

Celsion CORP  
Form 10-Q  
November 10, 2016  
**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, 2016

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

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As of November 9, 2016, the Registrant had 26,078,814 shares of common stock, \$0.01 par value per share, outstanding.

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**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, its wholly-owned subsidiaries CLSN Laboratories, Inc., also a Delaware corporation, and Celsion GmbH, a limited liability company in Zug Switzerland.

## 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 30, 2016  (unaudited)</b>	<b>December 31, 2015</b>
<b>ASSETS</b>		
<b>Current assets:</b>		
Cash and cash equivalents	\$4,184,222	\$9,265,144
Investment securities – available for sale, at fair value	4,515,479	10,799,890
Accrued interest receivable on investment securities	4,524	26,729
Advances, deposits and other current assets	326,424	189,553
Subtotal current assets	9,030,649	20,281,316
<b>Property and equipment</b> (at cost, less accumulated depreciation and amortization of \$2,418,483 and \$2,058,483, respectively)	543,800	854,872
<b>Other assets:</b>		
In-process research and development	25,801,728	25,801,728
Goodwill	1,976,101	1,976,101
Security deposit on letter of credit	100,000	100,000
Patent licensing fees and other assets, net	8,761	14,386
Subtotal other assets	27,886,590	27,892,215
<b>Total assets</b>	<b>\$37,461,039</b>	<b>\$49,028,403</b>

See accompanying notes to the financial statements.





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

	<b>September 30, 2016  (unaudited)</b>	<b>December 31, 2015</b>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
<b>Current liabilities:</b>		
Accounts payable – trade	\$3,025,943	\$2,830,227
Other accrued liabilities	2,645,429	1,919,769
Notes payable - current portion	3,593,112	4,073,716
Deferred revenue – current portion	500,000	500,000
<b>Total current liabilities</b>	<b>9,764,484</b>	<b>9,323,712</b>
Notes payable – non-current portion	-	2,350,018
Earn-out milestone liability	14,477,794	13,921,412
Deferred revenue – non-current portion	2,625,000	3,000,000
Other liabilities – non-current	21,616	47,597
<b>Total liabilities</b>	<b>26,888,894</b>	<b>28,642,739</b>
<b>Commitments and contingencies</b>	-	-
<b>Stockholders' equity:</b>		
Preferred Stock - \$0.01 par value (100,000 shares authorized and no shares issued or outstanding at September 30, 2016 and December 31, 2015, respectively)	-	-
Common stock - \$0.01 par value (112,500,000 shares authorized; 26,083,493 and 23,395,211 shares issued at September 30, 2016 and December 31, 2015, respectively and 26,060,573 and 23,319,287 shares outstanding at September 30, 2016 and December 31, 2015, respectively)	260,835	233,952
Additional paid-in capital	246,401,410	239,668,235
Accumulated other comprehensive income (loss)	464	(3,858 )
Accumulated deficit	(235,673,273)	(218,130,360)
Subtotal	10,989,436	21,767,969
	(417,291 )	(1,382,305 )

Treasury stock, at cost (22,920 and 75,924 shares at September 30, 2016 and December 31, 2015, respectively)

<b>Total stockholders' equity</b>	10,572,145	20,385,664
<b>Total liabilities and stockholders' equity</b>	\$37,461,039	\$49,028,403

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>2016</b>	<b>2015</b>	<b>2016</b>	<b>2015</b>
<b>Licensing revenue</b>	\$125,000	\$125,000	\$375,000	\$375,000
<b>Operating expenses:</b>				
Research and development	4,225,132	2,883,453	11,002,675	10,957,560
General and administrative	1,496,471	1,483,661	4,888,301	5,317,344
<b>Total operating expenses</b>	<b>5,721,603</b>	<b>4,367,114</b>	<b>15,890,976</b>	<b>16,274,904</b>
<b>Loss from operations</b>	<b>(5,596,603 )</b>	<b>(4,242,114 )</b>	<b>(15,515,976 )</b>	<b>(15,899,904 )</b>
<b>Other (expense) income:</b>				
(Loss) gain from change in valuation of earn-out milestone liability	(662,410 )	282,950	(556,382 )	41,422
Loss from change in valuation of common stock warrant liability	-	-	-	(61,246 )
Investment income, net	8,133	15,500	21,832	48,745
Interest expense	(161,025 )	(322,696 )	(608,576 )	(1,075,258 )
Other income (expense)	2,218	(1,053 )	1,965	(985 )
<b>Total other (expense) income, net</b>	<b>(813,084 )</b>	<b>(25,299 )</b>	<b>(1,141,161 )</b>	<b>(1,047,322 )</b>
<b>Net loss</b>	<b>\$(6,409,687 )</b>	<b>\$(4,267,413 )</b>	<b>\$(16,657,137 )</b>	<b>\$(16,947,226 )</b>
<b>Net loss per common share</b>				
<b>Basic and diluted</b>	<b>\$(0.23 )</b>	<b>\$(0.19 )</b>	<b>\$(0.66 )</b>	<b>\$(0.79 )</b>
<b>Weighted average shares outstanding</b>				
<b>Basic and diluted</b>	<b>27,905,261</b>	<b>23,023,402</b>	<b>25,146,573</b>	<b>21,335,228</b>

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



**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>2016</b>	<b>2015</b>	<b>2016</b>	<b>2015</b>
<b>Other comprehensive (loss) gain</b>				
Changes in:				
Realized loss on investment securities recognized in investment income, net	\$-	\$(106 )	\$3,858	\$104
Unrealized gain on investment securities	464	3,387	464	14,894
Other comprehensive gain	464	3,281	4,322	14,998
Net loss	(6,409,687)	(4,267,413)	(16,657,137)	(16,947,226)
Comprehensive loss	\$(6,409,223)	\$(4,264,132)	\$(16,652,815)	\$(16,932,228)

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

**CELSION CORPORATION**

**CONDENSED CONSOLIDATED**

**STATEMENTS OF CASH FLOWS**

**(Unaudited)**

	<b>Nine Months Ended</b>	
	<b>September 30, 2016</b>	<b>2015</b>
<b>Cash flows from operating activities:</b>		
Net loss	\$ (16,657,137 )	\$ (16,947,226 )
Non-cash items included in net loss:		
Depreciation and amortization	365,625	329,625
Change in fair value of common stock warrant liability	–	61,246
Change in fair value of earn-out milestone liability	556,382	(41,422 )
Deferred revenue	(375,000 )	(375,000 )
Stock-based compensation costs	1,331,094	1,616,864
Shares issued out of treasury	79,238	73,886
Amortization of deferred finance charges and debt discount associated with notes payable	198,806	349,090
Change in deferred rent liability	(25,981 )	(21,904 )
Loss realized on sale of investment securities	3,858	104
Net changes in:		
Accrued interest on short term investments	22,205	185,411
Advances, deposits and other current assets	(136,871 )	31,604
Accounts payable	195,716	(1,185,710 )
Accrued liabilities	725,660	(1,008,084 )
<b>Net cash (used in) operating activities:</b>	<b>(13,716,405 )</b>	<b>(16,931,516 )</b>
<b>Cash flows from investing activities:</b>		
Purchases of investment securities	(4,515,125 )	(21,078,733 )
Proceeds from sale and maturity of investment securities	10,800,000	28,494,325
Refund of security deposit on letter of credit	–	50,000
Purchases of property and equipment	(48,928 )	(108,191 )
<b>Net cash provided by investing activities</b>	<b>6,235,947</b>	<b>7,357,401</b>
<b>Cash flows from financing activities:</b>		
Proceeds from sale of common stock equity, net of issuance costs	5,428,965	7,163,068

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Principal payments on notes payable	(3,029,429 )	(2,700,959 )
<b>Net cash provided by financing activities</b>	2,399,536	4,462,109
<b>Decrease in cash and cash equivalents</b>	(5,080,922 )	(5,112,006 )
<b>Cash and cash equivalents at beginning of period</b>	9,265,144	12,686,881
<b>Cash and cash equivalents at end of period</b>	\$ 4,184,222	\$ 7,574,875
<b>Supplemental disclosures of cash flow information:</b>		
Interest paid	\$ 409,770	\$ 726,167

See accompanying notes to the financial statements.

**CELSION CORPORATION**

**NOTES TO THE CONDENSED CONSOLIDATED**

**FINANCIAL STATEMENTS (UNAUDITED)**

**FOR THE THREE AND NINE MONTHS ENDED SEPTEMBER 30, 2016 AND 2015**

**Note 1. Business Description**

Celsion Corporation, a Delaware corporation based in Lawrenceville, New Jersey, its wholly-owned subsidiaries CLSN Laboratories, Inc., also a Delaware corporation, and Celsion GmbH, a limited liability company in Zug Switzerland, 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. 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, CLSN Laboratories, Inc. and Celsion GmbH, 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, 2016 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 and Form 10K/A for the fiscal year ended December 31, 2015 filed with the Securities and Exchange Commission (SEC) on March 30, 2016 and April 29, 2016, respectively.

