Celsion CORP
Form 10-Q
August 14, 2017

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 June 30, 2017

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	**52-1256615**
(State or other jurisdiction of incorporation or organization)	(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, a smaller reporting company or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer", "smaller reporting company" and "emerging growth 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
Emerging growth company		

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the

Exchange

Indicate by check mark whether the Registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).

Yes No

As of August 11, 2017, the Registrant had 8,351,322 shares of common stock, $0.01 par value per share, outstanding.

CELSION CORPORATION

QUARTERLY REPORT ON

FORM 10-Q

TABLE OF CONTENTS

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® and ThermoDox® 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

	June 30, 2017 (unaudited)	**December 31, 2016**
ASSETS		
Current assets:		
Cash and cash equivalents	$3,629,038	$2,624,162
Investment securities – available for sale, at fair value	-	1,680,000
Accrued interest receivable on investment securities	-	4,008
Advances, deposits and other current assets	109,947	204,408
Subtotal current assets	3,738,985	4,512,578
Property and equipment (at cost, less accumulated depreciation and amortization of $2,740,422 and $2,513,022, respectively)	256,562	462,836
Other assets:		
In-process research and development	22,766,491	22,766,491
Other intangible assets, net	909,266	1,022,924
Goodwill	1,976,101	1,976,101
Security deposit on letter of credit	-	100,000
Patent licensing fees and other assets, net	8,761	8,761
Subtotal other assets	25,660,619	25,874,277
Total assets	$29,656,166	$30,849,691

See accompanying notes to the financial statements.

CELSION CORPORATION

CONDENSED CONSOLIDATED

BALANCE SHEETS

(Continued)

	June 30, 2017 (unaudited)	**December 31, 2016**
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable trade	$3,544,583	$2,878,978
Other accrued liabilities	2,911,891	2,483,756
Notes payable - current portion	-	2,560,553
Deferred revenue – current portion	500,000	500,000
Subtotal current liabilities	6,956,474	8,423,287
Earn-out milestone liability	13,764,205	13,188,226
Deferred revenue – non-current portion	2,250,000	2,500,000
Other liabilities – non-current	36,840	12,352
Total liabilities	23,007,519	24,123,865
Commitments and contingencies	-	-
Stockholders' equity:		
Preferred Stock - $0.01 par value (100,000 shares authorized and no shares issued or outstanding at June 30, 2017 and December 31, 2016, respectively)	-	-
Common stock - $0.01 par value (112,500,000 shares authorized; 5,914,560 and 2,230,452 shares issued at June 30, 2017 and December 31, 2016, respectively, and 5,914,226 and 2,230,118 shares outstanding at June 30, 2017 and December 31, 2016, respectively)	59,149	22,305
Additional paid-in capital	258,104,403	248,168,421
Accumulated deficit	(251,429,717)	(241,379,712)
Subtotal	6,733,835	6,811,014
Treasury stock, at cost (334 shares at June 30, 2017 and December 31, 2016)	(85,188)	(85,188)
	6,648,647	6,725,826

Total stockholders' equity		
Total liabilities and stockholders' equity	$29,656,166	$30,849,691

See accompanying notes to the financial statements.

CELSION CORPORATION

CONDENSED CONSOLIDATED

STATEMENTS OF OPERATIONS

(Unaudited)

	Three Months Ended		Six Months Ended	
	June 30, 2017	**2016**	**June 30, 2017**	**2016**
Licensing revenue	$125,000	$125,000	$250,000	$250,000
Operating expenses:				
Research and development	3,046,631	3,336,372	6,521,907	6,777,543
General and administrative	1,649,110	1,529,305	3,117,232	3,391,830
Total operating expenses	4,695,741	4,865,677	9,639,139	10,169,373
Loss from operations	(4,570,741)	(4,740,677)	(9,389,139)	(9,919,373)
Other (expense) income:				
(Loss) gain from change in valuation of earn-out milestone liability	(292,228)	408,684	(575,979)	106,028
Investment income, net	1,426	4,358	3,417	13,699
Interest expense	(29,416)	(203,353)	(91,756)	(447,551)
Other income (expense)	1,090	5	3,452	(253)
Total other (expense) income, net	(319,128)	209,694	(660,866)	(328,077)
Net loss	(4,889,869)	(4,530,983)	(10,050,005)	(10,247,450)
Deemed dividend related to warrant modification	(345,685)	-	(345,685)	-
Net loss attributable to common shareholders	$(5,235,554)	$(4,530,983)	$(10,395,690)	$(10,247,450)
Net loss per common share				
Basic and diluted	$(0.79)	$(2.63)	$(1.75)	$(6.04)

Weighted average shares outstanding				
Basic and diluted	6,628,778	1,723,147	5,948,570	1,696,590

See accompanying notes to the financial statements.

CELSION CORPORATION

CONDENSED CONSOLIDATED

STATEMENTS OF COMPREHENSIVE LOSS

(Unaudited)

	Three Months Ended		Six Months Ended	
	June 30, 2017	**2016**	**June 30, 2017**	**2016**
Other comprehensive (loss) gain				
Changes in:				
Realized loss on investment securities recognized in investment income, net				$3,858
Unrealized gain on investment securities				
Other comprehensive gain				3,858
Net loss	(4,889,869)	(4,530,983)	(10,050,005)	(10,247,450)
Comprehensive loss	$(4,889,869)	$(4,530,983)	$(10,050,005)	$(10,243,592)

See accompanying notes to the financial statements.

CELSION CORPORATION

CONDENSED CONSOLIDATED

STATEMENTS OF CASH FLOWS

(Unaudited)

	Six Months Ended June 30,	
	2017	**2016**
Cash flows from operating activities:		
Net loss	$(10,050,005)	$(10,247,450)
Non-cash items included in net loss:		
Depreciation and amortization	341,058	243,750
Change in fair value of earn-out milestone liability	575,979	(106,028)
Deferred revenue	(250,000)	(250,000)
Stock-based compensation costs	804,592	898,520
Shares issued out of treasury	-	41,113
Amortization of deferred finance charges and debt discount associated with notes payable	35,370	145,586
Change in deferred rent liability	24,488	(16,716)
Loss realized on sale of investment securities	-	3,858
Net changes in:		
Accrued interest on short term investments	4,008	26,708
Advances, deposits and other current assets	94,461	(311,222)
Accounts payable	665,605	118,925
Accrued liabilities	428,135	458,775
Net cash (used in) operating activities:	(7,326,309)	(8,994,181)
Cash flows from investing activities:		
Proceeds from sale and maturity of investment securities	1,680,000	10,799,890
Purchases of investment securities	-	(2,160,000)
Refund of security for letter of credit	100,000	-
Purchases of property and equipment	(21,126)	(42,758)
Net cash provided by investing activities	1,758,874	8,597,132
Cash flows from financing activities:		
Proceeds from sale of common stock equity, net of issuance costs	4,252,948	5,430,364

Proceeds from exercise of common stock warrants, net of issuance costs	4,915,286	-
Principal payment and end of term charges on note payable	(2,595,923)	(1,990,670)
Net cash provided by financing activities	6,572,311	3,439,694
Increase in cash and cash equivalents	1,004,876	3,042,645
Cash and cash equivalents at beginning of period	2,624,162	9,265,144
Cash and cash equivalents at end of period	$3,629,038	$12,307,789
Supplemental disclosures of cash flow information:		
Interest paid	$56,386	$301,996

See accompanying notes to the financial statements.

CELSION CORPORATION

NOTES TO THE CONDENSED CONSOLIDATED

FINANCIAL STATEMENTS

(UNAUDITED)

FOR THE THREE AND SIX MONTHS ENDED JUNE 30, 2017 AND 2016

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 development stage oncology drug company focused on developing a portfolio of innovative cancer treatments, including directed chemotherapies, DNA-mediated immunotherapy and RNA based therapies. Our lead product candidate is ThermoDox®, a proprietary dosage form of doxorubicin based on a heat-activated liposomal platform technology, currently in a Phase III clinical trial for the treatment of non-resectable hepatocellular carcinoma (“HCC”) also known as primary liver cancer, and a Phase II clinical trial for recurrent chest wall breast cancer. Our pipeline also includes GEN-1, a DNA-based immunotherapy currently in a Phase I clinical trial for the localized treatment of ovarian cancer and pre-clinical development for brain cancer. GEN-1 is based on a platform technology for the development of treatments using novel nucleic acid-based immunotherapies and other anti-cancer DNA or RNA therapies. We are working to develop and commercialize more efficient, effective and targeted oncology therapies based on our technologies, with the goal of developing novel therapeutics that maximize efficacy while minimizing side effects common to many 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 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 six month periods ended June 30, 2017 are not necessarily indicative of the results that may be expected for any other interim period(s) or for any full year. For further information, refer to the financial statements and notes thereto included in the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2016 filed with the Securities and Exchange Commission (SEC) on March 24, 2017.

