Celsion CORP
Form 10-Q
May 11, 2018

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 March 31, 2018

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 Act.

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 May 10, 2018, the Registrant had 17,740,035 shares of common stock, $0.01 par value per share, outstanding.

CELSION CORPORATION

QUARTERLY REPORT ON

FORM 10-Q

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Forward-Looking Statements

This report includes “forward-looking statements” within the meaning of Section 27A of the Securities Act of 1933, as amended and Section 21E of the Securities Exchange Act of 1934, as amended. All statements other than statements of historical fact are “forward-looking statements” for purposes of this Quarterly Report on Form 10-Q, including, without limitation, any projections of earnings, revenue or other financial items, any statements of the plans and objectives of management for future operations (including, but not limited to, pre-clinical development, clinical trials, manufacturing and commercialization), any statements concerning proposed drug candidates potential therapeutic benefits, 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 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

	March 31, 2018 (unaudited)	**December 31, 2017**
ASSETS		
Current assets:		
Cash and cash equivalents	$2,285,314	$11,444,055
Investment securities – available for sale, at fair value	18,411,162	12,724,020
Accrued interest receivable on investment securities	67,192	54,440
Advances, deposits and other current assets	89,186	89,186
Subtotal current assets	20,852,854	24,311,701
Property and equipment (at cost, less accumulated depreciation and amortization of $2,869,058 and $2,838,716 respectively)	175,066	175,771
Other assets:		
In-process research and development	20,246,491	20,246,491
Other intangible assets, net	738,779	795,608
Goodwill	1,976,101	1,976,101
Patent licensing fees and other assets, net	8,761	8,761
Subtotal other assets	22,970,132	23,026,961
Total assets	$43,998,052	$47,514,433

See accompanying notes to the condensed consolidated financial statements.

CELSION CORPORATION

CONDENSED CONSOLIDATED

BALANCE SHEETS

(Continued)

	March 31, 2018 (unaudited)	December 31, 2017
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable trade	$3,416,878	$3,416,863
Other accrued liabilities	1,716,867	2,282,827
Deferred revenue – current portion	500,000	500,000
Subtotal current liabilities	5,633,745	6,199,690
Earn-out milestone liability	12,808,720	12,538,525
Deferred revenue – non-current portion	1,875,000	2,000,000
Other liabilities – non-current portion	70,232	71,710
Total liabilities	20,387,697	20,809,925
Commitments and contingencies	-	-
Stockholders' equity:		
Preferred Stock - $0.01 par value (100,000 shares authorized and no shares issued or outstanding at March 31, 2018 and December 31, 2017)	-	-
Common stock - $0.01 par value (112,500,000 shares authorized; 17,740,369 and 17,277,299 shares issued at March 31, 2018 and December 31, 2017, respectively, and 17,740,035 and 17,276,965 shares outstanding at March 31, 2018 and December 31, 2017, respectively)	177,403	172,772
Additional paid-in capital	289,810,437	288,408,976
Accumulated other comprehensive loss	(33,414)	(10,164)
Accumulated deficit	(266,258,883)	(261,781,888)
Subtotal	23,695,543	26,789,696
Treasury stock, at cost (334 shares at March 31, 2018 and December 31, 2017)	(85,188)	(85,188)
Total stockholders' equity	23,610,355	26,704,508

Total liabilities and stockholders' equity	$43,998,052	$47,514,433

See accompanying notes to the condensed consolidated financial statements.

CELSION CORPORATION

CONDENSED CONSOLIDATED

STATEMENTS OF OPERATIONS

(Unaudited)

	Three Months Ended	
	March 31,	
	2018	**2017**
Licensing revenue	$125,000	$125,000
Operating expenses:		
Research and development	2,741,076	3,475,276
General and administrative	1,665,028	1,468,122
Total operating expenses	4,406,104	4,943,398
Loss from operations	(4,281,104)	(4,818,398)
Other (expense) income:		
Loss from change in valuation of earn-out milestone liability	(270,195)	(283,751)
Investment income	73,724	1,991
Interest expense	-	(62,340)
Other income (expense)	580	2,362
Total other (expense) income, net	(195,891)	(341,738)
Net loss	$(4,476,995)	$(5,160,136)
Net loss per common share		
Basic and diluted	$(0.25)	$(3.09)
Weighted average shares outstanding		
Basic and diluted	17,683,847	1,670,582

See accompanying notes to the condensed consolidated financial statements.

CELSION CORPORATION

CONDENSED CONSOLIDATED

STATEMENTS OF COMPREHENSIVE LOSS

(Unaudited)

	Three Months Ended	
	March 31,	
	2018	**2017**
Other comprehensive loss		
Change in unrealized loss on available for sale securities	$(23,250)	$-
Net loss	(4,476,995)	(5,160,136)
Comprehensive loss	$(4,500,245)	$(5,160,136)

See accompanying notes to the condensed consolidated financial statements.

CELSION CORPORATION

CONDENSED CONSOLIDATED

STATEMENTS OF CASH FLOWS

(Unaudited)

	Three Months Ended	
	March 31,	
	2018	**2017**
Cash flows from operating activities:		
Net loss	$(4,476,995)	$(5,160,136)
Non-cash items included in net loss:		
Depreciation and amortization	87,171	170,529
Change in fair value of earn-out milestone liability	270,195	283,751
Deferred revenue	(125,000)	(125,000)
Stock-based compensation costs	153,668	117,466
Restricted shares issued	15,840	-
Amortization of deferred finance charges and debt discount associated with notes payable	-	17,685
Change in deferred rent liability	(1,478)	(9,264)
Net changes in:		
Accrued interest on investment securities	(12,752)	4,008
Advances, deposits and other current assets	-	62,786
Accounts payable and accrued liabilities	(565,945)	1,508,171
Net cash (used in) operating activities:	(4,655,296)	(3,130,004)
Cash flows from investing activities:		
Purchases of investment securities	(5,710,392)	-
Proceeds from sale and maturity of investment securities	-	1,680,000
Purchases of property and equipment	(29,637)	(21,126)
Net cash (used in) provided by investing activities	(5,740,029)	1,658,874
Cash flows from financing activities:		
Proceeds from sale of common stock equity, net of issuance costs	1,236,584	4,284,373
Proceeds from exercise of common stock warrants	-	138,563
Principal payments on notes payable	-	(1,106,392)
Net cash provided by (used in) financing activities	1,236,584	3,316,544
(Decrease) increase in cash and cash equivalents	(9,158,741)	1,845,414

Cash and cash equivalents at beginning of period	11,444,055	2,624,162
Cash and cash equivalents at end of period	$2,285,314	$4,469,576
Supplemental disclosures of cash flow information:		
Interest paid	$-	$44,655

See accompanying notes to the condensed consolidated financial statements.

CELSION CORPORATION

NOTES TO THE CONDENSED CONSOLIDATED

FINANCIAL STATEMENTS

(UNAUDITED)

FOR THE THREE MONTHS ENDED MARCH 31, 2018 AND 2017

Note 1. Business Description

Celsion Corporation, a Delaware corporation based in Lawrenceville, New Jersey, and its wholly owned subsidiary, CLSN Laboratories, Inc., also a Delaware corporation, referred to herein as “Celsion”, “we”, or “the Company,” as the context requires, is a fully-integrated, development stage oncology drug company focused on developing a portfolio of innovative cancer treatments, including directed chemotherapies, immunotherapies and RNA- or DNA-based therapies. Our lead program is ThermoDox®, a proprietary heat-activated liposomal encapsulation of doxorubicin, currently in Phase III development for the treatment of primary liver cancer. Our product pipeline also includes GEN-1, a DNA-based immunotherapy for the localized treatment of ovarian and brain cancers. Our product pipeline is based on three platform technologies have demonstrated the potential to address a broad range of solid tumor cancer indications including novel nucleic acid-based immunotherapies, anti-cancer DNA or RNA therapies, and heat sensitive liposomal formulations of known chemotherapeutics. With these technologies we are working to develop and commercialize efficient, effective and targeted therapeutics that minimize the side-effects common to cancer treatments.