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. Management's Plan**

The Company has incurred an accumulated deficit of \$236 million through September 30, 2016. In addition, the Company has incurred negative cash flow from operations since it started the business. The Company has spent, and expects to continue to spend, substantial amounts in connection with implementing its business strategy, including the planned product development efforts, clinical trials, and research and discovery efforts.

The actual amount of funds the Company will need to operate is subject to many factors, some of which are beyond the Company's control. These factors include the following:

- the progress of research activities;
- the number and scope of research programs;
- the progress of preclinical and clinical development activities;

the progress of the development efforts of parties with whom the Company has entered into research and development agreements;

the costs associated with additional clinical trials of product candidates;

the ability to maintain current research and development licensing arrangements and to establish new research and development and licensing arrangements;

the ability to achieve milestones under licensing arrangements;

the costs involved in prosecuting and enforcing patent claims and other intellectual property rights; and

the costs and timing of regulatory approvals.

The Company has based its estimate on assumptions that may prove to be wrong. The Company may need to obtain additional funds sooner or in greater amounts than it currently anticipates. Potential sources of financing include strategic relationships, public or private sales of the Company's shares or debt and other sources. If the Company raises funds by selling additional shares of common stock or other securities convertible into common stock, the ownership interest of existing stockholders may be diluted.

The Company will be required to obtain additional funding in order to continue the development of its current product candidates within the anticipated time periods, if at all, and to continue to fund operations. As more fully discussed in Note 11, the Company has \$7.5 million available under a controlled equity offering facility it has with Cantor Fitzgerald & Co. Besides this equity facility, the Company does not have any committed sources of financing at this time, and there is substantial uncertainty whether additional funding will be available when needed on terms that will be acceptable to it, or at all. If the Company is not able to obtain financing when needed, there would be substantial doubt as to the Company's ability to continue as a going concern. As a result, the Company may have to significantly limit its operations and its business, financial condition and results of operations would be materially harmed.

#### **Note 4. 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 the financial reporting requirements for revenue from contracts with customers. In August 2015, the FASB issued Accounting Standard Update No. 2015-14 which delayed the effective date of Topic 606. It will be effective for our first quarter of 2018 and early adoption is only permitted for reporting periods beginning after December 15, 2016 including interim reporting periods within that period.

In August 2014, the FASB issued Accounting Standards Update No. 2014-15. This standard provides guidance which defines management's responsibility to evaluate whether there is substantial doubt about an entity's ability to continue as a going concern and to provide related footnote disclosures. This guidance is effective for the annual period ending after December 15, 2016, and for annual periods and interim periods thereafter. Early adoption is permitted. Management is currently evaluating the impact of the adoption of this standard on its condensed consolidated financial statements.

In April 2015, the FASB issued Accounting Standards Update No. 2015-03 Interest – Imputation of Interest (ASU Subtopic 835-30). The new standard requires that debt issuance costs related to a recognized debt liability be presented in the balance sheet as a direct deduction from the carrying amount of that debt liability, consistent with debt discounts. ASU Subtopic 835-30 became effective for the Company beginning January 1, 2016 and was applied retrospectively. This adoption resulted in the reclassification of unamortized deferred financing fees related to the Company's notes payable from other assets totaling \$6,151 and \$26,131 as of September 30, 2016 and December 31, 2015, respectively.

In January 2016, the FASB issued Accounting Standards Update No. 2016-01, Recognition and Measurement of Financial Assets and Financial Liabilities, which requires that most equity investments be measured at fair value, with subsequent changes in fair value recognized in net income (other than those accounted for under equity method of accounting). This guidance is effective for fiscal years, and interim periods within those years, beginning after December 15, 2017. The Company is currently assessing the impact of the adoption of this guidance on its consolidated financial statements and disclosures.

In February 2016, the FASB issued Accounting Standards Update No. 2016-02, Leases (Topic 842), which requires lessees recognize assets and liabilities for leases with lease terms greater than twelve months in the statement of financial position. Leases will be classified as either finance or operating, with classification affecting the pattern of expense recognition in the income statement. This update also requires improved disclosures to help users of financial statements better understand the amount, timing and uncertainty of cash flows arising from leases. The update is effective for fiscal years beginning after December 15, 2018, including interim reporting periods within that reporting period. Early adoption is permitted. The Company is currently evaluating the impact the adoption of this guidance will have on its consolidated financial statements and disclosures.

In March 2016, the FASB issued Accounting Standards Update No 2016-09, Compensation – Stock Compensation (Topic 718). The new standard simplifies several aspects of the accounting for employee share-based payment transactions, including the accounting for income taxes, forfeitures, and statutory tax withholding requirements, as well as classification in the statement of cash flows. The new standard is effective for public companies for annual reporting periods beginning after December 15, 2016, including interim periods within those annual reporting periods; however, early adoption is allowed. The Company is currently evaluating the impact of the pending adoption of the new standard on the Company's consolidated financial statements.

#### **Note 5. 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, 2016, the total number of shares of common stock issuable upon exercise of warrants and equity awards was 18,946,371. The Pre-funded Series B Warrants (as more fully described in Note 11 of these financial statements) convertible into shares of the Company's common stock totaling 1,850,000 are considered issued in calculating basic loss per share. For the three and nine month periods ended September 30, 2016, diluted loss per common share was the same as basic loss per common share as the other 17,096,371 warrants and equity awards that were convertible into shares of the Company's common stock were excluded from the calculation of diluted earnings 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. For the three and nine month periods ended September 30, 2015, diluted loss per common share was the same as basic loss per common share as all options and all 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.

**Note 6. Investment Securities - Available For Sale**

Short term investments available for sale of \$4,515,479 and \$10,799,890 as of September 30, 2016 and December 31, 2015, respectively, consist of certificates of deposit and corporate debt securities. They are valued at estimated fair value, with unrealized gains and losses reported as a separate component of stockholders' equity in Accumulated Other Comprehensive Income.

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, 2016</b>		<b>December 31, 2015</b>	
	<b>Cost</b>	<b>Fair Value</b>	<b>Cost</b>	<b>Fair Value</b>
<b>Short-term investments</b>				
Certificate of deposit	\$4,515,000	\$4,515,479	\$4,800,000	\$4,798,810
Corporate debt securities	—	—	6,003,748	6,001,080
<b>Total</b>	<b>\$4,515,000</b>	<b>\$4,515,479</b>	<b>\$10,803,748</b>	<b>\$10,799,890</b>

	<b>September 30, 2016</b>		<b>December 31, 2015</b>	
	<b>Cost</b>	<b>Fair Value</b>	<b>Cost</b>	<b>Fair Value</b>
<b>Short-term investment maturities</b>				
Within 3 months	\$2,835,000	\$2,835,251	\$10,803,748	\$10,799,890
Between 3-12 months	1,680,000	1,680,228	—	—
<b>Total</b>	<b>\$4,515,000</b>	<b>\$4,515,479</b>	<b>\$10,803,748</b>	<b>\$10,799,890</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:

<b>Description of Securities</b>	<b>Three Months Ended September 30,</b>	
	<b>2016</b>	<b>2015</b>
Interest and dividends accrued and paid	\$8,133	\$29,610
Accretion of investment premium	-	(14,216)
Realized gains	-	106
Investment income, net	\$8,133	\$15,500

<b>Description of Securities</b>	<b>Nine Months Ended September 30,</b>	
	<b>2016</b>	<b>2015</b>
Interest and dividends accrued and paid	\$31,478	\$161,584
Accretion of investment premium	(5,788)	(112,735)
Realized losses	(3,858)	(104)
Investment income, net	\$21,832	\$48,745

The following table shows the Company's investment securities gross unrealized losses and fair value by investment category and length of time that individual securities have been in a continuous unrealized gain or loss position at September 30, 2016. 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, 2016		December 31, 2015	
	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	\$4,515,479	\$ 479	\$240,024	\$ 24
Short-term investments with unrealized losses	—	—	10,559,866	(3,882 )
<b>Total</b>	<b>\$4,515,479</b>	<b>\$ 479</b>	<b>\$10,799,890</b>	<b>\$ (3,858 )</b>

The following table presents the change, by component, in accumulated other comprehensive loss for the first nine months of 2016.

