Celsion CORP
Form 10-Q
November 14, 2018

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 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 [X] No [ ]

Indicate by check mark whether the Registrant has submitted electronically every Interactive Data File required to be submitted 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 [X] 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 [ ] Smaller reporting company [X]

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 [X]

As of November 13, 2018, the Registrant had 18,731,834 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 and its wholly-owned subsidiary CLSN Laboratories, Inc., also a Delaware corporation.

Trademarks

The Celsion brand and product names, including but not limited to Celsion® 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

	September 30, 2018 **(unaudited)**	December 31, 2017
ASSETS		
Current assets:		
Cash and cash equivalents	$3,371,303	$11,444,055
Investment securities - available for sale, at fair value	18,579,731	12,724,020
Accrued interest receivable on investment securities	76,746	54,440
Advances, deposits and other current assets	224,614	89,186
Subtotal current assets	22,252,394	24,311,701
Property and equipment (at cost, less accumulated depreciation and amortization of $2,929,742 and $2,838,716, respectively)	166,523	175,771
Other assets:		
In-process research and development	15,736,491	20,246,491
Other intangible assets, net	625,121	795,608
Goodwill	1,976,101	1,976,101
Patent licensing fees, deposits and other assets, net	155,324	8,761
Subtotal other assets	18,493,037	23,026,961
Total assets	$40,911,954	$47,514,433

See accompanying notes to the condensed consolidated financial statements.

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CELSION CORPORATION

CONDENSED CONSOLIDATED

BALANCE SHEETS

(Continued)

	September 30, 2018 **(unaudited)**	December 31, 2017
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable trade	$3,159,627	$3,416,863
Other accrued liabilities	2,140,128	2,282,827
Deferred revenue - current portion	500,000	500,000
Subtotal current liabilities	5,799,755	6,199,690
Earn-out milestone liability	8,970,854	12,538,525
Notes payable - non-current portion	9,319,579	-
Deferred revenue - non-current portion	1,625,000	2,000,000
Other liabilities - non-current portion	65,701	71,710
Total liabilities	25,780,889	20,809,925
Commitments and contingencies		
Stockholders' equity:		
Preferred Stock - $0.01 par value (100,000 shares authorized; no shares issued or outstanding at September 30, 2018 and December 31, 2017)	-	-
Common stock - $0.01 par value (112,500,000 shares authorized; 17,911,454 and 17,277,299 shares issued at September 30, 2018 and December 31, 2017, respectively;17,911,120 and 17,276,965 shares outstanding at September 30, 2018 and December 31, 2017, respectively)	179,114	172,772
Additional paid-in capital	294,162,004	288,408,976
Accumulated other comprehensive gain (loss)	20,960	(10,164)
Accumulated deficit	(279,145,825)	(261,781,888)
Subtotal	15,216,253	26,789,696
Treasury stock, at cost (334 shares at September 30, 2018 and December 31, 2017)	(85,188)	(85,188)
Total stockholders' equity	15,131,065	26,704,508

Total liabilities and stockholders’ equity	$40,911,954	$47,514,433

See accompanying notes to the condensed consolidated financial statements.

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CELSION CORPORATION

CONDENSED CONSOLIDATED

STATEMENTS OF OPERATIONS

(Unaudited)

	Three Months Ended		**Nine Months Ended**	
	September 30,		**September 30,**	
	2018	2017	2018	2017
Licensing revenue	$125,000	$125,000	$375,000	$375,000
Operating expenses:				
Research and development	2,187,317	3,348,847	9,521,937	9,870,754
General and administrative	1,959,903	1,174,250	7,167,740	4,291,482
Total operating expenses	4,147,220	4,523,097	16,689,677	14,162,236
Loss from operations	(4,022,220)	(4,398,097)	(16,314,677)	(13,787,236)
Other (expense) income:				
Gain from change in valuation of earn-out milestone liability	4,114,995	1,246,151	3,567,671	670,172
Impairment of in-process research and development	(4,510,000)	(2,520,000)	(4,510,000)	(2,520,000)
Investment income	106,565	524	253,750	3,941
Interest expense	(345,728)	-	(360,759)	(91,756)
Other income	2	93	78	3,545
Total other (expense) income, net	(634,166)	(1,273,232)	(1,049,260)	(1,934,098)
Net loss	(4,656,386)	(5,671,329)	(17,363,937)	(15,721,334)
Deemed dividend related to warrant modification	-	-	-	(345,685)
Net loss attributable to common shareholders	$(4,656,386)	$(5,671,329)	$(17,363,937)	$(16,067,019)
Net loss per common share				
Basic and diluted	$(0.26)	$(0.70)	$(1.00)	$(3.04)
Weighted average shares outstanding				
Basic and diluted	17,801,230	8,054,658	17,447,921	5,171,699

See accompanying notes to the condensed consolidated financial statements.