Note 2. Basis of Presentation

The accompanying unaudited condensed consolidated financial statements, which include the accounts of Celsion Corporation, CLSN Laboratories, Inc. and Celsion GmbH, have been prepared in accordance with generally accepted accounting principles in the United States (GAAP) for interim financial information and with the instructions to Form 10-Q and Article 10 of Regulation S-X. All intercompany balances and transactions have been eliminated. Certain information and 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-month period ended March 31, 2018 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, 2017 filed with the Securities and Exchange Commission (SEC) on March 27, 2018.

The preparation of financial statements in conformity with GAAP requires management to make judgments, estimates, and assumptions that affect the amount reported in the Company's financial statements and accompanying notes. Actual results could differ materially from those estimates. Events and conditions arising subsequent to the most recent balance sheet date have been evaluated for their possible impact on the financial statements and accompanying notes. No events and conditions would give rise to any information that required accounting recognition or disclosure in the financial statements other than those arising in the ordinary course of business.

Note 3. Financial Condition and Business Plan

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. We have not generated significant revenue and have incurred significant net losses in each year since our inception. We have incurred approximately $266 million of cumulated net losses. As of March 31, 2018, we had approximately $20.8 million in cash, investment securities and interest receivable. 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 operating results of the Company have fluctuated significantly in the past. We have substantial future capital requirements associated with our continued research and development activities and to advance our product candidates through various stages of development. The Company believes these expenditures are essential for the commercialization of its technologies.

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

- the progress of research activities;
- the number and scope of research programs;
- the progress of preclinical and clinical development activities;
- the progress of the development efforts of parties with whom the Company has entered into research and development agreements;
- the costs associated with additional clinical trials of product candidates;
- the ability to maintain current research and development licensing arrangements and to establish new research and development and licensing arrangements;
- the ability to achieve milestones under licensing arrangements;
- the costs involved in prosecuting and enforcing patent claims and other intellectual property rights; and
- the costs and timing of regulatory approvals.

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

With the $20.8 million in cash, investment securities and interest receivable at March 31, 2018, the Company believes it has sufficient capital resources to fund its operations into the third quarter of 2019. The Company will be required to obtain additional funding in order to continue the development of its current product candidates within the anticipated

time periods, if at all, and to continue to fund operations. As more fully discussed in Note 11, the Company has $12.2 million available for future sale under a controlled equity offering facility it has with Cantor Fitzgerald & Co. as of March 31, 2018.

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 (ASU) 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 (collectively "the new revenue standards"). The new revenue standards allow for either "full retrospective" adoption, meaning the standard is applied to all periods presented, or "modified retrospective" adoption, meaning the standard is applied only to the most current period presented in the financial statements. The new revenue standard became effective for us on January 1, 2018. Under the new revenue standards, we recognize revenue following a five-step model prescribed under ASU No. 2014-09;(i) identify contract(s) with a customer;(ii) identify the performance obligations in the contract;(iii) determine the transaction price;(iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenues when (or as) we satisfy the performance obligation. As further described in Note 15, the Company currently has only one contract subject to the new revenue standards. After performance of the five-step model discussed above, the Company concluded the adoption of the new revenue standards as of January 1, 2018 did not change our revenue recognition policy nor does it have an effect on our financial statements using either the full retrospective or the modified retrospective adoption methods.

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. Based on the Company's evaluation, the adoption of the ASU 2016-01 does not have a material impact on its consolidated financial statements or its 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 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. Based on the Company's evaluation, the adoption of the ASU 2016-01 did not have a material impact on its consolidated financial statements or its 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. Based on the Company's evaluation, the adoption of the ASU 2016 - 01 did not have a material impact on its consolidated financial statements or its disclosures.

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 adopted this method for its impairment test of goodwill during 2017.

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 respectively upon exercise of warrants, stock option grants and equity awards was 3,655,643 and 2,684,841 shares for the three-month periods ended March 31, 2018 and 2017 respectively. For the three month periods ended March 31, 2018 and 2017, diluted loss per common share was the same as basic loss per common share as all options and all warrants that were exercisable into shares of the Company's common stock were excluded from the calculation of diluted earnings attributable to common shareholders per common share as their effect would have been anti-dilutive.

Note 6. Fair Value of Financial Instruments

Short-term investments available for sale of $18,411,162 and $12,724,020 as of March 31, 2018 and December 31, 2017, respectively, consist of money market funds, commercial paper, corporate debt securities, and government agency debt securities. They are valued at estimated fair value, with unrealized gains and losses reported as a separate component of stockholders' equity in accumulated other comprehensive loss.

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

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

	March 31, 2018		**December 31, 2017**	
	Cost	**Fair Value**	**Cost**	**Fair Value**

Short-term investments				
Certificate of deposit	$1,714,375	$1,713,833	$-	$-
Corporate debt securities	16,730,201	16,697,329	12,734,184	12,724,020
Total	$18,444,576	$18,411,162	$12,734,184	12,724,020

	March 31, 2018		**December 31, 2017**	
	Cost	**Fair Value**	**Cost**	**Fair Value**
Short-term investment maturities				
Within 3 months	$4,996,672	$4,993,850	$-	$-
Between 3-12 months	13,447,904	13,417,312	12,734,184	12,724,020
Total	$18,444,576	$18,411,162	$12,734,184	$12,724,020

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

	Three Months Ended	
	March 31,	
Description of Securities	**2018**	**2017**
Interest and dividends accrued and paid	$69,289	$1,991
Realized gains	4,435	-
Investment income	$73,724	$1,991

The following table shows the Company's investment securities gross unrealized losses and fair value by investment category and length of time that individual securities have been in a continuous unrealized loss position at March 31, 2018 and December 31, 2017. The Company has reviewed individual securities to determine whether a decline in fair value below the amortizable cost basis is other than temporary.

	March 31, 2018		December 31, 2017	
Description of Securities	**Fair Value**	**Unrealized Holding Gains (Losses)**	**Fair Value**	**Unrealized Holding Gains (Losses)**
Available for Sale (all unrealized holding gains and losses are less than 12 months at date of measurement)				
Investments with unrealized gains	$2,239,849	$ 1,463	$748,148	$ 570
Investments with unrealized losses	16,171,313	(35,877)	11,975,872	(10,734)
Total	$18,411,162	$ (34,414)	$12,724,020	$ (10,164)

Note 7. Fair Value 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 or liabilities between Level 1 and Level 2 and no transfers in or out of Level 3 during the three months ended March 31, 2018 or 2017. All changes in Level 3 liabilities were the result of changes in the fair value of the earn-out milestone liability included in earnings (see Note 13).

Assets and liabilities measured at fair value are summarized below:

	Total Fair Value	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 March 31, 2018				
Investment securities, available for sale	$18,411,162	$ 18,411,162		$
Recurring items as of December 31, 2017				
Investment securities, available for sale	$12,724,020	$ 12,724,020		$
Liabilities:				
Recurring items as of March 31, 2018				
Earn-out milestone liability (Note 13)	$12,808,720	$		$ 12,808,720
Recurring items as of December 31, 2017				
Earn-out milestone liability (Note 13)	$12,538,525	$		$ 12,538,525

Note 8. 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, 47,862 shares of common stock were held back by us at the closing and are issuable to EGEN pending satisfactory resolution of any post-closing adjustments for expenses or in relation to EGEN's indemnification obligations under the Asset Purchase Agreement. These shares were issued on June 16, 2017.

After its review in 2016, management concluded that there was no immediate opportunity to out-license TheraSilence. As a result of this analysis, the earnout payments were adjusted prior to 2017 and are now up to $24.4 million that may become payable, in cash, shares of our common stock or a combination thereof, at our option, upon achievement of two 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; and

$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.

The following table summarizes the fair values of these assets acquired and liabilities assumed related to the acquisition.