**Accumulated Other Comprehensive Loss**

Balance at January 1, 2016	\$(3,858)
Unrealized gain reclassified to other accumulated income	464
Realized loss reclassified from other accumulated comprehensive loss	3,858
Other comprehensive gain, net	4,322
Balance at September 30, 2016	\$464

**Note 7. Fair Value of Measurements**

FASB Accounting Standards Codification (ASC) Section 820 “*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, 2016 except for the change in the earn-out milestone liability included in earnings (Note 13).

Assets and liabilities measured at fair value are summarized below:

	<b>Total Fair Value on the Balance Sheet</b>	<b>Quoted Prices In Active Markets For Identical Assets</b>	<b>Significant Other Observable Inputs (Level 2)</b>	<b>Significant Unobservable Inputs (Level 3)</b>
<b>Assets:</b>				
Recurring items as of September 30, 2016				
Short-term investments available for sale	\$4,515,479	\$4,515,479	-	-
Recurring items as of December 31, 2015				
Short-term investments available for sale	\$10,799,890	\$10,799,890	-	-
<b>Liabilities:</b>				
Recurring items as of September 30, 2016				
Earn-out milestone liability (Note 13)	\$14,477,794	-	-	\$14,477,794
Recurring items as of December 31, 2015				
Earn-out milestone liability (Note 13)	\$13,921,412	-	-	\$13,921,412

#### **Note 8. Acquisition of EGEN, Inc.**

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 (EGEN Purchase Agreement). We acquired all of EGEN's right, title and interest in and to substantially all of the assets of EGEN, including cash and cash equivalents, patents, trademarks and other intellectual property rights, clinical data, certain contracts, licenses and permits, equipment, furniture, office equipment, furnishings, supplies and other tangible personal property. In addition, we 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, we paid approximately \$3.0 million in cash after expense adjustment and issued 2,712,188 shares of its common stock to EGEN. In addition, 670,070 shares of common stock are currently issuable to EGEN pending satisfactory resolution of any post-closing adjustments of expenses and EGEN's indemnification obligations under the EGEN Purchase Agreement (Holdback Shares).

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 milestones relating to the TheraSilence™ technology acquired from EGEN in 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 was approximately \$27.6 million. Under the acquisition method of accounting, the total purchase price was allocated to EGEN's net tangible and intangible assets and liabilities based on their estimated fair values as of the acquisition date. 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

Acquired In-Process Research and Development (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. 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. As of September 30, 2016, 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.

The purchase price exceeded the estimated fair value of the net assets acquired by approximately \$2.0 million which was recorded as Goodwill. 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 or sooner if we believe indicators of impairment exist. As of September 30, 2016, 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 9. Accrued Liabilities

Other accrued liabilities at September 30, 2016 and December 31, 2015 include the following:

	<b>September 30, 2016</b>	<b>December 31, 2015</b>
Amounts due to contract research organizations and other contractual agreements	\$ 1,287,749	\$ 571,615
Accrued payroll and related benefits	1,061,708	947,078
Accrued professional fees	244,450	319,200
Accrued interest on notes payable	31,782	62,136
Other	19,740	19,740
<b>Total</b>	<b>\$2,645,429</b>	<b>\$1,919,769</b>

**Note 10. Note Payable**

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 through December 17, 2015 and 11.50% since). Payments under the loan agreement were 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 of June 1, 2017.

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. In connection with adoption of ASU Subtopic 835-30 during the first quarter of 2016, unamortized deferred financing fees of \$6,151 and \$26,131 as of September 30, 2016 and December 31, 2015, respectively, have been classified as a direct deduction from the debt liability consistent with the presentation of a debt discount. 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. The common stock issuable pursuant to the Hercules Warrant was filed pursuant to Rule 415 under the Securities Act of 1933 on the Prospectus for Registration Statement No. 333-193936 and was declared effective on September 30, 2014. 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 warrants, 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 warrants and concluded the original amount should be reclassified from deferred financing fees and equity. 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 Company's 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 Company's 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 Company's 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. In 2014, 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 that 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 month periods ended September 30, 2016 and 2015, the Company incurred \$107,805 and \$218,836 in interest expense, respectively, and amortized \$53,220 and \$103,860, respectively as interest expense for deferred fees, debt discount and end of term charges in connection with the Hercules Credit Agreement. For the nine month periods ended September 30, 2016 and 2015, the Company incurred \$409,770 and \$726,167 in interest expense, respectively, and amortized \$198,806 and \$349,090, respectively, 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.

Total notes payable associated with the Hercules Credit Agreement consisted of the following at:

	<b>September 30, 2016</b>	<b>December 31, 2015</b>
Principal amount	\$3,316,341	\$6,345,769
Amortized end of term charges net of amortized debt discounts	282,922	265,859
Unamortized debt issuance costs	(6,151 )	(187,894 )
Total convertible notes payable	\$3,593,112	\$6,423,734

Following is a schedule of future principle payments before debt discount and end of term charges due on the Hercules Credit Agreement:

	<b>During the year ending September 30,</b>
2017	\$3,316,341
2018 and thereafter	–
Total	\$3,316,341

#### **Note 11. Stockholders' Equity**

In September 2015, the Company filed with the SEC a \$75 million shelf registration statement on Form S-3 (File No. 333-206789) that allows the Company to issue any combination of common stock, preferred stock or warrants to purchase common stock or preferred stock (the 2015 Registration Statement). This shelf registration was declared effective on September 25, 2015.

On June 13, 2016, the Company entered into a Securities Purchase Agreement (the June 2016 Purchase Agreement) with an investor, pursuant to which the Company issued and sold, in a registered direct offering (the June 2016 Offering), an aggregate of 2,311,764 shares of common stock, par value \$0.01 per share, of the Company at an offering price of \$1.36 per share. In addition, the Company sold Pre-Funded Series B Warrants (the Pre-Funded Series B Warrants) to purchase 2,100,000 shares of common stock (and the shares of common stock issuable upon exercise of the Pre-Funded Series B Warrants), in lieu of shares of common stock to the extent that the purchase of common stock would cause the beneficial ownership of the Purchaser, together with its affiliates and certain related parties, to exceed 9.99% of our common stock. The Company offered these shares and warrants under the June 2016 Purchase Agreement pursuant to the 2015 Registration Statement. The Company received gross proceeds of approximately \$6.0 million before the deduction of the placement agent fee and offering expenses in the June 2016 Offering. During the third quarter of 2016, 250,000 shares of common stock were issued in connection with the exercise of some of the Pre-Funded Series B Warrants. As of September 30, 2016, 1,850,000 of the Series B Pre-Funded warrants remain outstanding.

In a concurrent private placement (the June 2016 Private Placement), the Company issued to the investor Series A warrants (the June 2016 Series A Warrants), each to purchase 0.5 share of common stock, Series C warrants (the June



2016 Series C Warrants), each to purchase one share of common stock, and Series D warrants (the June 2016 Series D Warrants), each to purchase 0.5 share of common stock (collectively the June 2016 Warrants). The June 2016 Series A Warrants are initially exercisable six months following issuance and terminate five and one-half years following issuance. The June 2016 Series C Warrants are initially exercisable six months following issuance and terminate one year following issuance. The June 2016 Series D Warrants only become exercisable ratably upon the exercise of the June 2016 Series C Warrants, are initially exercisable six months following issuance, and terminate five and one-half years following issuance. The June 2016 Warrants have an exercise price of \$1.40 per share and are exercisable to purchase an aggregate of 8,823,528 shares of common stock. Subject to limited exceptions, a holder of a June 2016 Warrant will not have the right to exercise any portion of its warrants if the holder, together with its affiliates, would beneficially own in excess of 4.99% of the number of shares of common stock outstanding immediately after giving effect to such exercise (the “Beneficial Ownership Limitation”); provided, however, that upon 61 days’ prior notice to the Company, the holder may increase or decrease the Beneficial Ownership Limitation, provided that in no event shall the Beneficial Ownership Limitation exceed 9.99%. The June 2016 Warrants and the shares of our common stock issuable upon the exercise of the June 2016 Warrants are not being registered under the Securities Act of 1933, as amended (the “Securities Act”), are not being offered pursuant to the Registration Statement and are being offered pursuant to the exemption provided in Section 4(a)(2) under the Securities Act and Rule 506(b) promulgated thereunder. On October 31, 2016 we filed a registration statement on Form S-1 to provide for the resale of the shares of common stock issuable upon the exercise of the June 2016 Warrants and will be obligated to use our commercially reasonable efforts to keep such registration statement effective until the earliest of (i) the date on which all of the shares of commons stock issuable upon the exercise of the June 2016 Warrants have been sold under the registration statement or Rule 144 under the Securities Act, (ii) the date on which the shares of common stock issuable upon the exercise of the June 2016 Warrants may be sold without volume or manner-of-sale restrictions pursuant to Rule 144 under the Securities Act and (iii) the termination of the June 2016 Warrants.

