

Celsion CORP  
Form 10-Q  
November 05, 2015  
**UNITED STATES**

**SECURITIES AND EXCHANGE COMMISSION**

**WASHINGTON, D.C. 20549**

**FORM 10-Q**

(Mark One)

QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the quarterly period ended September 30, 2015

OR

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from \_\_\_\_\_ to \_\_\_\_\_

Commission file number: 001-15911

**CELSION CORPORATION**

(Exact name of Registrant as specified in its charter)

**Delaware**

(State or other jurisdiction of incorporation or organization)

**52-1256615**

(I.R.S. Employer Identification Number)

**997 Lenox Drive, Suite 100**

**Lawrenceville, NJ 08648**

(Address of principal executive offices)

**(609) 896-9100**

(Registrant's telephone number, including area code)

**NA**

(Former name, former address and former fiscal year, if changed since last report)

Indicate by check mark whether the Registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports) and (2) has been subject to such filing requirements for the past 90 days. Yes No

Indicate by check mark whether the Registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the Registrant was required to submit and post such files). Yes No

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

Indicate by check mark whether the Registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).  
Yes No

As of November 4, 2015, the Registrant had 23,237,617 shares of common stock, \$0.01 par value per share, outstanding.



**CELSION CORPORATION**  
**QUARTERLY REPORT ON**  
**FORM 10-Q**

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## Forward-Looking Statements

This report includes “forward-looking statements” within the meaning of Section 27A of the Securities Act of 1933, as amended and Section 21E of the Securities Exchange Act of 1934, as amended. All statements other than statements of historical fact are “forward-looking statements” for purposes of this Quarterly Report on Form 10-Q, including, without limitation, any projections of earnings, revenue or other financial items, any statements of the plans and objectives of management for future operations (including, but not limited to, pre-clinical development, clinical trials, manufacturing and commercialization), any statements concerning proposed drug candidates or other new products or services, any statements regarding future economic conditions or performance, any changes in the course of research and development activities and in clinical trials, any possible changes in cost and timing of development and testing, capital structure, financial condition, working capital needs and other financial items, any changes in approaches to medical treatment, any introduction of new products by others, any possible licenses or acquisitions of other technologies, assets or businesses, our ability to realize the full extent of the anticipated benefits of our acquisition of substantially all of the assets of Egen, Inc., including achieving operational cost savings and synergies in light of any delays we may encounter in the integration process and additional unforeseen expenses, any possible actions by customers, suppliers, partners, competitors and regulatory authorities, compliance with listing standards of The NASDAQ Capital Market and any statements of assumptions underlying any of the foregoing. In some cases, forward-looking statements can be identified by the use of terminology such as “may,” “will,” “expects,” “plans,” “anticipates,” “estimates,” “potential” or “continue,” or the negative thereof or other comparable terminology. Although we believe that our expectations are based on reasonable assumptions within the bounds of our knowledge of our industry, business and operations, we cannot guarantee that actual results will not differ materially from our expectations.

Our future financial condition and results of operations, as well as any forward-looking statements, are subject to inherent risks and uncertainties, including, but not limited to, the risk factors set forth in Part II, Item 1A “Risk Factors” below and for the reasons described elsewhere in this Quarterly Report on Form 10-Q. All forward-looking statements and reasons why results may differ included in this report are made as of the date hereof and we do not intend to update any forward-looking statements, except as required by law or applicable regulations. The discussion of risks and uncertainties set forth in this Quarterly Report on Form 10-Q 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 new risks will emerge, and that the nature and elements of existing risks will change, over time. 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.

Except where the context otherwise requires, in this Quarterly Report on Form 10-Q, the “Company,” “Celsion,” “we,” “us,” and “our” refer to Celsion Corporation, a Delaware corporation, and its wholly-owned subsidiary CLSN Laboratories, Inc., also a Delaware corporation.

## Trademarks

The Celsion brand and product names, including but not limited to Celsion®, ThermoDox®, EGEN®, TheraPlas™ and TheraSilence™, contained in this document are trademarks, registered trademarks or service marks of Celsion Corporation or its subsidiary in the United States (U.S.) and certain other countries. This document also contains references to trademarks and service marks of other companies that are the property of their respective owners.

**PART I: FINANCIAL INFORMATION****Item 1. FINANCIAL STATEMENTS****CELSION CORPORATION****CONDENSED CONSOLIDATED****BALANCE SHEETS**

|  | <b>September<br/>30,<br/>2015<br/><br/>(unaudited)</b> | <b>December<br/>31,<br/>2014</b> |
|--|--|----------------------------------|
| <b>ASSETS</b>  |  |                                  |
| <b>Current assets:</b>   |  |                                  |
| Cash and cash equivalents  | \$7,574,875  | \$12,686,881                     |
| Investment securities – available for sale, at fair value  | 16,772,708   | 24,173,406                       |
| Accrued interest receivable on investment securities   | 24,619   | 210,030                          |
| Advances, deposits and other current assets  | 404,350  | 435,954                          |
| Total current assets   | 24,776,552   | 37,506,271                       |
| <b>Property and equipment</b> (at cost, less accumulated depreciation<br>of \$1,957,517 and \$1,633,517, respectively) | 954,688  | 1,170,497                        |
| <b>Other assets:</b>   |  |                                  |
| In-process research and development  | 25,801,728   | 25,801,728                       |
| Goodwill   | 1,976,101  | 1,976,101                        |
| Deposits, deferred fees and other assets   | 142,535  | 226,810                          |
| Patent licensing fees, net   | 7,500  | 13,125                           |
| Total other assets   | 27,927,864   | 28,017,764                       |
| <b>Total assets</b>  | <b>\$53,659,104</b>                                    | <b>\$66,694,532</b>              |

**See accompanying notes to the financial statements.**

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**CELSION CORPORATION****CONDENSED CONSOLIDATED****BALANCE SHEETS****(Continued)**

|   | <b>September<br/>30,<br/>2015<br/><br/>(unaudited)</b> | <b>December 31,<br/>2014</b> |
|---|--|------------------------------|
| <b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>   |  |                              |
| <b>Current liabilities:</b>   |  |                              |
| Accounts payable – trade  | \$2,503,700  | \$3,480,225                  |
| Other accrued liabilities   | 1,448,281  | 2,456,365                    |
| Notes payable – current portion   | 3,977,412  | 3,654,231                    |
| Deferred revenue – current portion  | 500,000  | 500,000                      |
| <b>Total current liabilities</b>  | <b>8,429,393</b>                                       | <b>10,090,821</b>            |
| Earn–out milestone liability  | 13,622,288   | 13,663,710                   |
| Common stock warrant liability  | –  | 275,008                      |
| Notes payable – non-current portion   | 3,343,740  | 6,053,065                    |
| Deferred revenue – non-current portion  | 3,125,000  | 3,500,000                    |
| Other liabilities - non-current   | 55,503   | 286,592                      |
| <b>Total liabilities</b>  | <b>28,575,924</b>                                      | <b>33,869,196</b>            |
| <b>Stockholders' equity:</b>  |  |                              |
| Preferred stock, \$0.01 par value: 100,000 shares authorized; no shares issued or outstanding at September 30, 2015 and December 31, 2014, respectively   | –  | –                            |
| Common stock, \$0.01 par value; 75,000,000 shares authorized; 23,111,603 and 20,097,603 shares issued at September 30, 2015 and December 31, 2014, and 23,027,988 and 19,984,203 shares outstanding at September 30, 2015 and December 31, 2014, respectively | 231,116  | 200,976                      |
| Additional paid-in capital  | 238,864,749  | 229,778,703                  |
| Accumulated other comprehensive loss  | (1,034 )   | (16,032 )                    |
| Accumulated deficit   | (212,489,321)  | (195,073,702)                |

|   |              |              |
|---|--------------|--------------|
| Subtotal  | 26,605,510   | 34,889,945   |
| Treasury stock, at cost (83,615 and 113,400 shares at September 30, 2015 and December 31, 2014, respectively) | (1,522,330 ) | (2,064,609 ) |
| <b>Total stockholders' equity</b>   | 25,083,180   | 32,825,336   |
| <b>Total liabilities and stockholders' equity</b>   | \$53,659,104 | \$66,694,532 |

See accompanying notes to the financial statements.

**CELSION CORPORATION**

**CONDENSED CONSOLIDATED**

**STATEMENTS OF OPERATIONS**

**(Unaudited)**

|  | <b>Three Months Ended</b> |                       | <b>Nine Months Ended</b> |                        |
|--|---------------------------|-----------------------|--------------------------|------------------------|
|  | <b>September 30,</b>      |                       | <b>September 30,</b>     |                        |
|  | <b>2015</b>               | <b>2014</b>           | <b>2015</b>              | <b>2014</b>            |
| <b>Licensing revenue</b>   | \$125,000                 | \$125,000             | \$375,000                | \$375,000              |
| <b>Operating expenses:</b>   |                           |                       |                          |                        |
| Research and development   | 2,883,453                 | 4,629,628             | 10,957,560               | 10,688,269             |
| General and administrative   | 1,483,661                 | 2,044,163             | 5,317,344                | 6,783,228              |
| Acquisition costs  | –                         | 119,996               | –                        | 1,187,263              |
| <b>Total operating expenses</b>  | <b>4,367,114</b>          | <b>6,793,787</b>      | <b>16,274,904</b>        | <b>18,658,760</b>      |
| <b>Loss from operations</b>  | <b>(4,242,114 )</b>       | <b>(6,668,787 )</b>   | <b>(15,899,904 )</b>     | <b>(18,283,760 )</b>   |
| <b>Other (expense) income:</b>   |                           |                       |                          |                        |
| Gain (loss) from change in valuation of common stock warrant liability | –                         | 96,830                | (61,246 )                | 81,243                 |
| Gain from valuation of earn-out milestone liability                    | 282,950                   | –                     | 41,422                   | –                      |
| Investment income, net   | 15,500                    | 26,515                | 48,745                   | 57,268                 |
| Interest expense   | (322,696 )                | (418,711 )            | (1,075,258 )             | (912,539 )             |
| Other (expense) income   | (1,053 )                  | 21,807                | (985 )                   | 19,319                 |
| <b>Total other (expense) income, net</b>                               | <b>(25,299 )</b>          | <b>(273,559 )</b>     | <b>(1,047,322 )</b>      | <b>(754,709 )</b>      |
| <b>Net loss</b>  | <b>\$(4,267,413 )</b>     | <b>\$(6,942,346 )</b> | <b>\$(16,947,226 )</b>   | <b>\$(19,038,469 )</b> |
| <b>Net loss per common share</b>                                       |                           |                       |                          |                        |
| <b>Basic and diluted</b>   | <b>\$(0.19 )</b>          | <b>\$(0.40 )</b>      | <b>\$(0.79 )</b>         | <b>\$(1.12 )</b>       |
| <b>Weighted average shares outstanding</b>                             |                           |                       |                          |                        |
| <b>Basic and diluted</b>   | <b>23,023,402</b>         | <b>17,526,531</b>     | <b>21,335,228</b>        | <b>16,931,914</b>      |

**See accompanying notes to the financial statements.**

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**CELSION CORPORATION****CONDENSED CONSOLIDATED****STATEMENTS OF COMPREHENSIVE LOSS****(Unaudited)**

|  | <b>Three Months Ended</b> |               | <b>Nine Months Ended</b> |                |
|--|---------------------------|---------------|--------------------------|----------------|
|  | <b>September 30,</b>      |               | <b>September 30,</b>     |                |
|  | <b>2015</b>               | <b>2014</b>   | <b>2015</b>              | <b>2014</b>    |
| <b>Other comprehensive (loss) gain</b>   |                           |               |                          |                |
| Net loss   | \$(4,267,413)             | \$(6,942,346) | \$(16,947,226)           | \$(19,038,469) |
| Changes in:  |                           |               |                          |                |
| Realized (gain) loss on investment securities recognized in investment income, net | (106 )                    | (218 )        | 104                      | 23,473         |
| Unrealized gain (loss) on investment securities                                    | 3,387                     | (14,025 )     | 14,894                   | (5,379 )       |
| Other comprehensive gain (loss)  | 3,281                     | (14,243 )     | 14,998                   | 18,094         |
| Comprehensive loss   | \$(4,264,132)             | \$(6,956,589) | \$(16,932,228)           | \$(19,020,375) |

**See accompanying notes to the financial statements.**



**CELSION CORPORATION****CONDENSED CONSOLIDATED****STATEMENTS OF CASH FLOWS****(Unaudited)**

|  | <b>Nine Months Ended</b> |                     |
|--|--------------------------|---------------------|
|  | <b>September 30,</b>     |                     |
|  | <b>2015</b>              | <b>2014</b>         |
| <b>Cash flows from operating activities:</b>   |                          |                     |
| Net loss   | \$ (16,947,226)          | \$(19,038,469)      |
| Non-cash items included in net loss:   |                          |                     |
| Depreciation and amortization  | 329,625                  | 262,125             |
| Change in fair value of common stock warrant liability                                   | 61,246                   | (81,243 )           |
| Change in fair value of earn-out milestone liability                                     | (41,422 )                | -                   |
| Deferred revenue   | (375,000 )               | (375,000 )          |
| Stock-based compensation   | 1,616,864                | 2,253,636           |
| Shares issued out of treasury  | 73,886                   | 41,819              |
| Amortization of deferred finance charges and debt discount associated with notes payable | 349,090                  | 311,595             |
| Change in deferred rent liability  | (21,904 )                | (17,825 )           |
| Loss realized on sale of investment securities   | 104                      | 23,473              |
| Net changes in:  |                          |                     |
| Accrued interest on short term investments   | 185,411                  | 5,877               |
| Prepaid expenses, deposits and other assets  | 31,604                   | (11,332 )           |
| Accounts payable - trade   | (1,185,710 )             | 2,714,365           |
| Accrued liabilities  | (1,008,084 )             | (932,504 )          |
| <b>Net cash used in operating activities</b>   | <b>(16,931,516)</b>      | <b>(14,843,483)</b> |
| <b>Cash flows from investing activities:</b>   |                          |                     |
| Purchases of investment securities   | (21,078,733)             | (29,175,818)        |
| Proceeds from sale and maturity of investment securities                                 | 28,494,325               | 27,279,000          |
| Cash used in acquisition of EGEN, Inc. assets, net of cash received                      | -                        | (2,849,760 )        |
| Refund on security for letter of credit  | 50,000                   | 50,000              |
| Purchases of property and equipment  | (108,191 )               | (398,011 )          |
| <b>Net cash provided by (used in) investing activities</b>                               | <b>7,357,401</b>         | <b>(5,094,589 )</b> |

**Cash flows from financing activities:**

|  |                  |                   |
|--|------------------|-------------------|
| Proceeds from sale of common stock equity, net of issuance costs | 7,163,068        | 13,788,811        |
| Proceeds from note payable                                       | –                | 5,000,000         |
| Principal payments on notes payable                              | (2,700,959 )     | (10,891 )         |
| <b>Net cash provided by financing activities</b>                 | <b>4,462,109</b> | <b>18,777,920</b> |

**Decrease in cash and cash equivalents**

|   |                     |                     |
|---|---------------------|---------------------|
| <b>Decrease in cash and cash equivalents</b>            | <b>(5,112,006 )</b> | <b>(1,160,152 )</b> |
| <b>Cash and cash equivalents at beginning of period</b> | <b>12,686,881</b>   | <b>5,718,504</b>    |
| <b>Cash and cash equivalents at end of period</b>       | <b>\$ 7,574,875</b> | <b>\$ 4,558,352</b> |

**Supplemental disclosures of cash flow information:**

|   |            |               |
|---|------------|---------------|
| Fair value of common stock issued in acquisition of EGEN, Inc. assets | \$ –       | \$ 10,850,977 |
| Interest paid   | \$ 726,167 | \$ 605,100    |

See accompanying notes to the financial statements.



**CELSION CORPORATION**

**NOTES TO THE CONDENSED CONSOLIDATED**

**FINANCIAL STATEMENTS (UNAUDITED)**

**FOR THE THREE AND NINE MONTH PERIODS ENDED SEPTEMBER 30, 2015 AND 2014**

**Note 1. Business Description**

Celsion Corporation, a Delaware corporation based in Lawrenceville, New Jersey, and its wholly owned subsidiary, CLSN Laboratories, Inc., also a Delaware corporation, referred to herein as “Celsion”, “we”, or “the Company,” as the context requires, is a fully-integrated oncology drug development company focused on developing a portfolio of innovative cancer treatments, including directed chemotherapies, immunotherapies and RNA- or DNA-based therapies. Our lead program is ThermoDox®, a proprietary heat-activated liposomal encapsulation of doxorubicin, currently in Phase III development for the treatment of primary liver cancer and in Phase II development for the treatment of recurrent chest wall breast cancer. Our pipeline also includes GEN-1, a DNA-based immunotherapy for the localized treatment of ovarian and brain cancers. We have three platform technologies for the development of treatments for those suffering with difficult-to-treat forms of cancer, novel nucleic acid-based immunotherapies and other anti-cancer DNA or RNA therapies, including TheraPlas™ and TheraSilence™. We are working to develop and commercialize more efficient, effective and targeted oncology therapies based on our technologies, with the goal to develop novel therapeutics that maximize efficacy while minimizing side effects common to cancer treatments.

**Note 2. Basis of Presentation**

The accompanying unaudited condensed consolidated financial statements, which include the accounts of Celsion Corporation and CLSN Laboratories, Inc., have been prepared in accordance with generally accepted accounting principles in the United States (GAAP) for interim financial information and with the instructions to Form 10-Q and Article 10 of Regulation S-X. All intercompany balances and transactions have been eliminated. Certain information and footnote disclosures normally included in financial statements prepared in accordance with GAAP have been condensed or omitted pursuant to such rules and regulations.

In the opinion of management, all adjustments, consisting only of normal recurring accruals considered necessary for a fair presentation, have been included in the accompanying unaudited condensed consolidated financial statements. Operating results for the three and nine month periods ended September 30, 2015 are not necessarily indicative of the results that may be expected for any other interim period(s) or for any full year. For further information, refer to the financial statements and notes thereto included in the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2014 filed on March 12, 2015 with the Securities and Exchange Commission (SEC).

The preparation of financial statements in conformity with GAAP requires management to make judgments, estimates, and assumptions that affect the amount reported in the Company's financial statements and accompanying notes. Actual results could differ materially from those estimates.

Events and conditions arising subsequent to the most recent balance sheet date have been evaluated for their possible impact on the financial statements and accompanying notes. No events and conditions would give rise to any information that required accounting recognition or disclosure in the financial statements other than those arising in the ordinary course of business.

### **Note 3. New Accounting Pronouncements**

From time to time, new accounting pronouncements are issued by Financial Accounting Standards Board (FASB) and are adopted by us as of the specified effective date. Unless otherwise discussed, we believe that the impact of recently issued accounting pronouncements will not have a material impact on the Company's consolidated financial position, results of operations, and cash flows, or do not apply to our operations.

In May 2014, the FASB issued Accounting Standards Update No. 2014-09 Revenue from Contracts with Customers (Topic 606). This guidance is intended to improve and converge with international standards regarding the financial reporting requirements for revenue from contracts with customers. It will be effective for our first quarter of 2018 and early adoption is permitted. We are currently evaluating the impact of adoption of this new accounting pronouncement on our financial statements.

In April 2015, the FASB issued Accounting Standards Update No. 2015-03 Interest – Imputation of Interest (Subtopic 835-30). This guidance is to simplify the presentation of debt issuance costs by recognizing a debt liability in the balance sheet as a direct deduction from that debt liability consistent with the presentation of a debt discount. It will be effective for our first quarter of 2016 and early adoption is permitted. We are currently evaluating the impact of adoption of this new accounting pronouncement on our financial statements.

