks and 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.

Research and Development Expenditures

We are engaged in a limited amount of research and development in our own facilities and have sponsored research programs in partnership with various research institutions, including the National Cancer Institute and Duke University. We are currently, with minimal cash expenditures, sponsoring clinical and pre-clinical research at the University of Oxford, University of Utrecht, Brigham and Women's Hospital and the University of Washington. The majority of the spending in research and development is for the funding of ThermoDox® clinical trials. Research and development expenses were approximately $11.0 million for the nine-month period ended September 30, 2016, and approximately $14.7 million, $15.0 million and $9.4 million for the years ended December 31, 2015, 2014 and 2013, respectively.

Government Regulation

Government authorities in the United States, at the federal, state and local level, and in other countries extensively regulate, among other things, the research, development, testing, quality control, approval, manufacturing, labeling, post-approval monitoring and reporting, recordkeeping, packaging, promotion, storage, advertising, distribution, marketing and export and import of pharmaceutical products such as those we are developing. The process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state, local and foreign statutes and regulations require the expenditure of substantial time and financial resources.

Regulation in the United States

In the United States, the FDA regulates drugs under the Federal Food, Drug, and Cosmetic Act (the "FDCA") and implementing regulations. Failure to comply with the applicable FDA requirements at any time pre- or post-approval may result in a delay of approval or administrative or judicial sanctions. These sanctions could include the FDA's imposition of a clinical hold on trials, refusal to approve pending applications, withdrawal of an approval, issuance of warning or untitled letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, civil penalties or criminal prosecution.

Research and Development

The vehicle by which FDA approves a new pharmaceutical product for sale and marketing in the United States is a New Drug Application ("NDA"). The steps ordinarily required before a new drug can be marketed in the U.S. include (a) completion of pre-clinical and clinical studies; (b) submission and FDA acceptance of an Investigational New Drug application ("IND"), which must become effective before human clinical trials may commence; (c) completion of adequate and well-controlled human clinical trials to establish the safety and efficacy of the product to support each of its proposed indications; (d) submission and FDA acceptance of a NDA; and (e) FDA review and approval of the NDA.

Pre-clinical tests include laboratory evaluations of product chemistry, toxicity, formulation and stability, as well as animal studies, to assess the potential safety and efficacy of the product. Pre-clinical safety tests must be conducted by laboratories that comply with FDA regulations regarding good laboratory practice. The results of pre-clinical tests are submitted to the FDA as part of an IND and are reviewed by the FDA before the commencement of human clinical trials. Submission of an IND will not necessarily result in FDA authorization to commence clinical trials, and the absence of FDA objection to an IND does not necessarily mean that the FDA will ultimately approve an NDA or that a product candidate otherwise will come to market.

Clinical trials involve the administration of the investigational product to human subjects under the supervision of a qualified principal investigator. Clinical trials must be conducted in accordance with good clinical practices under protocols submitted to the FDA as part of an IND and with patient informed consent. Also, each clinical trial must be approved by an Institutional Review Board ("IRB"), and is subject to ongoing IRB monitoring.

Clinical trials are typically conducted in three sequential phases, but the phases may overlap or be combined. Phase I clinical trials may be conducted in patients or healthy volunteers to evaluate the product's safety, dosage tolerance and pharmacokinetics and, if possible, seek to gain an early indication of its effectiveness. Phase II clinical trials usually involve controlled trials in a larger but still relatively small number of subjects from the relevant patient population to evaluate dosage tolerance and appropriate dosage; identify possible short-term adverse effects and safety risks; and provide a preliminary evaluation of the efficacy of the drug for specific indications. Phase III clinical trials are typically conducted in a significantly larger patient population and are intended to further evaluate safety and efficacy, establish the overall risk-benefit profile of the product, and provide an adequate basis for physician labeling.

There can be no assurance that any of our clinical trials will be completed successfully within any specified time period or at all.

Either the FDA or we may suspend clinical trials at any time on various grounds, including among other things, if we, the FDA, or our independent DMC conclude that clinical subjects are being exposed to an unacceptable health risk. The FDA inspects and reviews clinical trial sites, informed consent forms, data from the clinical trial sites (including case report forms and record keeping procedures) and the performance of the protocols by clinical trial personnel to determine compliance with good clinical practices. The conduct of clinical trials is complex and difficult, and there can be no assurance that the design or the performance of the pivotal clinical trial protocols of any of our current or future product candidates will be successful.