Under the June 2016 Purchase Agreement, the Company is prohibited, for a period of six months after the closing, from effecting or entering into an agreement to issue common stock or 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.

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.

Controlled Equity Offering

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 Celsion 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 the Company’s 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. From February 1, 2013 through September 30, 2016, the Company sold and issued an aggregate of 1,479,535 shares of common stock under the ATM Agreement, receiving approximately \$7.4 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. On October 2, 2015, we filed a prospectus supplement to the base prospectus that forms a part of the Shelf Registration Statement, 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 common stock from time to time under the ATM Agreement. The Company currently has approximately \$17.4 million remaining under the ATM Agreement.

**Note 12. 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.

A summary of the Company's stock option and restricted stock awards for the nine months ended September 30, 2016 is as follows:

	<b>Stock Options</b>		<b>Restricted Stock</b>		<b>Weighted</b>
	<b>Options</b>	<b>Weighted</b>	<b>Awards</b>	<b>Non-vested</b>	<b>Average</b>
<b>Equity Awards</b>		<b>Outstanding</b>	<b>Restricted</b>	<b>Average</b>	<b>Contractual</b>
		<b>Average</b>	<b>Terms of</b>		

		<b>Exercise</b>	<b>Stock</b>	<b>Grant</b>	<b>Equity</b>
		<b>Price</b>	<b>Outstanding</b>	<b>Date</b>	<b>Awards</b>
				<b>Fair</b>	<b>(in years)</b>
				<b>Value</b>	
Equity awards outstanding at December 31, 2015	2,139,822	\$ 5.64	81,518	\$ 2.64	
Equity awards granted	841,283	\$ 1.29	110,000	\$ 1.63	
Equity awards exercised	–	–	(126,518)	\$ 1.72	
Equity awards forfeited, cancelled or expired	(48,278 )	\$ 10.68	–	–	
Equity awards outstanding at September 30, 2016	2,932,827	\$ 4.31	65,000	\$ 2.72	7.5
Aggregate intrinsic value of outstanding awards at September 30, 2016	\$–		\$79,300		
Equity awards exercisable at September 30, 2016	2,186,830	\$ 5.10			7.1
Aggregate intrinsic value of awards exercisable at September 30, 2016	\$–				

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:

	Nine Months Ended September 30,					
	2016			2015		
Risk-free interest rate	1.55	-	1.87%	2.06	-	2.93%
Expected volatility	87.4	-	89.1%	92.9	-	93.0%
Expected life (in years)			10.00			10.00
Expected forfeiture rate			10.0%			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 with terms that approximate the expected option lives 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 expiration of each option granted in fiscal 2016 and 2015 was used as the expected life.

Total compensation cost related to employee stock options and restricted stock awards totaled \$432,573 and \$289,683 for the three months ended September 30, 2016 and 2015, respectively. Total compensation cost related to employee stock options and restricted stock awards totaled \$1,331,094 and \$1,616,864 for the nine months ended September 30, 2016 and 2015, respectively. No compensation cost related to stock-based payment arrangements was capitalized as part of the cost of any asset as of September 30, 2016 and 2015.

As of September 30, 2016, there was \$0.5 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 0.9 years. The weighted average grant-date fair value was \$1.16 and \$2.15 per share for the options granted during the nine months ended September 30, 2016 and 2015, respectively. The weighted average grant-date fair value was \$1.63 and \$3.29 for the restricted stock awards granted during the nine months ended September 30, 2016 and 2015, respectively.

Collectively, for all of the Company's stock option plans there were a total of 535,925 equity awards available for future issuance as of September 30, 2016.

### Note 13. 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 2.5 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.

As of September 30, 2016, June 30, 2016, and December 31, 2015, the Company fair valued these milestones at \$14.5 million, \$13.8 million and \$13.9 million, respectively, and recognized a non-cash charge of \$662,410 and \$556,382 during the three and nine month periods ended September 30, 2016, respectively, as a result of the change in the fair value of these milestones from the beginning of each period respectively. As of September 30 2015, June 30, 2015, and December 31, 2014, the Company fair valued these milestones at \$13.6 million, \$13.9 million and \$13.7 million, respectively, 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 these milestones from the beginning of each period respectively.

The following is a summary of the changes in the earn-out milestone liability for 2016:

Balance at January 1, 2016	\$ 13,921,412
Non-cash charge from the adjustment for the change in fair value included in net loss	(556,382 )
Balance at September 30, 2016	\$ 14,477,794

The following is a schedule of the Company's risk-adjustment assessment of each milestone:

<b>Date</b>	<b>Risk-adjustment Assessment of each Milestone</b>	<b>Discount Rate</b>	<b>Estimated Time to Achieve (years)</b>
September 30, 2016	10% to 75%	9 %	0.05 to 1.75
June 30, 2016	10% to 75%	9 %	0.05 to 2.00
December 31, 2015	10% to 75%	9 %	0.05 to 2.50
September 30, 2015	10% to 75%	9 %	0.75 to 2.75
June 30, 2015	10% to 75%	9 %	0.92 to 3.00
December 31, 2014	10% to 75%	9 %	1.25 to 6.50

#### **Note 14. Warrants**

##### *Common Stock Warrants*

Following is a summary of all warrant activity for the nine months ended September 30, 2016:

<b>Warrants</b>	<b>Number of Warrants Issued</b>	<b>Weighted Average Exercise Price</b>
Warrants outstanding at December 31, 2015	5,894,675	\$ 6.37
Warrants issued during the nine months ended September 30, 2016 (see Note 11)	10,923,528	1.13
Warrants exercised during the nine months ended September 30, 2016 (see Note 11)	(250,000 )	0.01
Warrants expired during the nine months ended September 30, 2016	(619,659 )	16.76
Warrants outstanding at September 30, 2016	15,948,544	\$ 2.48
Aggregate intrinsic value of outstanding warrants at September 30, 2016	\$2,236,000	



Weighted average remaining contractual terms at September 30, 2016 (in years) 2.80

- (1) Does not include the Pre-Funded Warrants issued in the June 2016 Offering as these warrants have no expiration date.

#### **Note 15. Contingent Liabilities and Commitments**

In July 2011, the Company executed a lease (the "Lease") with Brandywine Operating Partnership, L.P. (Brandywine), a Delaware limited partnership 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 rent free, with the first monthly rent payment of approximately \$23,000 due and 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 Lease Term has expired. In connection with three \$50,000 reductions of the standby letter of credit in April 2013 and 2014 and 2015, the Company reduced the escrow deposit by \$50,000 each time. This lease has a remaining term of 7 months with rent payments of approximately \$24,900 per month.

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 16 months with rent payments of approximately \$23,200 per month.

## **Note 16. 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.

On August 9, 2016, we signed a long-term Technology Transfer, Manufacturing and Commercial Supply Agreement (the GEN-1 Agreement) with Hisun to pursue an expanded partnership for the technology transfer relating to the clinical and commercial manufacture and supply of GEN-1, Celsion's proprietary gene mediated, IL-12 immunotherapy, for the greater China territory, with the option to expand into other countries in the rest of the world after all necessary regulatory approvals are in effect. The GEN-1 Agreement will help to support supply for both ongoing and planned clinical studies in the United States, and for potential future studies of GEN-1 in China. GEN-1 is currently being evaluated by Celsion in first line ovarian cancer patients.

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

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

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

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

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

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

**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 the Company’s Annual Report on Form 10-K and Form 10K/A for the fiscal year ended December 31, 2015 filed with the Securities and Exchange Commission (SEC) on March 30, 2016 and April 29, 2016, respectively, 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 and Form 10-K/A, 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 stage company focused on advancing a portfolio of innovative cancer treatments, including directed chemotherapies, DNA-mediated immunotherapy and RNA based therapies. Our lead product candidate is ThermoDox®, a proprietary heat-activated liposomal encapsulation of doxorubicin, currently in a Phase III clinical trial for the treatment of primary liver cancer (the OPTIMA Study) and a Phase II clinical trial for the treatment of recurrent chest wall breast cancer (the DIGNITY Study). Second in our pipeline is GEN-1 (formerly known as EGEN-001), a DNA-mediated immunotherapy for the localized treatment of ovarian and brain cancers. We have three platform technologies providing the basis for the future development of a range of therapeutics for difficult-to-treat forms of cancer including: Lysolipid Thermally Sensitive Liposomes, a heat sensitive liposomal based dosage form that targets disease with known therapeutics in the presence of mild heat, TheraPlas™, a novel nucleic acid-based treatment for local transfection of therapeutic plasmids, and TheraSilence™, a systemic dosage form for lung directed anti-cancer RNA. With these technologies we are working to develop and commercialize more efficient, effective and targeted oncology therapies that maximize efficacy while minimizing side-effects common to cancer treatments.