#### **Note 4. Net Loss per Common Share**

Basic earnings per share is calculated based upon the net income (loss) available to common shareholders divided by the weighted average number of common shares outstanding during the period. Diluted earnings per share is calculated after adjusting the denominator of the basic earnings per share computation for the effects of all dilutive potential common shares outstanding during the period. The dilutive effects of preferred stock, options and warrants and their equivalents are computed using the treasury stock method.

For the three and nine month periods ended September 30, 2015 and 2014, diluted loss attributable to common shareholders per common share was the same as basic loss attributable to common shareholders per common share as all options and warrants that were convertible into shares of the Company's common stock were excluded from the calculation of diluted earnings attributable to common shareholders per common share as their effect would have been anti-dilutive. The total number of shares of common stock issuable upon exercise of warrants and equity awards were 8,110,136 for the three and nine month periods ended September 30, 2015 and were 8,188,708 for the three and nine month periods ended September 30, 2014.

#### **Note 5. Investment Securities - Available For Sale**

Investment securities available for sale of \$16,772,708 and \$24,173,406 as of September 30, 2015 and December 31, 2014, respectively, consist of commercial paper and corporate debt securities. They are valued at fair value, with unrealized gains and losses reported as a separate component of Stockholders' Equity in Accumulated Other Comprehensive Loss.

Investment securities available for sale are evaluated periodically to determine whether a decline in their value is other than temporary. The term "other than temporary" is not intended to indicate a permanent decline in value. Rather, it means that the prospects for near-term recovery of value are not necessarily favorable, or that there is a lack of evidence to support fair values equal to, or greater than, the carrying value of the security. Management reviews criteria such as the magnitude and duration of the decline, as well as the reasons for the decline, to predict whether the loss in value is other than temporary. Once a decline in value is determined to be other than temporary, the value of the security is reduced and a corresponding charge to earnings is recognized.

A summary of the cost, fair value and maturities of the Company's short-term investments is as follows:

|                                     | <b>September 30, 2015</b> |                     | <b>December 31, 2014</b> |                     |
|-------------------------------------|---------------------------|---------------------|--------------------------|---------------------|
|                                     | <b>Cost</b>               | <b>Fair Value</b>   | <b>Cost</b>              | <b>Fair Value</b>   |
| <b>Short-term investments</b>       |                           |                     |                          |                     |
| Certificate of deposit              | \$5,760,000               | \$5,761,018         | \$5,000,000              | \$4,996,568         |
| Bonds- corporate issuances          | 11,013,742                | 11,011,690          | 19,189,438               | 19,176,838          |
| <b>Total short-term investments</b> | <b>\$16,773,742</b>       | <b>\$16,772,708</b> | <b>\$24,189,438</b>      | <b>\$24,173,406</b> |

|   | <b>September 30, 2015</b> |                     | <b>December 31, 2014</b> |                     |
|---|---------------------------|---------------------|--------------------------|---------------------|
|   | <b>Cost</b>               | <b>Fair Value</b>   | <b>Cost</b>              | <b>Fair Value</b>   |
| <b>Short-term investment maturities</b> |                           |                     |                          |                     |
| Within 3 months                         | \$5,962,090               | \$5,962,325         | \$16,881,490             | \$16,872,158        |
| Between 3-12 months                     | 10,811,652                | 10,810,383          | 7,307,948                | 7,301,248           |
| <b>Total</b>                            | <b>\$16,773,742</b>       | <b>\$16,772,708</b> | <b>\$24,189,438</b>      | <b>\$24,173,406</b> |

The following table shows the Company's investment securities with unrealized holding gains and losses and their fair value by investment category and length of time that individual securities have been in a continuous unrealized loss position at September 30, 2015 and December 31, 2014. The Company has reviewed individual securities to determine whether a decline in fair value below the amortizable cost basis is other than temporary.

| Description of Securities   | September 30, 2015  |                                   | December 31, 2014   |                                   |
|---|---------------------|-----------------------------------|---------------------|-----------------------------------|
|   | Fair Value          | Unrealized Holding Gains (Losses) | Fair Value          | Unrealized Holding Gains (Losses) |
| Available for Sale (all unrealized holding gains and losses are less than 12 months at date of measurement) |                     |                                   |                     |                                   |
| Short-term investments with unrealized gains  | \$6,564,384         | \$ 1,291                          | \$-                 | \$-                               |
| Short-term investments with unrealized losses   | 10,208,324          | (2,326 )                          | 24,173,406          | (16,032 )                         |
| <b>Total</b>  | <b>\$16,772,708</b> | <b>\$ (1,034 )</b>                | <b>\$24,173,406</b> | <b>\$ (16,032 )</b>               |

Investment income, which includes net realized losses on sales of available for sale securities and investment income interest and dividends, is summarized as follows:

| Description of Securities               | Three Months Ended |           |
|---|--------------------|-----------|
|   | September 30, 2015 | 2014      |
| Interest and dividends accrued and paid | \$29,610           | \$252,303 |
| Accretion of investment premium         | (14,216)           | (226,006) |
| Realized gains                          | 106                | 218       |
| Investment income, net                  | \$15,500           | \$26,515  |

| Description of Securities               | Nine Months Ended  |           |
|---|--------------------|-----------|
|   | September 30, 2015 | 2014      |
| Interest and dividends accrued and paid | \$161,584          | \$833,315 |

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|                                 |           |           |
|---------------------------------|-----------|-----------|
| Accretion of investment premium | (112,735) | (752,574) |
| Realized losses                 | (104 )    | (23,473 ) |
| Investment income, net          | \$48,745  | \$57,268  |

The following table presents the change, by component, in accumulated other comprehensive loss for the first nine months of 2015.

|  | <b>Accumulated<br/>Other<br/>Comprehensive<br/>Loss</b> |
|--|---|
| Balance at January 1, 2015   | \$ (16,032 )  |
| Unrealized gains on investment securities                            | 14,894  |
| Realized loss reclassified from other accumulated comprehensive loss | 104   |
| Net other comprehensive loss, net                                    | 14,998  |
| Balance at September 30, 2015  | \$ (1,034 )   |

**Note 6. Fair Value of Measurements**

FASB Accounting Standards Codification (ASC) Section 820 (formerly SFAS No. 157) “*Fair Value Measurements and Disclosures*,” establishes a three level hierarchy for fair value measurements which requires an entity to maximize the use of observable inputs and minimize the use of unobservable inputs when measuring fair value. The three levels of inputs that may be used to measure fair value are as follows:

**Level 1:** Quoted prices (unadjusted) or identical assets or liabilities in active markets that the entity has the ability to access as of the measurement date;

**Level 2:** Significant other observable inputs other than Level 1 prices such as quoted prices for similar assets or liabilities; quoted prices in markets that are not active; or other inputs that are observable or can be corroborated by observable market data; and

**Level 3:** Significant unobservable inputs that reflect a reporting entity’s own assumptions that market participants would use in pricing an asset or liability.

The fair values of securities available for sale are determined by obtaining quoted prices on nationally recognized exchanges (Level 1 inputs) or matrix pricing, which is a mathematical technique widely used in the industry to value debt securities without relying exclusively on quoted prices for the specific securities but rather by relying on the securities’ relationship to other benchmark quoted securities (Level 2 inputs).

Cash and cash equivalents, other current assets, accounts payable and other accrued liabilities are reflected in the balance sheet at their estimated fair values primarily due to their short-term nature. There were no transfers of assets of liabilities between Level 1 and Level 2 and no transfers in or out of Level 3 during the nine months ended September 30, 2015 except for the change in the fair market value of the warrant liability and the change in the earn-out milestone liability were included in earnings.

Assets and liabilities measured at fair value are summarized below:

| <b>Total Fair</b> | <b>Quoted</b>    | <b>Significant</b> | <b>Significant</b> |
|-------------------|------------------|--------------------|--------------------|
| <b>Value</b>      | <b>Prices In</b> | <b>Other</b>       | <b>Other</b>       |

|   | <b>Value on<br/>the<br/>Balance<br/>Sheet</b> | <b>Active<br/>Markets<br/>For<br/>Identical<br/>Assets /<br/>Liabilities<br/><br/>(Level 1)</b> | <b>Other<br/>Observable Inputs<br/>Inputs<br/>(Level 2)</b> | <b>Unobservable<br/>Inputs<br/>(Level 3)</b> |
|---|---|---|---|--|
| <b>Assets:</b>  |   |   |   |  |
| Recurring items as of September 30, 2015                              |   |   |   |  |
| Short-term investments available for sale                             | \$16,772,708                                  | \$ 16,772,708   | \$ -  | \$ -   |
| Recurring items as of December 31, 2014                               |   |   |   |  |
| Short-term investments available for sale                             | \$24,173,406                                  | \$ 24,173,406   | \$ -  | \$ -   |
| Non-recurring items as of September 30, 2015 and<br>December 31, 2014 |   |   |   |  |
| In-process research and development (Note 7)                          | \$25,801,728                                  | \$ -  | \$ -  | \$ 25,801,728                                |
| Goodwill (Note 7)   | \$1,976,101                                   | \$ -  | \$ -  | \$ 1,976,101                                 |



|  | <b>Total Fair<br/>Value on<br/>the<br/>Balance<br/>Sheet</b> | <b>Quoted<br/>Prices In<br/>Active<br/>Markets<br/>For<br/>Identical<br/>Assets /<br/>Liabilities<br/>(Level 1)</b> | <b>Significant<br/>Other<br/>Observable<br/>Inputs<br/>(Level 2)</b> | <b>Significant<br/>Unobservable<br/>Inputs<br/>(Level 3)</b> |
|--|--|---|--|--|
| <b>Liabilities:</b>                      |  |   |  |  |
| Recurring items as of September 30, 2015 |  |   |  |  |
| Common stock warrant liability (Note 13) | \$   | \$  | \$   | \$   |
| Earn-out milestone liability (Note 12)   | \$ 13,622,288  | \$  | \$   | \$ 13,622,288  |
| Recurring items as of December 31, 2014  |  |   |  |  |
| Common stock warrant liability (Note 13) | \$ 275,008   | \$  | \$   | \$ 275,008   |
| Earn-out milestone liability (Note 12)   | \$ 13,663,710  | \$  | \$   | \$ 13,663,710  |

**Note 7. Acquisition of EGEN, Inc.**

On June 20, 2014, Celsion completed the acquisition of substantially all of the assets of Egen, Inc., an Alabama Corporation (EGEN) pursuant to an Asset Purchase Agreement (EGEN Purchase Agreement). CLSN Laboratories, Inc., a Delaware corporation and a wholly-owned subsidiary of Celsion (CLSN Laboratories), 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 aggregate purchase price for the acquisition is up to \$44.4 million, which includes potential future payments of up to \$30.4 million contingent upon achievement of certain milestones set forth in the EGEN Purchase Agreement (Earn-out Payments). At the closing, Celsion paid approximately \$3.0 million in cash after expense adjustment and issued 2,712,188 shares of its common stock to EGEN. The shares of common stock were issued in a private transaction exempt from registration under the Securities Act of 1933, as amended (the Securities Act), pursuant to Section 4(2) thereof. In addition, 670,070 shares of common stock are issuable to EGEN on or after August 2, 2016 pending satisfactory resolution of any post-closing adjustments of expenses and EGEN's indemnification obligations under the EGEN Purchase Agreement (Holdback Shares). A registration statement (File No. 333-198786) was filed on September 16, 2014 and declared effective on September 30, 2014 for the resale of the shares of common stock issued

and issuable to EGEN under the EGEN Purchase Agreement.

The Earn-out Payments of up to \$30.4 million will become payable, in cash, shares of Celsion common stock or a combination thereof, at Celsion's option, as follows:

\$12.4 million will become payable upon achieving certain specified development milestones relating to an ovarian cancer study of GEN-1 to be conducted by the Company or its 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 development milestones relating to the TheraSilence™ technology acquired from EGEN in the acquisition.

On June 9, 2014, Celsion borrowed an additional \$5 million pursuant to a certain Loan and Security Agreement dated as of November 25, 2013, by and between Celsion and Hercules Technology Growth Capital, Inc. (see Note 9). Celsion used the loan proceeds to pay the upfront cash payment at closing and certain transaction costs incurred by Celsion in connection with the acquisition.

The EGEN Purchase Agreement contains customary representations and warranties regarding EGEN and Celsion, covenants regarding the conduct of EGEN's business prior to the consummation of the acquisition, indemnification provisions, termination and other provisions customary for transactions of this nature.

The acquisition of EGEN was accounted for under the acquisition method of accounting which required the Company to perform an allocation of the purchase price to the assets acquired and liabilities assumed. The fair value of the consideration transferred for the acquisition is approximately \$27.6 million determined as follows:

#### Consideration Paid at Closing

|   |             |
|---|-------------|
| Cash, net of cash acquired  | \$2,821,000 |
| Celsion common stock (2,712,188 shares valued at \$3.48 which was the last closing price of our common stock at the time of closing the transaction on June 20, 2014) | 9,438,000   |

#### Future Consideration

|  |              |
|--|--------------|
| Holdback Shares (670,070 shares of Celsion common stock which were discounted by 38% to reflect the cost of the restriction) | 1,441,000    |
| Earn-out Payments (at fair value*)   | 13,878,000   |
| Total fair value of consideration  | \$27,578,000 |

\* The total aggregate purchase price for the acquisition of substantially all the assets of EGEN included potential future Earn-out Payments contingent upon achievement of certain milestones. The difference between the aggregate \$30.4 million in future Earn-out Payments and the \$13.9 million included in the fair value of the acquisition consideration at June 20, 2014 was based on the Company's risk-adjusted assessment of each milestone and utilizing a discount rate based on the estimated time to achieve the milestone. These milestone payments will be fair valued at the end of each quarter and any change in their value will be recognized in the financial statements. As of September 30, 2015, the Company fair valued these milestones at \$13.6 million and recognized a non-cash benefit of \$41,422 as a result of the change in the fair value of these milestones from December 31, 2014.

Under the acquisition method of accounting, the total purchase price is allocated to EGEN's net tangible and intangible assets and liabilities based on their estimated fair values as of the acquisition date. There were no subsequent adjustments to provisional amounts in finalizing the purchase price allocation of acquisition of substantially all of the assets of Egen, Inc. on June 20, 2014. The following table summarizes the fair values of these assets acquired and liabilities assumed related to the acquisition.

|  |            |
|--|------------|
| Property and equipment, net              | 35,000     |
| In-process research and development      | 25,802,000 |
| Goodwill                                 | 1,976,000  |
| Total assets                             | 27,813,000 |
| Accounts payable and accrued liabilities | (235,000 ) |

|                     |              |
|---------------------|--------------|
| Net assets acquired | \$27,578,000 |
|---------------------|--------------|

The purchase price exceeded the estimated fair value of the net assets acquired by approximately \$2.0 million which was recorded as goodwill.

***Acquired In-Process Research and Development (IPR&D)***

Acquired IPR&D consists of EGEN's drug technology platforms: TheraPlas™ and TheraSilence™. The fair value of the IPR&D drug technology platforms was estimated to be \$25.8 million as of the acquisition date using the Multi-Period Excess Earnings Method (MPEEM) which is a form of the income approach. Under the MPEEM, the fair value of an intangible asset is equal to the present value of the asset's incremental after-tax cash flows (excess earnings) remaining after deducting the market rates of return on the estimated value of contributory assets (contributory charge) over its remaining useful life.

To calculate fair value of the IPR&D programs under the MPEEM, we used projected cash flows discounted at a rate considered appropriate given the significant inherent risks associated with drug development by development-stage companies. Cash flows were calculated based on estimated projections of revenues and expenses related to the IPR&D programs and then reduced by a contributory charge on requisite assets employed. Contributory assets included debt-free working capital, net fixed assets and assembled workforce. Rates of return on the contributory assets were based on rates used for comparable market participants. Cash flows were assumed to extend through a seven-year market exclusivity period. The resultant cash flows were then discounted to present value using a weighted-average cost of equity capital for companies with profiles substantially similar to that of Celsion, which we believe represents the rate that market participants would use to value the assets. The projected cash flows were based on significant assumptions, including the indication in which we will pursue development of IPR&D programs, the time and resources needed to complete the development and regulatory approval of IPR&D programs, estimates of revenue and operating profit related to the program considering its stage of development, the life of the potential commercialized product, market penetration and competition, and risks associated with achieving commercialization, including delay or failure to obtain regulatory approvals to conduct clinical studies, failure of clinical studies, delay or failure to obtain required market clearances, and intellectual property litigation.

As of the closing of the acquisition, the IPR&D is considered indefinite lived intangible assets and will not be amortized. IPR&D is reviewed for impairment at least annually as of our third quarter ended September 30, and whenever events or changes in circumstances indicate that the carrying value of the assets might not be recoverable. When performing our impairment assessment, we have the option to first assess qualitative factors to determine whether it is necessary to recalculate the fair value of our acquired IPR&D. If we elect this option and believe, as a result of the qualitative assessment, that it is more-likely-than-not that the fair value of our acquired IPR&D is less than its carrying amount, we calculate the fair value using the same methodology as described above. If the carrying value of our acquired IPR&D exceeds its fair value, then the intangible asset is written-down to its fair value. Alternatively, we may elect to not first assess qualitative factors and immediately recalculate the fair value of our acquired IPR&D. As of September 30, 2015, after our assessment of the totality of the events that could impair IPR&D, it is the Company's conclusion "it is not more likely than not" that the indefinite-lived intangible assets are impaired. Therefore, the Company is not required to calculate the fair value of the intangible assets and perform a quantitative impairment test.

### ***Pro Forma Information***

The following unaudited pro forma information presents our condensed results of operations as if the acquisition of EGEN had occurred on January 1, 2014:

|          | <b>Three Months Ended</b> |             |
|----------|---------------------------|-------------|
|          | <b>September 30,</b>      |             |
|          | <b>2015</b>               | <b>2014</b> |
| Revenues | \$ 125,000                | \$ 125,000  |

|  |             |             |
|--|-------------|-------------|
| Loss from operations                       | (4,242,114) | (6,548,791) |
| Net loss applicable to common shareholders | (4,267,413) | (6,822,350) |

**Nine Months Ended**

|  | <b>September 30,</b> |              |
|--|----------------------|--------------|
|  | <b>2015</b>          | <b>2014</b>  |
| Revenues                                   | \$375,000            | \$375,000    |
| Loss from operations                       | (15,899,904)         | (18,665,291) |
| Net loss applicable to common shareholders | (16,947,226)         | (19,404,768) |

The above unaudited pro forma condensed consolidated financial information is presented for illustrative purposes only. It is not necessarily indicative of what the results of operations actually would have been had the acquisition been completed on the date indicated. In addition, it does not purport to project the future operating results of the combined entity.

Goodwill represents the difference between the total purchase price for the net assets purchased from EGEN and the aggregate fair values of tangible and intangible assets acquired, less liabilities assumed. Goodwill is reviewed for impairment at least annually as of our third quarter ended September 30 if we believe indicators of impairment exist. Such indicators could include, but are not limited to (1) a significant adverse change in legal factors or in business climate, (2) unanticipated competition, or (3) an adverse action or assessment by a regulator. We first assessed qualitative factors to determine whether it is more likely than not that the fair value of a reporting unit is less than its carrying amount, including goodwill. If we conclude that it is more likely than not that the fair value of a reporting unit is less than its carrying amount, we will conduct a two-step quantitative goodwill impairment test. As of September 30, 2015, after our assessment of the totality of the events that could impair Goodwill, it is the Company's conclusion "it is not more likely than not" that the Goodwill is impaired. Therefore, the Company is not required to conduct a two-step quantitative goodwill impairment test.