CELSION CORPORATION

CONDENSED CONSOLIDATED

STATEMENTS OF COMPREHENSIVE LOSS

(Unaudited)

	Three Months Ended September 30, 2018	Three Months Ended September 30, 2017	**Nine Months Ended September 30, 2018**	**Nine Months Ended September 30, 2017**
Other comprehensive (loss) gain				
Changes in:				
Realized gain on investment securities recognized in investment income, net	$(2,788)	$	$(11,125)	$
Unrealized gain on investment securities	29,665		42,249	
Change in unrealized gain on available for sale securities	26,877		31,124	
Net loss	(4,656,386)	(5,671,329)	(17,363,937)	(15,721,334)
Comprehensive loss	$(4,629,509)	$(5,671,329)	$(17,332,813)	$(15,721,334)

See accompanying notes to the condensed consolidated financial statements.

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CELSION CORPORATION

CONDENSED CONSOLIDATED

STATEMENTS OF CASH FLOWS

(Unaudited)

	Nine Months Ended September 30,	
	2018	2017
Cash flows from operating activities:		
Net loss	$(17,363,937)	$(15,721,334)
Non-cash items included in net loss:		
Depreciation and amortization	261,513	511,587
Change in fair value of earn-out milestone liability	(3,567,671)	(670,172)
Impairment of in-process research and development	4,510,000	2,520,000
Recognition of deferred revenue	(375,000)	(375,000)
Stock-based compensation costs	3,985,829	951,488
Restricted shares issued	29,841	-
Amortization of deferred finance charges and debt discount associated with notes payable	101,695	35,370
Change in deferred rent liability	(6,009)	61,328
Net changes in:		
Accrued interest on investment securities	(22,306)	4,008
Advances, deposits and other current assets	(231,991)	115,106
Accounts payable and accrued liabilities	(399,935)	134,440
Net cash (used in) operating activities:	(13,077,971)	(12,433,179)
Cash flows from investing activities:		
Purchases of investment securities	(15,574,587)	-
Proceeds from sale and maturity of investment securities	9,750,000	1,680,000
(Deposit) refund on corporate office lease	(50,000)	100,000
Purchases of property and equipment	(81,778)	(21,126)
Net cash (used in) provided by investing activities	(5,956,365)	1,758,874
Cash flows from financing activities:		
Proceeds from sale of common stock equity, net of issuance costs	1,236,584	8,405,190
Proceeds from notes payable, net of issuance costs	9,725,000	-
Proceeds from exercise of common stock warrants	-	4,925,886

Principal payments on notes payable	-	(2,595,923)
Net cash provided by financing activities	10,961,584	10,735,153
(Decrease) increase in cash and cash equivalents	(8,072,752)	60,848
Cash and cash equivalents at beginning of period	11,444,055	2,624,162
Cash and cash equivalents at end of period	$3,371,303	$2,685,010
Supplemental disclosures of cash flow information:		
Interest paid	$259,064	$56,386

See accompanying notes to the condensed consolidated financial statements.

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CELSION CORPORATION

CONDENSED CONSOLIDATED

STATEMENTS OF CASH FLOWS (continued)

(Unaudited)

	Nine Months Ended September 30,	
	2018	2017
Non-cash financing activities:		
Fair value of common stock issued as equity issuance costs and charged against paid in capital	$450,000	$ -
Fair value of warrants issued in connection with notes payable	507,116	-
	$957,116	$ -

See accompanying notes to the condensed consolidated financial statements.

CELSION CORPORATION

NOTES TO THE CONDENSED CONSOLIDATED

FINANCIAL STATEMENTS

(UNAUDITED)

FOR THE THREE AND NINE MONTHS ENDED SEPTEMBER 30, 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 that 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 and its wholly owned subsidiary CLSN Laboratories, Inc, have been prepared in accordance with generally accepted accounting principles in the United States (GAAP) for interim financial information and with the instructions to Form 10-Q and Article 10 of Regulation S-X. All intercompany balances and transactions have been eliminated. Certain information and disclosures normally included in financial statements prepared in accordance with GAAP have been condensed or omitted pursuant to such rules and regulations.