The results of pre-clinical studies and clinical trials, if successful, are submitted to FDA in the form of an NDA. The testing and approval process requires substantial time, effort, and financial resources, and there can be no assurance that any approval will be granted for any product at any time, according to any schedule, or at all. The FDA may refuse to accept or approve an application if it determines that applicable regulatory criteria are not satisfied. The FDA may also require additional testing for safety and efficacy. Even, if regulatory approval is granted, the approval will be limited to specific indications. There can be no assurance that any of our current product candidates will receive regulatory approvals for marketing or, if approved, that approval will be for any or all of the indications that we request.

Orphan Drug Designation

In 2009, the FDA granted orphan drug designation for ThermoDox® for the treatment of HCC. Orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process. However, if a product which has an orphan drug designation subsequently receives the first FDA approval for the indication for which it has such designation, the product is entitled to orphan drug exclusivity, which means the FDA may not approve any other application to market the same drug for the same indication for a period of seven years, except in limited circumstances, such as a showing of clinical superiority to the product with orphan exclusivity. Orphan drug designation can also provide opportunities for grant funding towards clinical trial costs, tax advantages and FDA user-fee benefits.

Hatch-Waxman Exclusivity

The FDCA provides a five-year period of non-patent data exclusivity within the United States to the first applicant to gain approval of an NDA for a new chemical entity. A drug is a new chemical entity if the FDA has not previously approved any other new drug containing the same active moiety. During the exclusivity period, the FDA generally may not accept for review an abbreviated new drug application ("ANDA") or a 505(b)(2) NDA submitted by another company that references the previously approved drug. However, an ANDA or 505(b)(2) NDA referencing the new chemical entity may be submitted after four years if it contains a certification of patent invalidity or non-infringement.

Post-Approval Requirements

After FDA approval of a product is obtained, we and our contract manufacturers are required to comply with various post-approval requirements, including establishment registration and product listing, record-keeping requirements, reporting of adverse reactions and production problems to the FDA, providing updated safety and efficacy information, and complying with requirements concerning advertising and promotional labeling. As a condition of approval of an NDA, the FDA may require the applicant to conduct additional clinical trials or other post market testing and surveillance to further monitor and assess the drug's safety and efficacy. The FDA can also impose other post-marketing controls on us as well as our products including, but not limited to, restrictions on sale and use, through the approval process, regulations and otherwise. The FDA also has the authority to require the recall of our products in the event of material deficiencies or defects in manufacture. A governmentally mandated recall, or a voluntary recall by us, could result from a number of events or factors, including component failures, manufacturing errors, instability of product or defects in labeling.

In addition, manufacturing establishments in the U.S. and abroad are subject to periodic inspections by the FDA and must comply with current good manufacturing practices ("cGMP"). To maintain compliance with cGMP, manufacturers must expend funds, time and effort in the areas of production and quality control.

Regulation Outside of the U.S.

In addition to regulations in the U.S., we will be subject to regulations of other countries governing any clinical trials and commercial sales and distribution of our product candidates. Whether or not we obtain FDA approval for a product, we must obtain approval by the comparable regulatory authorities of countries outside of the U.S. before we can commence clinical trials in such countries and approval of the regulators of such countries or economic areas, such as the European Union and China, before we may market products in those countries or areas. The approval process and requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary greatly from place to place, and the time may be longer or shorter than that required for FDA approval.

Under European Union regulatory systems, a company may submit marketing authorization applications either under a centralized or decentralized procedure. The centralized procedure, which is compulsory for medicines produced by biotechnology or those medicines intended to treat AIDS, cancer, neurodegenerative disorders or diabetes and is optional for those medicines that are highly innovative, provides for the grant of a single marketing authorization that is valid for all European Union member states. The decentralized procedure provides for mutual recognition of national approval decisions. Under this procedure, the holder of a national marketing authorization may submit an application to the remaining member states. Within 90 days of receiving the applications and assessments report, each member state must decide whether to recognize approval. If a member state does not recognize the marketing authorization, the disputed points are eventually referred to the European Commission, whose decision is binding on all member states.

In 2011, the European Commission granted orphan drug designation for ThermoDox® for the treatment of HCC in Europe. As established by the EMA, orphan drug designation provides for scientific advice and regulatory assistance from the EMA, direct access to centralized marketing authorization and certain financial incentives, such as reduction of fees associated with pre-authorization inspections and marketing authorization application fees. The orphan drug designation in Europe also provides 10 years of market exclusivity subsequent to product approval.