**Note 8. Accrued Liabilities**

Other accrued liabilities at September 30, 2015 and December 31, 2014 include the following:

|   | <b>September<br/>30,<br/>2015</b> | <b>December<br/>31,<br/>2014</b> |
|---|-----------------------------------|----------------------------------|
| Amounts due to Contract Research Organizations and other contractual agreements | \$402,961                         | \$857,730                        |
| Accrued payroll and related benefits  | 699,371                           | 961,440                          |
| Accrued professional fees   | 257,500                           | 502,300                          |
| Accrued interest on notes payable   | 68,429                            | 96,875                           |
| Other   | 20,020                            | 38,020                           |
| <br>Total Accrued Liabilities   | <br>\$1,448,281                   | <br>\$2,456,365                  |

**Note 9. Note Payable*****Hercules Credit Agreement***

In November 2013, the Company entered into a loan agreement with Hercules Technology Growth Capital, Inc. (Hercules) which permits up to \$20 million in capital to be distributed in multiple tranches (the Hercules Credit Agreement). The Company drew the first tranche of \$5 million upon closing of the Hercules Credit Agreement in November 2013 and used approximately \$4 million of the proceeds to repay the outstanding obligations under its loan agreement with Oxford Finance LLC and Horizon Technology Finance Corporation as discussed further below. On June 10, 2014, the Company closed the second \$5 million tranche under the Hercules Credit Agreement. The proceeds were used to fund the \$3.0 million upfront cash payment associated with Celsion's acquisition of EGEN, as well as the Company's transaction costs associated with the EGEN acquisition. Upon the closing of this second tranche, the Company has drawn down a total of \$10 million under the Hercules Credit Agreement.

The obligations under the Hercules Credit Agreement are in the form of secured indebtedness bearing interest at a calculated prime-based variable rate (11.25% per annum since inception). Payments under the loan agreement are interest only for the first twelve months after loan closing, followed by a 30-month amortization period of principal and interest through the scheduled maturity date.

In connection with the Hercules Credit Agreement, the Company incurred cash expenses of \$122,378 which were recorded as deferred financing fees. These deferred financing fees are being amortized as interest expense using the effective interest method over the life of the loan. Also in connection with the Hercules Credit Facility, the Company paid loan origination fees of \$230,000 which has been classified as debt discount. This amount is being amortized as interest expense using the effective interest method over the life of the loan.

As a fee in connection with the Hercules Credit Agreement, the Company issued Hercules a warrant for a total of 97,493 shares of the Company's common stock (the Hercules Warrant) at a per share exercise price of \$3.59, exercisable for cash or by net exercise from November 25, 2013. Upon the closing of the second tranche on June 10, 2014, this warrant became exercisable for an additional 97,493 shares of the Company's common stock. The Hercules Warrant will expire November 25, 2018. Hercules has certain rights to register the common stock underlying the Hercules Warrant pursuant to a Registration Rights Agreement with the Company dated November 25, 2013. The registration rights expire on the date when such stock may be sold under Rule 144 without restriction or upon the first year anniversary of the registration statement for such stock, whichever is earlier. A registration statement (File No. 333-193936) was filed on February 13, 2014, amended on September 16, 2014 and declared effective on September 30, 2014 for the resale of the shares of common stock issuable pursuant to the Hercules Warrant.



The Company valued the Hercules Warrant issued at the inception of the loan using the Black-Scholes option pricing model and recorded \$521,763 in 2013 as deferred financing fees. In calculating the value of the warrant, the Company assumed a volatility rate of 102%, risk free interest rate of 1.37%, an expected life of 5 years, a stock price of \$3.55 (closing price on date of the Hercules Warrant) and no expected forfeitures nor dividends. In the second quarter of 2014, the Company reassessed the classification of the warrant and concluded the original amount should be reclassified from deferred financing fees and equity as the warrant contains a provision which required the exercise price to be adjusted downward to a lower price at which time the Company would sell and issue shares in a financing for cash during the one-year anniversary of the date of issuance of the warrant. Therefore, other assets and additional paid in capital were both reduced by the \$521,763. The Company then valued the warrant for the initial 97,493 shares of the common stock as of the inception of the loan and recorded \$260,928 as a debt discount to be amortized as interest expense using the effective interest method over the life of the loan and recognized a warrant liability for this amount. In connection with the closing of the second \$5 million tranche on June 9, 2014, the Company then valued the warrant for the additional 97,493 shares of the common stock which became available and exercisable as of the date and recorded \$215,333 as a debt discount to be amortized as interest expense using the effective interest method over the life of the loan and recognized a warrant liability for this amount. In calculating the value of the warrant for the additional shares of the common stock on June 10, 2014, the Company assumed a volatility rate of 104%, risk free interest rate of 1.69%, an expected remaining life of 4.5 years, a stock price of \$3.07 (closing price June 9, 2014) and no expected forfeitures nor dividends. The warrant liability was fair valued at the end of each quarter and the resulting change in fair value will be recognized in net income.

In the second quarter of 2015, the Company concluded the warrant provision which provided for the exercise price to be adjusted downward as described above had expired. Therefore, the Company valued the warrant at \$336,254 immediately prior to this event and recorded non-cash charges to net income of \$18,018 and \$61,246 in the second quarter and year to date periods of 2015, respectively. The Company also reduced the liability to zero and increased equity by \$336,254 at this time.

Also in connection with each of the \$5.0 million tranches, the Company will be required to pay an end of term charge equal to 3.5% of each original loan amount at time of maturity. Therefore, these amounts totaling \$350,000 are being amortized as interest expense using the effective interest method over the life of the loan.

For the three and nine month periods ended September 30, 2015, the Company incurred \$218,836 and \$726,168 in interest expense and amortized \$103,860 and \$349,090 as interest expense for deferred fees, debt discount and end of term charges in connection with the Hercules Credit Agreement.

The Hercules Credit Agreement contains customary covenants, including covenants that limit or restrict the Company's ability to grant liens, incur indebtedness, make certain restricted payments, merge or consolidate and make dispositions of assets. Upon the occurrence of an event of default under the Hercules Credit Agreement, the lenders may cease making loans, terminate the Hercules Credit Agreement, declare all amounts outstanding to be immediately due and payable and foreclose on or liquidate the Company's assets that comprise the lenders' collateral. The Hercules Credit Agreement specifies a number of events of default (some of which are subject to applicable grace or cure

periods), including, among other things, non-payment defaults, covenant defaults, a material adverse effect on the Company or its assets, cross-defaults to other material indebtedness, bankruptcy and insolvency defaults and material judgment defaults. The Company has maintained compliance with these covenants.

Following is a schedule of future principal payments before debt discount due on the Hercules Credit Agreement:

**Principle payments before debt discount and end of term charges on the Hercules Credit Agreement**

|   |             |
|---|-------------|
| For the year period ending September 30, 2016 | \$3,977,412 |
| For the year period ending September 30, 2017 | 3,321,629   |
| Total   | \$7,299,041 |

***Oxford & Horizon Credit Agreement***

In June 2012, the Company entered into a Loan and Security Agreement (the Oxford & Horizon Credit Agreement) with Oxford Finance LLC (Oxford) and Horizon Technology Finance Corporation (Horizon). The Oxford & Horizon Credit Agreement provided for a secured term loan of up to \$10 million, with 50% of any loans to be funded by Oxford and 50% to be funded by Horizon. The aggregate loan amount could have been advanced in two tranches of \$5 million each. The first tranche (the Term A Loan) was made available to the Company on June 27, 2012 and the second tranche was to be made available, if at all, during the period beginning on the date that the Company achieved positive data in its Phase III clinical trial of RFA and ThermoDox® (the HEAT Study) and ending on March 31, 2013. On January 31, 2013, the Company announced it did not meet the primary endpoint of the HEAT Study.

The Term A Loan was originally scheduled to mature on October 15, 2015. As a result of the Hercules Credit Agreement discussed above, the Company terminated the Oxford & Horizon Credit Agreement and repaid the outstanding principal, accrued interest and termination fees totaling approximately \$4.1 million.

The proceeds of the Oxford & Horizon Credit Agreement were used to fund the Company's working capital and general corporate purposes. The obligations under the Oxford & Horizon Credit Agreement were secured by substantially all assets of the Company other than its intellectual property and certain other agreed-upon exclusions.

As a fee in connection with the Oxford & Horizon Credit Agreement, the Company issued warrants to Horizon and Oxford (the Oxford & Horizon Warrants) to purchase the number of shares of the Company's common stock equal to 3% of each loan amount divided by the exercise price of \$13.14 per share, which was calculated as the average NASDAQ closing price of the Company's common stock for the three days prior to the funding of the loan amount. This resulted in 11,415 warrant shares issued in connection with the Term A Loan. The Oxford & Horizon Warrants issued in connection with the Term A Loan are exercisable for cash or by net exercise and will expire seven years after their issuance, which is June 27, 2019.

**Note 10. Stockholders' Equity**

*May 2015 Common Stock Offering*

On May 27, 2015, the Company entered into a Securities Purchase Agreement with certain investors, pursuant to which the Company sold and issued on June 1, 2015, in a registered direct offering (the May 2015 Offering), an aggregate of 3,000,000 shares of common stock at an offering price of \$2.675 per share for gross proceeds of \$8.0 million before the deduction of the placement agent fee and offering expenses. The Shares were offered by the Company pursuant to a registration statement on Form S-3 (File No. 333-183286), which was initially filed with the SEC on August 13, 2012, as amended on August 20, 2012, and was declared effective by the SEC on September 14, 2012 (the Shelf Registration Statement).

In a concurrent private placement closed on June 1, 2015, the Company issued to the investors in the May 2015 Offering certain warrants (the May 2015 Warrants) at an exercise price of \$2.60 per share. The May 2015 Warrants are exercisable to purchase 0.65 share of common stock for each share of common stock purchased in the May 2015 Offering for an aggregate of 1,950,000 shares of common stock. Each May 2015 Warrant will be exercisable on the date of its issuance until the five-year anniversary of the date of issuance. On July 10, 2015, the Company filed a registration statement for the resale of any shares of common stock issuable upon the exercise of the May 2015 Warrants on Form S-3 (File No. 333-205608) which was declared effective by the SEC on July 30, 2015.

Under this purchase agreement, the Company was prohibited, for the period from the date of closing and ending September 1, 2015, from effecting or entering into an agreement to issue common stock or, for a period of five months after the closing, any other securities that are at any time convertible into, or exercisable or exchangeable for, or otherwise entitle the holder thereof to receive, common stock to the extent such issuance or sale involves certain variable conversion, exercise or exchange prices or such agreement provides for sale of securities at a price to be determined in the future.

### ***January 2014 Common Stock Offering***

On January 15, 2014, the Company entered into a Securities Purchase Agreement with certain institutional investors, pursuant to which the Company sold, in a registered offering, an aggregate of 3,603,604 shares of its common stock and warrants to purchase up to 1,801,802 shares of common stock, for an aggregate purchase price of approximately \$15 million (the January 2014 Offering). The shares of common stock and warrants were sold in units, with each unit consisting of one share of common stock, a Series A warrant to purchase 0.25 share of common stock and a Series B warrant to purchase 0.25 share of common stock. Each unit was sold at a purchase price of \$4.1625. Each Series A warrant will be exercisable during one year after its issuance date and until the five-year anniversary of the issuance date. Each Series B warrant was exercisable at any time on or after its issuance date had expired as of January 15, 2015. Each warrant has an exercise price of \$4.10 per share.

### ***Controlled Equity Offering***

On February 1, 2013, the Company entered into a Controlled Equity Offering<sup>SM</sup> Sales Agreement (the ATM Agreement) with Cantor Fitzgerald & Co., as sales agent (Cantor), pursuant to which the Company may offer and sell, from time to time, through Cantor, shares of its common stock having an aggregate offering price of up to \$25.0 million (the ATM Shares) pursuant to the Shelf Registration Statement. Under the ATM Agreement, Cantor may sell ATM Shares by any method deemed to be an “at-the-market” offering as defined in Rule 415 promulgated under the Securities Act of 1933, as amended, including sales made directly on The NASDAQ Capital Market, on any other existing trading market for the our common stock or to or through a market maker. From February 1, 2013 through February 25, 2013, the Company sold and issued an aggregate of 1,195,927 shares of common stock under the ATM Agreement, receiving approximately \$6.8 million in net proceeds.

The Company is not obligated to sell any ATM Shares under the ATM Agreement. Subject to the terms and conditions of the ATM Agreement, Cantor will use commercially reasonable efforts, consistent with its normal trading and sales practices and applicable state and federal law, rules and regulations and the rules of The NASDAQ Capital Market, to sell ATM Shares from time to time based upon the Company’s instructions, including any price, time or size limits or other customary parameters or conditions the Company may impose. In addition, pursuant to the terms and conditions of the ATM Agreement and subject to the instructions of the Company, Cantor may sell ATM Shares by any other method permitted by law, including in privately negotiated transactions.

The ATM Agreement will terminate upon the earlier of (i) the sale of ATM Shares under the ATM Agreement having an aggregate offering price of \$25 million and (ii) the termination of the ATM Agreement by Cantor or the Company. The ATM Agreement may be terminated by Cantor or the Company at any time upon 10 days' notice to the other party, or by Cantor at any time in certain circumstances, including the occurrence of a material adverse change in the Company. The Company pays Cantor a commission of 3.0% of the aggregate gross proceeds from each sale of ATM Shares and has agreed to provide Cantor with customary indemnification and contribution rights. The Company also reimbursed Cantor for legal fees and disbursements, of \$50,000, in connection with entering into the ATM Agreement. We have sold and issued an aggregate of 1,195,927 shares under the ATM Agreement as of September 30, 2015, receiving approximately \$6.8 million in net proceeds. On October 2, 2015, we filed a prospectus supplement to the base prospectus that forms a part of the registration statement on Form S-3 (File No. 333-206789), filed on September 4, 2015 and declared effective by the SEC on September 25, 2015, pursuant to which we may offer and sell up to \$7,500,000 of shares of common stock from time to time under the ATM Agreement.

### ***February 2013 Preferred Stock Offering***

On February 22, 2013, the Company entered into a Securities Purchase Agreement with certain institutional investors, pursuant to which the Company sold, in a registered offering, an aggregate of 15,000.00422 shares of its Series A 0% convertible preferred stock and the warrants to purchase shares of its common stock, for an aggregate purchase price of approximately \$15.0 million (the February 2013 Preferred Stock Offering). The closing of the February 2013 Preferred Stock Offering occurred on February 26, 2013, in which the Company received approximately \$15.0 million in gross proceeds. Subject to certain ownership limitations, shares of Series A 0% convertible preferred stock are convertible, at the option of the holder thereof, into an aggregate of up to 2,682,764 shares of common stock, and the warrants are exercisable to purchase an aggregate of up to 1,341,382 shares of common stock. Each warrant has an exercise price of \$5.31 per share, equal to the closing bid price of common stock on February 21, 2013. The warrants were immediately exercisable and expire five years after the date of issuance.

During 2013, 2,682,764 shares of common stock in the aggregate were issued upon conversion of all of the 15,000.00422 shares of the Series A 0% convertible preferred stock.

### ***Reverse Stock Split***

On October 28, 2013, the Company effected a 4.5-to-1 reverse stock split of its common stock which was made effective for trading purposes as of the commencement of trading on October 29, 2013. As of October 28, 2013, each nine shares of issued and outstanding common stock and equivalents were combined and converted into two shares of common stock outstanding at the time of the reverse stock split.

## **Note 11. Stock Based Compensation**

### ***Stock Options Plans***

The Company has long-term compensation plans that permit the granting of incentive awards in the form of stock options. Generally, the terms of these plans require that the exercise price of the options may not be less than the fair market value of Celsion's common stock on the date the options are granted. Options granted generally vest over various time frames or upon milestone accomplishments. The Company's options generally expire ten years from the date of the grant.

In 2007, the Company adopted the Celsion Corporation 2007 Stock Incentive Plan (the 2007 Plan) under which 222,222 shares were authorized for issuance. The purpose of the 2007 Plan is to promote the long-term growth and profitability of the Company by providing incentives to improve stockholder value and enable the Company to attract, retain and reward the best available persons for positions of substantial responsibility. The 2007 Plan permits the granting of equity awards in the form of incentive stock options, nonqualified stock options, restricted stock, restricted stock units, stock appreciation rights, phantom stock, and performance awards, or in any combination of the foregoing. At the Annual Meetings of Stockholders of Celsion held on June 25, 2010, June 7, 2012 and June 20, 2014, the stockholders approved amendments to the Plan. The only material difference between the original Plan and the amended Plan was the number of shares of common stock available for issuance under the amended Plan which was increased by 222,222 to a total of 444,444 shares in 2010, by 500,000 to a total of 944,444 shares in 2012 and by 2,500,000 to a total of 3,444,444 shares in 2014.

Prior to the adoption of the 2007 Plan, the Company adopted two stock plans for directors, officers and employees (one in 2001 and another in 2004) under which 148,148 shares were reserved for future issuance under each of these

plans. As these plans have been superseded by the 2007 Plan, any options previously granted which expire, forfeit, or cancel under these plans will be rolled into the 2007 Plan.

The fair values of stock options granted were estimated at the date of grant using the Black-Scholes option pricing model. The Black-Scholes model was originally developed for use in estimating the fair value of traded options, which have different characteristics from Celsion's stock options. The model is also sensitive to changes in assumptions, which can materially affect the fair value estimate.



The Company used the following assumptions for determining the fair value of options granted under the Black-Scholes option pricing model:

|                          | <b>Nine Months Ended</b>      |   |       |   |             |   |       |   |
|--------------------------|-------------------------------|---|-------|---|-------------|---|-------|---|
|                          | <b>September 30,<br/>2015</b> |   |       |   | <b>2014</b> |   |       |   |
| Risk-free interest rate  | 2.06                          | – | 2.93  | % | 2.63        | – | 2.75  | % |
| Expected volatility      | 92.9                          | – | 93.0  | % | 98.7        | – | 100.7 | % |
| Expected life (in years) |                               |   | 10.00 |   |             |   | 10.00 |   |
| Expected forfeiture rate |                               |   | 5.0   | % |             |   | 5.0   | % |
| Expected dividend yield  |                               |   | 0.0   | % |             |   | 0.0   | % |

Expected volatilities utilized in the model are based on historical volatility of the Company's stock price. The risk free interest rate is derived from values assigned to U.S. Treasury bonds as published in the Wall Street Journal in effect at the time of grant. The model incorporates exercise, pre-vesting and post-vesting forfeiture assumptions based on analysis of historical data. The expected life of the fiscal 2015 and 2014 grants was generated using the simplified method.