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.

As more fully described in Note 9, the Company effected a 1-for-14 reverse stock split of its common stock on May 26, 2017 which was made effective for trading purposes as of the commencement of trading on May 30, 2017. All prior period shares of common stock have been adjusted to reflect the 1-for-14 reverse stock split.

Note 3. Financial Condition and Going Concern

Since inception, the Company has incurred substantial operating losses, principally from expenses associated with the Company's research and development programs, clinical trials conducted in connection with the Company's product candidates, and applications and submissions to the Food and Drug Administration (FDA). We have not generated significant revenue and have incurred significant net losses in each year since our inception. We have incurred approximately $251 million of cumulated net losses. As of June 30, 2017, we had approximately $3.6 million in cash and cash equivalents. In July 2017, we completed a $5 million registered direct equity offering of shares of common stock, or pre-funded warrants in lieu thereof, and a concurrent private placement of warrants to purchase common stock with several institutional healthcare investors. We have substantial future capital requirements to continue our research and development activities and advance our product candidates through various development stages. The Company believes these expenditures are essential for the commercialization of its technologies.

The Company expects its operating losses to continue for the foreseeable future as it continues its product development efforts, and when it undertakes marketing and sales activities. The Company's ability to achieve profitability is dependent upon its ability to obtain governmental approvals, produce, and market and sell its new product candidates. There can be no assurance that the Company will be able to commercialize its technology successfully or that profitability will ever be achieved. The Company expects that its operating results will fluctuate significantly in the future and will depend on a number of factors, many of which are outside the Company's control. The Company will need substantial additional funding in order to complete the development, testing and commercialization of its oncology product candidates and we have made a significant commitment to heat-activated liposome research and development projects. It is our intention at least to maintain the pace and scope of these development activities.

The condensed consolidated financial statements have been prepared on the going concern basis. In making this assessment, management conducted a comprehensive review of the Company's business plan including, but not limited to:

- the Company's financial position for the three and six months periods ended June 30, 2017;
- significant events and transaction the Company has entered into since December 31, 2016;
- the Company's capitalization structure including common stock outstanding and common stock issuable on exercise of warrants and equity awards, and other common stock issuable under equity plans; and
- continued support of the Company's stockholders.

As a result of the uncertainties involved in our business, we are unable to estimate the duration and completion costs of our research and development projects or when, if ever, and to what extent we will receive cash inflows from the commercialization and sale of a product. Our inability to complete our research and development projects in a timely manner or our failure to enter into collaborative agreements, when appropriate, could significantly increase our capital requirements and could adversely impact our liquidity. These uncertainties could force us to seek additional, external sources of financing from time to time in order to continue with our business strategy. Our inability to raise additional capital, or to do so on terms reasonably acceptable to us, would jeopardize the future success of our business. Our estimated future capital requirements are uncertain and could change materially as a result of many factors, including the progress of our research, development, clinical, manufacturing, and commercialization activities.

Management has determined the Company has suffered recurring losses from operations and has an accumulated deficit that raises substantial doubt about our ability to continue as a going concern for the next twelve months from our issuance date. The financial statements do not include any adjustments that might result from the outcome of the uncertainty.

A fundamental component of the ability to continue as a going concern is the Company's ability to raise capital as required, as to which no assurances can be provided. To address the additional funding requirements of the Company, management has undertaken the following initiatives:

in February 2017, the Company raised approximately $5.0 million in gross proceeds through a public offering of its common stock and warrants to purchase common stock;

during the first six months of 2017, the Company raised approximately $5.1 million in gross proceeds through the exercise of warrants to purchase common stock;

in July 2017, the Company raised approximately $5.0 million in gross proceeds through a registered direct offering of its common stock and warrants to purchase common stock;

the Company's shareholders approved an increase of its authorized shares sufficient to allow for the funding of its clinical programs at its Annual Meeting of Stockholders on May 16, 2017;

the Company has $7.5 million under a controlled equity offering facility;

it assessed its current expenditures and has reduced the current spending requirements where necessary;

it will pursue additional capital funding in the public and private markets through equity sales and/or debt facilities;

it will pursue possible partnerships and collaborations; and

it will pursue potential out licensing for its drug candidates.

Our ability to continue as a going concern may depend on our ability to raise additional capital, attain further operating efficiencies, reduce expenditures, and, ultimately, to generate revenue. There are no assurances that these future funding and operating efforts will be successful. If management is unsuccessful in these efforts, our current capital is not sufficient to fund our operations for the next twelve months.

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)," which supersedes all existing revenue recognition requirements, including most industry-specific guidance. The new standard requires a company to recognize revenue when it transfers goods or services to customers in an amount that reflects the consideration that the company expects to receive for those goods or services. ASU 2014-09 was originally going to be effective on January 1, 2017; however, the FASB issued ASU 2015-14, "Revenue from Contracts with Customers (Topic 606) — Deferral of the Effective Date," which deferred the effective date of ASU 2014-09 by one year to January 1, 2018. In March 2016, the FASB issued ASU No. 2016-8, "Revenue from Contracts with Customers (Topic 606): Principal versus Agent Considerations. The amendments in this ASU do not change the core principle of ASU No. 2014-09 but the amendments clarify the implementation guidance on reporting revenue gross versus net. The effective date for the amendments in this ASU is the same as the effective date of ASU No. 2014-09. In April 2016, the FASB issued ASU No. 2016-10, "Revenue from Contracts with Customers (Identifying Performance Obligations and Licensing)," to clarify the implementation guidance on identifying performance obligations and licensing. The standard allows for either "full retrospective" adoption, meaning the standard is applied to all of the periods presented, or "modified retrospective" adoption, meaning the standard is applied only to the most current period presented in the financial statements. The Company is currently evaluating the impact of adopting these standards and at this point, nothing has come to the Company's attention that would indicate the adoption of these standards will have a material impact on the Company's consolidated financial statements.

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 the 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 that 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 adopted this standard in January 2017 and made the election to account for award forfeitures as they occur. The adoption of this standard did not have a material impact on the Company's consolidated financial statements.

In August 2016, the FASB issued Accounting Standard Update No. 2016-15, Statement of Cash Flows (Topic 230): Classification of Certain Cash Receipts and Cash Payments. This update clarifies how certain cash receipts and payments should be presented in the statement of cash flows and is effective for interim and annual reporting periods beginning after December 15, 2017, with early adoption permitted. The Company does not believe that this guidance will have an impact on the consolidated financial statements and related disclosures.

In November 2016, the FASB issued Accounting Standard Update No. 2016-18, Statement of Cash Flows (Topic 230): Restricted Cash. This update amends the guidance in ASC 230, including providing additional guidance related to transfers between cash and restricted cash and how entities present, in their statement of cash flows, the cash receipts and cash payments that directly affect the restricted cash accounts. This guidance is effective for annual reporting periods beginning after December 15, 2017, and interim periods within those years, with early adoption permitted. The Company is currently evaluating the impact of adoption on its consolidated financial statements.

In January 2017, the FASB issued Accounting Standard Update No. 2017-01, Business Combinations (Topic 805): Clarifying the Definition of a Business, which clarifies the definition of a business with the objective of adding guidance to assist entities with evaluating whether transactions should be accounted for as acquisitions (or disposals) of assets or businesses. This guidance is effective for annual reporting periods beginning after December 15, 2018, and interim periods within those years, with early adoption permitted. The Company is currently evaluating the impact of adoption on its consolidated financial statements.

In January 2017, the FASB issued Accounting Standard Update No. 2017-04, Intangibles-Goodwill and Other, Simplifying the Test for Goodwill impairment, which eliminates Step 2 from the goodwill impairment test. Under the revised test, an entity should perform its annual, or interim, goodwill impairment test by comparing the fair value of a reporting unit with its carrying amount. An entity should recognize an impairment charge for the amount by which the carrying amount exceeds the reporting unit's fair value; however, the loss recognized should not exceed the total amount of goodwill allocated to that reporting unit. This ASU is effective for any interim or annual impairment tests for fiscal years beginning after December 15, 2019, with early adoption permitted. The Company is currently evaluating the impact of adoption on its consolidated financial statements.

Note 5. Net Loss per Common Share

Basic loss per share is calculated based upon the net loss available to common shareholders divided by the weighted average number of common shares outstanding during the period. Diluted loss 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.

The total number of shares of common stock issuable upon exercise of warrants and equity awards was 1,284,154 shares for the three and six month periods ended June 30, 2017. For the three and six month periods ended June 30, 2017, 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.