In the opinion of management, all adjustments, consisting only of normal recurring accruals considered necessary for a fair presentation, have been included in the accompanying unaudited condensed consolidated financial statements. Operating results for the three and nine-month periods ended September 30, 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 U.S. 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 $279 million of cumulated net losses. As of September 30, 2018, we had approximately $22.0 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, manufacture, 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, the sale of its State of New Jersey net operating losses 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.

Annually, the State of New Jersey enables approved technology and biotechnology businesses with New Jersey net operating tax losses the opportunity to sell these losses through the Technology Business Tax Certificate Program (the

“NOL Program”), thereby providing cash to companies to help fund their operations. The Company determined it met the eligibility requirements of the NOL Program for 2018 and filed its application with the New Jersey Economic Development Authority (NJEDA) in June 2018. In this application, the Company requested authorization of up to $12.5 million in cumulative New Jersey net operating losses to be eligible for sale. In September 2018, the NJEDA notified the Company that its application received approval under the NOL Program for 2018. The Company expects that the successful transfer of these credits will result in receipt of approximately $10 million in net cash proceeds to the Company prior to the end of 2018.

With $22.0 million in cash, investment securities and interest receivable at September 30, 2018 and the impending sale of its New Jersey NOLs, the Company believes it has sufficient capital resources to fund its operations into the fourth quarter of 2020. 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 $15.0 million available for future sale of equity securities under a common stock purchase agreement with Aspire Capital Fund, LLC.

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. We are evaluating the impact of ASU 2016-2, which we plan to adopt on January 1, 2019, on our consolidated financial statements. To date, we have identified all of our leases which consist of the New Jersey corporate office lease and the Alabama lab facility lease, and we anticipate that adoption of ASU 2016-2 will result in the recognition of additional assets and lease liabilities, along with the associated recognition of amortization expense for the right-to-use assets.

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 does not believe the adoption of ASU 2017-01 will have an impact on our financial statement or disclosures.

In January 2017, the FASB issued Accounting Standard Update *No. 2017-04,* “Intangibles-Goodwill and Other, Simplifying the Test for Goodwill Impairment,” which eliminated 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 testing of goodwill during 2017 and 2018. Based on the Company’s evaluation, the adoption of the ASU 2017-04 did not have any material impact on its consolidated financial statements or its disclosures.

Note 5. Net Loss per Common Share

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

The total number of shares of common stock issuable upon exercise of warrants, stock option grants and equity awards were 6,496,261 and 6,208,389 shares for the three and nine-month periods ended September 30, 2018 and 2017, respectively. For the three and nine month periods ended September 30, 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 $18,579,731 and $12,724,020 as of September 30, 2018 and December 31, 2017, respectively, consist of money market funds, commercial paper, corporate debt securities, and government agency debt securities. These investments 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:

	September 30, 2018		December 31, 2017	
	Cost	Fair Value	Cost	Fair Value
Short-term investments				
Certificate of deposit	$3,128,390	$3,144,875	$-	$-
Corporate debt securities	15,430,381	15,434,856	12,734,184	12,724,020
Total	$18,558,771	$18,579,731	$12,734,184	12,724,020

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	September 30, 2018		December 31, 2017	
	Cost	Fair Value	Cost	Fair Value
Short-term investment maturities				
Within 3 months	$5,714,421	$5,724,554	$-	$-
Between 3-12 months	12,844,350	12,855,177	12,734,184	12,724,020
Total	$18,558,771	$18,579,731	$12,734,184	$12,724,020

The following table shows the Company's investment securities gross unrealized gains (losses) and fair value by investment category and length of time that individual securities have been in a continuous unrealized loss position at September 30, 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.

	September 30, 2018		December 31, 2017	
Available for sale securities (all unrealized holding gains and losses are less than 12 months at date of measurement)	Fair Value	**Unrealized Holding Gains (Losses)**	Fair Value	**Unrealized Holding Gains (Losses)**
Investments with unrealized gains	$10,845,595	$ 27,352	$748,148	$ 570
Investments with unrealized losses	7,734,136	(6,392)	11,975,872	(10,734)
Total	$18,579,731	$ 20,960	$12,724,020	$ (10,164)

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 September 30,	
	2018	2017
Interest and dividends accrued and paid	$103,777	$524
Realized gains	2,788	-
Investment income, net	$106,565	$524

Nine Months Ended

	September 30,	
	2018	2017
Interest and dividends accrued and paid	$242,625	$3,941
Realized gains	11,125	-
Investment income, net	$253,750	$3,941

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 condensed consolidated balance sheet at their approximate 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 nine months ended September 30, 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 September 30, 2018				
Investment securities, available for sale	$18,579,731	$ 18,579,731	$	$
Recurring items as of December 31, 2017				
Investment securities, available for sale	$12,724,020	$ 12,724,020	$	$
Liabilities:				
Recurring items as of September 30, 2018				
Earn-out milestone liability (Note 13)	$8,970,854	$	$	$ 8,970,854
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 (the "Holdback Shares"). These shares were issued to EGEN on June 16, 2017.