A summary of the Company's stock option and restricted stock awards for the nine months ended September 30, 2015 is as follows:

| <b>Equity Awards</b>                           | <b>Stock Options</b> |                 | <b>Restricted Stock Awards</b> |              | <b>Weighted</b>    |
|--|----------------------|-----------------|--------------------------------|--------------|--------------------|
|  | <b>Options</b>       | <b>Average</b>  | <b>Restricted</b>              | <b>Grant</b> | <b>Average</b>     |
|  | <b>Outstanding</b>   | <b>Exercise</b> | <b>Stock</b>                   | <b>Date</b>  | <b>Contractual</b> |
|  | <b>Price</b>         | <b>Price</b>    | <b>Outstanding</b>             | <b>Fair</b>  | <b>Terms of</b>    |
|  |                      |                 | <b>Fair</b>                    | <b>Value</b> | <b>Equity</b>      |
|  |                      |                 | <b>Value</b>                   |              | <b>Awards</b>      |
|  |                      |                 |                                |              | <b>(in years)</b>  |
| Equity awards outstanding at December 31, 2014 | 1,744,755            | \$ 7.20         | 7,018                          | \$ 3.32      |                    |
| Equity awards granted                          | 709,250              | \$ 2.44         | 43,500                         | \$ 3.29      |                    |
| Equity awards exercised                        | –                    | –               | (14,000)                       | \$ 2.72      |                    |
| Equity awards forfeited, cancelled or expired  | (275,062)            | \$ 9.65         | –                              | –            |                    |

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|   |           |         |           |         |     |
|---|-----------|---------|-----------|---------|-----|
| Equity awards outstanding at September 30, 2015                       | 2,178,943 | \$ 5.34 | 36,518    | \$ 3.51 | 7.6 |
| Aggregate intrinsic value of outstanding awards at September 30, 2015 | \$-       |         | \$110,853 |         |     |
| Equity awards exercisable at September 30, 2015                       | 1,467,857 | \$ 7.25 |           |         | 7.2 |
| Aggregate intrinsic value of awards exercisable at September 30, 2015 | \$-       |         |           |         |     |

Total compensation cost related to employee stock options and restricted stock awards amounted to \$289,683 and \$532,160 for the three months ended September 30, 2015 and 2014, respectively. Total compensation cost related to employee stock options and restricted stock awards amounted to \$1,616,864 and \$2,253,636 for nine months ended September 30, 2015 and 2014, respectively. No compensation cost related to share-based payments arrangements was capitalized as part of the cost of any asset as of September 30, 2015 and 2014.

As of September 30, 2015, there was \$0.9 million of total unrecognized compensation cost related to non-vested share-based compensation arrangements. That cost is expected to be recognized over a weighted-average period of 1.3 years. The weighted average grant-date fair value was \$2.15 and \$3.18 per share for the options granted during the nine months ended September 30, 2015 and 2014, respectively. The weighted average grant-date fair value was \$3.29 and \$3.49 for the restricted stock awards granted during the nine months ended September 30, 2015 and 2014, respectively.

Collectively, for all of the Company's stock option plans as of September 30, 2015, there were a total of 3,660,270 shares reserved with 2,215,461 equity awards granted and 1,444,809 equity awards available for future issuance.

## Note 12. Earn-out Milestone Liability

The total aggregate purchase price for the EGEN Acquisition included potential future Earn-out Payments contingent upon achievement of certain milestones. The difference between the aggregate \$30.4 million in future Earn-out Payments and the \$13.9 million included in the fair value of the acquisition consideration at June 20, 2014 was based on the Company's risk-adjusted assessment of each milestone (10% to 67%) and utilizing a discount rate based on the estimated time to achieve the milestone (1.5 to 7.0 years). The earn-out milestone liability will be fair valued at the end of each quarter and any change in their value will be recognized in the financial statements. At September 30, 2015, the Company fair valued the earn-out milestone liability at \$13.6 million and recognized a non-cash benefit of \$282,950 and \$41,422 during the three and nine month periods ended September 30, 2015, respectively, as a result of the change in the fair value of earn-out milestone liability from \$13.9 million and \$13.7 million at June 30, 2015 and December 31, 2014, respectively.

The fair value of the earn-out milestone liability at September 30, 2015 was based on the Company's risk-adjusted assessment of each milestone (10% to 75%) utilizing a discount rate based on the estimated time to achieve the milestone (0.8 to 2.8 years). The fair value of the earn-out milestone liability at December 31, 2014 was based on the Company's risk-adjusted assessment of each milestone (10% to 67%) utilizing a discount rate based on the estimated time to achieve the milestone (1.2 to 6.5 years).

The following is a summary of the changes in the earn-out milestone liability for 2015:

|  |               |
|--|---------------|
| Balance at January 1, 2015   | \$ 13,663,710 |
| Non-cash benefit from the adjustment for the change in fair value included in net loss | (41,422 )     |
| Balance at September 30, 2015  | \$ 13,622,288 |

## Note 13. Warrants

### *Common Stock Warrants*

Following is a summary of all warrant activity for the nine months ended September 30, 2015:

| <b>Warrants</b>  | <b>Number of<br/>Warrants<br/>Issued</b> | <b>Weighted<br/>Average<br/>Exercise Price</b> |
|--|--|--|
| Warrants<br>outstanding at<br>December 31,<br>2014                                     | 5,069,815                                | \$ 8.18  |
| Warrants issued<br>during the nine<br>months ended<br>September 30,<br>2015            | 1,950,000                                | \$ 2.60  |
| Warrants expired<br>during the nine<br>months ended<br>September 30,<br>2015           | (1,125,140 )                             | \$ 7.98  |
| Warrants<br>outstanding at<br>September 30,<br>2015                                    | 5,894,675                                | \$ 6.37  |
| Aggregate<br>intrinsic value of<br>outstanding<br>warrants at<br>September 30,<br>2015 | —  |  |
| Weighted average<br>remaining<br>contractual terms<br>(in years)                       | 3.0                                      |  |

In September 2009, the Company closed a registered direct offering with a select group of institutional investors that raised gross proceeds of \$7.1 million and net proceeds of \$6.3 million. In connection with this registered direct offering, the Company issued 448,478 shares of its common stock and warrants to purchase 224,239 shares of common stock. On March 31, 2015, all unexercised warrants associated with this registered direct offering expired. As discussed in Note 10, the Series B warrants to purchase 900,901 shares of common stock issued in connection with the January 2014 Offering expired in January 2015.

### *Common Stock Warrant Liability*

As of December 31, 2014, the Company recorded a common stock warrant liability of \$275,008. The fair value of the warrants associated with the September 2009 registered direct offering at December 31, 2014 and the warrants associated with the Hercules loan, as more fully described in Note 9, at December 31, 2014 was calculated using the Black-Scholes option-pricing model with the following assumptions:

|                          | <b>December 31,<br/>2014</b> |   |         |
|--------------------------|------------------------------|---|---------|
| Risk-free interest rate  | 0.04                         | - | 1.66 %  |
| Expected volatility      | 40.9                         | - | 98.35 % |
| Expected life (in years) | 0.25                         | - | 3.9     |
| Expected forfeiture rate |                              |   | 0.0 %   |
| Expected dividend yield  |                              |   | 0.00 %  |

Under the terms of the warrants associated with the September 2009 registered direct offering, upon certain transactions, including a merger, tender offer or sale of all or substantially all of the assets of the Company, each warrant holder could have elected to receive a cash payment in exchange for the warrant, in an amount determined by application of the Black-Scholes option valuation model. Accordingly, pursuant to ASC 815.40, *Derivative Instruments and Hedging - Contracts in Entity's Own Equity*, the warrants were recorded as a liability and marked to market each period through the Statement of Operations in other income or expense. At the end of each subsequent quarter, the Company revalued the fair value of the warrants and the change in fair value was recorded as a change to the warrant liability and the difference was recorded through the Statement of Operations in other income or expense. The warrants expired in March 2015.

As discussed in Note 9, the Company concluded in the second quarter of 2015 the warrant provision which required the exercise price of the warrant to be adjusted downward to a lower price at which the Company would sell and issue shares in a financing for cash during the one-year anniversary of the warrant had expired. Therefore, the Company valued the warrant at \$336,254 immediately prior to this event using a risk-free interest rate of 1.98%, expected volatility of 99.71%, an expected remaining life of 4 years and no forfeiture nor dividends expected. The Company recorded non-cash charges to net income of \$18,018 and \$61,246 in the second quarter and year to date periods of 2015, respectively, and reduced the liability to zero and increased equity by \$336,254 at this time.

The following is a summary of the changes in the common stock warrant liability for the nine month period ended September 30, 2015:

|  |           |
|--|-----------|
| Beginning balance as of January 1, 2015                                    | \$275,008 |
| Loss from the adjustment for the change in fair value included in net loss | 61,246    |
| Fair value of warrants reclassified as equity (Note 9)                     | (336,254) |
| Ending balance as of September 30, 2015                                    | \$-       |

#### **Note 14. Contingent Liabilities and Commitments**

In July 2011, the Company, as a tenant, and a landlord executed a lease (the Lease) for a 10,870 square foot premises located in Lawrenceville, New Jersey. In October 2011, the Company relocated its offices to Lawrenceville, New Jersey from Columbia, Maryland. The Lease has a term of 66 months and provides for 6 months of free rent; with the first monthly rent payment of approximately \$23,000 paid in April 2012. Also, as required by the Lease, the Company provided Brandywine with an irrevocable and unconditional standby letter of credit for \$250,000, which the Company secured with an escrow deposit at its banking institution of this same amount. The standby letter of credit will be reduced by \$50,000 on each of the 19th, 31st and 43rd months from the initial term, with the remaining \$100,000 amount remaining until the term of the Lease has expired. In connection with two \$50,000 reductions of the standby letter of credit in April 2013 and 2014, the Company reduced the escrow deposit by \$50,000 each time. The Company received the third and final reduction in April 2015.

In connection with the EGEN Asset Purchase Agreement in June 2014, the Company assumed the existing lease with another landlord for an 11,500 square foot premises located in Huntsville Alabama. This lease has a remaining term of 32 months with monthly rent payments of approximately \$23,200.

#### **Note 15. Technology Development and Licensing Agreements**

On May 7, 2012 the Company entered into a long term commercial supply agreement with Zhejiang Hisun Pharmaceutical Co. Ltd. (Hisun) for the production of ThermoDox® in the China territory. In accordance with the terms of the agreement, Hisun will be responsible for providing all of the technical and regulatory support services, including the costs of all technical transfer, registration and bioequivalence studies, technical transfer costs, Celsion consultative support costs and the purchase of any necessary equipment and additional facility costs necessary to support capacity requirements for the manufacture of ThermoDox®. Celsion will repay Hisun for the aggregate amount of these development costs and fees commencing on the successful completion of three registration batches of ThermoDox®. Hisun is also obligated to certain performance requirements under the agreement. The agreement will initially be limited to a percentage of the production requirements of ThermoDox® in the China territory with Hisun retaining an option for additional global supply after local regulatory approval in the China territory. In addition, Hisun will collaborate with Celsion around the regulatory approval activities for ThermoDox® with the China State Food and Drug Administration (CHINA FDA). During the first quarter of 2015, Hisun completed the successful manufacture of three registration batches of ThermoDox® and the Company accrued \$685,787 for the aggregate development costs and fees associated with these batches in March 2015. This amount was paid in April 2015.

On January 18, 2013, we entered into a technology development contract with Hisun, pursuant to which Hisun paid us a non-refundable research and development fee of \$5 million to support our development of ThermoDox® in mainland China, Hong Kong and Macau (the China territory). Following our announcement on January 31, 2013 that the HEAT study failed to meet its primary endpoint, Celsion and Hisun have agreed that the Technology Development Contract entered into on January 18, 2013 will remain in effect while the parties continue to collaborate and are evaluating the next steps in relation to ThermoDox®, which include the sub-group analysis of patients in the Phase III HEAT Study for the hepatocellular carcinoma clinical indication and other activities to further the development of ThermoDox® for the Greater China market. The \$5.0 million received as a non-refundable payment from Hisun in the first quarter 2013 has been recorded to deferred revenue and will continue to be amortized over the 10 year term of the agreement, until such time as the parties find a mutually acceptable path forward on the development of ThermoDox® based on findings of the ongoing post-study analysis of the HEAT Study data.

On July 19, 2013, the Company and Hisun entered into a Memorandum of Understanding to pursue ongoing collaborations for the continued clinical development of ThermoDox® as well as the technology transfer relating to the commercial manufacture of ThermoDox® for the China territory. This expanded collaboration includes development of the next generation liposomal formulation with the goal of creating safer, more efficacious versions of marketed cancer chemotherapeutics.

Among the key provisions of the Celsion-Hisun Memorandum of Understanding are:

Hisun will provide the Company with non-dilutive financing and the investment necessary to complete the technology transfer of its proprietary manufacturing process and the production of registration batches for the China territory;

Hisun will collaborate with the Company around the clinical and regulatory approval activities for ThermoDox® as well as other liposomal formations with the CHINA FDA; and

Hisun will be granted a right of first offer for a commercial license to ThermoDox® for the sale and distribution of ThermoDox® in the China territory.



*Development, Product Supply and Commercialization Agreement with Yakult Honsha*

In the fourth quarter of 2008, the Company entered into a Development, Product Supply and Commercialization Agreement with Yakult Honsha Co. LTD (Yakult) under which Yakult was granted the exclusive right to commercialize and market ThermoDox® for the Japanese market. We were paid a \$2.5 million up-front licensing fee and we have the potential to receive additional payments from Yakult upon receipt of marketing approval by the Japanese Ministry of Health, Labor and Welfare as well as upon the achievement of certain levels of sales and approval for new indications. We will receive double digit escalating royalties on the sale ThermoDox® in Japan, when and if any such sales occur. We also will be the exclusive supplier of ThermoDox® to Yakult.

In January 2011, the Company amended its Development, Product Supply and Commercialization Agreement with Yakult to provide for up to \$4.0 million in an accelerated partial payment to the Company of a future drug approval milestone, which included \$2.0 million paid to the Company upon the closing of the preferred equity financing the Company conducted in January 2011 and an additional \$2.0 million conditioned upon the resumption of enrollment of Japanese patients in the Japan cohort of the HEAT Study. In consideration of these accelerated milestone payments from Yakult, the Company agreed to reduce future drug approval milestone payments by approximately 40%.

*License and Distribution Agreement*

On January 20, 2015 the Company announced it had signed a license and distribution agreement with myTomorrows to implement an Early Access Program for ThermoDox®, its proprietary heat-activated liposomal encapsulation of doxorubicin, in all countries of the European Union (EU) territory, Iceland, Liechtenstein, Norway and Switzerland for the treatment of patients with recurrent chest wall (RCW) breast cancer. On August 10, 2015 the Company announced it had expanded its Early Access Program with myTomorrows to include patients with primary liver cancer, also known as hepatocellular carcinoma (HCC) and liver cancer metastases, in all countries of the European Union (EU) territory, Switzerland, Turkey and Israel.

Early Access Programs allow biopharmaceutical companies to provide eligible patients with ethical access to investigational medicines for unmet medical needs within the scope of the existing early access legislation. Access is provided in response to physician requests in a fully compliant manner, where no alternative treatment options are available to these patients. Celsion will provide ThermoDox® to centers of excellence in the EU and Switzerland through its Early Access Program with myTomorrows, at prices that are comparable to chemotherapeutics used to treat this and other aggressive form of cancer.



**Item 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS.**

**Forward-Looking Statements**

*Statements and terms such as “expect”, “anticipate”, “estimate”, “plan”, “believe” and words of similar import regarding our expectations as to the development and effectiveness of our technologies, the potential demand for our products, and other aspects of our present and future business operations, constitute forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Although we believe that our expectations are based on reasonable assumptions within the bounds of our 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, readers should specifically consider the various factors contained in our Annual Report on Form 10-K for the fiscal year ended December 31, 2014 filed on March 12, 2015 with the Securities and Exchange Commission, which factors include, without limitation, plans and objectives of management for future operations or programs or proposed new products or services; changes in the course of research and development activities and in clinical trials; possible changes in cost and timing of development and testing; possible changes in capital structure, financial condition, working capital needs and other financial items; changes in approaches to medical treatment; clinical trial analysis and future plans relating thereto; our ability to realize the full extent of the anticipated benefits of our acquisition of substantially all of the assets of Egen, Inc., including achieving operational cost savings and synergies in light of any delays we may encounter in the integration process and additional unforeseen expenses; introduction of new products by others; possible licenses or acquisitions of other technologies, assets or businesses; and possible actions by customers, suppliers, partners, competitors and regulatory authorities. These and other risks and uncertainties could cause actual results to differ materially from those indicated by forward-looking statements.*

*The discussion of risks and uncertainties set forth in this Quarterly Report on Form 10-Q and in our most recent Annual Report on Form 10-K, as well as in other filings with the SEC, is not a complete or exhaustive list of all risks facing the Company at any particular point in time. We operate in a highly competitive, highly regulated and rapidly changing environment and our business is constantly evolving. Therefore, it is likely that new risks will emerge, and that the nature and elements of existing risks will change, over time. 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. We disclaim any obligation to revise or update any forward-looking statement that may be made from time to time by us or on our behalf.*

**Strategic and Clinical Overview**

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

### *ThermoDox®*

Our lead product ThermoDox® is being evaluated in a Phase III clinical trial for primary liver cancer (the OPTIMA study) which was initiated in the first half of 2014 and a Phase II clinical trial for recurrent chest wall breast cancer (the DIGNITY Studies). 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 mild hyperthermia temperatures (greater than 39.5° Celsius) releases the encapsulated doxorubicin from the liposome enabling high concentrations of doxorubicin to be deposited preferentially in and around the targeted tumor.

**The HEAT Study.** On January 31, 2013, we announced that ThermoDox® in combination with radio frequency ablation (RFA) did not meet the primary endpoint of Progression Free Survival (PFS) for the 701 patient clinical trial in patients with hepatocellular carcinoma (HCC), also known as primary liver cancer (the HEAT Study). Specifically, we determined, after conferring with the HEAT Study independent Data Monitoring Committee (iDMC), that the HEAT study did not meet the goal of demonstrating persuasive evidence of clinical effectiveness that could form the basis for regulatory approval. In the trial, ThermoDox® was well-tolerated with no unexpected serious adverse events. Following the announcement of the HEAT Study results, we continue to follow patients for overall survival (OS), the secondary endpoint of the HEAT Study, on a quarterly basis. We have conducted a comprehensive analysis of the data from the HEAT Study to assess the future strategic value of ThermoDox®. As part of this analysis, we also evaluated our product pipeline and research and development priorities. In April 2013, we announced the deferral of expenses associated with the Company's Phase II study of ThermoDox® in combination with RFA for the treatment of colorectal liver metastases.

The data from the HEAT Study post-hoc analysis suggest that ThermoDox® may substantially improve overall survival, 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 seven OS sweeps have been conducted since the top line PFS data from the HEAT Study were announced in January 2013, with each data set showing clinical benefit with progressive improvement in statistical significance. The most recent post-hoc OS analysis data from the HEAT Study as of July 15, 2015 (announced on August 6, 2015) demonstrated that in a large, well bounded, subgroup of patients (n=285, 41% of the study patients), the combination of ThermoDox® and optimized RFA provided a 58% improvement in OS compared to optimized RFA alone. The Hazard Ratio at this latest quarterly OS analysis is 0.63 (95% CI 0.43 – 0.93) with a p-value of 0.0198. Median overall survival for the ThermoDox® group has been reached which translates into a 25.4 month (2.1 year) survival benefit over the optimized RFA only group (79 months for the ThermoDox® plus optimized RFA group versus 53.6 months for the optimized RFA only group). These data continue to support the protocol for the Phase III OPTIMA Study, which is evaluating ThermoDox® in combination with optimized RFA, which will be standardized to a minimum of 45 minutes across all investigators and clinical sites for treating lesions 3 to 7 centimeters, versus standardized RFA alone. The study is expected to enroll up to 550 patients globally in up to 75 clinical sites in the United States, Europe, China and elsewhere in the Asia Pacific region.

Data from the HEAT Study post-hoc analysis have been presented at multiple scientific and medical conferences in 2013, 2014 and thus far in 2015 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

We also completed computational modeling with supplementary preclinical animal studies supporting the relationship between heating duration and clinical outcomes.