### **ThermoDox®**

ThermoDox® is being evaluated in a Phase III clinical trial for primary liver cancer (the OPTIMA Study) which was initiated in 2014 and a Phase II clinical trial for recurrent chest wall breast cancer (the DIGNITY Study).

ThermoDox® is a liposomal encapsulation of doxorubicin, an approved and frequently used oncology drug for the treatment of a wide range of cancers. Localized heat at hyperthermia temperatures (greater than 40° 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 for the 701 patient clinical trial in patients with hepatocellular carcinoma (HCC), also known as primary liver cancer (the HEAT Study). We determined, after conferring with the HEAT Study's independent Data Monitoring Committee (iDMC), that the HEAT Study did not meet the goal of demonstrating persuasive evidence of clinical effectiveness, that being a clinically meaningful improvement in progression free survival (PFS), 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 followed patients for overall survival (OS), the secondary endpoint of the HEAT Study. We have conducted a comprehensive analysis of the data from the HEAT Study to assess the future strategic value and development strategy for ThermoDox®.

Findings from the HEAT Study post-hoc data analysis suggest that ThermoDox® may substantially improve OS, when compared to the control group, in patients if their lesions undergo a 45 minute RFA procedure standardized for a lesion greater than 3 cm in diameter. Data from nine OS sweeps have been conducted since the top line PFS data from the HEAT Study were announced in January 2013, with each data set showing progressive improvement in statistical significance. On August 15, 2016, the Company announced updated results from its final retrospective OS analysis of the data from the HEAT Study. These results demonstrated that in a large, well bounded, subgroup of patients (n= 285, 41% of the HEAT Study patients), treatment with a combination of ThermoDox® and optimized RFA provided an average 54% risk improvement in OS compared to optimized RFA alone. The Hazard Ratio (HR) at this analysis is 0.65 (95% CI 0.45 - 0.94) with a p-value of 0.02. Median overall survival for the ThermoDox® group has been reached which translates into a two year survival benefit over the optimized RFA group (projected to be greater than 80 months for the ThermoDox® plus optimized RFA group compared to less than 60 months projection for the optimized RFA only group).

Additional findings from this most recent analysis specific to the Chinese patient cohort of 223 patients are summarized below:

In the population of 154 patients with single lesions (70% of the HEAT Study Chinese patient cohort) who received optimized RFA treatment for 45 minutes or more showed a 53% risk improvement in OS (HR = 0.66) when treated with ThermoDox® plus optimized RFA.

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

Findings from the HEAT Study post-hoc data analysis have shown to be well balanced and not diminished in anyway by other factors. Supplementary computational modeling and prospective preclinical animal studies have shown additional support the relationship between heating duration and clinical outcomes. These data have been presented, without objection, at multiple scientific and medical conferences in 2013 through 2016 by key HEAT Study

investigators and leading liver cancer experts. The presentations include:

World Conference on Interventional Oncology in May 2013;

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

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

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

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

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

On September 12, 2016, we announced that the National Institutes of Health (NIH) had conducted an independent retrospective analysis of data from the intent-to-treat population of the Company's HEAT Study, a 701-patient study investigating ThermoDox®. The findings of the NIH study will be presented during an oral session on November 28, 2016 during the 102<sup>nd</sup> Scientific Assembly and Annual Meeting of the Radiological Society of North America (RSNA) to be held on November 26 - December 2, 2016 in Chicago, IL. Celsion is currently studying the use of RFA as a heat source both for tumor ablation and to activate ThermoDox® as a means of treating the area surrounding the tumor, where untreated tumor may be present. The NIH analysis, which sought to evaluate the correlation between RFA burn time per tumor volume (min/ml) and clinical outcome in patients treated with ThermoDox®, concluded that increased burn time per tumor volume substantially improved survival in patients with solitary lesions treated with RFA + ThermoDox® compared to patients treated with RFA alone. These findings are consistent with Celsion's analysis of the HEAT Study data showing that in patients treated with RFA for more than 45 minutes, standardized RFA plus ThermoDox® resulted in a statistically significant improvement in overall survival (OS) compared to standardized RFA alone.



**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 our IND without comment, subject to compliance with regulatory standards, for 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 a 54% improvement in OS 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, Canada, 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 OS, and the secondary endpoints for the trial are PFS and safety. The statistical plan calls for two interim efficacy analyses by an independent DMC.

On December 16, 2015, we announced that we had received the clinical trial application approval from the CFDA to conduct the OPTIMA Study in China. This clinical trial application approval will now allow Celsion to enroll patients at up to 20 additional clinical sites in China. With the addition of these Chinese clinical sites, the Company expects to complete enrollment in the OPTIMA Study during the first half of 2018. On April 26, 2016, we announced that the first patient in China has been enrolled in the OPTIMA Study. Results from the OPTIMA Study, if successful, will provide the basis for a global registration filing and marketing approval.

**The DIGNITY Study.** On December 14, 2015, we announced final data from the Phase I/II study of ThermoDox® in recurrent chest wall (RCW) breast cancer (the DIGNITY Study) at the San Antonio Breast Cancer Symposium. The DIGNITY Study is designed to establish a safe therapeutic dose in Phase I, and in Phase II to demonstrate local control, including complete and partial responses, and stable disease as its primary endpoint. The DIGNITY Study is also planned to evaluate kinetics in ThermoDox® produced from more than one manufacturing site. Of the 28 patients enrolled and treated, 21 patients were eligible for evaluation of efficacy. Approximately 62% of evaluable patients experienced a local response, including six complete responses and seven partial responses.

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

**The Euro-DIGNITY Study.** The Company anticipates that a Phase II study of Radiation Therapy, Hyperthermia and ThermoDox® to treat patients with local-regional recurrent chest wall breast cancer will be initiated by five clinical

sites located in Italy, Israel, Poland and the Czech Republic (the Euro-DIGNITY Study). The Euro-DIGNITY Study will be Phase II study enrolling up to 70 patients affected by recurrent breast adenocarcinoma on the chest wall with/without nodes over a period of two years.

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

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

**Early Access Program for ThermoDox for the Treatment of Patients with RCW Breast Cancer.** 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 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 of the European Union territory, Switzerland, Turkey and Israel.

In consideration for Impatiens' 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 Impatiens, 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.

### ***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. We acquired all of EGEN's right, title and interest in and to substantially all of the assets of EGEN, including cash and cash equivalents, patents, trademarks and other intellectual property rights, clinical data, certain contracts, licenses and permits, equipment, furniture, office equipment, furnishings, supplies and other tangible personal property. In addition, CLSN Laboratories assumed certain specified liabilities of EGEN, including the liabilities arising out of the acquired contracts and other assets relating to periods after the closing date. The consideration of the acquisition includes 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:

- a) \$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;
- b) \$12.0 million will become payable upon achieving certain specified development milestones relating to a glioblastoma multiforme brain cancer study of GEN-1 to be conducted by the Company or its subsidiary; and

- c) Up to \$6.0 million will become payable upon achieving certain specified milestones relating to the TheraSilence™ technology.

Our obligations to make the Earn-Out Payments will terminate on the seventh anniversary of the closing date.

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 was approximately \$27.6 million.

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. The table below summarizes the preliminary estimated fair values of EGEN's net tangible and intangible assets and liabilities on the acquisition date.

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

With the acquisition, we obtained GEN-1, a DNA-based immunotherapy for the localized treatment of ovarian and brain cancers, and three platform technologies for the development of treatments for those suffering with difficult-to-treat forms of cancer, novel nucleic acid-based immunotherapies and other anti-cancer DNA or RNA therapies, including TheraPlas™ and TheraSilence™. Acquired In-Process Research and Development (IPR&D) consists of EGEN's drug technology platforms: GEN-1, 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. As of the closing of the acquisition, the IPR&D is considered indefinite lived intangible assets and will not be amortized. IPR&D will be reviewed for possible impairment on an annual basis or more frequently if there appears to be an indication of impairment. The purchase price exceeds the estimated fair value of the net assets acquired by approximately \$2.0 million which was recorded as goodwill.

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

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

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

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

We have initiated the study at four clinical sites at the University of Alabama at Birmingham, Oklahoma University Medical Center, Washington University in St. Louis and the Medical College of Wisconsin. In February 2016, we announced the completion of enrollment of the first cohort of patients in the OVATION Study. The OVATION Study will continue into 2016 at higher doses of GEN-1 with the goal to identify a safe, tolerable and therapeutically active dose of GEN-1 by recruiting and maximizing an immune response.