Property and equipment, net	$35,000
In-process research and development	24,211,000
Other Intangible assets (Covenant not to compete)	1,591,000
Goodwill	1,976,000
Total assets:	27,813,000
Accounts payable and accrued liabilities	(235,000)
Net assets acquired	$27,578,000

Acquired in-process research and development (IPR&D) consists of EGEN's drug technology platforms: TheraPlas and TheraSilence. The fair value of the IPR&D drug technology platforms was estimated to be $24.2 million as of the acquisition date. As of the closing of the acquisition, the IPR&D was considered indefinite lived intangible assets and will not be amortized. IPR&D is reviewed for impairment at least annually as of our third quarter ended September 30, and whenever events or changes in circumstances indicate that the carrying value of the assets might not be recoverable.

At September 30, 2017, after the Company’s annual assessment of the totality of the events that could impair IPR&D, the Company determined certain IPR&D assets related to the development of its glioblastoma multiforme cancer (GBM) product candidate may be impaired. To arrive at this determination, the Company assessed the status of studies in GBM conducted by its competitors and the Company’s strategic commitment of resources to its studies in primary liver cancer and ovarian cancer. The Company estimated the fair value of the IPR&D related to GBM at September 30, 2017 using the multi-period excess earnings method (MPEEM). The Company concluded that the GBM asset, valued at $9.4 million, was partially impaired and wrote down the GBM asset to $6.9 million incurring a non-cash charge of $2.5 million in the third quarter of 2017.

At December 31, 2016, the Company determined one of the IPR&D assets related to the development of its RNA delivery system being developed with collaborators using their RNA product candidates may be impaired and after an assessment, the Company concluded that this asset, valued at $1.4 million, was impaired. Therefore, the Company wrote off the value of this IPR&D asset incurring a non-cash charge of $1.4 million in the fourth quarter of 2016.

As no indicators of impairment existed during the first quarter of 2018, the Company concluded none of the other IPR&D assets were impaired at March 31, 2018.

Pursuant to the EGEN Purchase Agreement, EGEN provided certain covenants (“Covenant Not To Compete”) to the Company whereby EGEN agreed, during the period ending on the seventh anniversary of the closing date of the

acquisition on June 20, 2014, not to enter into any business, directly or indirectly, which competes with the business of the Company nor will it contact, solicit or approach any of the employees of the Company for purposes of offering employment. The Covenant Not To Compete which was valued at approximately $1.6 million at the date of the EGEN acquisition has a definitive life and is amortized on a straight-line basis over its life of 7 years. The Company recognized amortization expense of $56,829 in each of the three months ended March 31, 2018 and 2017. The fair value of the Covenant Not to Compete was $738,779 net of $852,435 accumulated amortization as of March 31, 2018 and $795,608 net of $795,606 accumulated amortization as of December 31, 2017

The purchase price exceeded the estimated fair value of the net assets acquired by approximately $2.0 million which was recorded as Goodwill. Goodwill represents the difference between the total purchase price for the net assets purchased from EGEN and the aggregate fair values of tangible and intangible assets acquired, less liabilities assumed. Goodwill is reviewed for impairment at least annually as of our third quarter ended September 30 or sooner if we believe indicators of impairment exist. As of September 30, 2017, we concluded that the Company’s fair value exceeded its carrying value therefore “it is not more likely than not” that the Goodwill was impaired.

Note 9. Accrued Liabilities

Other accrued liabilities at March 31, 2018 and December 31, 2017 include the following:

	Year Ended December 31,	
	2018	**2017**
Amounts due to contract research organizations and other contractual agreements	$837,955	$665,373
Accrued payroll and related benefits	550,143	1,258,265
Accrued professional fees	308,748	264,668
Other	20,021	94,521
Total	$1,716,867	$2,282,827

Note 10. Note Payable

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

The obligations under the Hercules Credit Agreement are in the form of secured indebtedness bearing interest at a calculated prime-based variable rate (11.25% per annum since inception through December 17, 2015, 11.50% from December 18, 2015 through December 15, 2016 and 11.75% since). Payments under the loan agreement were interest only for the first twelve months after loan closing, followed by a 30 -month amortization period of principal and interest through the scheduled maturity date of June 1, 2017. In connection with the Hercules Credit Agreement, the Company incurred cash expenses of $122,378 which were recorded as deferred financing fees. These deferred financing fees were amortized as interest expense using the effective interest method over the life of the loan. In addition, the Company paid loan origination fees of $230,000 which has been classified as debt discount. This amount is being amortized as interest expense using the effective interest method over the life of the loan.

As a fee associated 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 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. Also, in connection with each of the $5.0 million tranches, the Company was 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. For the three-month period ended March 31, 2017 the Company incurred $44,655 in interest expense and amortized $17,685 as interest expense for deferred fees, debt discount and end of term charges in connection with the Hercules Credit Agreement.

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

Note 11. 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 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 remains 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, will be 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 share of common stock. All shares have been restated to reflect the effects of the 14-for-1 reverse stock split. 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.

October 2017 *Underwritten Offering*

On October 27, 2017, the Company entered into an underwriting agreement (the "Underwriting Agreement") with Oppenheimer & Co. Inc. (the "Underwriter"), relating to the issuance and sale (the "Offering") of 2,640,000 shares (the "Shares") of the Company's common stock, $0.01 par value per share (the "Common Stock"), and warrants to purchase an aggregate of 1,320,000 shares of Common Stock. Each share of Common Stock is being sold together with 0.5 warrants (the "Investor Warrants"), each whole Investor Warrant being exercisable for one share of Common Stock, at an offering price of $2.50 per share and related Investor Warrants.

Pursuant to the terms of the Underwriting Agreement, the Underwriter agreed to purchase the Shares and related Investor Warrants from the Company at a price of $2.325 per share and related Investor Warrants. Each Investor Warrant is exercisable six months from the date of issuance. The Investor Warrants have an exercise price of $3.00 per whole share, and expire five years from the date first exercisable.

The Company received $6.6 million of gross proceeds from the sale of the Shares and Investor Warrant. This Offering was made pursuant to the Company's effective shelf registration statement on Form S-3 (File No. 333-206789) filed with the Securities and Exchange Commission on September 4, 2015, and declared effective on September 25, 2015, including the base prospectus dated September 25, 2017 included therein and the related prospectus supplement. The Company also issued to the Underwriter warrants to purchase up to 66,000 shares of the Company's common stock, such issuance being exempt from registration pursuant to Section 4(a)(2) of the Securities Act. Each Underwriter warrant is exercisable six months from the date of issuance, have an exercise price of $2.87 per whole share, and expire five years from the date first exercisable.

July 6, 2017 *Common Stock Offering*

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. During the fourth quarter of 2017, all 385,000 of the Series CCC Pre-Funded warrants were exercised in full.

On October 4, 2017, the Company entered into letter agreements (the “Exercise Agreements”) with the holders of the Series AAA and Series BBB Warrants issued in the July 6, 2017 Common Stock Offering (the “Exercising Holders”). The Exercise Agreements amended the Series AAA Warrants to permit their immediate exercise. Prior to the execution of the Exercise Agreements, the Series AAA Warrants were not exercisable until January 11, 2018. Pursuant to the Exercise Agreements, the Exercising Holders and the Company agreed that the Exercising Holders would exercise all of their Existing Warrants with respect to 4,665,000 shares of Common Stock underlying such Existing Warrants. The Series AAA Warrants and Series BBB Warrants were exercised at a price of $2.07 per share and $4.75 per share, respectively, which were their respective original exercise prices. The Company received approximately $16.6 million in gross proceeds from the sale of these warrants.

The Exercise Agreements also provide for the issuance of 1,166,250 Series DDD Warrants, each to purchase one share of Common Stock (the “Series DDD Warrants”). The Series DDD Warrants have an exercise price $6.20, are exercisable one year following issuance and terminate six months after they are initially exercisable. The Series DDD Warrants and the shares of Common Stock issuable upon the exercise of the Series DDD Warrants were offered pursuant to the exemption provided in Section 4(a)(2) under the Securities Act or Rule 506(b) promulgated thereunder. Pursuant to the Exercise Agreements, the Series DDD Warrants shall be substantially in the form of the Existing Warrants and the Company will be required to register for resale the shares of Common Stock underlying the Series DDD Warrants.