**The OPTIMA Study.** On February 24, 2014, we announced that the U.S. Food and Drug Administration (FDA), after its customary 30 day review period, accepted without comment, subject to compliance with regulatory standards, our pivotal, double-blind, placebo-controlled Phase III trial of ThermoDox®, our proprietary heat-activated liposomal encapsulation of doxorubicin in combination with RFA in primary liver cancer, also known as HCC (the OPTIMA Study). The OPTIMA Study trial design is based on the comprehensive analysis of data from the HEAT study, which, as described previously, demonstrated that treatment with ThermoDox® resulted in an approximate 58% improvement in overall survival in a large number of HCC patients that received an optimized RFA treatment for longer than 45 minutes. Designed with extensive input from globally recognized HCC researchers and clinicians and, after formal written consultation with the FDA, the OPTIMA Study was launched in the first half of 2014. The OPTIMA Study is expected to enroll up to 550 patients globally at up to 75 sites in the United States, Europe, China and elsewhere in the Asia Pacific region, 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 3 to 7 centimeters, versus standardized RFA alone. The primary endpoint for the trial is overall survival, and the secondary endpoints for the trial are PFS and Safety. The statistical plan calls for two interim efficacy analyses by an independent Data Monitoring Committee.

In addition, the Company has met with the China State Food and Drug Administration (CHINA FDA) to discuss the OPTIMA Phase III Study including minimum patient enrollment requirements supporting the registration of ThermoDox® in China. Based on those discussions, we have submitted an application for accelerated approval of the OPTIMA Study in China. We also filed a request for a Voluntary Harmonization Procedure (VHP) in Europe, which provides for the assessment of multinational clinical trial applications across several European countries, including Germany, Italy and Spain. Our request for a VHP in Europe was approved on October 23, 2014.

***The DIGNITY Study.*** On July 6, 2015, we announced positive interim data from the DIGNITY Trial of ThermoDox® in recurrent chest wall (RCW) breast cancer. The trial is designed to enroll up to 20 patients at five clinical sites in the United States and is evaluating ThermoDox® in connection with mild hyperthermia. Of the 17 patients enrolled and treated in the DIGNITY Study, 13 were eligible for evaluation of efficacy. Based on data available to date, every patient experienced a clinical benefit of their highly refractory disease with a local response rate of 69% observed in the 13 evaluable patients, notably five complete responses, four partial responses and four patients with stable disease. The Company remains on track to complete enrollment in the study in the third quarter of 2015 and will present the final results at the San Antonio Breast Cancer Conference on December 12, 2015. These data are consistent with the previously reported Phase 1 data for ThermoDox® plus hyperthermia in RCW breast cancer, including combined clinical data from the Company's Phase 1 DIGNITY Study and a Duke University sponsored Phase 1 trial of ThermoDox®. The two similarly designed studies enrolled patients with highly resistant tumors found on the chest wall and who had progressed on previous therapies. 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% was reported in 14 of the 23 evaluable patients, with five complete responses and nine partial responses.

#### ***Acquisition of EGEN***

On June 20, 2014, we completed the acquisition of substantially all of the assets of EGEN, Inc., an Alabama Corporation (EGEN), pursuant to an Asset Purchase Agreement. CLSN Laboratories, Inc., a Delaware corporation and a wholly-owned subsidiary of ours (CLSN Laboratories), 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 consideration of the acquisition included an initial payment of approximately \$3.0 million in cash plus 2.7 million shares of Celsion's common stock. Additional consideration included contingent value rights totaling \$30.4 million, payable in cash, shares of Celsion common stock or a combination thereof, at Celsion's option, upon achievement of three major milestone events as follows:

\$12.4 million will become payable upon achieving certain specified development milestones relating to an ovarian cancer study of GEN-1 to be conducted by the Company or its 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 development milestones relating to the TheraSilence™ technology acquired from EGEN in the acquisition.

On June 9, 2014, Celsion borrowed an additional \$5 million pursuant to a certain Loan and Security Agreement dated as of November 25, 2013, by and between Celsion and Hercules Technology Growth Capital, Inc. Celsion used the loan proceeds to pay the upfront cash payment to EGEN at closing and certain transaction costs incurred in connection with the acquisition.

The acquisition of EGEN was accounted for under the acquisition method of accounting which required the Company to perform an allocation of the purchase price to the assets acquired and liabilities assumed. The fair value of the consideration transferred for the acquisition is approximately \$27.6 million. The preliminary purchase price exceeds the estimated fair value of the net assets acquired by approximately \$2.0 million which was recorded as goodwill.

Under the acquisition method of accounting, the total purchase price is allocated to EGEN's net tangible and intangible assets and liabilities based on their estimated fair values as of the acquisition date. There were no subsequent adjustments to provisional amounts in finalizing the purchase price allocation of acquisition of substantially all of the assets of EGEN on June 20, 2014. The following table summarizes the fair values of these assets acquired and liabilities assumed related to the acquisition.

|  |              |
|--|--------------|
| Property and equipment, net              | \$35,000     |
| In-process research and development      | 25,802,000   |
| Goodwill                                 | 1,976,000    |
| Total assets:                            | 27,813,000   |
| Accounts payable and accrued liabilities | (235,000 )   |
| Net assets acquired                      | \$27,578,000 |



**GEN-1 OVATION Study.** In February 2015, we announced that the FDA accepted, without comment, 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 we enrolled the first patient in the Ovation Study. The Ovation Study will seek to identify a safe, tolerable and 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 affects 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.

**GEN-1 Plus Doxil® and Avastin® Trial.** On April 29, 2015, we announced the expansion of our ovarian cancer development program to include a Phase I dose escalating trial to evaluate GEN-1 in combination with Avastin® and Doxil® in platinum-resistant ovarian cancer patients. We expect to enroll patients beginning in the first half of 2016.

**Early Access Program.** On January 13, 2015, we entered into an Early Access Agreement with Impatiens N.V., a Netherlands company (Impatiens), pursuant to which Impatiens will develop and execute through its brand myTomorrows an early access program for ThermoDox® in all countries of the European Union territory, Iceland, Liechtenstein, Norway and Switzerland (the Territory) for the treatment of patients with RCW breast cancer. Under the early access program, Impatiens will engage in activities to secure authorization, exemption or waiver from regulatory authorities for patient use of ThermoDox® that may otherwise be subject to approvals from such regulatory authorities before the sale and distribution of ThermoDox® in the relevant territories. We will be responsible for the manufacture and supply of quantities of ThermoDox® to Impatiens for use in the early access program and Impatiens will distribute and sell ThermoDox® pursuant to such authorization, exemptions or waivers.

On August 10, 2015, we expanded the Early Access Program with myTomorrows to include patients with primary liver cancer, also known as hepatocellular carcinoma and liver cancer metastases, in all countries of the European Union territory, Switzerland, Turkey and Israel.

Under the Early Access Agreement, we granted to Impatients, specifically for the treatment of RCW breast cancer in the Territory, an exclusive, royalty-free right to perform the early access program activities, reference regulatory documentation and approvals that we own, and use our trademarks relating to ThermoDox®. In addition, we granted to Impatients an option to negotiate an exclusive license to distribute ThermoDox® in the Territory after ThermoDox® receives regulatory approval in a country within the Territory.

In consideration for Impatients' services to implement the early access program and in the event we receive regulatory authorization to sell, distribute or market ThermoDox® in the Territory, we will be obligated to pay Impatients, subject to a maximum cap, a low single-digit royalty of net sales of ThermoDox® in the countries where such regulatory authorization has been obtained. The Early Access Agreement has a term of five years, with automatic renewals for consecutive two-year periods, unless earlier terminated by either party with notice or in the event of material breach, bankruptcy, or insolvency without notice.

To the extent that we are dependent on the success of one or a few product candidates, 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. As demonstrated by the HEAT Study results in January 2013, 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, results of operations, financial condition and market value.

### *Funding Overview*

To support our research and development, we have raised gross proceeds of approximately \$118 million in equity financings and warrant and option exercises in the years 2009 through 2014 and thus far in 2015.

On May 27, 2015, the Company entered into a Securities Purchase Agreement with certain investors, pursuant to which the Company sold and issued on June 1, 2015, in a registered direct offering (the May 2015 Offering Offering), an aggregate of 3,000,000 shares of common stock at an offering price of \$2.675 per share for gross proceeds of \$8.0 million before the deduction of the placement agent fee and offering expenses. In a concurrent private placement closed on June 1, 2015, the Company issued to the investors in the May 2015 Offering certain warrants (the May 2015 Warrants) at an exercise price of \$2.60 per share. The May 2015 Warrants are exercisable to purchase 0.65 share of common stock for each share of common stock purchased in the May 2015 Offering for an aggregate of 1,950,000 shares of common stock. Each May 2015 Warrant will be exercisable on the date of its issuance until the five-year anniversary of the date of issuance.

In November 2013, we entered into a loan and security agreement with Hercules Technology Growth Capital, Inc. (Hercules) which permits us to borrow up to \$20 million in multiple tranches (the Hercules Credit Agreement). We currently have up to \$10 million remaining under this facility. We drew the first tranche of \$5 million upon closing of the Hercules Credit Agreement in November 2013 and used approximately \$4.0 million of the proceeds to repay the then outstanding obligations under our former loan agreement with Oxford Finance LLC and Horizon Technology Finance Corporation. On June 9, 2014, we closed the second \$5 million tranche under the Hercules Credit Agreement and used the proceeds to fund the \$3.1 million upfront cash payment associated with the acquisition of EGEN, as well as our transaction costs associated with that acquisition. Upon the closing of the second tranche, we had drawn down a total of \$10 million under the Hercules Credit Agreement.

On May 6, 2012, we entered into a long-term commercial supply agreement with Zhejiang Hisun Pharmaceutical Co. Ltd. (Hisun) for the production of ThermoDox® in mainland China, Hong Kong and Macau (the China territory). Hisun will be responsible for providing all of the technical and regulatory support services for the manufacture of ThermoDox® in the China territory and we will repay Hisun the related development costs and fees, which we expect to be approximately \$2.0 million in total, commencing on the successful completion of three registrational batches of ThermoDox®. On January 18, 2013, we broadened our relationship with Hisun by entering into a technology development contract, pursuant to which Hisun paid us a non-refundable research and development fee of \$5.0 million to support our development of ThermoDox® and we will provide research data and other technical support in relation to a regulatory filing by Hisun in China for approval of ThermoDox®. Following our announcement of the HEAT Study results on January 31, 2013, we and Hisun have agreed that the technology development contract entered into on January 18, 2013 will remain in effect while the parties continue to collaborate the next steps in relation to ThermoDox®, which include the continued subgroup analysis of the Chinese cohort of patients in the HEAT Study for primary liver cancer and other activities to further the development of ThermoDox® for the China territory.

On July 19, 2013, we entered into a Memorandum of Understanding with Hisun to pursue ongoing collaborations for the continued clinical development of ThermoDox® as well as the technology transfer relating to the commercial manufacture of ThermoDox® for the China territory. This expanded collaboration includes development of the next generation liposomal formulation with the goal of creating safer, more efficacious versions of marketed cancer chemotherapeutics.

As a result of the risks and uncertainties discussed in this Quarterly Report on Form 10-Q, among others, we are unable to estimate the duration and completion costs of our research and development projects or when, if ever, and to what extent we will receive cash inflows from the commercialization and sale of a product. Our inability to complete any of our research and development activities, preclinical studies or clinical trials in a timely manner or our failure to enter into collaborative agreements when appropriate could significantly increase our capital requirements and could adversely impact our liquidity. While our estimated future capital requirements are uncertain and could increase or decrease as a result of many factors, including the extent to which we choose to advance our research, development activities, preclinical studies and clinical trials, or if we are in a position to pursue manufacturing or commercialization activities, we will need significant additional capital to develop our product candidates through development and clinical trials, obtain regulatory approvals and manufacture and commercialize approved products, if any. We do not know whether we will be able to access additional capital when needed or on terms favorable to us or our stockholders. Our inability to raise additional capital, or to do so on terms reasonably acceptable to us, would jeopardize the future success of our business.

As a clinical stage biopharmaceutical company, our business and our ability to execute our strategy to achieve our corporate goals are subject to numerous risks and uncertainties. Material risks and uncertainties relating to our business and our industry are described in "Item 1A. Risk Factors" under "Part II: Other Information" included herein.

## FINANCIAL REVIEW FOR THE THREE AND NINE MONTHS ENDED SEPTEMBER 30, 2015 AND 2014

### Results of Operations

For the three months ended September 30, 2015, our net loss was \$4.3 million compared to a net loss of \$6.9 million for the same period of 2014. For the nine months ended September 30, 2015, our net loss was \$16.9 million compared to a net loss of \$19.0 million for the same period of 2014. As of September 30, 2015, we had \$24.4 million in cash and short-term investments including accrued interest from short term investments.

|                                       | Three Months Ended September 30, |                  | Change              |             |          |
|---------------------------------------|----------------------------------|------------------|---------------------|-------------|----------|
|                                       | (In thousands)                   |                  | Increase (Decrease) |             |          |
|                                       | 2015                             | 2014             |                     |             | %        |
| <b>Licensing Revenue:</b>             | \$125                            | \$125            | \$-                 | -           | %        |
| <b>Operating Expenses:</b>            |                                  |                  |                     |             |          |
| Clinical Research                     | 1,888                            | 4,012            | (2,124)             | (52.9)      | %        |
| Chemistry, Manufacturing and Controls | 995                              | 618              | 377                 | 61.0        | %        |
| Research and development              | 2,883                            | 4,630            | (1,747)             | (37.7)      | %        |
| General and administrative            | 1,484                            | 2,044            | (560)               | (27.4)      | %        |
| Acquisition costs                     | -                                | 120              | (120)               | (100.0)     | %        |
| Total operating expenses              | 4,367                            | 6,794            | (2,427)             | (35.7)      | %        |
| <b>Loss from operations</b>           | <b>\$(4,242)</b>                 | <b>\$(6,669)</b> | <b>\$2,427</b>      | <b>36.4</b> | <b>%</b> |

|                                       | <b>Nine Months Ended September 30,</b> |                   |                                |             |          |
|---------------------------------------|--|-------------------|--------------------------------|-------------|----------|
|                                       | <b>Change</b>                          |                   |                                |             |          |
|                                       | <b>(In thousands)</b>                  |                   | <b>Increase<br/>(Decrease)</b> |             |          |
| <b>2015</b>                           | <b>2014</b>                            | <b>\$</b>         | <b>%</b>                       |             |          |
| <b>Licensing Revenue:</b>             | \$375                                  | \$375             | \$-                            | -           | %        |
| <b>Operating Expenses:</b>            |  |                   |                                |             |          |
| Clinical Research                     | 8,265                                  | 7,824             | 441                            | 5.6         | %        |
| Chemistry, Manufacturing and Controls | 2,693                                  | 2,864             | (171 )                         | (6.0 )      | %        |
| Research and development              | 10,958                                 | 10,688            | 270                            | 2.5         | %        |
| General and administrative            | 5,317                                  | 6,783             | (1,466)                        | (21.6 )     | %        |
| Acquisition costs                     | -                                      | 1,188             | (1,188)                        | (100.0)     | %        |
| Total operating expenses              | 16,275                                 | 18,659            | (2,384)                        | (12.8 )     | %        |
| <b>Loss from operations</b>           | <b>\$(15,900)</b>                      | <b>\$(18,284)</b> | <b>\$2,384</b>                 | <b>13.0</b> | <b>%</b> |

*Comparison of the Three Months ended September 30, 2015 and 2014*

Licensing Revenue

In January 2013, we entered into a technology development contract with Hisun, pursuant to which Hisun paid us a non-refundable technology transfer fee of \$5.0 million to support our development of ThermoDox® in the China territory. The \$5.0 million received as a non-refundable payment from Hisun in the first quarter 2013 has been recorded to deferred revenue and will be amortized over the ten year term of the agreement; therefore we recorded deferred revenue of \$125,000 in each of the first, second and third quarters of 2015 and 2014.

Research and Development Expenses

Research and development (R&D) expenses decreased by \$1.7 million to \$2.9 million in the third quarter of 2015 from \$4.6 million in the same period of 2014. Costs associated with the OPTIMA Study were \$1.0 million in the third quarter of 2015 compared to \$2.2 million in the same period of 2014 when we began initiating sites and enrolling patients in the OPTIMA Study. Study costs associated with the HEAT Study remained relatively insignificant in each of the third quarters of 2015 and 2014. The costs associated with the HEAT Study are expected to be minimal as we continue to follow patients for overall survival only. Costs associated with our recurrent chest wall breast cancer clinical trial remained relatively unchanged at \$0.1 million in each of the third quarters of 2015 and 2014. Other clinical costs were \$0.4 million and \$0.5 million in the third quarters of 2015 and 2014, respectively. Other R&D costs

were \$0.9 million lower in the third quarter of 2015 compared the same period of 2014 as the Company adjusted down \$0.8 million of liability as the result of an amendment to a cooperative research and development agreement. Costs associated with the production of clinical supplies of ThermoDox® to support the OPTIMA Study were \$1.0 million in the third quarter of 2015 compared to \$0.6 million in the same period of 2014.

During the second half of 2014, the Company completed the integration of the operations of the business acquired on June 20, 2014 from EGEN, Inc. into our wholly owned subsidiary, CLSN Laboratories. Costs associated with CLSN Laboratories were \$0.9 million for the third quarter of 2015 compared to \$0.7 million in the same period of 2014.

General and Administrative Expenses

General and administrative (G&A) expenses decreased by \$0.5 million to \$1.5 million in the third quarter of 2015 compared to \$2.0 million in the same period of 2014. This decrease is primarily the result of decreases in personnel related costs of \$0.3 million and insurance costs of \$0.2 million.

Acquisition Transaction Related Expenses

We recognized transaction-related expenses for the three months ended September 30, 2014 which consisted of legal and professional fees related to the June 20, 2014 acquisition of substantially all of the assets of EGEN.

Change in Earn-out Milestone Liability

The total aggregate purchase price for the acquisition of assets from EGEN included potential future earn-out payments contingent upon achievement of certain milestones. The difference between the aggregate \$30.4 million in future earn-out payments and the \$13.9 million included in the fair value of the acquisition consideration at June 20, 2014 was based on the Company's risk-adjusted assessment of each milestone and utilizing a discount rate based on the estimated time to achieve the milestone. These milestone payments will be fair valued at the end of each quarter and any change in their value will be recognized in the financial statement. As of September 30, 2015, the Company fair valued these milestones at \$13.6 million and recognized non-cash benefit of \$0.3 million as a result of the change in the fair value of these milestones from \$13.9 million at June 30, 2015.

Change in Warrant Liabilities

A warrant liability was incurred as a result of warrants we issued in a public offering in September 2009. On March 30, 2015, all remaining warrants associated with this equity offering expired. The liability associated with these warrants was calculated at its fair market value using the Black-Scholes option-pricing model and was adjusted at the end of each quarter with changes in fair value recorded in earnings during the term of the warrants. The warrants expired in March 2015. These warrants' fair value was zero at December 31, 2014 and when they expired at March 31, 2015. Therefore, no change in warrant liability was required to be recorded or reclassified during 2015. For the three months ended September 30, 2014, there was no change in the liability associated with these warrants.