For the three and six month periods ended June 30, 2016, the total number of shares of common stock issuable upon exercise of warrants and equity awards was 1,395,290 shares. The Pre-funded Series B Warrants (as more fully described in Note 9 of these financial statements) convertible into shares of the Company’s common stock totaling 150,000 shares was considered issued in calculating basic loss per share. For the three and six month periods ended June 30, 2016, diluted loss per common share was the same as basic loss per common share as the other 1,245,290 warrants and equity awards that were convertible into shares of the Company’s common stock were excluded from the calculation of diluted loss per common share as their effect would have been anti-dilutive.

Note 6. 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 six months ended June 30, 2017 except for the change in the earn-out milestone liability included in earnings (Note 11).

Assets and liabilities measured at fair value are summarized below:

	Total Fair Value on the Balance Sheet	Quoted Prices In Active Markets For Identical Assets/Liabilities (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Assets:				
Recurring items as of December 31, 2016 Investment securities, available for sale	$1,680,000	$ 1,680,000	$	$
Liabilities:				
Recurring items as of June 30, 2017 Earn-out milestone liability (Note 11)	$13,764,205	$	$	$ 13,764,205
Recurring items as of December 31, 2016 Earn-out milestone liability (Note 11)	$13,188,226			$ 13,188,226

Note 7. Accrued Liabilities

Other accrued liabilities at June 30, 2017 and December 31, 2016 include the following:

	June 30, 2017	December 31, 2016
Amounts due to contract research organizations and other contractual agreements	$804,762	$1,115,193
Accrued payroll and related benefits	1,841,208	1,066,751
Accrued professional fees	245,900	259,550

Accrued interest on notes payable	–	22,241
Other	20,021	20,021
Total	$2,911,891	$2,483,756

Note 8. 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 were 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. Also in connection with the Hercules Credit Facility, the Company paid loan origination fees of $230,000. Collectively, these deferred fees have been classified as a direct deduction from the debt liability consistent with the presentation of a debt discount and are 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 6,963 shares of the Company's common stock (the Hercules Warrant) at a per share exercise price of $50.26, 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 6,963 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 Warrants issued using the Black-Scholes option pricing model and recorded a total of $476,261 as a direct deductions from the debt liability consistent with the presentation of a debt discount and are being amortized as interest expense using the effective interest method over the life of the loan. Also in connection with each of the $5.0 million tranches, the Company is 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 were amortized as interest expense using the effective interest method over the life of the loan.

The loan balance and end of term charges on the Hercules Credit Agreement was paid in full in June 2017.

For the three month periods ended June 30, 2017 and 2016, the Company incurred $11,731 and $136,438 in interest expense, respectively, and amortized $17,685 and $66,915, respectively as interest expense for deferred fees, debt discount and end of term charges in connection with the Hercules Credit Agreement. For the six month periods ended June 30, 2017 and 2016, the Company incurred $56,386 and $301,996 in interest expense, respectively, and amortized $35,370 and $145,586, 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.

Note 9. Stockholders' Equity

In September 2015, the Company filed with the Securities and Exchange Commission (the SEC) a $75 million shelf registration statement on Form S-3 (the 2015 Shelf Registration Statement) (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. This shelf registration was declared effective on September 25, 2015.

At the 2016 Annual Meeting of Stockholders of the Company in June 2016, the Company's stockholders of the Company approved an increase in the number of the authorized shares of the Company's common stock from 75,000,000 shares to 112,500,000 shares. The number of the authorized shares of preferred stock remained at 100,000 shares. The aggregate number of shares of all classes of stock that the Company may issue, after giving effect to such amendment as approved by the stockholders, is 112,600,000 shares.

Reverse Stock Split

On May 26, 2017, the Company effected a 14-for-1 reverse stock split of its common stock which was made effective for trading purposes as of the commencement of trading on May 30, 2017. As of that date, each 14 shares of issued and outstanding common stock and equivalents was consolidated into one shares of common stock. In addition, at the market open on May 30, 2017, the Company's common stock started trading under a new CUSIP number 15117N503 although the Company's ticker symbol, CLSN, remained unchanged.

The reverse stock split was previously approved by the Company's stockholders at the 2017 Annual Meeting held on May 16, 2017, and the Company subsequently filed a Certificate of Amendment to its Certificate of Incorporation to effect the stock consolidation. The primary reasons for the reverse stock split and the amendment are:

- To increase the market price of the Company's common stock making it more attractive to a broader range of institutional and other investors, and
- To provide the Company with additional capital resources and flexibility sufficient to execute its business plans including the establishment of strategic relationships with other companies and to ensure its ability to raise additional capital as necessary.

Immediately prior to the reverse stock split, the Company had 56,982,418 shares of common stock outstanding which consolidated into 4,070,172 shares of the Company's common stock. No fractional shares were issued in connection with the reverse stock split. Holders of fractional shares have been paid out in cash for the fractional portion with the Company's overall exposure for such payouts consisting of a nominal amount. The number of outstanding options and warrants were adjusted accordingly, with outstanding options being reduced from approximately 2.4 million to approximately 0.2 million and outstanding warrants being reduced from approximately 33.5 million to approximately 2.4 million.

11

February 14, 2017 Public Offering

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

In connection with the February 14, 2017 Public Offering, the Company filed with the Securities and Exchange Commission a registration statement on Form S-1 (Registration No. 333-215321) on December 23, 2016, as amended by Pre-Effective Amendment No. 1 filed with the Commission on January 20, 2017, as further amended by Pre-Effective Amendment No. 2 filed with the Commission on February 13, 2017, as further amended by Pre-Effective Amendment No. 3 filed with the Commission on February 13, 2017 and as further amended by Pre-Effective Amendment No. 4 filed with the Commission on February 14, 2017 for the registration of the securities issued and sold under the Securities Act of 1933, as amended.

During the first half of 2017, all 185,713 of the Series BB Pre-Funded warrants were exercised in full. During the first half of 2017, we received approximately $2.1 million from the exercise of Series AA Warrants to purchase 636,713 shares of common stock.

December 2016 Common Stock Offering

On December 20, 2016, the Company entered into a securities purchase agreement with certain investors, pursuant to which the Company sold and issued on December 23, 2016, in a registered direct offering, an aggregate of 367,346 shares of the Company's common stock at an offering price of $4.90 per share for gross proceeds of approximately $1.8 million before the deduction of the placement agent fee and offering expenses (the "December 2016 Offering"). In a concurrent private placement (the "Private Placement Transaction"), the Company agreed to issue to the investors certain warrants at an exercise price of $6.44 per share (the December 2016 Warrants). The December 2016 Warrants are exercisable to purchase common stock for an aggregate of 367,343 shares of common stock. The warrants are initially exercisable six months following issuance and terminate five and one-half years following the date of issuance. The December 2016 Warrants may be exercised from time to time beginning on June 20, 2017 and expire on

June 20, 2022. On April 5, 2017, the Company filed a registration statement on Form S-1 for the resale of any share of common stock issued upon exercise of the December 2016 Warrants on Form S-1 (File No. 333-217156) which was declared effective by the SEC on April 19, 2017.

The private placement of the December 2016 Warrants was structured to comply with the requirements of Section 4(a)(2) under the Securities Act and Rule 506(b) promulgated thereunder.

June 2016 Common Stock Offering

On June 13, 2016, the Company entered into a securities purchase agreement with investors, pursuant to which the Company issued and sold, in a registered direct offering, an aggregate of 165,126 shares of common stock, par value $0.01 per share, of the Company at an offering price of $19.04 per share for gross proceeds of approximately $6.0 million before the deduction of the placement agent fee and offering expenses. In a concurrent private placement, the Company issued to the investor Series A warrants (the "June 2016 Series A Warrants"), each to purchase 0.5 share of the Company's common stock, Series C warrants (the "June 2016 Series C Warrants"), each to purchase one share of the Company's common stock, and Series D warrants (the "June 2016 Series D Warrants"), each to purchase 0.5 share of the Company's 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 $19.60 per share and are exercisable to purchase an aggregate of 630,252 shares of Common Stock. On October 31, 2016, the Company filed a registration statement on Form S-1 for the resale of any share of common stock issued upon exercise of the warrants on Form S-1 (File No. 333-212353) which was declared effective by the SEC on November 16, 2016.

The private placement of the June 2016 Warrants was structured to comply with the requirements of Section 4(a)(2) under the Securities Act and Rule 506(b) promulgated thereunder.