Manufacturing and Supply

We do not currently own or operate manufacturing facilities for the production of preclinical, clinical or commercial quantities of any of our product candidates. We currently contract with third party contract manufacturing organizations ("CMOs") for our preclinical and clinical trial supplies, and we expect to continue to do so to meet the

preclinical and any clinical requirements of our product candidates. We have agreements for the supply of such drug materials with manufacturers or suppliers that we believe have sufficient capacity to meet our demands. In addition, we believe that adequate alternative sources for such supplies exist. However, there is a risk that, if supplies are interrupted, it would materially harm our business. We typically order raw materials and services on a purchase order basis and do not enter into long-term dedicated capacity or minimum supply arrangements.

Manufacturing is subject to extensive regulations that impose various procedural and documentation requirements, which govern record keeping, manufacturing processes and controls, personnel, quality control and quality assurance, among others. Our CMOs manufacture our product candidates under current cGMP conditions. cGMP is a regulatory standard for the production of pharmaceuticals that will be used in humans.

Sales and Marketing

Our current focus is on the development of our existing portfolio, the completion of clinical trials and, if and where appropriate, the registration of our product candidates. We currently do not have marketing, sales and distribution capabilities. If we receive marketing and commercialization approval for any of our product candidates, we intend to market the product either directly or through strategic alliances and distribution agreements with third parties. The ultimate implementation of our strategy for realizing the financial value of our product candidates is dependent on the results of clinical trials for our product candidates, the availability of regulatory approvals and the ability to negotiate acceptable commercial terms with third parties.

Product Liability and Insurance

Our business exposes us to potential product liability risks that are inherent in the testing, manufacturing and marketing of human therapeutic products. We presently have product liability insurance limited to $10 million per incident, and if we were to be subject to a claim in excess of this coverage or to a claim not covered by our insurance and the claim succeeded, we would be required to pay the claim out of our own limited resources.

Competition

Competition in the discovery and development of new methods for treating and preventing disease is intense. We face, and will continue to face, intense competition from pharmaceutical and biotechnology companies, as well as academic and research institutions and government agencies both in the U.S. and abroad. We face significant competition from organizations pursuing the same or similar technologies used by us in our drug discovery efforts and from organizations developing pharmaceuticals that are competitive with our product candidates.

Most of our competitors, either alone or together with their collaborative partners, have substantially greater financial resources and larger research and development staffs than we do. In addition, most of these organizations, either alone or together with their collaborators, have significantly greater experience than we do in developing products, undertaking preclinical testing and clinical trials, obtaining FDA and other regulatory approvals of products, and manufacturing and marketing products. Mergers and acquisitions in the pharmaceutical industry may result in even more resources being concentrated among our competitors. These companies, as well as academic institutions, governmental agencies, and private research organizations, also compete with us in recruiting and retaining highly qualified scientific personnel and consultants. Our ability to compete successfully with other companies in the pharmaceutical and biotechnology field also depends on the status of our collaborations and on the continuing availability of capital to us.

ThermoDox®

Although there are many drugs and devices marketed and under development for the treatment of cancer, the Company is not aware of any other heat activated drug delivery product either being marketed or in human clinical development. In addition, the Company is not aware of any other Phase III clinical trial for the treatment of HCC or primary liver cancer.

GEN-1

Studied indications for GEN-1 include ovarian cancer and glioblastoma multiforme (“GBM”) brain cancer. In evaluating the competitive landscape for both indications, early stage indications are treated with chemotherapy (temozolomide, BCNU, CCNU for brain cancer; docetaxel, doxil and cisplatinum for ovarian cancer), while later stage ovarian and GBM cancer are treated with Bevacizumab - Avastin®, an anti-angiogenesis inhibitor. Avastin® is currently also being evaluated for early stage disease.

In product positioning for both indications, there currently is no direct immunotherapy competitor for GEN-1, which will be studied as an adjuvant to both chemotherapy standard of care regimens, as well as anti-angiogenesis compounds. To support these cases, we have conducted clinical studies in combination with chemotherapy for ovarian cancer, and preclinical studies in combination with both temozolomide and Bevacizumab-Avastin®.

Intellectual Property

Licenses

Duke University License Agreement

In 1999, we entered into a license agreement with Duke University under which we received exclusive rights, subject to certain exceptions, to commercialize and use Duke’s thermo-liposome technology. In relation to these liposome patents licensed from Duke University, we have filed two additional patents related to the formulation and use of liposomes. We have also licensed from Valentis, CA certain global rights covering the use of pegylation for temperature sensitive liposomes.

In 2003, our obligations under the license agreement with Duke University with respect to the testing and regulatory milestones and other licensed technology performance deadlines were eliminated in exchange for a payment of shares of our common stock. The license agreement continues to be subject to agreements to pay a royalty based upon future sales. In conjunction with the patent holder, we have filed international applications for a certain number of the United States patents.