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, were 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.

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.

As of December 31, 2017, all 185,713 of the Series BB Pre-Funded warrants were exercised in full. During 2017, we received approximately $2.4 million from the exercise of Series AA Warrants to purchase 747,254 shares of common stock.

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 790,410 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 790,410 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 and it 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 506,627 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 and it increased the net loss available to common shareholders on the consolidate statement of operations.

Common Stock Warrants

As of March 31, 2018, and December 31, 2017, the Company had outstanding warrants to purchase 3,058,402 shares of common stock with a weighted average exercise price of $5.29. These warrants had weighted average remaining contractual terms of 3.3 years as of March 31, 2018.

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 our common stock or to or through a market maker. From February 1, 2013 through March 31, 2018, the Company sold and issued an aggregate of 1,784,396 shares of common stock under the ATM Agreement, receiving approximately $12.8 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.

On October 2, 2015 and again on February 6, 2018, we filed prospectus supplements to the base prospectus that forms a part of the 2015 Shelf Registration Statement, pursuant to which we may offer and sell up to $17.5 million of shares collectively of common stock from time to time under the ATM Agreement. In January 2018 and thus far in 2018, we have sold 457,070 shares of common stock for net proceeds of $1.3 million under the ATM. As of the date of this filing, we have approximately $12.2 million remaining under the ATM.

Note 12. Stock-Based Compensation

The Company has long-term compensation plans that permit the granting of equity based-awards in the form of stock options, restricted stock, restricted stock units, stock appreciation rights, phantom stock, and performance awards. 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 688,531 shares 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. 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 expired, were forfeited, or canceled under these plans were rolled into the 2007 Plan.

The Company has issued stock awards to employees, directors and vendors out of the stock option plans. Options are generally granted with strike prices equal to the market value on the date of the grant.

Incentive stock options may be granted to purchase shares of common stock at a price not less than 100% of the fair market value of the underlying shares on the date of grant, provided that the exercise price of any incentive stock option granted to an eligible employee owning more than 10% of the outstanding stock must be at least 110% of the such fair market value on the date of grant. Only officers and key employees may receive incentive stock options; all other qualified participants may receive non-qualified stock options.

Option awards vest upon terms determined by the Board of Directors. Restricted stock awards, performance stock awards and stock options are subject to accelerated vesting in the event of a change of control. The Company issues new shares to satisfy its obligations from the exercise of options.

As of March 31, 2018, there were a total of 705,893 shares reserved, which were comprised of 597,241 equity awards granted and 102,652 equity awards available for future issuance.

Total compensation cost charged related to employee stock options and restricted stock awards amounted to $169,508 and $117,466 for the three-month periods ended March 31, 2018 and 2017, respectively. As of March 31, 2018, there was $0.4 million of total unrecognized compensation cost related to non-vested stock-based compensation arrangements. That cost is expected to be recognized over a weighted-average period of 0.9 years. The weighted average grant-date fair values of the stock option awards granted during three-month periods ended March 31, 2018 was $2.27. No stock option awards or restricted stock grants were granted during the three-month period ended March 31, 2017.

A summary of stock option awards and restricted stock grants for the three months ended March 31, 2018 is presented below:

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 January 1, 2018	703,442	$ 10.34	–	$ –	
Equity awards granted	7,500	$ 2.52	6,000	$ 2.64	
Vested and issued	–	$ –	(6,000)	$ 2.64	
Equity awards forfeited, cancelled or expired	(113,701)	$ 40.23	–	$ –	
Equity awards outstanding at March 31, 2018	597,241	$ 4.48	–	$ –	9.1
Aggregate intrinsic value of outstanding awards at March 31, 2018	$2,750		$–		
Equity awards exercisable at March 31, 2018	320,877	$ 5.79			9.0
Aggregate intrinsic value of awards exercisable at March 31, 2018	$–				

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

	Three months ended March 31, 2018	
Risk-free interest rate	2.82	%
Expected volatility	99.9	%
Expected life (in years)	10	
Expected dividend yield	0.0	%

Expected volatilities utilized in the model are based on historical volatility of the Company's stock price. The risk-free interest rate is derived from values assigned to U.S. Treasury bonds with terms that approximate the expected option lives in effect at the time of grant. Starting in 2017, the Company elected to account for any forfeitures when they occur. The expiration of each option granted in fiscal year 2018 was used as the expected life.

Note 13. Earn-out Milestone Liability

The total aggregate purchase price for the EGEN Acquisition included potential future Earn-out Payments contingent upon achievement of certain milestones. The difference between the aggregate $30.4 million in future Earn-out Payments and the $13.9 million included in the fair value of the acquisition consideration at June 20, 2014 was based on the Company's risk-adjusted assessment of each milestone (10% to 67%) and utilizing a discount rate based on the estimated time to achieve the milestone (1.5 to 2.5 years). The earn-out milestone liability will be fair valued at the end of each quarter and any change in their value will be recognized in the financial statements.

As of March 31, 2018, and December 31, 2017, the Company fair valued these milestones at $12.8 million and $12.5 million, respectively, and recognized a non-cash charge of $270,195 during the three months ended March 31, 2018 as a result of the change in the fair value of these milestones from December 31, 2015. As of March 31, 2017, and December 31, 2016, the Company fair valued these milestones at $13.5 million and $13.2 million, respectively, and recognized a non-cash charge of $283,751 during the three months ended March 31, 2017 as a result of the change in the fair value of these milestones from December 31, 2016.

The following is a summary of the changes in the earn-out milestone liability for 2018:

Balance at January 1, 2018	$12,538,525
Non-cash charge from the adjustment for the change in fair value included in net loss	270,195
Balance at March 31, 2018	$12,808,720

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 (in years)
March 31, 2018	35% to 80%	9%	1.08 to 1.25
December 31, 2017	35% to 80%	9%	1.33 to 1.50
March 31, 2017	50% to 80%	9%	1.75 to 2.25
December 31, 2016	50% to 80%	9%	2.00 to 2.50

Note 14. 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 was reduced by $50,000 on each of the 19th, 31st and 43rd months from the initial term, and the remaining $100,000 amount was reduced when the Lease term expired in April 2017. 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 of the agreement for an additional 64 months, reduced the premises to 7,565 square feet, reduced the monthly rent and provided four months free rent. 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 24th 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 expired at the end of January 2018. In January 2018, the Company and this landlord entered into a new 60-month lease which reduced the premises to 9,049 square feet with rent payments of approximately $18,100 per month.

Note 15. Technology Development and Licensing Agreements

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

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.

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, 2017 filed with the Securities and Exchange Commission (SEC) on March 27, 2018, 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). 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. 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 April 9, 2018, the Company announced that the independent Data Monitoring Committee (DMC) for the Company's OPTIMA Study completed its last regularly scheduled review of the patients enrolled in the trial and has unanimously recommended that the OPTIMA Study continue according to protocol to its final data readout. The DMC’s recommendation was based on the Committee’s assessment of safety and data integrity of the first 75% of patients randomized in the trial as of February 5, 2018. 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 413 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.

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 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.

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.

After its review in 2016, management concluded that there was no immediate opportunity to out-license TheraSilence. As a result of this analysis, the earnout payments were adjusted prior to 2017 and are now up to $24.4 million that may become payable, in cash, shares of our common stock or a combination thereof, at our option, upon achievement of two 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; and

- $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.

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; and

- Ideal for long-term maintenance therapy.

GEN-I 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 is designed to (i) to identify a safe, tolerable and potentially therapeutically active dose of GEN-1 by recruiting and maximizing an immune response and (ii) 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. 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 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 in the OVATION Study, who completed treatment.

On October 3, 2017, we announced final clinical and translational research data from the OVATION Study, a Phase Ib dose escalating clinical trial combining GEN-1 with the standard of care for the treatment of newly-diagnosed patients with advanced Stage III/IV ovarian cancer who will undergo neoadjuvant chemotherapy followed by interval debulking surgery.