In addition, we issued warrants for 194,986 shares of the Company's common stock in connection with the Hercules Credit Agreement in November 2013 and June 2014. The liability associated with these warrants was calculated at its fair market value using the Black-Scholes option-pricing model and was adjusted at the end of each quarter with changes in fair value recorded in earnings during the term of the warrants. As discussed in Note 9 of the financial statement, the Company concluded in the second quarter of 2015 the warrant provision which required the exercise price of the warrant to be adjusted downward to a lower price at which the Company would sell and issue shares in a financing for cash during the one-year anniversary of the warrant had expired. Therefore, the Company valued the warrant at \$336,254 immediately prior to this event and reduced the liability to zero and increased equity by \$336,254 in the second quarter of 2015. The Company also recorded a non-cash charge to net income of \$61,246 in the nine month period ended September 30, 2015.



At September 30, 2014, the fair value of these liabilities was \$0.4 million and the resulting benefit was approximately \$0.1 million in each of the three and nine month periods ended September 30, 2014.

Investment income and interest expense

In connection with its debt facilities the Company incurred \$0.3 million and \$0.4 million in interest expense in the three month periods ended September 30, 2015 and 2014, respectively.

Other (expense) income

Other (expense) income for the third quarters of 2015 and 2014 was not significant.

*Comparison of the Nine Months ended September 30, 2015 and 2014*

Licensing Revenue

In January 2013, we entered into a technology development contract with Hisun, pursuant to which Hisun paid us a non-refundable technology transfer fee of \$5.0 million to support our development of ThermoDox® in the China territory. The \$5.0 million received as a non-refundable payment from Hisun in the first quarter 2013 has been recorded to deferred revenue and will be amortized over the ten year term of the agreement; therefore we recorded deferred revenue of \$375,000 in each of the first nine months of 2015 and 2014.

Research and Development Expenses

Research and development (R&D) expenses increased by \$0.3 million to \$11.0 million in the first nine months of 2015 from \$10.7 million in the same period of 2014. Costs associated with the OPTIMA Study were \$2.8 million in the first nine months of 2015 compared to \$3.8 million in the same period of 2014 when we initiated the OPTIMA Study. Study costs associated with the HEAT Study were \$0.3 million in the first nine months of 2015 compared to \$0.4 million in the same period of 2014. The costs associated with the HEAT Study are expected to be minimal as we continue to follow patients for overall survival only. Costs associated with our recurrent chest wall breast cancer clinical trial were \$0.2 million in the first nine months of 2015 compared to \$0.3 million in the same period of 2014. Other clinical costs were \$1.5 million in the first nine months of 2015 compared to \$1.4 million in the same period of 2014. Other R&D costs were \$0.2 million in the first nine months of 2015 compared to \$1.1 million in the same period of 2014 as the Company adjusted down \$0.8 million of liability as the result of an amendment to a cooperative research and development agreement. Costs associated with the production of clinical supplies of ThermoDox® to support the OPTIMA Study were \$2.7 million in the first nine months of 2015 compared to \$2.9 million in the same period of 2014.

During the 2<sup>nd</sup> half of 2014, the Company completed the integration of the operations of the business acquired on June 20, 2014 from EGEN, Inc. into our wholly owned subsidiary, CLSN Laboratories. Costs associated with CLSN Laboratories were \$3.3 million in the first nine months of 2015 compared to \$0.9 million in the same period of 2014.

General and Administrative Expenses

General and administrative (G&A) expenses decreased by \$1.5 million to \$5.3 million in the first nine months of 2015 compared to \$6.8 million in the same period of 2014. This decrease is primarily the result of decreases in personnel costs of \$0.8 million, insurance costs of \$0.7 million and other administrative costs of \$0.2 million partially offset by an increase of \$0.2 million in legal fees associated with trademarks and patents associated with the product pipeline acquired in the EGEN acquisition.

Acquisition Transaction Related Expenses

We recognized transaction-related expenses of \$1.2 million for the nine months ended September 30, 2014 which consisted of legal and professional fees related to the June 20, 2014 acquisition of substantially all of the assets of EGEN.

Change in Earn-out Milestone Liability

The total aggregate purchase price for the acquisition of assets from EGEN included potential future earn-out payments contingent upon achievement of certain milestones. The difference between the aggregate \$30.4 million in future earn-out payments and the \$13.9 million included in the fair value of the acquisition consideration at June 20, 2014 was based on the Company's risk-adjusted assessment of each milestone and utilizing a discount rate based on the estimated time to achieve the milestone. These milestone payments will be fair valued at the end of each quarter and any change in their value will be recognized in the financial statement. As of September 30, 2015, the Company fair valued these milestones at \$13.6 million and recognized non-cash benefit of \$41,422 as a result of the change in the fair value of these milestones from \$13.7 million at December 31, 2014.

Change in Warrant Liabilities

A warrant liability was incurred as a result of warrants we issued in a public offering in September 2009. On March 30, 2015, all remaining warrants associated with this equity offering expired. The liability associated with these warrants was calculated at its fair market value using the Black-Scholes option-pricing model and was adjusted at the end of each quarter with changes in fair value recorded in earnings during the term of the warrants. The warrants expired in March 2015. These warrants' fair value was zero at December 31, 2014 and when they expired at March 31, 2015. Therefore, no change in warrant liability was required to be recorded or reclassified during 2015. For the first nine months of 2014, the Company recorded a non-cash benefit of \$3,026 for these warrants.

In addition, we issued warrants for 194,986 shares of the Company's common stock in connection with the Hercules Credit Agreement in November 2013 and June 2014. The liability associated with these warrants was calculated at its fair market value using the Black-Scholes option-pricing model and was adjusted at the end of each quarter with changes in fair value recorded in earnings during the term of the warrants. As discussed in Note 9 of the financial statement, the Company concluded in the second quarter of 2015 the warrant provision which required the exercise price of the warrant to be adjusted downward to a lower price at which the Company would sell and issue shares in a financing for cash during the one-year anniversary of the warrant had expired. Therefore, the Company valued the warrant at \$336,254 immediately prior to this event and reduced the liability to zero and increased equity by \$336,254 in the second quarter of 2015. The Company also recorded a non-cash charge to net income of \$61,246 in the nine month period ended September 30, 2015.

At September 30, 2014, the fair value of these liabilities was \$0.4 million and the Company recorded a non-cash benefit to net income of \$81,243 in the nine month period ended September 30, 2014.

Investment income and interest expense

In connection with its debt facilities the Company incurred \$1.1 million and \$0.9 million in interest expense in the first nine months of 2015 and 2014, respectively.

Other (expense) income

Other (expense) income for the first nine months of 2015 and 2014 was not significant.

**Financial Condition, Liquidity and Capital Resources**

Since inception, excluding the net aggregate payments received from Boston Scientific of \$43 million through the divestiture of our medical device business in 2007 (which we received in installments of \$13 million in 2007 and \$15 million in each of 2008 and 2009), we have incurred significant losses and negative cash flows from operations. We have financed our operations primarily through the net proceeds we received in this divestiture, subsequent sales of equity, credit facilities and amounts received under our product licensing agreement with Yakult and our technology development agreement with Hisun. The process of developing and commercializing ThermoDox®, GEN-1 and other product candidates and technologies requires significant research and development work and clinical trial studies, as well as significant manufacturing and process development efforts. We expect these activities, together with our general and administrative expenses to result in significant operating losses for the foreseeable future. Our expenses have significantly and regularly exceeded our revenue, and we had an accumulated deficit of \$212 million at September 30, 2015.

At September 30, 2015, we had total current assets of \$24.8 million (including cash, cash equivalents and short term investments and related interest receivable on short term investments of \$24.4 million) and current liabilities of \$8.4 million, resulting in net working capital of \$16.4 million. At December 31, 2014, we had total current assets of \$37.5 million (including cash, cash equivalents and short term investments and related interest receivable on short term investments of \$37.1 million) and current liabilities of \$10.1 million, resulting in net working capital of \$27.4 million.

Net cash used in operating activities for the first nine months of 2015 was \$16.9 million. The net loss for the first nine months of 2015 included \$1.6 million in non-cash stock-based compensation expense. The \$16.9 million net cash used in operating activities was funded from cash and short term investments. At September 30, 2015, we had cash, cash equivalents and short term investments and related interest receivable on short term investments of \$24.4 million.

Net cash provided by financing activities was \$4.5 million during the first nine months of 2015 which resulted from net proceeds of \$7.2 million from the sale of our common stock in the second quarter of 2015 partially offset by principal payments of \$2.7 million on the Hercules Credit Agreement.

On February 1, 2013, the Company entered into a Controlled Equity Offering SM Sales Agreement (the ATM Agreement) with Cantor Fitzgerald & Co., as sales agent (Cantor), pursuant to which we may offer and sell, from time to time, through Cantor, shares of our common stock having an aggregate offering price of up to \$25.0 million (the ATM Shares) pursuant to our previously filed and effective registration statement on Form S-3. Under the ATM Agreement, Cantor may sell ATM Shares by any method deemed to be an “at-the-market” offering as defined in Rule 415 promulgated under the Securities Act of 1933, as amended, including sales made directly on The NASDAQ Capital Market, on any other existing trading market for the our common stock or to or through a market maker. We will pay Cantor a commission of three percent of the aggregate gross proceeds from each sale of ATM Shares. We have sold and issued an aggregate of 1,195,927 shares under the ATM Agreement as of September 30, 2015, receiving approximately \$6.8 million in net proceeds. On October 2, 2015, we filed a prospectus supplement to the base prospectus that forms a part of the registration statement on Form S-3 (File No. 333-206789), filed on September 4, 2015 and declared effective by the SEC on September 25, 2015, pursuant to which we may offer and sell up to \$7,500,000 of shares of common stock from time to time under the ATM Agreement.

We believe that our cash and investment resources of \$24.4 million on hand at September 30, 2015 are sufficient to fund operations into the first half of 2017. However, our future capital requirements will depend upon numerous unpredictable factors, including, without limitation, the cost, timing, progress and outcomes of clinical studies and regulatory reviews of our proprietary drug candidates, our efforts to implement new collaborations, licenses and strategic transactions, general and administrative expenses, capital expenditures and other unforeseen uses of cash.

We may seek additional capital through further public or private equity offerings, debt financing, additional strategic alliance and licensing arrangements, collaborative arrangements, or some combination of these financing alternatives. If we raise additional funds through the issuance of equity securities, the percentage ownership of our stockholders could be significantly diluted and the newly issued equity securities may have rights, preferences, or privileges senior to those of the holders of our common stock. If we raise funds through the issuance of debt securities, those securities may have rights, preferences, and privileges senior to those of our common stock. If we seek strategic alliances, licenses, or other alternative arrangements, such as arrangements with collaborative partners or others, we may need to relinquish rights to certain of our existing or future technologies, product candidates, or products we would otherwise seek to develop or commercialize on our own, or to license the rights to our technologies, product candidates, or products on terms that are not favorable to us. The overall status of the economic climate could also result in the terms of any equity offering, debt financing, or alliance, license, or other arrangement being even less favorable to us and our stockholders than if the overall economic climate were stronger. We also will continue to look for government sponsored research collaborations and grants to help offset future anticipated losses from operations and, to a lesser extent, interest income.

If adequate funds are not available through either the capital markets, strategic alliances, or collaborators, we may be required to delay or, reduce the scope of, or terminate our research, development, clinical programs, manufacturing, or commercialization efforts, or effect additional changes to our facilities or personnel, or obtain funds through other arrangements that may require us to relinquish some of our assets or rights to certain of our existing or future technologies, product candidates, or products on terms not favorable to us.

If adequate funds are not available through either the capital markets, strategic alliances, or collaborators, we may be required to delay or, reduce the scope of, or eliminate our research, development, clinical programs, manufacturing, or commercialization efforts, or effect additional changes to our facilities or personnel, or obtain funds through other arrangements that may require us to relinquish some of our assets or rights to certain of our existing or future technologies, product candidates, or products on terms not favorable to us.

#### **Off-Balance Sheet Arrangements and Contractual Obligations**

We have no off-balance sheet financing arrangements. There were no material changes during the nine months ended September 30, 2015 to our operating leases, which are disclosed in the contractual commitments table in our Annual Report on Form 10-K for the fiscal year ended December 31, 2014 filed on March 12, 2015 with the Securities and

Exchange Commission.

**Item 3. QUANTITATIVE AND QUALITATIVE DISCLOSURE ABOUT MARKET RISK**

The primary objective of our investment activities is to preserve our capital until it is required to fund operations while at the same time maximizing the income we receive from our investments without significantly increasing risk. Our cash flow and earnings are subject to fluctuations due to changes in interest rates in our investment portfolio. We maintain a portfolio of various issuers, types, and maturities. These securities are classified as available-for-sale and, consequently, are recorded on the balance sheet at fair value with unrealized gains or losses reported as a component of accumulated other comprehensive loss included in stockholders' equity.

**Item 4. CONTROLS AND PROCEDURES**

We have carried out an evaluation, under the supervision and with the participation of management, including our principal executive officer and principal financial officer, of the effectiveness of the design and operation of our disclosure controls and procedures, as that term is defined in Rule 13a-15(e) under the Securities Exchange Act of 1934, as amended. Based on that evaluation, our principal executive officer and principal financial officer have concluded that, as of September 30, 2015, which is the end of the period covered by this report, our disclosure controls and procedures are effective at the reasonable assurance level in alerting them in a timely manner to material information required to be included in our periodic reports with the Securities and Exchange Commission.

There were no changes in our internal controls over financial reporting identified in connection with the evaluation required by paragraph (d) of Rule 13a-15 of the Securities Exchange Act of 1934, as amended, that occurred during the nine months ended September 30, 2015 that have materially affected, or are reasonably likely to materially affect, our internal controls over financial reporting.

Our management, including our chief executive officer and chief financial officer, does not expect that our disclosure controls and procedures or our internal control over financial reporting will prevent all error and all fraud. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within the company have been detected. These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of simple errors or mistakes. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by management override of the control. The design of any system of controls also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions. Over time, controls may become inadequate because of changes in conditions, or the degree of compliance with the policies or procedures may deteriorate. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected.



## **PART II: OTHER INFORMATION**

### **Item 1. Legal Proceedings**

None.

### **Item 1A. Risk Factors**

The following is a summary of the risk factors, uncertainties and assumptions that we believe are most relevant to our business. These are factors that, individually or in the aggregate, we think could cause our actual results to differ significantly from anticipated or historical results and our forward-looking statements. Additional risks that we currently believe are immaterial may also impair our business operations. Investors should carefully consider the risks described below before making an investment decision, and understand that it is not possible to predict or identify all such factors. Consequently, investors should not consider the following to be a complete discussion of all potential risks or uncertainties. Moreover, we operate in a competitive and rapidly changing environment. New factors emerge from time to time and it is not possible to predict the impact of all of these factors on our business, financial condition or results of operations. We undertake no obligation to publicly update forward-looking statements, whether as a result of new information, future events, or otherwise. The description provided in this Item 1A includes any material changes to and supersedes the description of the risk factors associated with our business previously disclosed in Item 1A of our Annual Report on Form 10-K for the fiscal year ended December 31, 2014 filed on March 12, 2015 with the Securities and Exchange Commission (SEC). In assessing these risks, investors should also refer to the other information contained or incorporated by reference in this Quarterly Report and our other filings made from time to time with the SEC.

## **RISKS RELATED TO OUR BUSINESS**

**We have a history of significant losses from operations and expect to continue to incur significant losses for the foreseeable future.**

Since our inception, our expenses have substantially exceeded our revenue, resulting in continuing losses and an accumulated deficit of \$212 million at September 30, 2015. For the years ended December 31, 2014, 2013, 2012 and the nine months ended September 30, 2015, we incurred a net loss of \$25.5 million, \$12.9 million, \$26.6 million and \$16.9 million, respectively. We currently have no product revenue and do not expect to generate any product revenue for the foreseeable future other than through sales of our proprietary reagent products for life science research, which products are based on our newly acquired proprietary delivery platform technologies, TheraPlas™ and TheraSilence™. We do not expect revenue from the sale of our reagent products to be a significant source of revenue. Because we are

committed to continuing our product research, development, clinical trial and commercialization programs, we will continue to incur significant operating losses unless and until we complete the development of ThermoDox®, GEN-1 or other new product candidates and these product candidates have been clinically tested, approved by the U.S. Food and Drug Administration (FDA) and successfully marketed. The amount of future losses is uncertain. Our ability to achieve profitability, if ever, will depend on, among other things, us or our collaborators successfully developing product candidates, obtaining regulatory approvals to market and commercialize product candidates, manufacturing any approved products on commercially reasonable terms, establishing a sales and marketing organization or suitable third party alternatives for any approved product and raising sufficient funds to finance business activities. If we or our collaborators are unable to develop and commercialize one or more of our product candidates or if sales revenue from any product candidate that receives approval is insufficient, we will not achieve profitability, which could have a material adverse effect on our business, financial condition, results of operations and prospects.

**Drug development is an inherently uncertain process with a high risk of failure at every stage of development as demonstrated when our lead drug candidate failed to meet its primary endpoint in the Phase III HEAT Study.**

On January 31, 2013, we announced that our lead product ThermoDox® in combination with radiofrequency ablation (RFA) failed to meet the primary endpoint of the Phase III clinical trial for primary liver cancer, known as the HEAT Study. We have not completed our final analysis of the data and do not know the extent to which, if any, the failure of ThermoDox® to meet its primary endpoint in the Phase III trial could impact our other ongoing studies of ThermoDox®, including a pivotal, double-blind, placebo-controlled Phase III trial of ThermoDox® in combination with RFA in primary liver cancer, known as the OPTIMA Study, which we launched in the first half of 2014. The trial design of the OPTIMA Study is based on the overall survival data from the post-hoc analysis of results from the HEAT Study.

ThermoDox® is also being evaluated in a Phase II clinical trial for recurrent chest wall breast cancer and other preclinical studies.

Preclinical testing and clinical trials are long, expensive and highly uncertain processes and failure can unexpectedly occur at any stage of clinical development, as evidenced by the failure of ThermoDox® to meet its primary endpoint in the HEAT Study. Drug development is inherently risky and clinical trials take several years to complete. The start or end of a clinical trial is often delayed or halted due to changing regulatory requirements, manufacturing challenges, required clinical trial administrative actions, slower than anticipated patient enrollment, changing standards of care, availability or prevalence of use of a comparator drug or required prior therapy, clinical outcomes including insufficient efficacy, safety concerns, or our own financial constraints. The results from preclinical testing or early clinical trials of a product candidate may not predict the results that will be obtained in later phase clinical trials of the product candidate. We, the FDA or other applicable regulatory authorities may suspend clinical trials of a product candidate at any time for various reasons, including a belief that subjects participating in such trials are being exposed to unacceptable health risks or adverse side effects. We may not have the financial resources to continue development of, or to enter into collaborations for, a product candidate if we experience any problems or other unforeseen events that delay or prevent regulatory approval of, or our ability to commercialize, product candidates. The failure of one or more of our drug candidates or development programs could have a material adverse effect on our business, financial condition and results of operations.

**If we do not obtain or maintain FDA and foreign regulatory approvals for our drug candidates on a timely basis, or at all, or if the terms of any approval impose significant restrictions or limitations on use, we will be unable to sell those products and our business, results of operations and financial condition will be negatively affected.**

To obtain regulatory approvals from the FDA and foreign regulatory agencies, we must conduct clinical trials demonstrating that our products are safe and effective. We may need to amend ongoing trials or the FDA and/or foreign regulatory agencies may require us to perform additional trials beyond those we planned. This process generally takes a number of years and requires the expenditure of substantial resources. The time required for completing testing and obtaining approvals is uncertain, and the FDA and foreign regulatory agencies have substantial discretion, at any phase of development, to terminate clinical studies, require additional clinical development or other testing, delay or withhold registration and marketing approval and mandate product withdrawals, including recalls. In addition, undesirable side effects caused by our drug candidates could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restricted label or the delay or denial of regulatory approval by regulatory authorities. Even if we receive regulatory approval of a product, the approval may limit the indicated uses for which the drug may be marketed. The failure to obtain timely regulatory approval of product candidates, any product marketing limitations or a product withdrawal would negatively impact our business, results of operations and financial condition.