Our rights under the license agreement with Duke University extend for the longer of 20 years or the end of any term for which any relevant patents are issued by the United States Patent and Trademark Office. Currently we have rights to Duke's patent for its thermo-liposome technology in the United States, which expires in 2018, and to future patents received by Duke in Canada, Europe, Japan and Australia, where it has patent applications have been granted. The European grant provides coverage in the European Community. For this technology, our license rights are worldwide, including the United States, Canada, certain European countries, Australia, Hong Kong, and Japan.

Patents and Proprietary Rights

Celsion holds a license agreement with Duke University under which we received exclusive rights, subject to certain exceptions, for its temperature-sensitive liposome technology that covers the ThermoDox® formulation. Celsion's newly issued patents pertain specifically to methods of storing stabilized, temperature-sensitive liposomal formulations and will assist in the protection of global rights. These patents will extend the overall term of the ThermoDox® patent portfolio to 2026. The patents are the first in this family, which includes pending applications in the U.S., Europe and additional key commercial geographies in Asia. This extended patent runway to 2026 allows for the evaluation of future development activities for ThermoDox® and Celsion's heat-sensitive liposome technology platform.

For the ThermoDox® technology, we either exclusively license or own US and international patents with claims and methods and compositions of matters that cover various aspects of lysolipid thermally-sensitive liposomes technology, with expiration dates ranging from 2018 to 2026.

For the TheraPlas™ technology, we own three US and international patent families and related applications with claims and methods and compositions of matters that cover various aspects of TheraPlas™ and GEN-1 technologies, with expiration dates ranging from 2020 to 2028.

For the TheraSilence™ technology, we own multiple US and international patents and related applications with claims and methods and compositions of matters that cover various aspects of TheraSilence™ technology, with expiration dates to 2031.

There can be no assurance that an issued patent will remain valid and enforceable in a court of law through the entire patent term. Should the validity of a patent be challenged, the legal process associated with defending the patent can be costly and time consuming. Issued patents can be subject to oppositions, interferences and other third party challenges that can result in the revocation of the patent or maintenance of the patent in amended form (and potentially in a form that renders the patent without commercially relevant or broad coverage). Competitors may be able to circumvent our patents. Development and commercialization of pharmaceutical products can be subject to

substantial delays and it is possible that at the time of commercialization any patent covering the product has expired or will be in force for only a short period of time following commercialization. We cannot predict with any certainty if any third party U.S. or foreign patent rights, other proprietary rights, will be deemed infringed by the use of our technology. Nor can we predict with certainty which, if any, of these rights will or may be asserted against us by third parties. Should we need to defend ourselves and our partners against any such claims, substantial costs may be incurred. Furthermore, parties making such claims may be able to obtain injunctive or other equitable relief, which could effectively block our ability to develop or commercialize some or all of our products in the U.S. and abroad, and could result in the award of substantial damages. In the event of a claim of infringement, we or our partners may be required to obtain one or more licenses from a third party. There can be no assurance that we can obtain a license on a reasonable basis should we deem it necessary to obtain rights to an alternative technology that meets our needs. The failure to obtain a license may have a material adverse effect on our business, results of operations and financial condition.

In addition to the rights available to us under completed or pending license agreements, we rely on our proprietary know-how and experience in the development and use of heat for medical therapies, which we seek to protect, in part, through proprietary information agreements with employees, consultants and others. There can be no assurance that these proprietary information agreements will not be breached, that we will have adequate remedies for any breach, or that these agreements, even if fully enforced, will be adequate to prevent third-party use of the Company’s proprietary technology. Similarly, we cannot guarantee that technology rights licensed to us by others will not be successfully challenged or circumvented by third parties, or that the rights granted will provide us with adequate protection.

Employees

As of December 22, 2016, we employed 22 full-time employees. We also maintain active independent contractor relationships with various individuals, most of whom have month-to-month or annual consulting agreements. None of our employees are covered by a collective bargaining agreement, and we consider our relations with our employees to be good.

Legal Proceedings

We are not currently a party to any material legal proceedings.

Corporate Information

We were founded in 1982 and are a Delaware corporation. Our shares of common stock trade on NASDAQ 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.

SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT

The following table sets forth certain information regarding beneficial ownership of our common stock as of September 30, 2016 by:

- each person known by us to own beneficially more than five percent of our outstanding common stock;
- each of our directors, as well as each executive officer named in the Summary Compensation Table as set forth under the heading "Executive Compensation" in our proxy statement for our 2016 Annual Meeting of Stockholders; and
- our current directors and executive officers as a group.