Key translational research findings from all evaluable patients are consistent with the earlier reports from partial analysis of the data and are summarized below:

- The intraperitoneal treatment of GEN-1 in conjunction with neoadjuvant chemotherapy resulted in dose dependent increases in IL-12 and Interferon-gamma (IFN-g) levels that were predominantly in the peritoneal fluid compartment with little to no changes observed in the patients' systemic circulation. These and other post-treatment changes including decreases in VEGF levels in peritoneal fluid are consistent with an IL-12 based immune mechanism;

- Consistent with the previous partial reports, the effects observed in the IHC analysis were pronounced decreases in the density of immunosuppressive T-cell signals (Foxp3, PD-1, PDL-1, IDO-1) and increases in CD8+ cells in the tumor microenvironment;

- The ratio of CD8+ cells to immunosuppressive cells was increased in approximately 75% of patients suggesting an overall shift in the tumor microenvironment from immunosuppressive to pro-immune stimulatory following treatment with GEN-1. An increase in CD8+ to immunosuppressive T-cell populations is a leading indicator and believed to be a good predictor of improved overall survival; and

- Analysis of peritoneal fluid by cell sorting, not reported before, shows treatment-related decrease in the percentage of immunosuppressive T-cell (Foxp3+), which is consistent with the reduction of Foxp3+ T-cells in the primary tumor tissue, and a shift in tumor naïve CD8+ cell population to more efficient tumor killing memory effector CD8+ cells.

The Company also reported positive clinical data from the first fourteen patients who have completed treatment in the OVATION Study. GEN-1 plus standard chemotherapy produced positive clinical results, with no dose limiting toxicities and positive dose dependent efficacy signals which correlate well with positive surgical outcomes as summarized below:

- Of the fourteen patients treated in the entire study, two patients demonstrated a complete response, ten patients demonstrated a partial response and two 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 complete response and four partial responses;

- Fourteen patients had successful resections of their tumors, with nine 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. Seven out of eight (87%) patients in the highest two dose cohorts experienced a R0 surgical resection. All five

patients treated at the highest dose cohort experienced a R0 surgical resection;

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; and

Of the 13 patients who received GEN-1 treatment in all four dose escalating cohorts, only five patients' cancers have progressed as of March 31, 2018. Median PFS for all 13 patients in the OVATION Study is 21.4 months as of March 15, 2018 and counting. This compares favorably to the historical median progression-free survival of 12 months for newly diagnosed patients with Stage III and IV ovarian cancer that undergo neoadjuvant chemotherapy followed by interval debulking surgery.

GEN-1 OVATION II Study. The Company held an Advisory Board Meeting on September 27, 2017 with the clinical investigators and scientific experts including those from Roswell Park Cancer Institute, Vanderbilt University Medical School, and M.D. Anderson Cancer Center to review and finalize clinical, translational research and safety data from the Phase IB OVATION Study in order to determine the next steps forward for our GEN-1 immunotherapy program.

On November 13, 2017, the Company filed its Phase I/II clinical trial protocol with the U.S. Food and Drug Administration for GEN-1 for the localized treatment of ovarian cancer. The protocol is designed with a single dose escalation phase to 100 mg/m² to identify a safe and tolerable dose of GEN-1 while maximizing an immune response. The 12 patient Phase I portion of the study will be followed by a continuation at the selected dose in up to 118 patient randomized Phase II study. GEN-1 has demonstrated positive safety and efficacy data in the recently completed dose escalation Phase IB trial in combination with neoadjuvant chemotherapy.

The study protocol was unanimously supported by an expert medical advisory board and lead investigators from the Phase IB OVATION Study and is summarized below:

- Open label, 1:1 randomized design;
- Enrollment up to 130 patients with Stage III/IV ovarian cancer patients at ten U.S. centers; and
- Primary endpoint of improvement in progression-free survival (PFS) comparing GEN-1 with neoadjuvant chemotherapy versus neoadjuvant chemotherapy alone.

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

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.

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. We have not generated significant revenue and have incurred significant net losses in each year since our inception. We have incurred approximately $266 million of cumulated net losses. As of March 31, 2018, we had approximately $20.8 million in cash, investment securities and interest receivable. 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 operating results of the Company have fluctuated significantly in the past. We have substantial future capital requirements associated with our continued research and development activities and to advance our product candidates through various stages of development. The Company believes these expenditures are essential for the commercialization of its technologies.

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

- the progress of research activities;
- the number and scope of research programs;
- the progress of preclinical and clinical development activities;
- the progress of the development efforts of parties with whom the Company has entered into research and development agreements;
- the costs associated with additional clinical trials of product candidates;
- the ability to maintain current research and development licensing arrangements and to establish new research and development and licensing arrangements;
- the ability to achieve milestones under licensing arrangements;
- the costs involved in prosecuting and enforcing patent claims and other intellectual property rights; and
- the costs and timing of regulatory approvals.

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

With the $20.8 million in cash, investment securities and interest receivable at March 31, 2018, the Company believes it has sufficient capital resources to fund its operations into the third quarter of 2019. The Company will be required to obtain additional funding in order to continue the development of its current product candidates within the anticipated

time periods, if at all, and to continue to fund operations. As more fully discussed in Note 11, the Company has $12.2 million available for future sale under a controlled equity offering facility it has with Cantor Fitzgerald & Co. as of March 31, 2018.

Financing Overview

Equity and Debt Financings

During 2017 and thus far in 2018, we issued a total of 15.4 million shares of common stock; in the following equity transactions for an aggregate $43.9 million in gross proceeds.

The Company received gross proceeds of $22.0 million from the exercise of warrants to purchase approximately 7.6 million shares of common stock in 2017.

On October 27, 2017, the Company entered into an underwriting agreement (the "Underwriting Agreement") with Oppenheimer & Co. Inc. (the "Underwriter"), relating to the issuance and sale (the "October 2007 Offering") of 2,640,000 shares of common stock of the Company and warrants to purchase an aggregate of 1,320,000 shares of common stock of the Company. Each share of common stock was sold together with 0.5 warrants (the "Investor Warrants"), each whole Investor Warrant being exercisable for one share of common stock, at a offering price of $2.50 per share and related Investor Warrants. Pursuant to the terms of the Underwriting Agreement, the Underwriter has agreed to purchase the shares and related Investor Warrants from the Company at a price of $2.325 per share and related Investor Warrant. Each Investor Warrant is exercisable six months from the date of issuance. The Investor Warrants have an exercise price of $3.00 per whole share, and expire five years from the date first exercisable. The Company received $6.6 million of gross proceeds from the sale of the Shares and Investor Warrant. The October 2017 Offering closed on October 31, 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 $4.2 million 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 $0.8 million, 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 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 1,177,790 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 $0.14 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.

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, 2016, 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. During 2017, the Company sold 1,221,348 shares of common stock under the ATM, receiving approximately $3.9 million in net proceeds. Thus far in 2018, the Company sold 457,070 shares of common stock under the ATM, receiving approximately $1.2 million in net proceeds. On October 2, 2015 and again on February 6, 2018, we filed prospectus supplements to the base prospectus that forms a part of the 2015 Shelf Registration Statement, pursuant to which we may offer and sell up to $17.5 million of shares collectively of common stock from time to time under the ATM Agreement. We had $12.2 million available for sale under the ATM Agreement as of March 31, 2018.

On June 20, 2014, we completed the acquisition of substantially all the assets of EGEN, Inc. At the closing, we paid approximately $3.0 million in cash and issued 193,728 shares of its common stock to EGEN. In addition, 47,862 shares of common stock were issuable to EGEN pending satisfactory resolution of any post-closing adjustments of expenses and EGEN’s indemnification obligations under the EGEN Purchase Agreement. These shares were issued on June 16, 2017.