Reduced Exercise Price of Warrants

On February 22, 2013, the Company entered into a securities purchase agreement with certain investors pursuant to which the Company agreed, among other things, to issue warrants (the "2013 Warrants") to purchase up to 95,811 shares of our common stock at an exercise price of $74.34 per share to such investors in a registered direct offering. On January 15, 2014, the Company entered into a securities purchase agreement with certain investors pursuant to which the Company agreed, among other things, to issue warrants (the "2014 Warrants") to purchase up to 64,348 shares of our common stock at an exercise price of $57.40 per share to such investors in a registered direct offering. On June 9, 2017, the Company entered into warrant exercise agreements (the "Exercise Agreements") with certain holders of the 2013 Warrants, the 2014 Warrants and the June 2016 Warrants (the "Exercising Holders"), which Exercising Holders own, in the aggregate, warrants exercisable for 790,411 shares of our common stock. Pursuant to the Exercise Agreements, the Exercising Holders and the Company agreed that the Exercising Holders would exercise their 2013 Warrants, the 2014 Warrants and the June 2016 Warrants with respect to 790,411 shares of our common stock underlying such warrants for a reduced exercise price equal to $2.70 per share. The Company received aggregate gross proceeds of approximately $2.1 million from the exercise of the 2013 Warrants, the 2014 Warrants and the June 2016 Warrants by the Exercising Holders.

The reduced exercise price of the 2013 Warrants, the 2014 Warrants and the June 2016 Series C Warrants increased the fair value of the warrants by approximately $0.2 million. This increase in fair value is recorded as a deemed dividend in additional paid in capital due to the retained deficit increased the net loss available to common shareholders on the consolidate statement of operations.

On May 27, 2015 entered into a securities purchase agreement with certain investors pursuant to which the Company agreed, among other things, to issue warrants (the "2015 Warrants") to purchase up to 139,284 shares of the Company's common stock at an exercise price of $36.40 per share, to such investors in a registered direct offering. Between June 22, 2017 through June 26, 2017, the Company and holders of the 2015 Warrants and the December 2016 Warrants (the Exercising Investors) entered into agreements whereby the Company agreed that the Exercising investors would exercise their 2015 Warrants and the June 2016 Warrants with respect to 506,630 shares of our common stock underlying such warrants for a reduced exercise price equal to $1.65 per share. The Company received aggregate gross proceeds of approximately $0.8 million from the exercise of the 2015 Warrants and the June 2016 Warrants by the Exercising Investors.

The reduced exercise price of the 2015 Warrants increased the fair value of the warrants by approximately $0.1 million. This increase in fair value is recorded as a deemed dividend in additional paid in capital due to the retained deficit increased the net loss available to common shareholders on the consolidate statement of operations.

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 June 30, 2017, the Company sold and issued an aggregate of 1,479,535 shares of common stock under the ATM Agreement, receiving approximately $7.6 million in gross 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. In connection with the February common stock offering, the Company agreed to not sell any ATM Shares until June 23, 2017.

On October 2, 2015, we filed a prospectus supplement to the base prospectus that forms a part of the 2015 Shelf Registration Statement, pursuant to which we may offer and sell up to $7.5 million of shares of common stock from time to time under the ATM Agreement of the $17.4 million remaining under the ATM Agreement.

Note 10. 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.

The Celsion Corporation 2007 Stock Incentive Plan (the 2007 Plan), as adopted and amended, permits the granting of 688,531shares of stock as 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.

In 2007, the Company adopted the Celsion Corporation 2007 Stock Incentive Plan (the 2007 Plan) under which 15,873 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, June 20, 2014, and May 16, 2017 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 15,873 to a total of 31,746 shares in 2010, by 35,714 to a total of 67,460 shares in 2012, by 178,571 to a total of 246,031 shares in 2014 and by 442,500 to a total of 688,531 shares in 2017.

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 21,164 shares collectively were reserved for future issuance under both 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 six months ended June 30, 2017 is as follows:

Equity Awards	Stock Options		Restricted Stock Awards		Weighted Average Contractual Terms of Equity Awards (in years)
	Options Outstanding	Weighted Average Exercise Price	Non-vested Restricted Stock Outstanding	Weighted Average Grant Date Fair Value	
Equity awards outstanding at December 31, 2016	210,023	$ 59.77	4,785	$ 37.42	
Equity awards granted	513,464	$ 2.69	–	–	
Equity awards forfeited, cancelled or expired	(42,545)	$ 157.97	(1,428)	$ 26.18	
Equity awards outstanding at June 30, 2017	680,942	$ 10.59	3,357	$ 42.20	9.38
Aggregate intrinsic value of outstanding awards at June 30,2017	$–		$6,882		
Equity awards exercisable at June 30, 2017	405,075	$ 14.97			9.10
Aggregate intrinsic value of awards exercisable at June 30, 2017	$–				

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 during the six month periods of 2017 and 2016 under the Black-Scholes option pricing model:

	Six Months Ended June 30,	
	2017	2016
Risk-free interest rate	2.21 %	1.87 %
Expected volatility	90.4 %	89.1 %
Expected life (in years)	10.00	10.00
Expected forfeiture rate	%	10 %
Expected dividend yield	%	%

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 2017 and 2016 was used as the expected life.

Total compensation cost related to employee stock options and restricted stock awards totaled $676,918 and $283,186 for the three months ended June 30, 2017 and 2016, respectively. Total compensation cost related to employee stock options and restricted stock awards totaled $804,592 and $898,520 for the six months ended June 30, 2017 and 2016, respectively. No compensation cost related to share-based payments arrangements was capitalized as part of the cost of any asset as of June 30, 2017 and 2016.

As of June 30, 2017, there was $0.6 million of total unrecognized compensation cost related to non-vested share-based compensation arrangements. That cost is expected to be recognized over a weighted-average period of 1.4 years. The weighted average grant-date fair value was $2.32 and $15.93 per share for the options granted during the six months ended June 30, 2017 and 2016, respectively. The weighted average grant-date fair value was $18.62 for the restricted stock awards granted during six months ended June 30, 2016.

Collectively, for all of the Company’s stock option plans there were a total of 24,951 equity awards available for future issuance as of June 30, 2017.

Note 11. 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 condensed consolidated financial statements.

As of June 30, 2017, March 31, 2017 and December 31, 2016, the Company fair valued these milestones at $13.8 million, $13.5 million and $13.2 million, respectively, and recognized a non-cash charge of $292,228 and $575,979 during the three and six months ended June 30, 2017 as a result of the change in the fair value of these milestones from the beginning of each period respectively.

As of June 30, 2016, March 31, 2016 and December 31, 2015, the Company fair valued these milestones at $13.8 million, $14.2 million and $13.9 million, respectively, and recognized a non-cash benefit of $408,684 and $106,028 during the three and six month periods ended June 30, 2016, 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 2017:

Balance at January 1, 2017	$13,188,226
Non-cash charge from the adjustment for the change in fair value included in net loss	575,979
Balance at June 30, 2017	$13,764,205

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

Date	Risk-adjustment Assessment of each Milestone			Discount Rate	Estimated Time to Achieve (years)		
June 30, 2017	50%	to	80%	9%	1.50	to	2.00
March 31, 2017	50%	to	80%	9%	1.75	to	2.25
December 31, 2016	50%	to	80%	9%	2.00	to	2.50
June 30, 2016	10%	to	75%	9%	0.50	to	2.00
March 31, 2016	10%	to	75%	9%	0.25	to	2.25
December 31, 2015	10%	to	75%	9%	0.50	to	2.50

Note 12. Warrants

Common Stock Warrants

Following is a summary of all warrant activity for the six months ended June 30, 2017:

Warrants	Number of Warrants Issued	Weighted Average Exercise Price
Warrants outstanding at December 31, 2016	1,487,958	$ 9.39
Warrants issued during the six months ended June 30, 2017 (see Note 9)	1,363,503	2.80
Warrants exercised during the six months ended June 30, 2017 (see Note 9)	(2,251,606)	2.25
Warrants outstanding at June 30, 2017	599,855	$ 21.22
Aggregate intrinsic value of outstanding warrants at June 30, 2017	$	
Weighted average remaining contractual terms at June 30, 2017 (in years)	4.26	

Note 13. 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. In late 2015, Lenox Drive Office Park LLC, purchased the real estate and office building and assumed the lease. This lease was set to expire on April 30, 2017. In April 2017, the Company and the landlord amended the Lease effective May 1, 2017. The Lease amendment extended the term for an additional 64 months, reduced the premises to 7,565 square feet, reduced the monthly rent, provided four months free rent and reduced the escrow deposit to $50,000. The monthly rent will range from approximately $18,900 in the first year to approximately $20,500 in the final year of the amendment. The Company also has a one-time option to cancel the lease as of the 40th month after the commencement date of the Lease

amendment.

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

Note 14. 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 8, 2016, we signed a Technology Transfer, Manufacturing and Commercial Supply Agreement (“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 U.S., 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.