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

Of the first six patients dosed, one patient demonstrated a complete response (CR), two patients demonstrated a partial response (PR) and three patients demonstrated stable disease (SD), as measured by RECIST criteria.

Five patients had successful resections of their tumors, with two patients having an R0 resection, which indicates a microscopically margin-negative resection in which no gross or microscopic tumor remains in the tumor bed and three patients with a R1 resection, indicating microscopic residual tumor. One patient in the second cohort is currently ineligible for debulking surgery due to a medical complication unrelated to the study or the study drug.

Of the five surgically treated and evaluable patients, one patient (20%) demonstrated a pathological complete response (pCR), two patients (40%) demonstrated a micro pathological response (microPR), and two patients (40%) demonstrated a macroPR. These data compare favorably to historical data, which indicate that pCRs are typically seen in less than 7% of patients receiving neoadjuvant chemotherapy followed by surgical resection. pCRs have been associated with a median overall survival of 72 months, which is more than three years longer than those who do not experience a pCR. In addition, microPRs are seen in approximately 30% of patients, and are associated with a median overall survival of 38 months.

On September 15, 2016, we announced that the independent Data Safety Monitoring Board (DSMB) completed its safety review of data from the first three patient cohorts in the ongoing Phase Ib OVATION Study. Based on the DSMB's recommendation, the study will continue as planned and the Company will proceed with dosing in its fourth and final patient cohort at an escalated dose.

***GEN-1 Plus Doxil® and Avastin® Trial.*** On April 29, 2015, we announced the expansion of our ovarian cancer development program to include a Phase I dose escalating trial to evaluate GEN-1 in combination with Avastin® and Doxil® in platinum-resistant ovarian cancer patients. We expect to enroll patients beginning in the first half of 2017. This new combination study in platinum-resistant ovarian cancer is supported by three preclinical studies indicating that the combination of GEN-1 with Avastin® may result in significant clinical benefit with a favorable safety profile. Specifically:

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

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

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

### ***Technology Development and Licensing Agreements***

On August 9, 2016, we signed a long-term Technology Transfer, Manufacturing and Commercial Supply Agreement (the GEN-1 Agreement) with Hisun to pursue an expanded partnership for the technology transfer relating to the clinical and commercial manufacture and supply of GEN-1, Celsion's proprietary gene mediated, IL-12 immunotherapy, for the greater China territory, with the option to expand into other countries in the rest of the world after all necessary regulatory approvals are in effect. The GEN-1 Agreement will help to support supply for both ongoing and planned clinical studies in the United States, and for potential future studies of GEN-1 in China. GEN-1 is currently being evaluated by Celsion in first line ovarian cancer patients.

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

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

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

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

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

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

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

## ***Financing Overview***

### **Equity and Debt Financings**

During 2014 and 2015 and thus far in 2016, we issued a total of 9.2 million shares of common stock in the following equity transactions for an aggregate \$29.6 million in gross proceeds.



On June 16, 2016, we entered into a Securities Purchase Agreement with certain institutional investors, pursuant to which the Company sold, in a registered offering, an aggregate of 2,311,764 shares of its common stock and warrants to purchase up to 10,923,528 shares of common stock, for an aggregate purchase price of approximately \$6.0 million.

On May 27, 2015, the Company entered into a Securities Purchase Agreement with certain institutional investors, pursuant to which the Company sold, in a registered direct offering, an aggregate of 3,000,000 shares of common stock, for an aggregate purchase price of approximately \$8.0 million. In a concurrent private placement, the Company issued to the same investors warrants to purchase up to 1,950,000 shares of common stock.

On January 15, 2014, we 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.

We are a party to a Controlled Equity Offering SM Sales Agreement (ATM) dated as of February 1, 2013 with Cantor Fitzgerald & Co., pursuant to which we may sell additional shares of our common stock having an aggregate offering price of up to \$25 million through “at-the-market” equity offerings from time to time. From February 1, 2013 through February 25, 2013, the Company sold and issued an aggregate of 1,195,927 shares of common stock under the ATM, receiving approximately \$6.8 million in net proceeds. The Company did not have any sales under the ATM from February 25, 2013 through September 30, 2015. On October 2, 2015, the Company filed a prospectus supplement whereby it registered \$7.5 million of the remaining availability under the ATM. During the fourth quarter of 2015, the Company sold an aggregate of 283,608 shares for gross proceeds of \$0.6 million.

On June 20, 2014, we completed the acquisition of substantially all of the assets of EGEN, Inc. At the closing, we paid approximately \$3.0 million in cash and issued 2,712,188 shares of its common stock to EGEN. 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

In addition, we entered into a loan agreement on November 25, 2013 with Hercules Technology Growth Capital, Inc. (Hercules), pursuant to which we may borrow a secured term loan of up to \$20 million in multiple tranches (the Hercules Credit Agreement). The loan bears interest at a floating per annum rate equal to the greater of (i) 11.25 percent and (ii) the sum of 11.25 percent plus the prime rate minus 3.25 percent. 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. We drew the first tranche of \$5 million on November 25, 2013 and may request, subject to Hercules’ consent in its sole discretion, an additional \$15 million in up to three advances with each advance in a minimum amount of \$5 million before June 30, 2014 unless extended upon Hercules’ consent. We used approximately \$4 million of the first tranche to repay the outstanding obligations under a loan agreement with Oxford Finance LLC and Horizon Technology Finance Corporation. On June 9, 2014, we borrowed an additional \$5 million and used the loan proceeds to pay the upfront cash payment to EGEN at closing and certain

transaction costs incurred in connection with the acquisition.

We believe that our cash and cash equivalents and short-term investments of \$8.7 million on hand at September 30, 2016, coupled with our access to the ATM, are sufficient to fund operations into the second quarter 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. To complete the development and commercialization of our products, we will need to raise substantial amounts of additional capital to fund our operations. We do not have any committed sources of financing and cannot give assurance 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, preferred stock, convertible debt or other convertible or exercisable securities, which financings could dilute the percentage ownership of our current common stockholders and could significantly lower the market value of our common stock.

Please refer to Item IA, Risk Factors, including, but not limited to, ***“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 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, 2016 AND 2015****Results of Operations**

For the three months ended September 30, 2016, our net loss was \$6.4 million compared to a net loss of \$4.3 million for the same period of 2015. For the nine months ended September 30, 2016, our net loss was \$16.7 million compared to a net loss of \$16.9 million for the same period of 2015. As of September 30, 2016, we had \$8.7 million in cash and short-term investments.

	<b>Three Months Ended September 30,</b>			
	<b>(In thousands)</b>		<b>Change</b>	
	<b>2016</b>	<b>2015</b>	<b>Increase (Decrease)</b>	<b>%</b>
<b>Licensing Revenue:</b>	\$125	\$125	\$-	- %
<b>Operating Expenses:</b>				
Clinical research	3,826	1,888	1,938	102.6 %
Chemistry, manufacturing and controls	399	995	(596 )	(59.9 )%
Research and development	4,225	2,883	1,342	46.5 %
General and administrative	1,496	1,484	12	0.8 %
Total operating expenses	5,721	4,367	1,354	91.2 %
<b>Loss from operations</b>	<b>\$(5,596)</b>	<b>\$(4,242)</b>	<b>\$(1,354)</b>	<b>(31.9 )%</b>

	<b>Nine Months Ended September 30,</b>			
	<b>(In thousands)</b>		<b>Change</b>	
	<b>2016</b>	<b>2015</b>	<b>Increase (Decrease)</b>	<b>%</b>
<b>Licensing Revenue:</b>	\$375	\$375	\$-	- %
<b>Operating Expenses:</b>				
Clinical research	9,827	8,265	1,562	18.9 %

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Chemistry, manufacturing and controls	1,176	2,693	(1,517)	(56.3)%
Research and development	11,003	10,958	45	0.4 %
General and administrative	4,888	5,317	(429 )	(8.1 )%
Total operating expenses	15,891	16,275	(384 )	(2.4 )%
<b>Loss from operations</b>	<b>\$(15,516)</b>	<b>\$(15,900)</b>	<b>\$384</b>	<b>2.4 %</b>

*Comparison of the Three Months ended September 30, 2016 and 2015*

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 third quarters of 2016 and 2015.