**We do not expect to generate significant revenue for the foreseeable future.**

We have devoted our resources to developing a new generation of products and will not be able to market these products until we have completed clinical trials and obtain all necessary governmental approvals. Our lead product candidate, ThermoDox®, and the product candidates we purchased in our acquisition of substantially all of the assets of Egen, Inc., an Alabama corporation which has changed its company name to EGWU, Inc. after the acquisition (EGEN) are still in various stages of development and trials and cannot be marketed until we have completed clinical testing and obtained necessary governmental approval. Following our announcement on January 31, 2013 that the HEAT Study failed to meet its primary endpoint of progression free survival, we continue to follow the patients enrolled in the Heat Study to the secondary endpoint, overall survival. Based on the overall survival data from the post-hoc analysis of results from the HEAT Study, launched a pivotal, double-blind, placebo-controlled Phase III trial of ThermoDox® in combination with RFA in primary liver cancer, known as the OPTIMA Study, in the first half of 2014. ThermoDox® is currently also being evaluated in a Phase II clinical trial for the treatment of recurrent chest wall breast cancer, known as the Dignity Study, and other preclinical studies. GEN-1 is currently in an early stage of clinical development for the treatment of ovarian cancer. We plan to initiate a Phase I dose escalation clinical trial in combination with the standard of care in neo-adjuvant ovarian cancer in the second half of 2015 and conduct additional preclinical studies to support a Phase I dose escalating trial evaluating GEN-1 in combination with Avastin® and Doxil® in platinum-resistant ovarian cancer patients. The delivery technology platforms that we purchased from EGEN are in preclinical stages of development. We do not expect to realize any revenue from product sales in the next several years, if at all, other than minimal revenue from the sale of reagent products we acquired from EGEN. We do not expect to realize any revenue from product sales in the next several years, if at all. Accordingly, our revenue sources are, and will remain, extremely limited until our product candidates are clinically tested, approved by the FDA or foreign regulatory agencies and successfully marketed. We cannot guarantee that any of our product candidates will be successfully tested, approved by the FDA or foreign regulatory agency or marketed, successfully or otherwise, at any time in the foreseeable future or at all.

**We will need to raise substantial additional capital to fund our planned future operations, and we may be unable to secure such capital without dilutive financing transactions. If we are not able to raise additional capital, we may not be able to complete the development, testing and commercialization of our product candidates.**

As of September 30, 2015, we had approximately \$24.4 million in cash, cash equivalents and short-term investments, including accrued interest from short term investments. We have substantial future capital requirements to continue our research and development activities and advance our drug candidates through various development stages, including the product candidates that we purchased from EGEN in June 2014. For example, ThermoDox® is being evaluated in a Phase III clinical trial for the treatment of primary liver cancer, a Phase II clinical trial for the treatment of recurrent chest wall breast cancer and other preclinical studies. In addition, GEN-1 is currently in an early stage of clinical development for the treatment of ovarian cancer. We enrolled our first patient in a Phase I dose escalation clinical trial in combination with the standard of care in neo-adjuvant ovarian cancer in the third quarter of 2015 and conduct additional preclinical studies to support a Phase I dose escalating trial evaluating GEN-1 in combination with Avastin® and Doxil® in platinum-resistant ovarian cancer patients. The delivery technology platforms that we purchased from EGEN are in preclinical stages of development. We will continue to conduct additional analyses of the data from the HEAT Study to assess the future strategic value of ThermoDox® and are performing sub-group analysis of the Chinese cohort of patients in the HEAT Study and other activities for further development of ThermoDox® for mainland China, Hong Kong and Macau. To complete the development and commercialization of our product candidates, we will need to raise substantial amounts of additional capital to fund our operations. Our future capital requirements will depend upon numerous unpredictable factors, including, without limitation, the cost, timing, progress and outcomes of clinical studies and regulatory reviews of our proprietary drug candidates, our efforts to implement new collaborations, licenses and strategic transactions, general and administrative expenses, capital expenditures and other unforeseen uses of cash. We do not have any committed sources of financing and cannot assure you that alternate funding will be available in a timely manner, on acceptable terms or at all. We may need to pursue dilutive equity financings, such as the issuance of shares of common stock, convertible debt or other convertible or exercisable securities. Such dilutive equity financings could dilute the percentage ownership of our current common stockholders and could significantly lower the market value of our common stock. In addition, a financing could result in the issuance of new securities that may have rights, preferences or privileges senior to those of our existing stockholders.

If we are unable to obtain additional capital on a timely basis or on acceptable terms, we may be required to delay, reduce or terminate our research and development programs and preclinical studies or clinical trials, if any, limit strategic opportunities or undergo corporate restructuring activities. We also could be required to seek funds through arrangements with collaborators or others that may require us to relinquish rights to some of our technologies, product candidates or potential markets or that could impose onerous financial or other terms. Furthermore, if we cannot fund our ongoing development and other operating requirements, particularly those associated with our obligations to conduct clinical trials under our licensing agreements, we will be in breach of these licensing agreements and could therefore lose our license rights, which could have material adverse effects on our business.

**Failure to successfully integrate the assets we acquired from EGEN in June 2014 into our operations could adversely affect our ability to develop and commercialize product candidates or negatively impact our business,**

**results of operations and financial conditions.**

On June 20, 2014, we completed the acquisition of substantially all of the assets of EGEN, a privately-held biopharmaceutical company focused on the development of nucleic acid-based therapeutics for the treatment of cancer and other difficult to treat diseases. The acquisition included EGEN's Phase Ib DNA-based immunotherapy product candidate GEN-1 and its therapeutic platform technologies, TheraPlas™ for delivery of DNA and mRNA, and TheraSilence™ for delivery of RNA. The success of the EGEN acquisition, including the realization of anticipated benefits and cost savings, will depend, in part, on our ability to combine successfully the business we acquired from EGEN with the business of Celsion. Our integration of the operations and product candidates acquired requires significant efforts, including the coordination of research and development, manufacturing, finance, information technologies and management and administration. These integration efforts will result in additional expenses and require significant time and dedication from management, and may divert management attention and resources. The integration may be more difficult, costly or time consuming than expected. It is possible that the integration process could result in the loss of key employees or the disruption of our ongoing business or that the alignment of standards, controls, procedures and policies may adversely affect the combined company's ability to maintain relationships with suppliers, manufacturers, other vendors or employees or to fully achieve the anticipated benefits and cost savings of the transaction.

In addition, the EGEN acquisition may result in our assumption of material unknown or unexpected liabilities. If we experience difficulties with the integration process, the anticipated benefits of the transaction may not be realized fully or at all, or may take longer to realize than expected. Factors that will affect the success of the acquisition include our ability to execute our business strategy, results of clinical trials and regulatory approvals related to the acquired product candidates and platform technologies, our ability to adequately fund acquired in-process research and development projects and retain key employees, as well as our ability to achieve financial and operational synergies with the acquired business, such as by achieving cost savings and effectively developing product candidates. Our failure to successfully manage and coordinate the growth of our newly acquired business could have a material adverse impact on our business, results of operations and financial condition. In addition, we cannot be certain that the product candidates we acquired will be approved for marketing and commercialization, become profitable or remain so or that we will realize operational cost savings or other expected synergies of the acquisition. If the acquisition and integration are not successful, we may record related asset impairment charges in the future.

**We have incurred, and will continue to incur, significant costs in connection with our acquisition of substantially all of the assets of EGEN.**

We have incurred a number of non-recurring costs associated with our integration of the assets purchased from EGEN. These costs and expenses include the incurrence of \$5.0 million of new indebtedness and approximately \$1.2 million in financial advisory, legal, accounting, consulting and other advisory fees and expenses, reorganization and restructuring costs, severance/employee benefit-related expenses, filing fees, printing expenses and other related charges. There are also a large number of processes, policies, procedures, operations, technologies and systems that must be integrated and implemented. We expect to continue to incur costs and expenses in connection with the continuous integration of the assets and operations in connection with the acquisition. There are many factors beyond our control that could affect the total amount or the timing of integration and implementation expense, and we may incur unanticipated expense in connection with the EGEN acquisition. These costs and expenses could, particularly in the near term, exceed the cost savings that we expect to achieve from the elimination of duplicative expenses and the realization of economies of scale, other efficiencies and cost savings, which benefit may not be achieved in the near term or at all.

**We may not successfully engage in future strategic transactions, which could adversely affect our ability to develop and commercialize product candidates, impact our cash position, increase our expense and present significant distractions to our management.**

In the future, we may consider other strategic alternatives intended to further the development of our business, which may include acquiring businesses, technologies or products, out- or in-licensing product candidates or technologies or entering into a business combination with another company. Any strategic transaction may require us to incur non-recurring or other charges, increase our near- and long-term expenditures and pose significant integration or implementation challenges or disrupt our management or business. These transactions would entail numerous operational and financial risks, including exposure to unknown liabilities, disruption of our business and diversion of our management's time and attention in order to manage a collaboration or develop acquired products, product

candidates or technologies, incurrence of substantial debt or dilutive issuances of equity securities to pay transaction consideration or costs, higher than expected collaboration, acquisition or integration costs, write-downs of assets or goodwill or impairment charges, increased amortization expenses, difficulty and cost in facilitating the collaboration or combining the operations and personnel of any acquired business, impairment of relationships with key suppliers, manufacturers or customers of any acquired business due to changes in management and ownership and the inability to retain key employees of any acquired business. Accordingly, although there can be no assurance that we will undertake or successfully complete any transactions of the nature described above, any transactions that we do complete may be subject to the foregoing or other risks and have a material adverse effect on our business, results of operations, financial condition and prospects. Conversely, any failure to enter any strategic transaction that would be beneficial to us could delay the development and potential commercialization of our product candidates and have a negative impact on the competitiveness of any product candidate that reaches market.

Strategic transactions, such as acquisitions, partnerships and collaborations, including the EGEN acquisition, involve numerous risks, including:

- the failure of markets for the products of acquired businesses, technologies or product lines to develop as expected;
- uncertainties in identifying and pursuing acquisition targets;
- the challenges in achieving strategic objectives, cost savings and other benefits expected from acquisitions;



- the risk that the financial returns on acquisitions will not support the expenditures incurred to acquire such businesses or the capital expenditures needed to develop such businesses;
- difficulties in assimilating the acquired businesses, technologies or product lines;
- the failure to successfully manage additional business locations, including the additional infrastructure and resources necessary to support and integrate such locations;
- the existence of unknown product defects related to acquired businesses, technologies or product lines that may not be identified due to the inherent limitations involved in the due diligence process of an acquisition;
- the diversion of management's attention from other business concerns;
- risks associated with entering markets or conducting operations with which we have no or limited direct prior experience;
- risks associated with assuming the legal obligations of acquired businesses, technologies or product lines;
- risks related to the effect that internal control processes of acquired businesses might have on our financial reporting and management's report on our internal control over financial reporting;
- the potential loss of key employees related to acquired businesses, technologies or product lines; and
- the incurrence of significant exit charges if products or technologies acquired in business combinations are unsuccessful.

We may never realize the perceived benefits of the EGEN acquisition or potential future transactions. We cannot assure you that we will be successful in overcoming problems encountered in connection with any transactions, and our inability to do so could significantly harm our business, results of operations and financial condition. These transactions could dilute a stockholder's investment in us and cause us to incur debt, contingent liabilities and amortization/impairment charges related to intangible assets, all of which could materially and adversely affect our business, results of operations and financial condition. In addition, our effective tax rate for future periods could be negatively impacted by the EGEN acquisition or potential future transactions.

**Our business depends on license agreements with third parties to permit us to use patented technologies. The loss of any of our rights under these agreements could impair our ability to develop and market our products.**

Our success will depend, in a substantial part, on our ability to maintain our rights under license agreements granting us rights to use patented technologies. For instance, we are party to license agreements with Duke University, under which we have exclusive rights to commercialize medical treatment products and procedures based on Duke's thermo-sensitive liposome technology. The Duke University license agreement contains a license fee, royalty and/or research support provisions, testing and regulatory milestones, and other performance requirements that we must meet by certain deadlines. Additionally, we have a joint research agreement with Philips Healthcare, a division of Royal

Philips Electronics, to evaluate the combination of Philips' high intensity focused ultrasound (HIFU) with ThermoDox® to determine the potential of this combination to treat a broad range of cancers. As part of the assets we acquired from EGEN in June 2014, we became party to a license agreement with The Wistar Institute of Anatomy and Biology pursuant to which we in-license certain technologies use in the development of our newly acquired proprietary delivery platform technologies, TheraPlas™ and TheraSilence™. If we breach any provisions of the license and research agreements, we may lose our ability to use the subject technology, as well as compensation for our efforts in developing or exploiting the technology. Any such loss of rights and access to technology could have a material adverse effect on our business.

Further, we cannot guarantee that any patent or other technology rights licensed to us by others will not be challenged or circumvented successfully by third parties, or that the rights granted will provide adequate protection. We may be required to alter any of our potential products or processes, or enter into a license and pay licensing fees to a third party or cease certain activities. There can be no assurance that we can obtain a license to any technology that we determine we need on reasonable terms, if at all, or that we could develop or otherwise obtain alternate technology. If a license is not available on commercially reasonable terms or at all, our business, results of operations, and financial condition could be significantly harmed and we may be prevented from developing and commercializing the product. Litigation, which could result in substantial costs, may also be necessary to enforce any patents issued to or licensed by us or to determine the scope and validity of others' claimed proprietary rights.

**If any of our pending patent applications do not issue, or are deemed invalid following issuance, we may lose valuable intellectual property protection.**

The patent positions of pharmaceutical and biotechnology companies, such as ours, are uncertain and involve complex legal and factual issues. We own various U.S. and international patents and have pending U.S. and international patent applications that cover various aspects of our technologies. There can be no assurance that patents that have issued will be held valid and enforceable in a court of law through the entire patent term. Even for patents that are held valid and enforceable, the legal process associated with obtaining such a judgment is time consuming and costly. Additionally, issued patents can be subject to opposition, interferences or other proceedings 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). Further, our competitors may be able to circumvent and otherwise design around our patents. Even if a patent is issued and enforceable, because development and commercialization of pharmaceutical products can be subject to substantial delays, patents may expire early and provide only a short period of protection, if any, following the commercialization of products encompassed by our patents. We may have to participate in interference proceedings declared by the U.S. Patent and Trademark Office, which could result in a loss of the patent or substantial cost to us.

We have filed patent applications, and plan to file additional patent applications, covering various aspects of our technologies and our proprietary product candidates. There can be no assurance that the patent applications for which we apply would actually issue as patents, or do so with commercially relevant or broad coverage. The coverage claimed in a patent application can be significantly reduced before the patent is issued. The scope of our claim coverage can be critical to our ability to enter into licensing transactions with third parties and our right to receive royalties from our collaboration partnerships. Since publication of discoveries in scientific or patent literature often lags behind the date of such discoveries, we cannot be certain that we were the first inventor of inventions covered by our patents or patent applications. In addition, there is no guarantee that we will be the first to file a patent application directed to an invention.

An adverse outcome in any judicial proceeding involving intellectual property, including patents, could subject us to significant liabilities to third parties, require disputed rights to be licensed from or to third parties or require us to cease using the technology in dispute. In those instances where we seek an intellectual property license from another, we may not be able to obtain the license on a commercially reasonable basis, if at all, thereby raising concerns on our ability to freely commercialize our technologies or products.

**We rely on trade secret protection and other unpatented proprietary rights for important proprietary technologies, and any loss of such rights could harm our business, results of operations and financial condition.**

We rely on trade secrets and confidential information that we seek to protect, in part, by confidentiality agreements with our corporate partners, collaborators, employees and consultants. We cannot assure you that these agreements are

adequate to protect our trade secrets and confidential information or will not be breached or, if breached, we will have adequate remedies. Furthermore, others may independently develop substantially equivalent confidential and proprietary information or otherwise gain access to our trade secrets or disclose such technology. Any loss of trade secret protection or other unpatented proprietary rights could harm our business, results of operations and financial condition.

**Our products may infringe patent rights of others, which may require costly litigation and, if we are not successful, could cause us to pay substantial damages or limit our ability to commercialize our products.**

Our commercial success depends on our ability to operate without infringing the patents and other proprietary rights of third parties. There may be third party patents that relate to our products and technology. We may unintentionally infringe upon valid patent rights of third parties. Although we currently are not involved in any material litigation involving patents, a third party patent holder may assert a claim of patent infringement against us in the future. Alternatively, we may initiate litigation against the third party patent holder to request that a court declare that we are not infringing the third party's patent and/or that the third party's patent is invalid or unenforceable. If a claim of infringement is asserted against us and is successful, and therefore we are found to infringe, we could be required to pay damages for infringement, including treble damages if it is determined that we knew or became aware of such a patent and we failed to exercise due care in determining whether or not we infringed the patent. If we have supplied infringing products to third parties or have licensed third parties to manufacture, use or market infringing products, we may be obligated to indemnify these third parties for damages they may be required to pay to the patent holder and for any losses they may sustain. We can also be prevented from selling or commercializing any of our products that use the infringing technology in the future, unless we obtain a license from such third party. A license may not be available from such third party on commercially reasonable terms, or may not be available at all. Any modification to include a non-infringing technology may not be possible or if possible may be difficult or time-consuming to develop, and require revalidation, which could delay our ability to commercialize our products. Any infringement action asserted against us, even if we are ultimately successful in defending against such action, would likely delay the regulatory approval process of our products, harm our competitive position, be expensive and require the time and attention of our key management and technical personnel.

**We rely on third parties to conduct all of our clinical trials. If these third parties are unable to carry out their contractual duties in a manner that is consistent with our expectations, comply with budgets and other financial obligations or meet expected deadlines, we may not receive certain development milestone payments or be able to obtain regulatory approval for or commercialize our product candidates in a timely or cost-effective manner.**

We rely, and expect to continue to rely, on third-party clinical investigators, clinical research organizations (CROs), clinical data management organizations and consultants to design, conduct, supervise and monitor our clinical trials. Because we do not have the ability to conduct our own clinical trials, we must rely on the efforts of others and have limited control over, and cannot predict accurately, the timing of such trials, the costs associated with such trials or the procedures that are followed for such trials. We do not expect to significantly increase our personnel in the foreseeable future and may continue to rely on third parties to conduct all of our future clinical trials.

If we cannot contract with acceptable third parties on commercially reasonable terms or at all, if these third parties are unable to carry out their contractual duties or obligations in a manner that is consistent with our expectations or meet expected deadlines, if they do not carry out the trials in accordance with budgeted amounts, if the quality or accuracy of the clinical data they obtain is compromised due to their failure to adhere to our clinical protocols or for other reasons, or if they fail to maintain compliance with applicable government regulations and standards, our clinical trials may be extended, delayed or terminated or may become significantly more expensive, we may not receive development milestone payments when expected or at all, and we may not be able to obtain regulatory approval for or successfully commercialize our product candidates.

In all events, we are responsible for ensuring that each of our clinical trials is conducted in accordance with the general investigational plan and protocols for the trial. The FDA requires clinical trials to be conducted in accordance with good clinical practices, including for conducting, recording and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of clinical trial participants are protected. Our reliance on third parties that we do not control does not relieve us of these responsibilities and requirements. Any such event could have a material adverse effect on our business, financial condition, results of operations and prospects.