Note 15. Subsequent Events

On July 6, 2017, the Company entered into a securities purchase agreement with several investors, pursuant to which the Company agreed to issue and sell, in a registered direct offering, an aggregate of 2,050,000 shares of common stock of the Company at an offering price of $2.07 per share for gross proceeds of $4,243,500 before the deduction of the placement agent fee and offering expenses. In addition, the Company sold Pre-Funded Series CCC Warrants to purchase 385,000 shares of common stock (and the shares of common stock issuable upon exercise of the Pre-Funded Series CCC Warrants), in lieu of shares of common stock to the extent that the purchase of common stock would cause the beneficial ownership of the Purchaser, together with its affiliates and certain related parties, to exceed 9.99% of our common stock. The Pre-Funded Series CCC Warrants were sold at an offering price of $2.06 per share for gross proceeds of $793,100, are immediately exercisable for $0.01 per share of common stock and do not have an expiration date. In a concurrent private placement, the Company agreed to issue to each investor, for each share of common stock and pre-funded warrant purchased in the offering, a Series AAA Warrant and Series BBB Warrant, each to purchase one share of common stock. The Series AAA Warrants are initially exercisable six months following issuance, and terminate five and one-half years following issuance. The Series AAA Warrants have an exercise price of $2.07 per share and are exercisable to purchase an aggregate of 2,435,000 shares of common stock. The Series BBB Warrants are immediately exercisable following issuance, and terminate twelve months following issuance. The Series BBB Warrants have an exercise price of $4.75 per share and are exercisable to purchase an aggregate of 2,435,000 shares of common stock. Subject to limited exceptions, a holder of a Series AAA and Series BBB Warrant will not have the right to exercise any portion of its warrants if the holder, together with its affiliates, would beneficially own in excess of 9.99% of the number of shares of common stock outstanding immediately after giving effect to such exercise

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 for the fiscal year ended December 31, 2016 filed with the Securities and Exchange Commission (SEC) on March 24, 2017, which factors include, without limitation, plans and objectives of management for future operations or programs or proposed new products or services; changes in the course of research and development activities and in clinical trials; possible changes in cost and timing of development and testing; possible changes in capital structure, financial condition, working capital needs and other financial items; changes in approaches to medical treatment; clinical trial analysis and future plans relating thereto; our ability to realize the full extent of the anticipated benefits of our acquisition of substantially all of the assets of EGEN, Inc., including achieving operational cost savings and synergies in light of any delays we may encounter in the integration process and additional unforeseen expenses; introduction of new products by others; possible licenses or acquisitions of other technologies, assets or businesses; and possible actions by customers, suppliers, partners, competitors and regulatory authorities. These and other risks and uncertainties could cause actual results to differ materially from those indicated by forward-looking statements.

The discussion of risks and uncertainties set forth in this Quarterly Report on Form 10-Q and in our most recent Annual Report on Form 10-K, as well as in other filings with the SEC, is not a complete or exhaustive list of all risks facing the Company at any particular point in time. We operate in a highly competitive, highly regulated and rapidly changing environment and our business is constantly evolving. Therefore, it is likely that new risks will emerge, and that the nature and elements of existing risks will change, over time. It is not possible for management to predict all such risk factors or changes therein, or to assess either the impact of all such risk factors on our business or the extent to which any individual risk factor, combination of factors, or new or altered factors, may cause results to differ materially from those contained in any forward-looking statement. We disclaim any obligation to revise or update any forward-looking statement that may be made from time to time by us or on our behalf.

Strategic and Clinical Overview

Celsion is a fully-integrated development stage oncology drug company focused on advancing a portfolio of innovative cancer treatments, including directed chemotherapies, DNA-mediated immunotherapy and RNA based

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

ThermoDox®

ThermoDox ® is being evaluated in a Phase III clinical trial for primary liver cancer, which we call the OPTIMA Study, which was initiated in 2014 and a Phase II clinical trial for recurrent chest wall breast cancer, 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 OPTIMA Study. The OPTIMA Study represents an evaluation of ThermoDox® in combination with a first line therapy, radio frequency ablation (RFA), for newly diagnosed, intermediate stage HCC patients. HCC incidence globally is approximately 850,000 new cases per year and is the third largest cancer indication globally. Approximately 30% of newly diagnosed patients can be addressed with RFA alone.

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

We initiated the OPTIMA Study in the first half of 2014. The OPTIMA Study was designed with extensive input from globally recognized hepatocellular carcinoma (“HCC”) researchers and expert clinicians and after receiving formal written consultation from the FDA. The OPTIMA Study is expected to enroll up to 550 patients globally at up to 70 sites in the United States, Canada, Europe Union, China and other countries 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 three to seven centimeters, versus standardized RFA alone. The primary endpoint for this clinical trial is overall survival (“OS”), and the secondary endpoints are progression free survival and safety. The statistical plan calls for two interim efficacy analyses by an independent Data Monitoring Committee (DMC).

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

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

The Company hosted an Investigators Meeting with physicians in South East Asia and key opinion leaders on July 22-23, 2017 in Bangkok, Thailand. A second Investigators Meeting is being planned for October 2017 with physicians in China. The Company has initiated approximately 70 clinical sites in 14 countries with plans to activate up to 8 additional clinical trial sites in China or Vietnam by the end of 2017. In addition, the Company announced that patient enrollment in the 550 patient Phase III global study has reached over 60%. Based on current enrollment rates, the Company expects to complete enrollment of the study by mid-2018.

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

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

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

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

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

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

- One unit increase in RFA duration per tumor volume improved overall survival by 20% (p=0.017; n=227);
- More significant differences in subgroup of patients with RFA burn times per tumor volume greater than 2.5 minutes per ml;
- Cox multiple covariate analysis showed overall survival to be significant (p=0.038; Hazard Ratio = 0.85); and
- Burn time per tumor volume did not have a significant effect on overall survival in single lesion patients treated with RFA only.

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

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

The Euro-DIGNITY Study. We anticipate that a Phase II study of RadioTherapy, HyperThermia and ThermoDox® to treat patients with local-regional recurrent chest wall breast cancer will be initiated by five to six clinical sites located in Italy, Israel, Poland and the Czech Republic (the "Euro-DIGNITY Study"). The Euro-DIGNITY Study is expected to commence in the second half of 2017 and should enroll up to 70 patients affected by recurrent breast adenocarcinoma on the chest wall with/without nodes over a period of two years.

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

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

Acquisition of EGEN Assets

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

The total purchase price for the asset acquisition is up to $44.4 million, including potential future earnout payments of up to $30.4 million contingent upon achievement of certain earnout milestones set forth in the Asset Purchase Agreement. At the closing, we paid approximately $3.0 million in cash after the expense adjustment and issued 193,728 shares of our common stock to EGEN. The shares of common stock were issued in a private transaction exempt from registration under the Securities Act, pursuant to Section 4(2) thereof. In addition, the Company held back 47,862 shares of common stock 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). These shares were issued on June 16, 2017.

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

- $12.4 million will become payable upon achieving certain specified development milestones relating to an ovarian cancer study of GEN-1 (formerly known as EGEN-001) to be conducted by us or our subsidiary;
- $12.0 million will become payable upon achieving certain specified development milestones relating to a GEN-1 glioblastoma multiforme brain cancer study to be conducted by us or our subsidiary; and
- up to $6.0 million will become payable upon achieving certain specified milestones relating to the TheraSilence technology acquired from EGEN in the acquisition.

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

GEN-1

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

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

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

Ideal for long-term maintenance therapy

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

- infiltration of cancer fighting T-cell lymphocytes into primary tumor and tumor microenvironment including peritoneal cavity, which is the primary site of metastasis of ovarian cancer;
- changes in local and systemic levels of immuno-stimulatory and immunosuppressive cytokines associated with tumor suppression and growth, respectively; and
- expression profile of a comprehensive panel of immune related genes in pre-treatment and GEN-1-treated tumor tissue.

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

- Of the fourteen patients treated to date in the entire study, two (2) patients demonstrated a complete response, ten (10) patients demonstrated a partial response and two (2) patients demonstrated stable disease, as measured by RECIST criteria. This translates to a 100% disease control rate ("DCR") and an 86% objective response rate ("ORR"). Of the five patients treated in the highest dose cohort, there was a 100% objective response rate with one (1) complete response and four (4) partial responses.
- Fourteen patients had successful resections of their tumors, with nine (9) patients (64%) having an R0 resection, which indicates a microscopically margin-negative resection in which no gross or microscopic tumor remains in the tumor bed. Of the five patients treated at the highest dose cohort, all five patients (100%) experienced a R0 surgical resection.
- One patient demonstrated a pathological complete response (pCR). pCRs are typically seen in less than 7% of patients receiving neoadjuvant chemotherapy followed by surgical resection, and have been associated with a median OS of 72 months, which is more than three years longer than those who do not experience a pCR.
- All patients experienced a clinically significant decrease in their CA-125 protein levels as of their most recent study visit. CA-125 is used to monitor certain cancers during and after treatment. CA-125 is present in greater concentrations in ovarian cancer cells than in other cells.