Research and Development Expenses

Research and development (R&D) expenses increased by \$1.3 million to \$4.2 million in the third quarter of 2016 from \$2.9 million in the same period of 2015. Costs associated with the OPTIMA Study were \$1.9 million in the third quarter of 2016 compared to \$1.0 million in the same period of 2015. Increased costs in the OPTIMA Study are associated with patient enrollment and treatment costs and investigator site initiation expenses. Study costs associated with the HEAT Study were \$0.2 million in the third quarter of 2016 as the Company performed its final post-hoc survival analysis for this study. These costs were insignificant in the third quarter of 2015. The costs associated with the HEAT Study are expected to be minimal as we will be in the process of closing out the study. Costs associated with our recurrent chest wall breast cancer clinical trial were \$0.1 million in each of the third quarters of 2016 and 2015. Other clinical costs were \$0.8 million in the third quarter of 2016 compared to \$0.4 million in the same period of 2015. The increase of other clinical costs is associated with activities to support the Company's ThermoDox® studies in Europe. Preclinical and regulatory costs were \$0.1 million in the third quarter of 2016. The Company signed an amendment to a Cooperative Research and Development Agreement with the NIH which resulted in a \$0.8 million downward adjustment to previously accrued contract liability costs. Preclinical and regulatory costs were \$0.6 million lower in the third quarter of 2015 compared the same period of 2016 mainly as the result of the one-time adjustment recognized in the prior year. Costs associated with the production of ThermoDox® to support the OPTIMA Study decreased to \$0.4 million in the third quarter of 2016 compared to \$1.0 million the same period of 2015. R&D costs associated with GEN-1 were \$0.7 million in the third quarter of 2016 compared to \$0.9 million the same period of 2015. In 2015, the Company produced sufficient quantities of GEN-1 and related components to fulfil its GEN-1 clinical study requirements into 2017.

General and Administrative Expenses

General and administrative (G&A) expenses remained relatively unchanged at \$1.5 million in the third quarter of 2016 compared to the same period of 2015. We continue to take those steps necessary to reduce our overhead expenses.

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, 2016, the Company fair valued these milestones at \$14.5 million and recognized a non-cash charge of \$0.7 million in the third quarter of 2016 as a result of the change in the fair value of these milestones from \$13.8 million at June 30, 2016. The Company

recognized a non-cash benefit of \$0.3 million in the third quarter of 2015 as a result of the change in the fair value of these milestones at \$13.6 million at September 30, 2015 from \$13.9 million at June 30, 2015.

#### Investment income and interest expense

In connection with its debt facilities the Company incurred \$0.2 million and \$0.3 million in interest expense in the three month periods ended September 30, 2016 and 2015, respectively.

#### *Comparison of the Nine Months ended September 30, 2016 and 2015*

#### 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 2016 and 2015.

#### Research and Development Expenses

R&D expenses remained relatively unchanged at \$11.0 million in each of the first nine months of 2016 and 2015. Costs associated with the OPTIMA Study were \$4.4 million in the first nine months of 2016 compared to \$2.8 million in the same period of 2015. Increased costs in the OPTIMA Study are associated with patient enrollment and treatment costs and investigator site initiation expenses. Study costs associated with the HEAT Study were \$0.2 million in the first nine months of 2016 compared to \$0.3 million in the same period of 2015. Costs are expected to be minimal as we will be in the process of closing out the study. Costs associated with our recurrent chest wall breast cancer clinical trial were \$0.2 million in each of the first nine months of 2016 and 2015. Other clinical costs were \$2.5 million in the first nine months of 2016 compared to \$1.5 million in the same period of 2015. The increase of other clinical costs is associated with costs to support the Company's ThermoDox® studies in Europe. ThermoDox® preclinical and regulatory costs were \$0.3 million in the first nine months of 2016 compared to \$0.2 million in the same period of 2015. As noted above, the Company signed an amendment to a Cooperative Research and Development Agreement with the NIH which resulted in a \$0.8 million downward adjustment to previously accrued contract liability costs in the current year. Costs associated with the production of ThermoDox® to support the OPTIMA Study decreased to \$1.2 million in the first nine months of 2016 compared to \$2.7 million the same period of 2015. R&D costs associated with GEN-1 were \$2.3 million in the first nine months of 2016 compared to \$3.3 million the same period of 2015. In 2015, the Company produced sufficient quantities of GEN-1 and related components to fulfill its GEN-1 clinical study requirements into 2017.



General and Administrative Expenses

General and administrative (G&A) expenses decreased by \$0.4 million to \$4.9 million in the first nine months of 2016 compared to \$5.3 million the same period of 2015. This decrease is attributable to lower personnel costs and profession fees in 2016. We continue to take those steps necessary to reduce our overhead expenses.

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 statements. As of September 30, 2016, the Company fair valued these milestones at \$14.5 million and recognized a non-cash charge of \$0.6 million in the first nine months of 2016 as a result of the change in the fair value of these milestones from \$13.9 million at December 31, 2015. In the first nine months of 2015, the fair value of these milestones of \$13.6 million remained relatively unchanged at September 30, 2015 and December 31, 2014. The Company recognized a non-cash benefit of \$41,422 during the first nine months of 2015.

Investment income and interest expense

In connection with its debt facilities the Company incurred \$0.6 million and \$1.1 million in interest expense in the nine month periods ended September 30, 2016 and 2015, respectively.

**Financial Condition, Liquidity and Capital Resources**

Since inception we have incurred significant losses and negative cash flows from operations. We have financed our operations primarily through the net proceeds from the 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 \$236 million at September 30, 2016.

At September 30, 2016, we had total current assets of \$9.0 million (including cash and cash equivalents and short-term investments of \$8.7 million) and current liabilities of \$9.8 million, resulting in net working capital deficit of \$0.8 million. At December 31, 2015, we had total current assets of \$20.3 million (including cash, cash equivalents and short term investments and related interest receivable on short-term investments of \$20.1 million) and current liabilities of \$9.3 million, resulting in net working capital of \$11.0 million.

Net cash used in operating activities for the first nine months of 2016 was \$13.7 million. Our 2016 net loss for the nine month period ended September 30, 2016 included \$1.3 million in non-cash stock-based compensation expense and \$0.6 million in a non-cash loss based on the change in the earn-out milestone liability.

The \$13.7 million net cash used in operating activities was mostly funded from cash and short term investments. At September 30, 2016, we had cash and short term investments of \$8.7 million.

Net cash provided by financing activities was \$2.4 million during the nine month period ended September 30, 2016 which resulted from net proceeds of \$5.4 million from the sale of our common stock in the second quarter of 2016 partially offset by principal payments of \$3.0 million on the Hercules Credit Agreement.

On June 16, 2016, we entered into a Securities Purchase Agreement with certain institutional investors, pursuant to which the Company sold, in a registered offering, an aggregate of 2,311,764 shares of its common stock and warrants to purchase up to 10,923,528 shares of common stock, for an aggregate purchase price of approximately \$6.0 million.

In February 2013, we entered into a Controlled Equity Offering SM Sales Agreement (ATM) 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 1,479,535 shares under the ATM Agreement so far, receiving approximately \$7.4 million in net proceeds.

We believe that our cash and short-term investment resources of \$8.7 million on hand at September 30, 2016, coupled with the remaining availability of \$17.4 million under the ATM, are sufficient to fund operations into the second quarter 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. As explained in the notes to our financial statements, if the Company is not able to raise additional funds when needed, there would be substantial doubt as to the Company’s ability to continue as a going concern.

## **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, 2016 to our operating leases, which are disclosed in the contractual commitments table in our Annual Report on Form 10-K and on Form 10-K/A for the fiscal year ended December 31, 2015 filed on March 30, 2016 and April 29, 2016, respectively, 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, 2016, 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, 2016 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, 2015 filed on March 30, 2016 with the Securities and Exchange Commission (SEC) and on Form 10-K/A for the fiscal year ended December 31, 2015 filed on April 29, 2016 with the 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 \$236 million at September 30, 2016. For the years ended December 31, 2013, 2014 and 2015 and the nine months ended September 30, 2016, we incurred a net loss of \$8.3 million, \$25.5 million, \$22.5 million and \$16.7 million, respectively. We currently have no product revenue and do not expect to generate any product

revenue for the foreseeable future other than through the sale of our proprietary reagent products for life science research, which products are based on our newly acquired proprietary delivery platform technologies, TheraPlas™ and TheraSilence™. 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 and 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. 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. In addition, we have initiated a Phase I dose-escalation clinical trial of GEN-1 in combination with the standard of care in neo-adjuvant ovarian cancer, known as the OVATION Study, and plan to expand our ovarian cancer development program to include a Phase I dose escalating trial evaluating GEN-1 in combination with Avastin® and Doxil® in platinum-resistant ovarian cancer patients.

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 us 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. The testing and approval process requires substantial time, effort and resources, and generally takes a number of years to complete. The time to complete 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 studies or other testing, delay or withhold approval, and mandate product withdrawals, including recalls. In addition, our drug candidates may have undesirable side effects or other unexpected characteristics that 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, the imposition of marketing limitations, or a product withdrawal would negatively impact our business, results of operations and financial condition.