In November 2013, the Company entered into a loan agreement with Hercules Technology Growth Capital, Inc. (Hercules) which permits up to $20 million in capital to be distributed in multiple tranches (the Hercules Credit Agreement). The Company drew the first tranche of $5 million upon closing of the Hercules Credit Agreement in November 2013 and used approximately $4 million of the proceeds to repay the outstanding obligations under its loan agreement with Oxford Finance LLC and Horizon Technology Finance Corporation as discussed further below. On June 10, 2014, the Company closed the second $5 million tranche under the Hercules Credit Agreement. The proceeds were used to fund the $3.0 million upfront cash payment associated with Celsion's acquisition of EGEN, as well as the Company’s transaction costs associated with the EGEN acquisition. Upon the closing of this second tranche, the Company has drawn down a total of $10 million under the Hercules Credit Agreement. The obligations under the Hercules Credit Agreement are in the form of secured indebtedness bearing interest at a calculated prime-based variable rate (11.25% per annum since inception through December 17, 2015, 11.50% from December 18, 2015 through December 15, 2016 and 11.75% 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 June 1, 2017, at which time this loan was paid in full.

Significant Accounting Policies

Our significant accounting policies are more fully described in Note 1 to our consolidated financial statements included in our 2017 Annual Report on Form 10-K for the year ended December 31, 2017 filed with the SEC on March 27, 2018.

In May 2014, the FASB issued Accounting Standards Update (ASU) 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 (collectively “the new revenue standards”). The new revenue standards allow for either “full retrospective” adoption, meaning the standard is applied to all periods presented, or “modified retrospective” adoption, meaning the standard is applied only to the most current period presented in the financial statements. The new revenue standard became effective for us on January 1, 2018. Under the new revenue standards, we recognize revenue following a five-step model prescribed under ASU No. 2014-09;(i) identify contract(s) with a customer;(ii) identify the performance obligations in the contract;(iii) determine the transaction price;(iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenues when (or as) we satisfy the performance obligation. As further described in Note 15, the Company currently has only one contract subject to the new revenue standards. After performance of the five-step model discussed above, the

Company concluded the adoption of the new revenue standards as of January 1, 2018 did not change our revenue recognition policy nor does it have an effect on our financial statements using either the full retrospective or the modified retrospective adoption methods.

Please refer to Note 2 of the Financial Statements contained in this Form 10-K. Also refer to **Item IA, Risk Factors**, including, but not limited to, *"We will need to raise substantial additional capital to fund our planned future operations, and we may be unable to secure such capital without dilutive financing transactions. If we are not able to raise additional capital, we may not be able to complete the development, testing and commercialization of our product candidates."*

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

FINANCIAL REVIEW FOR THE THREE MONTHS ENDED MARCH 31, 2018 AND 2017

Results of Operations

For the three months ended March 31, 2018, our net loss was $4.5 million compared to a net loss of $5.2 million for the same period of 2017. With the $20.8 million in cash and investments on hand at March 31, 2018, the Company believes it has sufficient capital resources to fund its operations well into the third quarter of 2019.

	Three Months Ended March 31,		**Change**	
	(In thousands)		**Increase (Decrease)**	
	2018	**2017**		**%**
Licensing Revenue:	$125	$125	$–	– %
Operating Expenses:				
Clinical Research	1,884	2,634	(750)	(28.5)%
Chemistry, Manufacturing and Controls	857	841	16	1.9 %
Research and development	2,741	3,475	(734)	(21.1)%
General and administrative	1,665	1,468	197	13.4 %
Total operating expenses	4,406	4,943	(537)	(10.9)%
Loss from operations	$(4,281)	$(4,818)	$537	11.1 %

Comparison of the Three Months ended March 31, 2018 and 2017

Licensing Revenue

In January 2013, we entered into a technology development contract with Hisun, pursuant to which Hisun paid us a non-refundable technology transfer fee of $5.0 million to support our development of ThermoDox® in the China territory. The $5.0 million received as a non-refundable payment from Hisun in the first quarter 2013 has been recorded to deferred revenue and will be amortized over the ten-year term of the agreement; therefore, we recorded deferred revenue of $125,000 in each of the first quarters of 2018 and 2017.

Research and Development Expenses

Research and development (R&D) expenses decreased by $0.7 million to $2.7 million in the first quarter of 2018 from $3.5 million in the same period of 2017. Costs associated with the OPTIMA Study decreased by $0.3 million to $1.3 million in the first quarter of 2018 compared to $1.6 million in the same period of 2017. Other clinical costs decreased by $0.4 million to $0.5 million in the first quarter of 2018 compared to $0.9 million in the same period of 2017. Costs associated with the OVATION Studies remained relatively unchanged at $0.1 million in each of the first quarters of 2018 and 2017. Preclinical and regulatory costs were insignificant in each of the first quarters of 2018 and 2017. Costs associated with the production and distribution of ThermoDox® to support the OPTIMA Study remained unchanged at $0.3 million in each of the first quarters of 2018 and 2017. R&D costs associated with the development of GEN-1 to support the OVATION Studies increased by $0.1 million to $0.6 million in the first quarter of 2018 compared to $0.5 million in the same period of 2017. The Company announced the completion of enrollment of all cohorts of the OVATION I Study in July 2017 and reported final clinical and translational research data in October 2017 and expects to initiate enrollment in the Phase I/II OVATION II Study in the second quarter of 2018.

General and Administrative Expenses

General and administrative (G&A) expenses increased to $1.7 million in the first quarter of 2018 compared to $1.5 million in the same period of 2017. This increase is mostly attributable to an increase in professional fees of approximately $0.1 million and an increase compensation expense which includes $0.1 million in non-cash stock compensation expense in the first quarter of 2018 compared to the same period of 2017.

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 March 31, 2018, the Company fair valued these milestones at $12.8 million and recognized a non-cash charge of $0.3 million in the first quarter of 2018 as a result of the change in the fair value of these milestones from $12.5 million at December 31, 2017. At March 31, 2017, the Company fair valued these milestones at $13.5 million and recognized a non-cash charge of $0.3 million in the first quarter of 2017 as a result of the change in the fair value of these milestones from $13.2 million at December 31, 2016.

Investment income and interest expense

The Company realized $0.1 million of interest income from its short-term investments during the first quarter of 2018. Investment income was negligible in first quarter of 2017.

In connection with its debt facilities, the Company incurred $0.1 million in interest expense in the first quarter of 2017. The loan balance and end of term charges on its debt facilities were paid in full in June 2017. The Company did not have any interest expense in the first quarter of 2018.

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 $266 million at March 31, 2018.

At March 31, 2018 we had total current assets of $20.9 million (including cash, cash equivalents and short-term investments and related interest receivable on short-term investments of $20.8 million) and current liabilities of $5.6 million, resulting in net working capital of $15.3 million. At December 31, 2017 we had total current assets of $24.3 million (including cash, cash equivalents and short-term investments and related interest receivable on short-term investments of $24.2 million) and current liabilities of $6.2 million, resulting in net working capital of $18.1 million.

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.

Net cash used in operating activities for the first three months of 2018 was $4.7 million. Our 2018 net loss of $4.7 million for the three-month period ended March 31, 2018 included (i) $0.1 million in non-cash stock-based compensation expense and (ii) $0.3 million in a non-cash charge based on the change in the earn-out milestone liability. The $4.7 million net cash used in operating activities was mostly funded from cash and cash equivalents.

Net cash provided by financing activities was $1.2 million during the three-month period ended March 31, 2018 from the sale of our common stock through our ATM Facility.