Celsion also reported supportive translational research data from the first two patient cohorts who have completed treatment in the OVATION Study. Celsion believes that this translational data demonstrates that GEN-1 is potentially producing beneficial cytokines and potentially impacting T-cells in the tumor.

Top Line Translational Data from First Two Cohorts

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

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

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

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

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

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

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

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

Technology Development and Licensing Agreements. Our current efforts and resources are applied on the development and commercialization of cancer drugs including tumor-targeting chemotherapy treatments using focused heat energy in combination with heat-activated drug delivery systems, immunotherapies and RNA-based therapies.

On August 8, 2016, we signed a Technology Transfer, Manufacturing and Commercial Supply Agreement (the “GEN-1 Agreement”) with Zhejiang Hisun Pharmaceutical Co. Ltd. (Hisun) to pursue an expanded partnership for the technology transfer relating to the clinical and commercial manufacture and supply of GEN-1, Celsion’s proprietary

gene mediated, IL-12 immunotherapy, for the greater China territory, with the option to expand into other countries in the rest of the world after all necessary regulatory approvals are obtained. The GEN-1 Agreement will help to support supply for both ongoing and planned clinical studies in the United States, and for potential future studies of GEN-1 in China. GEN-1 is currently being evaluated by Celsion in first line ovarian cancer patients.

In June 2012, Celsion and Hisun signed a long-term commercial supply agreement for the production of ThermoDox®. 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 approved indications.

Business Plan and Going Concern

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 "Part II, Item 1A. Risk Factors" in this Quarterly Report on Form 10-Q.

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

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

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

Reverse Stock Split

On May 26, 2017, the Company effected a reverse stock split of our common stock at an exchange ratio of 14-to-1 (the “Reverse Stock Split”) and set the number of authorized shares of common stock outstanding immediately after the split at 112.5 million shares. As a result of the Reverse Stock Split, every fourteen shares of common stock outstanding immediately prior to the effectiveness of the Reverse Stock Split were combined and converted into one share of common stock immediately thereafter without any change in the per share par value. The Company’s common stock started to trade on the post-split basis at the commencement of trading on May 30, 2017 under a new CUSIP number 15117N503 with the same ticker symbol, CLSN. Unless otherwise expressly stated, the share and per share data in this section and elsewhere in this Quarterly Report on Form 10-Q have been adjusted to reflect the Reverse Stock Split.

Financing Overview

Equity and Debt Financings

During 2016 and thus far in 2017, the Company issued a total of 6.6 million shares of common stock in the following equity transactions for an aggregate $22.1 million in gross proceeds.

On February 14, 2017, the Company entered into a securities purchase agreement whereby it sold, in a public offering (the February 14, 2017 Public Offering), an aggregate of 1,384,705 shares of common stock of the Company at an offering price of $3.22 per share. In addition, the Company sold Series AA Warrants (the Series AA Warrants) to purchase up to 1,177,814 shares of common stock and Pre-Funded Series BB Warrants (the Pre-Funded Series BB Warrants) to purchase up to 185,713 shares of common stock. The Series AA Warrants have an exercise price of $3.22 per share, have a five year life and are immediately exercisable. The Pre-Funded Series BB Warrants were offered at $3.08 per share, are immediately exercisable for $0.14 per share of common stock, do not have an expiration date and were issued in lieu of shares of common stock to the extent that the purchase of common stock would cause the beneficial ownership of the purchaser of such shares, together with its affiliates and certain related parties, to exceed 9.99% of our common stock. The Company received approximately $5.0 million in gross proceeds before the deduction of the placement agent fees and offering expenses (excluding any proceeds from the exercise of the warrants) in the February 14, 2017 Public Offering. During the first quarter of 2017, all 185,713 of the Series BB Pre-Funded warrants were exercised in full.

The Company received gross proceeds of $5.1 million from the exercise of warrants to purchase 2,251,606 shares of common stock during the first half of 2017.

On July 6, 2017, the Company entered into a securities purchase agreement with several investors, pursuant to which the Company agreed to issue and sell, in a registered direct offering, an aggregate of 2,050,000 shares of common stock of the Company at an offering price of $2.07 per share for gross proceeds of $4,243,500 before the deduction of the placement agent fee and offering expenses. In addition, the Company sold Pre-Funded Series CCC Warrants to purchase 385,000 shares of common stock (and the shares of common stock issuable upon exercise of the Pre-Funded Series CCC Warrants), in lieu of shares of common stock to the extent that the purchase of common stock would cause the beneficial ownership of the Purchaser, together with its affiliates and certain related parties, to exceed 9.99% of our common stock. The Pre-Funded Series CCC Warrants were sold at an offering price of $2.06 per share for gross proceeds of $793,100, are immediately exercisable for $0.01 per share of common stock and do not have an expiration date. As of August 11, 2017, the Prefunded Series CCC Warrants were fully exercised. In a concurrent private placement, the Company agreed to issue to each investor, for each share of common stock and pre-funded warrant purchased in the offering, a Series AAA Warrant and Series BBB Warrant, each to purchase one share of common stock. The Series AAA Warrants are initially exercisable six months following issuance, and terminate five and one-half years following issuance. The Series AAA Warrants have an exercise price of $2.07 per share and are exercisable to purchase an aggregate of 2,435,000 shares of common stock. The Series BBB Warrants are immediately exercisable following issuance, and terminate twelve months following issuance. The Series BBB Warrants have an exercise price of $4.75 per share and are exercisable to purchase an aggregate of 2,435,000 shares of common stock. Subject to limited exceptions, a holder of a Series AAA and Series BBB Warrant will not have the

right to exercise any portion of its warrants if the holder, together with its affiliates, would beneficially own in excess of 9.99% of the number of shares of common stock outstanding immediately after giving effect to such exercise.

On December 23, 2016, 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 367,343 shares of common stock at an offering price of $4.90 per share for gross proceeds of approximately $1.8 million. In a concurrent private placement, the Company issued to the same investors warrants to purchase up to 367,343 shares of common stock at an exercise price of $6.22 per share.

On June 13, 2016, the Company entered into a Securities Purchase Agreement with an institutional investor, pursuant to which the Company sold, in a registered direct offering, an aggregate of 165,126 shares of common stock and Pre-funded Series B Warrants to purchase 150,000 shares of common stock for an aggregate purchase price of approximately $6.0 million. In a concurrent private placement, the Company issued to the same investor warrants to purchase up to 630,252 shares of common stock. As of August 11, 2017, the Pre-funded Series B Warrants were fully exercised.

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

As of June 30, 2017, we have $3.6 million in cash and cash equivalents. In July 2017, the Company completed a $5 million registered direct equity offering of shares of common stock, or pre-funded warrants in lieu thereof, and a concurrent private placement of warrants to purchase common stock with several institutional healthcare investors. Given our development plans, we anticipate cash resources, coupled with our access to the ATM, will be sufficient to fund our operations through the end 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.

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 SIX MONTHS ENDED JUNE 30, 2017 AND 2016

Results of Operations

For the three months ended June 30, 2017, our net loss was $4.9 million compared to a net loss of $4.5 million for the same period of 2016. For the six months ended June 30, 2017, our net loss was $10.1 million compared to a net loss of $10.2 million for the same period of 2016. As of June 30, 2017, we had $3.6 million in cash and cash equivalents. In July 2017, the Company completed a $5 million registered direct equity offering of shares of common stock, or pre-funded warrants in lieu thereof, and a concurrent private placement of warrants to purchase common stock with several institutional healthcare investors.

	Three Months Ended June 30,		Change
	(In thousands)		Increase (Decrease)
	2017	2016	%

Licensing Revenue:	$125	$125	$	%
Operating Expenses:				
Clinical Research	2,760	3,192	(432)	(13.5)%
Chemistry, Manufacturing and Controls	287	145	142	97.9 %
Research and development expenses	3,047	3,337	(290)	(8.7)%
General and administrative expenses	1,649	1,529	120	7.8 %
Total operating expenses	4,696	4,866	(170)	(3.5)%
Loss from operations	$(4,571)	$(4,741)	$170	3.6 %

	Six Months Ended June 30,		**Change**	
	(In thousands)		**Increase (Decrease)**	
	2017	**2016**	**$**	**%**
Licensing Revenue:	$250	$250	$	%
Operating Expenses:				
Clinical Research	5,907	6,000	(93)	(1.6)%
Chemistry, Manufacturing and Controls	615	777	(162)	(20.8)%
Research and development expenses	6,522	6,777	(255)	(3.8)%
General and administrative expenses	3,117	3,392	(275)	(8.1)%
Total operating expenses	9,639	10,169	(530)	(5.2)%
Loss from operations	$(9,389)	$(9,919)	$530	5.3 %

Comparison of the Three Months ended June 30, 2017 and 2016

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 second quarters of 2017 and 2016.