Our calculation of the percentage of beneficial ownership prior to this offering is based on 26,060,573 shares of our common stock outstanding as of September 30, 2016. We have based our calculation of the percentage of beneficial ownership after this offering on 43,838,351 shares of our common stock outstanding (including pre-funded warrants) immediately after the closing of this offering, assuming no exercise of the base warrants. Unless otherwise noted, we believe that all persons named in the table have sole voting and investment power with respect to all the shares beneficially owned by them.

		Percentage of Shares Beneficially Owned[2]	
Name and Address of Beneficial Owner*	**Shares Beneficially Owned[1]**	**Before Offering**	**After Offering**
5% or more stockholders			
Sabby Management LLC [3]	2,606,057	9.9 %	5.9 %
EGWU, Inc. [4]	2,309,367	8.9 %	5.3 %
Directors and named executive officers			
Augustine Chow [5]	161,106	**	**
Robert W. Hooper [6]	142,418	**	**
Alberto Martinez [7]	197,744	**	**
Frederick J. Fritz [8]	139,755	**	**

Donald P. Braun	5,000	**	**	
Andreas Voss	5,000	**	**	
Michael H. Tardugno [9]	902,368	3.5 %	2.1	%
Nicholas Borys [10]	286,694	1.1 %	**	
Jeffrey Church [11]	283,064	1.1 %	**	
Khursheed Anwer [12]	55,833	**	**	
Current Directors and Executive Officers as a group (10 persons) [13]	2,178,982	8.4 %	5.0	%

* The address of each of the individuals named is c/o Celsion Corporation, 997 Lenox Drive, Suite 100, Lawrenceville, NJ 08648.

** Less than one percent.

(1) Beneficial ownership is determined in accordance with the rules of the Securities and Exchange Commission and generally includes voting or investment power with respect to securities. Shares of common stock subject to options, warrants and convertible securities currently exercisable or convertible, or exercisable or convertible within 60 days of September 30, 2016, are deemed outstanding, including for purposes of computing the percentage ownership of the person holding such option, warrant or convertible security, but not for purposes of computing the percentage of any other holder.

(2) Based on 26,060,573 shares of common stock outstanding as of September 30, 2016.

(3) 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 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 and excluding (i) 8.823,528 shares of common stock, issuable upon exercise of the common stock purchase warrants exercisable at $1.40 per share, 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 Management LLC, in the aggregate, does not exceed 9.99% of our common stock.

(4) Based on information supplied to us by EGWU, Inc. (formerly known as Egen, Inc.), an Alabama corporation ("EGEN") including reports and amendments thereto filed with the SEC on Schedule 13G. EGEN has the sole voting power and sole dispositive power with respect to 2,309,367 shares of common stock. The address of EGEN is 601 Genome Way, Suite 3400, Huntsville, Alabama 35806.

(5) Includes 140,891 shares of common stock underlying options and warrants currently exercisable or exercisable within 60 days of September 30, 2016.

(6) Includes 113,419 shares of common stock underlying options and warrants currently exercisable or exercisable within 60 days of September 30, 2016.

(7) Includes 97,663 shares of common stock underlying options currently exercisable or exercisable within 60 days of September 30, 2016.

(8) Includes 92,885 shares of common stock underlying options and warrants currently exercisable or exercisable within 60 days of September 30, 2016.

(9) Includes 759,347 shares of common stock underlying options and warrants currently exercisable or exercisable within 60 days of September 30, 2016.

(10) Includes 266,768 shares of common stock underlying options and warrants currently exercisable or exercisable within 60 days of September 30, 2016.

(11) Includes 250,836 shares of common stock underlying options currently exercisable or exercisable within 60 days of September 30, 2016.

(12) Includes 50,833 shares of common stock underlying options currently exercisable or exercisable within 60 days of September 30, 2016.

(13) Includes 1,772,642 shares of common stock underlying options and warrants currently exercisable or exercisable within 60 days of September 30, 2016.

EXECUTIVE COMPENSATION

Summary Compensation Table

The following table sets forth the aggregate cash and other compensation paid for the year ended December 31, 2016 and, to the extent required under SEC executive compensation disclosure rules, for the years ended December 31, 2015 and 2014.

Name and Principal Position	Year	Salary	Bonus	Stock Awards (1)	Option Awards (1)	Non-Equity Incentive Plan Compensation (2)	All Other Compensation (3)	Total ($)
Michael H. Tardugno (4)	2016	$509,418	$ &#					