**Because we rely on third party manufacturing and supply partners, our supply of research and development, preclinical and clinical development materials may become limited or interrupted or may not be of satisfactory quantity or quality.**

We rely on third party supply and manufacturing partners to supply the materials and components for, and manufacture, our research and development, preclinical and clinical trial drug supplies. We do not own manufacturing facilities or supply sources for such components and materials. There can be no assurance that our supply of research and development, preclinical and clinical development drugs and other materials will not be limited, interrupted,

restricted in certain geographic regions or of satisfactory quality or continue to be available at acceptable prices. Suppliers and manufacturers must meet applicable manufacturing requirements and undergo rigorous facility and process validation tests required by FDA and foreign regulatory authorities in order to comply with regulatory standards, such as current Good Manufacturing Practices. In the event that any of our suppliers or manufacturers fails to comply with such requirements or to perform its obligations to us in relation to quality, timing or otherwise, or if our supply of components or other materials becomes limited or interrupted for other reasons, we may be forced to manufacture the materials ourselves, for which we currently do not have the capabilities or resources, or enter into an agreement with another third party, which we may not be able to do on reasonable terms, if at all.

**Our business is subject to numerous and evolving state, federal and foreign regulations and we may not be able to secure the government approvals needed to develop and market our products.**

Our research and development activities, pre-clinical tests and clinical trials, and ultimately the manufacturing, marketing and labeling of our products, are all subject to extensive regulation by the FDA and foreign regulatory agencies. Pre-clinical testing and clinical trial requirements and the regulatory approval process typically take years and require the expenditure of substantial resources. Additional government regulation may be established that could prevent or delay regulatory approval of our product candidates. Delays or rejections in obtaining regulatory approvals would adversely affect our ability to commercialize any product candidates and our ability to generate product revenue or royalties.

The FDA and foreign regulatory agencies require that the safety and efficacy of product candidates be supported through adequate and well-controlled clinical trials. If the results of pivotal clinical trials do not establish the safety and efficacy of our product candidates to the satisfaction of the FDA and other foreign regulatory agencies, we will not receive the approvals necessary to market such product candidates. Even if regulatory approval of a product candidate is granted, the approval may include significant limitations on the indicated uses for which the product may be marketed.

We are subject to the periodic inspection of our clinical trials, facilities, procedures and operations and/or the testing of our products by the FDA to determine whether our systems and processes, or those of our vendors and suppliers, are in compliance with FDA regulations. Following such inspections, the FDA may issue notices on Form 483 and warning letters that could cause us to modify certain activities identified during the inspection. A Form 483 notice is generally issued at the conclusion of an FDA inspection and lists conditions the FDA inspectors believe may violate FDA regulations. FDA guidelines specify that a warning letter is issued only for violations of “regulatory significance” for which the failure to adequately and promptly achieve correction may be expected to result in an enforcement action.

Failure to comply with the FDA and other governmental regulations can result in fines, unanticipated compliance expenditures, recall or seizure of products, total or partial suspension of production and/or distribution, suspension of the FDA’s review of product applications, enforcement actions, injunctions and criminal prosecution. Under certain circumstances, the FDA also has the authority to revoke previously granted product approvals. Although we have internal compliance programs, if these programs do not meet regulatory agency standards or if our compliance is deemed deficient in any significant way, it could have a material adverse effect on the Company.

We are also subject to recordkeeping and reporting regulations. These regulations require, among other things, the reporting to the FDA of adverse events alleged to have been associated with the use of a product or in connection with certain product failures.

Labeling and promotional activities also are regulated by the FDA. We must also comply with record keeping requirements as well as requirements to report certain adverse events involving our products. The FDA can 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.

Many states in which we do or may do business, or in which our products may be sold, if at all, impose licensing, labeling or certification requirements that are in addition to those imposed by the FDA. There can be no assurance that one or more states will not impose regulations or requirements that have a material adverse effect on our ability to sell our products.

In many of the foreign countries in which we may do business or in which our products may be sold, we will be subject to regulation by national governments and supranational agencies as well as by local agencies affecting, among other things, product standards, packaging requirements, labeling requirements, import restrictions, tariff regulations, duties and tax requirements. There can be no assurance that one or more countries or agencies will not impose regulations or requirements that could have a material adverse effect on our ability to sell our products.

**Legislative and regulatory changes affecting the healthcare industry could adversely affect our business.**

Political, economic and regulatory influences are subjecting the healthcare industry to potential fundamental changes that could substantially affect our results of operations. There have been a number of government and private sector initiatives during the last few years to limit the growth of healthcare costs, including price regulation, competitive pricing, coverage and payment policies, comparative effectiveness of therapies, technology assessments and managed-care arrangements. It is uncertain whether or when any legislative proposals will be adopted or what actions federal, state, or private payors for health care treatment and services may take in response to any healthcare reform proposals or legislation. We cannot predict the effect healthcare reforms may have on our business and we can offer no assurances that any of these reforms will not have a material adverse effect on our business. These actual and potential changes are causing the marketplace to put increased emphasis on the delivery of more cost-effective treatments. In addition, uncertainty remains regarding proposed significant reforms to the U.S. health care system.



**The success of our products may be harmed if the government, private health insurers and other third-party payers do not provide sufficient coverage or reimbursement.**

Our ability to commercialize our new cancer treatment systems successfully will depend in part on the extent to which reimbursement for the costs of such products and related treatments will be available from government health administration authorities, private health insurers and other third-party payors. The reimbursement status of newly approved medical products is subject to significant uncertainty. We cannot guarantee that adequate third-party insurance coverage will be available for us to establish and maintain price levels sufficient for us to realize an appropriate return on our investment in developing new therapies. Government, private health insurers and other third-party payors are increasingly attempting to contain healthcare costs by limiting both coverage and the level of reimbursement for new therapeutic products approved for marketing by the FDA. Accordingly, even if coverage and reimbursement are provided by government, private health insurers and third-party payors for uses of our products, market acceptance of these products would be adversely affected if the reimbursement available proves to be unprofitable for health care providers.

**Our products may not achieve sufficient acceptance by the medical community to sustain our business.**

The commercial success of our products will depend upon their acceptance by the medical community and third-party payors as clinically useful, cost effective and safe. Any of our drug candidates may prove not to be effective in practice. If testing and clinical practice do not confirm the safety and efficacy of our product candidates or even if further testing and clinical practice produce positive results but the medical community does not view these new forms of treatment as effective and desirable, our efforts to market our new products may fail, which would have an adverse effect on our business, financial condition and results of operations.

**The commercial potential of a drug candidate in development is difficult to predict. If the market size for a new drug is significantly smaller than we anticipate, it could significantly and negatively impact our revenue, results of operations and financial condition.**

It is very difficult to predict the commercial potential of product candidates due to important factors such as safety and efficacy compared to other available treatments, including potential generic drug alternatives with similar efficacy profiles, changing standards of care, third party payor reimbursement standards, patient and physician preferences, the availability of competitive alternatives that may emerge either during the long drug development process or after commercial introduction, and the availability of generic versions of our successful product candidates following approval by government health authorities based on the expiration of regulatory exclusivity or our inability to prevent generic versions from coming to market by asserting our patents. If due to one or more of these risks the market potential for a drug candidate is lower than we anticipated, it could significantly and negatively impact the revenue potential for such drug candidate and would adversely affect our business, financial condition and results of operations.

**We have no internal sales or marketing capability. If we are unable to create sales, marketing and distribution capabilities or enter into alliances with others possessing such capabilities to perform these functions, we will not be able to commercialize our products successfully.**

We currently have no sales, marketing or distribution capabilities. We intend to market our products, if and when such products are approved for commercialization by the FDA and foreign regulatory agencies, either directly or through other strategic alliances and distribution arrangements with third parties. If we decide to market our products directly, we will need to commit significant financial and managerial resources to develop a marketing and sales force with technical expertise and with supporting distribution, administration and compliance capabilities. If we rely on third parties with such capabilities to market our products, we will need to establish and maintain partnership arrangements, and there can be no assurance that we will be able to enter into third-party marketing or distribution arrangements on acceptable terms or at all. To the extent that we do enter into such arrangements, we will be dependent on our marketing and distribution partners. In entering into third-party marketing or distribution arrangements, we expect to incur significant additional expense and there can be no assurance that such third parties will establish adequate sales and distribution capabilities or be successful in gaining market acceptance for our products and services.

**Technologies for the treatment of cancer are subject to rapid change, and the development of treatment strategies that are more effective than our technologies could render our technologies obsolete.**

Various methods for treating cancer currently are, and in the future are expected to be, the subject of extensive research and development. Many possible treatments that are being researched, if successfully developed, may not require, or may supplant, the use of our technologies. The successful development and acceptance of any one or more of these alternative forms of treatment could render our technology obsolete as a cancer treatment method.

**We may not be able to hire or retain key officers or employees that we need to implement our business strategy and develop our product candidates and business, including those purchased in the EGEN acquisition.**

Our success depends significantly on the continued contributions of our executive officers, scientific and technical personnel and consultants, including those retained in the EGEN acquisition, and on our ability to attract additional personnel as we seek to implement our business strategy and develop our product candidates and businesses. Our operations associated with the EGEN acquisition are located in Huntsville, Alabama. Key employees may depart if we fail to successfully manage this additional business location or in relation to any uncertainties or difficulties of integration with Celsion. We cannot guarantee that we will retain key employees to the same extent that we and EGEN retained each of our own employees in the past, which could have a negative impact on our business, results of operations and financial condition. Our integration of EGEN and ability to operate in the fields we acquired from EGEN may be more difficult if we lose key employees. Additionally, as our business and the demands on our key employees expand, we have been, and will continue to be, required to recruit additional qualified employees. The competition for such qualified personnel is intense, and the loss of services of certain key personnel or our inability to attract additional personnel to fill critical positions could adversely affect our business. Further, we do not carry “key man” insurance on any of our personnel. Therefore, loss of the services of key personnel would not be ameliorated by the receipt of the proceeds from such insurance.

**Our success will depend in part on our ability to grow and diversify, which in turn will require that we manage and control our growth effectively.**

Our business strategy contemplates growth and diversification. Our ability to manage growth effectively will require that we continue to expend funds to improve our operational, financial and management controls, reporting systems and procedures. In addition, we must effectively expand, train and manage our employees. We will be unable to manage our business effectively if we are unable to alleviate the strain on resources caused by growth in a timely and successful manner. There can be no assurance that we will be able to manage our growth and a failure to do so could have a material adverse effect on our business.

**We face intense competition and the failure to compete effectively could adversely affect our ability to develop and market our products.**

There are many companies and other institutions engaged in research and development of various technologies for cancer treatment products that seek treatment outcomes similar to those that we are pursuing. We believe that the level of interest by others in investigating the potential of possible competitive treatments and alternative technologies will continue and may increase. Potential competitors engaged in all areas of cancer treatment research in the United States and other countries include, among others, major pharmaceutical, specialized technology companies, and universities and other research institutions. Most of our current and potential competitors have substantially greater financial, technical, human and other resources, and may also have far greater experience than do we, both in pre-clinical testing

and human clinical trials of new products and in obtaining FDA and other regulatory approvals. One or more of these companies or institutions could succeed in developing products or other technologies that are more effective than the products and technologies that we have been or are developing, or which would render our technology and products obsolete and non-competitive. Furthermore, if we are permitted to commence commercial sales of any of our products, we will also be competing, with respect to manufacturing efficiency and marketing, with companies having substantially greater resources and experience in these areas.

**We may be subject to significant product liability claims and litigation.**

Our business exposes us to potential product liability risks inherent in the testing, manufacturing and marketing of human therapeutic products. We presently have product liability insurance limited to \$10 million per incident and \$10 million annually. 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 with our own limited resources, which could have a severe adverse effect on our business. Whether or not we are ultimately successful in any product liability litigation, such litigation would harm the business by diverting the attention and resources of our management, consuming substantial amounts of our financial resources and by damaging our reputation. Additionally, we may not be able to maintain our product liability insurance at an acceptable cost, if at all.

**Our internal computer systems, or those of our CROs or other contractors or consultants, may fail or suffer security breaches, which could result in a material disruption of our product development programs.**

Despite the implementation of security measures, our internal computer systems and those of our CROs and other contractors and consultants are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. Such events could cause interruptions of our operations. For instance, the loss of preclinical data or data from any clinical trial involving our product candidates could result in delays in our development and regulatory filing efforts and significantly increase our costs. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data, or inappropriate disclosure of confidential or proprietary information, we could incur liability and the development of our product candidates could be delayed.

## **RISKS RELATED TO OUR SECURITIES**

**The market price of our common stock has been, and we expect it to 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. More recently, our acquisition of the assets of EGEN in June 2014 has been followed with increased volatility in the price of our common stock. 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 \$4.57 and a low price of \$2.30 in the 52-week period ended December 31, 2014 and a high price of \$3.15 and a low price of \$1.65 from January 2, 2015 through November 4, 2015. 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.

**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 November 4, 2015, we had 23,027,988 shares of common stock outstanding, all of which shares, 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.

**Our stockholders may experience significant dilution as a result of future equity offerings or issuances and exercise of outstanding options and warrants.**

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 issuance. Investors purchasing shares or other securities in the future could have rights superior to existing stockholders. As of November 4, 2015, we have a significant number of securities convertible into, or allowing the purchase of, our common stock, including 5,894,675 shares of common stock issuable upon exercise of warrants outstanding, 2,150,363 options to purchase shares of our common stock and restricted stock awards outstanding, and 1,524,425 shares of common stock reserved for future issuance under our stock incentive plans. Under the Controlled Equity Offering<sup>SM</sup> 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 1,397,865 shares under the agreement for total net proceeds of \$7.2 million.

**We may be unable to maintain compliance with 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 November 4, 2015, the closing sale price of our common stock was \$1.94, 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 \$40, million and the total market value of our listed securities was approximately \$45, million. There is no assurance that we will continue to meet the minimum closing price requirement and other listing requirements. As of September 30, 2015, we had stockholders' equity of \$24.3 million.

On October 28, 2013, we effected a 4.5-to-1 reverse stock split of our common stock primarily for purposes of increasing the market price of our common stock, among others, and our common stock started to trade on the post-split basis on October 29, 2013. Other companies have found that the increased stock prices resulting from reverse splits tend to diminish over time unless supported by positive developments in the business. The closing price of our common stock as reported on The NASDAQ Capital Market has declined from \$5.14 on October 29, 2013 to \$1.94, on November 4, 2015.

If the closing bid price of our common stock is below \$1.00 per share or the total market value of our publicly held shares of common stock is below \$35 million for 30 consecutive business days, we 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.

**The adverse capital and credit market conditions could affect our liquidity.**

Adverse capital and credit market conditions could affect our ability to meet liquidity needs, as well as our access to capital and cost of capital. The capital and credit markets have experienced extreme volatility and disruption in recent years. Our results of operations, financial condition, cash flows and capital position could be materially adversely affected by continued disruptions in the capital and credit markets.

**Our ability to use net operating losses to offset future taxable income are subject to certain limitations.**

We currently have significant net operating losses (NOLs) that may be used to offset future taxable income. In general, under Section 382 of the Internal Revenue Code of 1986, as amended (the Code), a corporation that undergoes an “ownership change” is subject to limitations on its ability to utilize its pre-change NOLs to offset future taxable income. The Company annually performs analyses to determine if there were changes in ownership, as defined by Section 382 of the Internal Revenue Code that would limit its ability to utilize certain net operating loss and tax credit carry forwards. The Company determined that it experienced an ownership change, as defined by Section 382, in connection with certain common stock offerings on July 25, 2011, February 5, 2013 and on June 3, 2013. As a result, the utilization of the Company's federal tax net operating loss carry forwards generated prior to the ownership changes is limited. Future changes in our stock ownership, some of which are outside of our control, could result in an ownership change under Section 382 of the Code, which would significantly limit our ability to utilize NOLs to offset future taxable income.

**Our effective tax rate may be impacted by a number of factors, including tax effects of the EGEN acquisition.**

Our effective tax rate may be impacted by the tax effects of the EGEN acquisition, dispositions, changes to tax laws or regulations, examinations by tax authorities, stock-based compensation, uncertain tax positions, and changes in our ability to realize deferred tax assets. Significant judgment and estimates are required in determining the impact on our effective tax rate related to these items, including whether it is more likely than not that some or all of our deferred tax assets will be realized. Such estimates are subject to uncertainty due to various factors, including the economic environment, industry and market conditions, and the length of time of the projections included in the analyses. If our actual results are less favorable than current estimates, or we revise our estimates downward in future analyses, a valuation allowance may be required related to our deferred tax assets with a corresponding adjustment to earnings in the period in which such determination is made, which could have a material effect on our results of operations.

**We have never paid cash dividends on our common stock in the past and do not anticipate paying cash dividends on our common stock in the foreseeable future.**

We have never declared or paid cash dividends on our common stock. We do not anticipate paying any cash dividends on our common stock in the foreseeable future. We currently intend to retain all available funds and any future earnings to fund the development and growth of our business. As a result, capital appreciation, if any, of our common stock will be the sole source of gain for the foreseeable future for holders of our common stock.

**Anti-takeover provisions in our charter documents and Delaware law could prevent or delay a change in control.**

Our certificate of incorporation and bylaws may discourage, delay or prevent a merger or acquisition that a stockholder may consider favorable by authorizing the issuance of “blank check” preferred stock. This preferred stock may be issued by our board of directors on such terms as it determines, without further stockholder approval. Therefore, our board of directors may issue such preferred stock on terms unfavorable to a potential bidder in the event that our board of directors opposes a merger or acquisition. In addition, our classified board of directors may discourage such transactions by increasing the amount of time necessary to obtain majority representation on our board of directors. Certain other provisions of our bylaws and of Delaware law may also discourage, delay or prevent a third party from acquiring or merging with us, even if such action were beneficial to some, or even a majority, of our stockholders.

**Item 2. Unregistered Sales of Equity Securities and Use of Proceeds.**

None.

**Item 3. Defaults Upon Senior Securities.**

None.

**Item 4. Mine Safety Disclosures.**

Not applicable.

**Item 5. Other Information.**

None.

**Item 6. Exhibits.**

- 31.1+ Certification of Chief Executive Officer pursuant to Rule 13a-14(a)/15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
- 31.2+ Certification of Chief Financial Officer pursuant to Rule 13a-14(a)/15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
- 32.1\* Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
- + Filed herewith.

101\*\* The following materials from the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2015, formatted in XBRL (Extensible Business Reporting Language): (i) the unaudited Consolidated Balance Sheets, (ii) the unaudited Consolidated Statements of Operations, (iii) the unaudited Consolidated Statements of Comprehensive Loss, (iv) the unaudited Consolidated Statements of Cash Flows, (v) the unaudited Consolidated Statements of Change in Stockholders' Equity (Deficit), and (vi) Notes to Consolidated Financial Statements.

\* Exhibit 32.1 is being furnished and shall not be deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liability of that section, nor shall such exhibit be deemed to be incorporated by reference in any registration statement or other document filed under the Securities Act of 1933, as amended, or the Securities Exchange Act, except as otherwise stated in such filing.

\*\* XBRL information is filed herewith.

**SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

November 5, 2015 CELSION CORPORATION

Registrant

By: /s/ Michael H. Tardugno  
Michael H. Tardugno  
Chairman, President and Chief Executive Officer

By: /s/ Jeffrey W. Church  
Jeffrey W. Church  
Senior Vice President and Chief Financial Officer

## EXHIBIT INDEX

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