Research and Development Expenses

Research and development (R&D) expenses decreased by $0.3 million to $3.0 million in the second quarter of 2017 from $3.3 million in the same period of 2016. Costs associated with the OPTIMA Study costs remained unchanged at $1.5 million in each of the second quarter of 2017 and 2016. Other clinical costs decreased to $0.5 million in the second quarter of 2017 compared to $0.8 million in the same period of 2016. Preclinical and regulatory costs were insignificant in the second quarter of 2017 compared to $0.1 million in the same period of 2016. Costs associated with the production and distribution of ThermoDox® to support the OPTIMA Study increased to $0.3 million in the second quarter of 2017 compared to $0.1 million the same period of 2016. R&D costs associated with GEN-1 decreased to $0.7 million in the second quarter of 2017 compared to $0.8 million the same period of 2016. The Company announced the completion of enrollment of all cohorts of the OVATION Study in July 2017.

General and Administrative Expenses

General and administrative (G&A) expenses increased to $1.6 million in the second quarter of 2017 compared to $1.5 million in the same period of 2017. This increase is attributable to an increase of $0.3 million in non-cash stock compensation expense partially offset by reduced professional fees totaling $0.2 million in the second quarter of 2017 compared to the same period of 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 are fair valued at the end of each quarter and any change in their value will be recognized in the condensed consolidated financial statements. As of June 30, 2017, the Company fair valued these milestones at $13.8 million and recognized a non-cash charge of $0.3 million in the second quarter of 2017 as a result of the change in the fair value of these milestones from $13.5 million at March 31, 2017. The Company recognized a non-cash benefit of $0.4 million in the second quarter of 2016 as a result of the change in the fair value of these milestones at $13.8 million at June 30, 2016 from $14.2 million at March 31, 2016.

Investment income and interest expense

In connection with its debt facilities, the Company incurred $29,416 and $203,353 in interest expense in the three month periods ended June 30, 2017 and 2016, respectively. The loan balance and end of term charges on its debt facilities were paid in full in June 2017.

Deemed dividend

During the three months ended June 30, 2017, we recognized deemed dividends totaling $0.4 million collectively in regard to multiple agreements with certain warrant holders, pursuant to which these warrant holders agreed to exercise, and the Company agreed to reprice, certain warrants. A total of warrants to purchase 790,410 shares of common stock were repriced at $2.70 and warrants to purchase 506,627 shares of common stock were repriced at $1.65 and the Company received $3.0 million in gross proceeds from the sale of these repriced warrants.

Comparison of the Six Months ended June 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 $250,000 in each of the first halves of 2017 and 2016.

Research and Development Expenses

Research and development (R&D) expenses decreased by $0.3 million to $6.5 million in the first half of 2017 from $6.8 million in the same period of 2016. Costs associated with the OPTIMA Study were $3.0 million in the first half of 2017 compared to $2.4 million in the same period of 2016. This is mostly due to the increase in enrollment in during the first half of 2017 compared to the same period of 2016. Other clinical costs were $1.4 million in the first half of 2017 compared to $1.7 million in the same period of 2016, respectively. The decrease of other clinical costs is associated with the reduction of costs to support the Company's ThermoDox® studies in Europe. ThermoDox® preclinical and regulatory R&D costs were relatively unchanged at $0.1 million in each of the first six months of 2017 and 2016. Costs associated with the production of ThermoDox® to support the OPTIMA Study decreased to $0.6 million in the first six months of 2017 compared to $0.8 million the same period of 2016. Costs associated with the research and development of GEN-1 was $0.5 million in the first half of 2017 compared to $0.7 million the same period of 2016. In 2015, the Company produced sufficient quantities of GEN-1 and related components to fulfil its GEN-1clinical study requirements into 2017.

General and Administrative Expenses

General and administrative expenses decreased by $0.3 million to $3.1 million in the first six months of 2017 compared to $3.4 million the same period of 2016. This decrease is attributable to lower personnel related costs and professional fees in 2017. We continue to take those steps necessary to reduce our overall G&A 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 are fair valued at the end of each quarter and any change in their value will be recognized in the condensed consolidated financial statements. As of June 30, 2017, the Company fair valued these milestones at $13.8 million and recognized a non-cash charge of $0.6 million in the first half of 2017 as a result of the change in the fair value of these milestones from $13.2 million at December 31, 2016. The Company recognized a non-cash benefit of $0.1 million in the first half of 2016 as a result of the change in the fair value of these milestones at $13.8 million at June 30, 2016 from $13.9 million at December 31, 2015.

Investment income and interest expense

In connection with its debt facilities the Company incurred $0.1 million and $0.4 million in interest expense in the six month periods ended June 30, 2017and 2016, respectively. The loan balance and end of term charges on its debt facilities were paid in full in June 2017.

Deemed dividend

During the six months ended June 30, 2017, we recognized deemed dividends totaling $0.4 million collectively in regard to multiple agreements with certain warrant holders, pursuant to which these warrant holders agreed to exercise, and the Company agreed to reprice, certain warrants. A total of warrants to purchase 790,410 shares of common stock were repriced at $2.70 and warrants to purchase 506,627 shares of common stock were repriced at $1.65 and the Company received $3.0 million in gross proceeds from the sale of these repriced warrants.

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 $251 million at June 30, 2017.

30

At June 30, 2017, we had total current assets of $3.7 million (including cash and cash equivalents of $3.6 million) and current liabilities of $6.9 million, resulting in net working capital deficit of $3.2 million. At December 31, 2016, we had total current assets of $4.5 million (including cash, cash equivalents and short term investments and related interest receivable on short-term investments of $4.3 million) and current liabilities of $8.4 million, resulting in net working capital deficit of $3.9 million.

Net cash used in operating activities for the first six months of 2017 was $7.3 million. Our 2017 net loss of $10.1 million for the six month period ended June 30, 2017 included $0.8 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 $7.3 million net cash used in operating activities was mostly funded from cash and cash equivalents. At June 30, 2017, we had cash and cash equivalents of $3.6 million. In July 2017, the Company completed a $5 million registered direct equity offering of shares of common stock, or pre-funded warrants in lieu therof, and a concurrent private placement of warrants to purchase common stock with several institutional healthcare investors.

Net cash provided by financing activities was $6.6 million during the six month period ended June 30, 2017 which resulted from net proceeds of $9.2 million from the sale of our common stock and exercise of warrants in the first six months of 2017 partially offset by principal payments and end of term charges of $2.6 million on the Hercules Credit Agreement.

On February 14, 2017, the Company entered into a securities purchase agreement whereby it sold, in a public offering, an aggregate of 1,384,705 shares of common stock, Series AA Warrants to purchase up to 1,177,814 shares of common stock and Pre-Funded Series BB Warrants to purchase up to 185,713 shares of common stock for an aggregate of approximately $5.0 million in gross proceeds. During the first quarter of 2017, all 185,713 of the Series BB Pre-Funded warrants were exercised in full. The Company received gross proceeds of $2.1 million from the exercise of Series AA Warrants to purchase 636,713 shares of common stock during the first six months of 2017.

During June 2017, the Company entered into multiple agreements with certain warrant holders, pursuant to which these warrant holders agreed to exercise, and the Company agreed to reprice, certain warrants. A total of warrants to purchase 790,410 shares of common stock were repriced at $2.70 and warrants to purchase 506,627 shares of common stock were repriced at $1.65 and the Company received $3.0 million in gross proceeds from the sale of these repriced warrants.