We expect to 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 July 2011, we entered into a lease with Brandywine Operating Partnership, L.P., a Delaware limited partnership for a 10,870 square foot premises located in Lawrenceville, New Jersey in connection with the relocation of our offices from Columbia, Maryland. In late 2015, Lenox Drive Office Park LLC, purchased the real estate and office building and assumed the lease. Under the current terms of the lease, which was amended effective May 1, 2017 and is set to expire on September 1, 2022, we reduced the size of the premises to 7,565 square feet and are paying a monthly rent that ranges from approximately $18,900 in the first year to approximately $20,500 in the final year of the amendment. We also have a one-time option to cancel the lease as of the 24th month after the commencement date of the amendment. In connection with the Asset Purchase Agreement, in June 2014, we assumed the existing lease with another landlord for an 11,500 square foot premises located in Huntsville, Alabama. In January 2018, we entered into a new 60-month lease agreement for 9,049 square feet with rent payments of approximately $18,100 per month. Other than this lease amendment, there were no material changes during the three months ended March 31, 2018 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, 2017 filed on March 27, 2018 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 March 31, 2018, 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 three months ended March 31, 2018 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, 2017 filed on March 27, 2018 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 $266 million at March 31, 2018. For the years ended December 31, 2016 and 2017, and for the three months ended March 31, 2018, we incurred a net loss of $22.1 million, $20.4 million and $4.5 million, respectively. We currently have no product revenue and do not expect to generate any product revenue for the foreseeable future. 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 United States 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 , and plan to expand our ovarian cancer development program to include a Phase I/II dose escalating trial evaluating GEN-1, known as the OVATION II Study, in 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.

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 $266 million at March 31, 2018. For the years ended December 31, 2016 and 2017 and the three months ended March 31, 2018, we incurred a net loss of $22.1 million, $20.4 million and $4.5 million, respectively. As of March 31, 2018, we had approximately $20.8 million in cash and short-term investments including interest receivable.

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 and other preclinical studies. We completed a Phase I dose-escalation clinical trial of GEN-1 in combination with the standard of care in neo-adjuvant ovarian cancer in the third quarter of 2017 and plan to expand our clinical development program for GEN-1 in ovarian cancer in 2018.

To complete the development and commercialization of our product candidates, we will need to raise substantial amounts of additional capital to fund our operations. Our future capital requirements will depend upon numerous unpredictable factors, including, without limitation, the cost, timing, progress and outcomes of clinical studies and regulatory reviews of our proprietary drug candidates, our efforts to implement new collaborations, licenses and strategic transactions, general and administrative expenses, capital expenditures and other unforeseen uses of cash. We do not have any committed sources of financing and cannot assure you that alternate funding will be available in a

timely manner, on acceptable terms or at all. We may need to pursue dilutive equity financings, such as the issuance of shares of common stock, convertible debt or other convertible or exercisable securities. Such dilutive equity financings could dilute the percentage ownership of our current common stockholders and could significantly lower the market value of our common stock. In addition, a financing could result in the issuance of new securities that may have rights, preferences or privileges senior to those of our existing stockholders.

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

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. Even if we receive approval, we will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense and subject us to restrictions, withdrawal from the market, or penalties if we fail to comply with applicable regulatory requirements or if we experience unanticipated problems with our product candidates, when and if approved. Finally, even if we obtain FDA approval of any of our product candidates, we may never obtain approval or commercialize such products outside of the United States, given that we may be subject to additional or different regulatory burdens in other markets. This could limit our ability to realize their full market potential.

Our industry is highly regulated by the FDA and comparable foreign regulatory agencies. We must comply with extensive, strictly enforced regulatory requirements to develop, obtain, and maintain marketing approval for any of our product candidates.

Securing FDA or comparable foreign regulatory approval requires the submission of extensive preclinical and clinical data and supporting information for each therapeutic indication to establish the product candidate’s safety and efficacy for its intended use. It takes years to complete the testing of a new drug or biological product and development delays and/or failure can occur at any stage of testing. Any of our present and future clinical trials may be delayed, halted, not authorized, or approval of any of our products may be delayed or may not be obtained due to any of the following:

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any preclinical test or clinical trial may fail to produce safety and efficacy results satisfactory to the FDA or comparable foreign regulatory authorities;

- preclinical and clinical data can be interpreted in different ways, which could delay, limit or prevent marketing approval;

- negative or inconclusive results from a preclinical test or clinical trial or adverse events during a clinical trial could cause a preclinical study or clinical trial to be repeated or a development program to be terminated, even if other studies relating to the development program are ongoing or have been completed and were successful;

- the FDA or comparable foreign regulatory authorities can place a clinical hold on a trial if, among other reasons, it finds that subjects enrolled in the trial are or would be exposed to an unreasonable and significant risk of illness or injury;

- the facilities that we utilize, or the processes or facilities of third party vendors, including without limitation the contract manufacturers who will be manufacturing drug substance and drug product for us or any potential collaborators, may not satisfactorily complete inspections by the FDA or comparable foreign regulatory authorities; and

- we may encounter delays or rejections based on changes in FDA policies or the policies of comparable foreign regulatory authorities during the period in which we develop a product candidate or the period required for review of any final marketing approval before we are able to market any product candidate.

In addition, information generated during the clinical trial process is susceptible to varying interpretations that could delay, limit, or prevent marketing approval at any stage of the approval process. Moreover, early positive preclinical or clinical trial results may not be replicated in later clinical trials. As more product candidates within a particular class of drugs proceed through clinical development to regulatory review and approval, the amount and type of clinical data that may be required by regulatory authorities may increase or change. Failure to demonstrate adequately the quality, safety, and efficacy of any of our product candidates would delay or prevent marketing approval of the applicable product candidate. We cannot assure you that if clinical trials are completed, either we or our potential collaborators will submit applications for required authorizations to manufacture or market potential products or that any such application will be reviewed and approved by appropriate regulatory authorities in a timely manner, if at all.

New gene-based products for therapeutic applications are subject to extensive regulation by the FDA and comparable agencies in other countries. The precise regulatory requirements with which we will have to comply, now and in the future, are uncertain due to the novelty of the gene-based products we are developing.

The regulatory approval process for novel product candidates such as ours can be significantly more expensive and take longer than for other, better known or more extensively studied product candidates. Limited data exist regarding the safety and efficacy of DNA-based therapeutics compared with conventional therapeutics, and government regulation of DNA-based therapeutics is evolving. Regulatory requirements governing gene and cell therapy products have changed frequently and may continue to change in the future. The FDA has established the Office of Cellular, Tissue and Gene Therapies within its Center for Biologics Evaluation and Research (CBER), to consolidate the review of gene therapy and related products, and has established the Cellular, Tissue and Gene Therapies Advisory Committee to advise CBER in its review. It is difficult to determine how long it will take or how much it will cost to obtain regulatory approvals for our product candidates in either the U.S. or the European Union or how long it will take to commercialize our product candidates.

Adverse events or the perception of adverse events in the field of gene therapy generally, or with respect to our product candidates specifically, may have a particularly negative impact on public perception of gene therapy and result in greater governmental regulation, including future bans or stricter standards imposed on gene-based therapy clinical trials, stricter labeling requirements and other regulatory delays in the testing or approval of our potential products. For example, if we were to engage an NIH-funded institution to conduct a clinical trial, we may be subject to review by the NIH Office of Biotechnology Activities' Recombinant DNA Advisory Committee (the RAC). If undertaken, RAC can delay the initiation of a clinical trial, even if the FDA has reviewed the trial design and details and approved its initiation. Conversely, the FDA can put an investigational new drug (IND) application on a clinical hold even if the RAC has provided a favorable review or an exemption from in-depth, public review. Such committee and advisory group reviews and any new guidelines they promulgate may lengthen the regulatory review process, require us to perform additional studies, increase our development costs, lead to changes in regulatory positions and interpretations, delay or prevent approval and commercialization of our product candidates or lead to significant post-approval limitations or restrictions. Any increased scrutiny could delay or increase the costs of our product development efforts or clinical trials.

Even if our products receive regulatory approval, they may still face future development and regulatory difficulties. Government regulators may impose significant restrictions on a product's indicated uses or marketing or impose ongoing requirements for potentially costly post-approval studies. This governmental oversight may be particularly strict with respect to gene-based therapies.

Serious adverse events, undesirable side effects or other unexpected properties of our product candidates may be identified during development or after approval, which could lead to the discontinuation of our clinical development programs, refusal by regulatory authorities to approve our product candidates or, if discovered following marketing approval, revocation of marketing authorizations or limitations on the use of our product candidates thereby limiting the commercial potential of such product candidate.