**We do not expect to generate 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 EGEN, Inc., including

GEN-1, 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 continued 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, we 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 initiated a Phase I dose-escalation clinical trial of GEN-1 in combination with the standard of care in neo-adjuvant ovarian cancer in the second half of 2015 and plan to expand our ovarian cancer development program to include 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, TheraPlas™ and TheraSilence™, are in preclinical stages of development. 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 approved by the FDA or any 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. If we were not able to raise additional capital when needed, there would be substantial doubt as to the our ability to continue as a going concern,**

As of September 30, 2016, we had approximately \$8.7 million in cash and cash equivalents. 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 and technology platforms that we purchased from EGEN, Inc. in June 2014. For example, ThermoDox® is being evaluated in a Phase III clinical trial in combination with RFA 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. We initiated a Phase I dose-escalation clinical trial of GEN-1 in combination with the standard of care in neo-adjuvant ovarian cancer in the second half of 2015 and plan to expand our ovarian cancer development program to include a Phase I dose escalating trial evaluating GEN-1 in combination with Avastin® and Doxil® in platinum-resistant ovarian cancer patients .

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. As explained in the notes to our financial statements, if the Company is not able to raise additional funds when needed, there would be substantial doubt as to the Company's ability to continue as a going concern. 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.

**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 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. 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 been 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 and/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 do not independently conduct clinical trials for our drug candidates. 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 conduct our own clinical trials, we must rely on the efforts of others and have reduced control over aspects of these activities, including, the timing of such trials, the costs associated with such trials and 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.

Despite our reliance on third parties to conduct our clinical trials, we are ultimately responsible for ensuring that each of our clinical trials is conducted in accordance with the general investigational plan and protocols for the trial. Moreover, the FDA requires clinical trials to be conducted in accordance with good clinical practices 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. We also are required to register ongoing clinical trials and post the results of completed clinical trials on a government-sponsored database, [ClinicalTrials.gov](http://ClinicalTrials.gov), within certain timeframes. Failure to do so can result in fines, adverse publicity and civil and criminal sanctions. Our reliance on third parties that we do not control does not relieve us of these responsibilities and requirements. If we or a third party we rely on fails to meet these requirements, we may not be able to obtain, or may be delayed in obtaining, marketing authorizations for our drug candidates and will not be able to, or may be delayed in our efforts to, successfully commercialize our drug candidates. This 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.

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.

**We may seek Orphan Drug Designation for some of our product candidates, and we may be unsuccessful or may be unable to maintain the benefits associated with Orphan Drug Designation, including the potential for market exclusivity.**

As part of our business strategy, we may seek Orphan Drug Designation for our product candidates, and we may be unsuccessful. Regulatory authorities in some jurisdictions, including the United States and Europe, may designate drugs for relatively small patient populations as orphan drugs. Under the Orphan Drug Act, the FDA may designate a drug as an orphan drug if it is a drug intended to treat a rare disease or condition, which is generally defined as a patient population of fewer than 200,000 individuals annually in the United States, or a patient population greater than 200,000 in the United States where there is no reasonable expectation that the cost of developing the drug will be recovered from sales in the United States.

Even if we obtain Orphan Drug Designation for our product candidates in specific indications, we may not be the first to obtain marketing approval of these product candidates for the orphan-designated indication due to the uncertainties associated with developing pharmaceutical products. In addition, exclusive marketing rights in the United States may be limited if we seek approval for an indication broader than the orphan-designated indication or may be lost if the FDA later determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantities of the product to meet the needs of patients with the rare disease or condition. Further, even if we obtain orphan drug exclusivity for a product, that exclusivity may not effectively protect the product from competition because different drugs with different active moieties can be approved for the same condition. Even after an orphan product is approved, the FDA can subsequently approve the same drug with the same active moiety for the same condition if the FDA concludes that the later drug is safer, more effective or makes a major contribution to patient care. Orphan Drug Designation neither shortens the development time or regulatory review time of a drug nor gives the drug any advantage in the regulatory review or approval process. In addition, while we may seek Orphan Drug Designation for our product candidates, we may never receive such designations.

**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. 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. Our testing and clinical practice may not confirm the safety and efficacy of our product candidates or even if further testing and clinical practice produce positive results, the medical community may not view these new forms of treatment as effective and desirable or our efforts to market our new products may fail. Market acceptance depends upon physicians and hospitals obtaining adequate reimbursement rates from third-party payors to make our products commercially viable. Any of these factors could 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 expenses 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, during our operating history, we have assigned many essential responsibilities to a relatively small number of individuals. However, 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 may continue to be volatile and fluctuate significantly, which could result in substantial losses for investors and subject us to securities class action litigation.**

The trading price for our common stock has been, and we expect it to continue to be, volatile. Our January 31, 2013 announcement that the HEAT Study failed to meet its primary endpoint has resulted in significant volatility and a steep decline in the price of our common stock, a level of decline that could result in securities litigation. Plaintiffs' securities litigation firms have publicly announced that they are investigating potential securities fraud claims that they may wish to make against us. The price at which our common stock trades depends upon a number of factors, including our historical and anticipated operating results, our financial situation, announcements of technological innovations or new products by us or our competitors, our ability or inability to raise the additional capital we may need and the terms on which we raise it, and general market and economic conditions. Some of these factors are beyond our control. Broad market fluctuations may lower the market price of our common stock and affect the volume of trading in our stock, regardless of our financial condition, results of operations, business or prospect. The closing price of our common stock as reported on The NASDAQ Capital Market had a high price of \$3.15 and a low price of \$1.65 in the 52-week period ended December 31, 2015 and a high price of \$1.93 and a low price of \$0.89 from January 2, 2016 through November 9, 2016. 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; and

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 9, 2016, we had 26,078,814 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 issuances. Investors purchasing shares or other securities in the future could have rights superior to existing stockholders. As of November 9, 2016, we have a significant number of securities convertible into, or allowing the purchase of, our common stock, including 15,948,544 shares of common stock issuable upon exercise of warrants outstanding, 2,997,827 options to purchase shares of our common stock and restricted stock awards outstanding, and 535,679 shares of common stock reserved for future issuance under our stock incentive plans. Under the Controlled Equity Offering SM Sales Agreement entered into with Cantor Fitzgerald & Co. on February 1, 2013, we may offer and sell, from time to time through “at-the-market” offerings, up to an aggregate of \$25 million of shares of our common stock. We had only sold \$7.6 million under the Sales Agreement as of November 9, 2016.

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

Our common stock is currently listed on The NASDAQ Capital Market. To maintain the listing of our common stock on The NASDAQ Capital Market, we are required to meet certain listing requirements, including, among others, either: (i) a minimum closing bid price of \$1.00 per share, a market value of publicly held shares (excluding shares held by our executive officers, directors and 10% or more stockholders) of at least \$1 million and stockholders’ equity of at least \$2.5 million; or (ii) a minimum closing bid price of \$1.00 per share, a market value of publicly held shares (excluding shares held by our executive officers, directors and 10% or more stockholders) of at least \$1 million and a total market value of listed securities of at least \$35 million. As of November 9, 2016, the closing sale price of our common stock was \$0.92, 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 \$24 million and the total market value of our listed securities was approximately \$24 million. There is no assurance that we will continue to meet the minimum closing price requirement and other listing requirements. As of September 30, 2016, we had stockholders’ equity of \$10.6 million.

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. During 2015, 2014, 2013 and years prior, we performed analyses to determine if there were changes in ownership, as defined by Section 382 of the Internal Revenue Code that would limit our ability to utilize certain net operating loss and tax credit carry forwards. We determined we experienced an ownership change, as defined by Section 382, in connection with certain common stock offerings on July 25, 2011, February 5, 2013, June 3, 2013 and on June 1, 2015. As a result, the utilization of our 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.

**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.

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**Item 6. Exhibits.**

10.1+\*\*\* Amended and Restated Change in Control Agreement dated as of September 6, 2016, by and between the Company and Michael H. Tardugno.

10.2+\*\*\* Amended and Restated Change in Control Agreement dated as of September 6, 2016, by and between the Company and Nicholas Borys, M.D.

10.3+\*\*\* Amended and Restated Change in Control Agreement dated as of September 6, 2016, by and between the Company and Jeffrey W. Church.

10.4+\*\*\* Amended and Restated Change in Control Agreement dated as of September 6, 2016, by and between the Company and Timothy J Tumminello.

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, 2016, 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.

\*\*\* Management contract or compensatory plan or arrangement.

**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 10, 2016 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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