On July 6, 2017, the Company entered into a securities purchase agreement with several investors, pursuant to which the Company agreed to issue and sell, in a registered direct offering, an aggregate of 2,050,000 shares of common stock of the Company at an offering price of $2.07 per share for gross proceeds of $4,243,500 before the deduction of

the placement agent fee and offering expenses. In addition, the Company sold Pre-Funded Series CCC Warrants to purchase 385,000 shares of common stock (and the shares of common stock issuable upon exercise of the Pre-Funded Series CCC Warrants), in lieu of shares of common stock to the extent that the purchase of common stock would cause the beneficial ownership of the Purchaser, together with its affiliates and certain related parties, to exceed 9.99% of our common stock. The Pre-Funded Series CCC Warrants were sold at an offering price of $2.06 per share for gross proceeds of $793,100, are immediately exercisable for $0.01 per share of common stock and do not have an expiration date. In a concurrent private placement, the Company agreed to issue to each investor, for each share of common stock and pre-funded warrant purchased in the offering, a Series AAA Warrant and Series BBB Warrant, each to purchase one share of common stock. The Series AAA Warrants are initially exercisable six months following issuance, and terminate five and one-half years following issuance. The Series AAA Warrants have an exercise price of $2.07 per share and are exercisable to purchase an aggregate of 2,435,000 shares of common stock. The Series BBB Warrants are immediately exercisable following issuance, and terminate twelve months following issuance. The Series BBB Warrants have an exercise price of $4.75 per share and are exercisable to purchase an aggregate of 2,435,000 shares of common stock. Subject to limited exceptions, a holder of a Series AAA and Series BBB Warrant will not have the right to exercise any portion of its warrants if the holder, together with its affiliates, would beneficially own in excess of 9.99% of the number of shares of common stock outstanding immediately after giving effect to such exercise

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 105,681 shares under the ATM Agreement so far, receiving approximately $7.4 million in net proceeds.

As of June 30, 2017, we have $3.6 million dollars in cash and cash equivalents. In July 2017, the Company completed a $5 million registered direct equity offering of shares of common stock, or pre-funded warrants in lieu thereof, and a concurrent private placement of warrants to purchase common stock with several institutional healthcare investors. Given our development plans, we anticipate cash resources, coupled with our access to the ATM, will be sufficient to fund our operations into the first quarter of 2018. 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.

Off-Balance Sheet Arrangements and Contractual Obligations

We have no off-balance sheet financing arrangements. In April 2017, the Company and its landlord amended the lease for the corporate offices located in Lawrenceville NJ effective May 1, 2017. The lease amendment extends the term of the lease for an additional 64 months, reduced the premises to 7,565 square feet, reduced the monthly rent, provided four months free rent and reduced the escrow deposit from $100,000 to $50,000. The monthly rent will range from approximately $18,900 in the first year to approximately $20,500 in the final year of the amendment. The Company also has a one-time option to cancel the lease as of the 40th month after the commencement date of the Lease amendment. Other than this lease amendment, there were no material changes during the three months ended

June 30, 2017 to our operating leases, which are disclosed in the contractual commitments table in our Annual Report on Form 10-K for the fiscal year ended December 31, 2016 filed on March 24, 2017 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 condensed consolidated 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 June 30, 2017, 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 six months ended June 30, 2017 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 expected or historical results and our forward-looking statements. We note these factors for investors as permitted by Section 21E of the Securities Exchange Act of 1934, as amended and Section 27A of the Securities Act of 1933, as amended. 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 that may impact our business. 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, 2016 filed on March 24, 2017 with the Securities and Exchange Commission (SEC). In assessing these risks, investors should also refer to the other information contained or incorporated by reference in this Quarterly Report and our other filings made from time to time with the SEC.

RISKS RELATED TO OUR BUSINESS

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

Since our inception, our expenses have substantially exceeded our revenue, resulting in continuing losses and an accumulated deficit of $251 million at June 30, 2017. For the years ended December 31, 2014, 2015 and 2016 and the six months ended June 30, 2017, we incurred a net loss of $25.5 million, $22.5 million, $22.1 million and $10.1

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 meets 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.

We will need to raise 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 are not able to raise additional capital when needed, there would continue to be substantial doubt as to our ability to continue as a going concern.

We have not generated significant revenue and have incurred significant net losses in each year since our inception. Since our inception, our expenses have substantially exceeded our revenue, resulting in continuing losses and an accumulated deficit of $251 million at June 30, 2017. For the years ended December 31, 2014, 2015 and 2016 and the six months ended June 30, 2017, we incurred a net loss of $25.5 million, $22.5 million, $22.1 million and $10.1 million, respectively. As of June 30, 2017, we had approximately $3.6 million in cash and cash equivalents. In July 2017, we completed a $5 million registered direct equity offering of shares of common stock, or pre-funded warrants in lieu thereof, and a concurrent private placement of warrants to purchase common stock with several institutional healthcare investors. We have substantial future capital requirements to continue our research and development activities and advance our product candidates through various development stages. 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.

We continue to seek additional financial resources to fund the further development of our product candidates. 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 continue to 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. Based on the above, our management has determined there is substantial doubt regarding our ability to continue as a going concern. The report of our independent registered accounting firm included in our 2016 Form 10-K dated March 24, 2017, includes an explanatory paragraph which express substantial doubt about our ability to continue as a going concern.

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 may not successfully engage in future strategic transactions, which could adversely affect our ability to develop and commercialize product candidates, impact our cash position, and 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*** , 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 $27.86 and a low price of $4.20 in the 52-week period ended December 31, 2016 and a high price of $7.14 and a low price of $1.30 from January 3, 2017 through August 11, 2017. Among the factors that may cause the market price of our common stock to fluctuate are the risks described in this "Risk Factors" section and other factors, including:

- results of preclinical and clinical studies of our product candidates or those of our competitors;
- regulatory or legal developments in the U.S. and other countries, especially changes in laws and regulations applicable to our product candidates;

actions taken by regulatory agencies with respect to our product candidates, clinical studies, manufacturing process or sales and marketing terms;

introductions and announcements of new products by us or our competitors, and the timing of these introductions or announcements;

announcements by us or our competitors of significant acquisitions or other strategic transactions or capital commitments;

fluctuations in our quarterly operating results or the operating results of our competitors;

variance in our financial performance from the expectations of investors;

changes in the estimation of the future size and growth rate of our markets;

changes in accounting principles or changes in interpretations of existing principles, which could affect our financial results;

failure of our products to achieve or maintain market acceptance or commercial success;

conditions and trends in the markets we serve;

changes in general economic, industry and market conditions;

success of competitive products and services;

changes in market valuations or earnings of our competitors;

changes in our pricing policies or the pricing policies of our competitors;

changes in legislation or regulatory policies, practices or actions;

the commencement or outcome of litigation involving our company, our general industry or both;

recruitment or departure of key personnel;

changes in our capital structure, such as future issuances of securities or the incurrence of additional debt;

actual or anticipated changes in earnings estimates or changes in stock market analyst recommendations regarding our common stock, other comparable companies or our industry generally;

actual or expected sales of our common stock by our stockholders;

acquisitions and financings, including the EGEN acquisition; and

the trading volume of our common stock.

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

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 August 11, 2017, we had 8,351,322 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 August 11, 2017, we have a significant number of securities convertible into, or allowing the purchase of, our common stock, including 5,528,634 shares of common stock issuable upon exercise of warrants outstanding, 684,299 options to purchase shares of our common stock and restricted stock awards outstanding, and 24,951 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 August 11, 2017.

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 August 11, 2017, the closing sale price per share of our common stock was $1.32, 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 $11.0 million and the total market value of our listed securities was approximately $11.0 million. There is no assurance that we will continue to meet the minimum closing price requirement and other listing requirements. As of June 30, 2017, we had stockholders' equity of approximately $6.6 million.

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 2016, 2015, 2014 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 of the Code, in connection with certain common stock offerings in 2011, 2013, and 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.

Item 6. Exhibits.

31.1+	Certification of Chief Executive Officer pursuant to Rule 13a-14(a)/15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2+	Certification of Chief Financial Officer pursuant to Rule 13a-14(a)/15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1*	Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
+	Filed herewith.
101**	The following materials from the Company’s Quarterly Report on Form 10-Q for the quarter ended June 30, 2017, formatted in XBRL (Extensible Business Reporting Language): (i) the unaudited Consolidated Balance Sheets, (ii) the unaudited Consolidated Statements of Operations, (iii) the unaudited Consolidated Statements of Comprehensive Loss, (iv) the unaudited Consolidated Statements of Cash Flows, (v) the unaudited Consolidated Statements of Change in Stockholders' Equity (Deficit), and (vi) Notes to Consolidated Financial Statements.
*	Exhibit 32.1 is being furnished and shall not be deemed to be “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liability of that section, nor shall such exhibit be deemed to be incorporated by reference in any registration statement or other document filed under the Securities Act of 1933, as amended, or the Securities Exchange Act, except as otherwise stated in such filing.
**	XBRL information is filed herewith.

SIGNATURES

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

August 14, 2017 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

Item 6. Exhibits.

31.1+	Certification of Chief Executive Officer pursuant to Rule 13a-14(a)/15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2+	Certification of Chief Financial Officer pursuant to Rule 13a-14(a)/15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1*	Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
+	Filed herewith.
101**	The following materials from the Company’s Quarterly Report on Form 10-Q for the quarter ended June 30, 2017, 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.