As we continue our development of our product candidates and initiate clinical trials of our additional product candidates, serious adverse events, undesirable side effects or unexpected characteristics may emerge causing us to abandon these product candidates or limit their development to more narrow uses or subpopulations in which the serious adverse events, undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective.

Even if our product candidates initially show promise in these early clinical trials, the side effects of drugs are frequently only detectable after they are tested in large, Phase III clinical trials or, in some cases, after they are made available to patients on a commercial scale after approval. Sometimes, it can be difficult to determine if the serious adverse or unexpected side effects were caused by the product candidate or another factor, especially in oncology subjects who may suffer from other medical conditions and be taking other medications. If serious adverse or unexpected side effects are identified during development and are determined to be attributed to our product candidate, we may be required to develop a Risk Evaluation and Mitigation Strategy (REMS) to mitigate those serious safety risks, which could impose significant distribution and use restrictions on our products.

In addition, drug-related side effects could also affect subject recruitment or the ability of enrolled subjects to complete the trial, result in potential product liability claims, reputational harm, withdrawal of approvals, a requirement to include additional warnings on the label or to create a medication guide outlining the risks of such side effects for distribution to patients. It can also result in patient harm, liability lawsuits, and reputational harm. Any of these occurrences could prevent us from achieving or maintaining market acceptance and may harm our business, financial condition and prospects significantly.

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 conducted a Phase I dose-escalation clinical trial of GEN-1 in combination with the standard of care in neo-adjuvant ovarian cancer starting 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 ovarian cancer patients and additional trials in newly diagnosed 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 have obtained Orphan Drug Designation for ThermoDox® and may seek Orphan Drug Designation for other product candidates, but we may be unsuccessful or may be unable to maintain the benefits associated with Orphan Drug Designation, including the potential for market exclusivity.

ThermoDox® has been granted orphan drug designation for primary liver cancer in both the U.S. and Europe. As part of our business strategy, we may seek Orphan Drug Designation for other 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.

Fast Track designation may not actually lead to a faster development or regulatory review or approval process.

ThermoDox® has received U.S. FDA Fast Track Designation. However, we may not experience a faster development process, review, or approval compared to conventional FDA procedures. The FDA may withdraw our Fast Track designation if the FDA believes that the designation is no longer supported by data from our clinical or pivotal development program. Our Fast Track designation does not guarantee that we will qualify for or be able to take advantage of the FDA's expedited review procedures or that any application that we may submit to the FDA for regulatory approval will be accepted for filing or ultimately approved.

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. For example, the Affordable Care Act, passed in 2010, enacted a number of reforms to expand access to health insurance while also reducing or constraining the growth of healthcare spending, enhancing remedies against fraud and abuse, adding new transparency requirements for healthcare industries, and imposing new taxes on fees on healthcare industry participants, among other policy reforms. Further, the 2016 Presidential and Congressional elections and subsequent developments have caused the future state of many core aspects of the current health care marketplace to be uncertain, as the new Presidential Administration and Congress have repeatedly expressed a desire to repeal all or portions of the Affordable Care Act. 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. For example, Congress passed the Affordable Care Act in 2010 which enacted a number of reforms to expand access to health insurance while also reducing or constraining the growth of healthcare spending, enhancing remedies against fraud and abuse, adding new transparency requirements for healthcare industries, and imposing new taxes on fees on healthcare industry participants, among other policy reforms. Federal agencies, Congress and state legislatures have continued to show interest in implementing cost containment programs to limit the growth of health care costs, including price controls, restrictions on reimbursement and other fundamental changes to the healthcare delivery system. In addition, in recent years, Congress has enacted various laws seeking to reduce the federal debt level and contain healthcare expenditures, and the Medicare and other healthcare programs are frequently identified as potential targets for spending cuts. New government legislation or regulations related to pricing or other fundamental changes to the healthcare delivery system as well as a government or third-party payer decision not to approve pricing for, or provide adequate coverage or reimbursement of, our product candidates hold the potential to severely limit market opportunities of such products. 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 or similar product candidates being investigated by our competitors may prove not to be effective in trial or in practice, cause adverse events or other undesirable side effects. 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.

Several of our current clinical trials are being conducted outside the United States, and the FDA may not accept data from trials conducted in foreign locations.

Several of our current clinical trials are being conducted outside the United States. Although the FDA may accept data from clinical trials conducted outside the United States, acceptance of these data is subject to certain conditions imposed by the FDA. For example, the clinical trial must be well designed and conducted and performed by qualified investigators in accordance with ethical principles. The trial population must also adequately represent the U.S. population, and the data must be applicable to the U.S. population and U.S. medical practice in ways that the FDA deems clinically meaningful. In general, the patient population for any clinical trials conducted outside of the United States must be representative of the population for whom we intend to label the product in the United States. In addition, while these clinical trials are subject to the applicable local laws, FDA acceptance of the data will be

dependent upon its determination that the trials also complied with all applicable U.S. laws and regulations. We cannot assure you that the FDA will accept data from trials conducted outside of the United States. If the FDA does not accept the data from such clinical trials, it would likely result in the need for additional trials, which would be costly and time-consuming and delay or permanently halt our development of our product candidates.

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 employees, clinical trial investigators, CROs, consultants, vendors and any potential commercial partners may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements and insider trading.

We are exposed to the risk of fraud or other misconduct by our employees, clinical trial investigators, CROs, consultants, vendors and any potential commercial partners. Misconduct by these parties could include intentional, reckless and/or negligent conduct or disclosure of unauthorized activities to us that violates: (i) FDA laws and regulations or those of comparable foreign regulatory authorities, including those laws that require the reporting of true, complete and accurate information, (ii) manufacturing standards, (iii) federal and state health and data privacy, security, fraud and abuse, government price reporting, transparency reporting requirements, and other healthcare laws and regulations in the United States and abroad, or (iv) laws that require the true, complete and accurate reporting of financial information or data. Such misconduct could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and cause serious harm to our

reputation.

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 be subject to reputational harm, monetary fines, civil suits, civil penalties or criminal sanctions and requirements to disclose the breach, and other forms of 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. 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 $27.02 and a low price of $4.20 in the 52-week period ended December 31, 2016, a high price of $7.14 and a low price of $1.28 in the 52-week period ended December 31, 2017, and a high price of $3.13 and a low price of $1.95 from January 1, 2018 through May 10, 2018. Among the factors that may cause the market price of our common stock to fluctuate are the risks described in

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 May 10, 2018, we had 17,740,035 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 May 10, 2018, we have a significant number of securities convertible into, or allowing the purchase of, our common stock, including 3,058,402 shares of common stock issuable upon exercise of warrants outstanding, 597,241 options to purchase shares of our common stock and restricted stock awards outstanding, and 102,652 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 sold $12.8 million under the Sales Agreement as of March 31, 2018.

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 May 10, 2018, the closing sale price per share of our common stock was $2.55, 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 $45.1 million and the total market value of our listed securities was approximately $45.3 million. There is no assurance that we will continue to meet the minimum closing price requirement and other listing requirements. As of March 31, 2018, we had stockholders' equity of approximately $23.6 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.

On December 22, 2017, the President of the United States signed into law the Tax Reform Act. The Tax Reform Act significantly changes U.S. tax law by, among other things, lowering corporate income tax rates, implementing a quasi-territorial tax system, providing a one-time transition toll charge on foreign earnings, creating a new limitation on the deductibility of interest expenses and modifying the limitation on officer compensation. The Tax Reform Act permanently reduces the U.S. corporate income tax rate from a maximum of 35% to a flat 21% rate, effective January 1, 2018. 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 2017, 2016 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 ownership, as defined by Section 382, in

connection with certain common stock offerings in 2011, 2013, 2015 and 2017. 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.

10.1+	Lease Agreement dated January 15, 2018, by and between Celsion Corporation and HudsonAlpha Institute of Biotechnology for office and lab space located in Huntsville, Alabama.
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 March 31, 2018, 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.

May 11, 2018 CELSION CORPORATION

Registrant

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

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