After its review in 2017, management concluded that there was no immediate opportunity to out-license TheraSilence. Because of this analysis, the earnout payments were adjusted prior to 2017. In conjunction with its review, management determined the earnout payments may be 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 the remaining 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 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.

At September 30, 2018 and 2017, after the Company's annual assessments 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, 2018 and 2017 using the multi-period excess earnings method (MPEEM). After its assessment on September 30, 2017, 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 on September 30, 2017, incurring a non-cash charge of $2.5 million in the third quarter of 2017. In connection with the write down of this IPR&D asset on September 30, 2017, the Company concluded there was a reduced probability of payments of the earn-out milestones associated with the GBM asset and therefore reduced the earn-out milestone liability from $13.8 million to $12.5 million, recording a non-cash gain of approximately $1.3 million in the third quarter of 2017. After its assessment on September 30, 2018, the Company concluded that the GBM asset, valued at $6.9 million, was partially impaired and wrote down the GBM asset to $2.4 million on September 30, 2018, incurring a non-cash charge of $4.5 million in the third quarter of 2018. In connection with the write down of this IPR&D asset, the Company concluded there was a reduced probability of payment of the earn-out milestones associated with the GBM asset and therefore reduced the earn-out milestone liability from $13.1 million to $9.0 million, recording a non-cash gain of approximately $4.1 million in the third quarter of 2018.

As no other indicators of impairment existed during the first nine months of 2018, the Company concluded none of the other IPR&D assets were impaired at September 30, 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 and $170,487 in each of the three and nine-month periods ended September 30, 2018 and 2017, respectively. The carrying value of the Covenant Not to Compete was $625,121, net of $966,093 accumulated amortization, as of September 30, 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, 2018, 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 as of September 30, 2018 and December 31, 2017 include the following:

	September 30, 2018	December 31, 2017
Amounts due to contract research organizations and other contractual agreements	$730,811	$665,373
Accrued payroll and related benefits	1,048,077	1,258,265
Accrued professional fees	341,240	264,668
Other	20,000	94,521
Total	$2,140,128	$2,282,827

Note 10. Note Payable

Horizon Credit Agreement

On June 27, 2018, the Company entered into a loan agreement with Horizon Technology Finance Corporation ("Horizon") that provided $10 million in new capital (the "Horizon Credit Agreement"). The Company drew down $10 million upon closing of the Horizon Credit Agreement on June 27, 2018. The Company will use the funding provided under the Horizon Credit Agreement for working capital and advancement of its product pipeline.

The obligations under the Horizon Credit Agreement are secured by a first-priority security interest in substantially all assets of Celsion other than intellectual property assets. The obligations will bear interest at a rate calculated based on one-month LIBOR plus 7.625%. Payments under the loan agreement are interest only for the first twenty-four (24) months after loan closing, followed by a 24-month amortization period of principal and interest through the scheduled maturity date. At its option, the Company can prepay all of the outstanding principal balance by prepaying the outstanding principal balance and an amount equal to 1-3% of the outstanding principal balance at that time, based on the amount of time prior to the maturity date of the notes.

The Horizon Credit Agreement contains customary representations, warranties and affirmative and negative covenants including, among other things, covenants that limit or restrict Celsion's ability to grant liens, incur indebtedness, make certain restricted payments, merge or consolidate and make dispositions of assets. Upon the occurrence of an event of default under the Horizon Credit Agreement, the lenders may cease making loans, terminate the Horizon Credit Agreement, declare all amounts outstanding to be immediately due and payable and foreclose on or liquidate Celsion's assets that comprise the lenders' collateral. The Horizon Credit Agreement specifies a number of events of default (some of which are subject to applicable grace or cure periods), including, among other things, non-payment defaults, covenant defaults, a material adverse effect on Celsion or its assets, cross-defaults to other material indebtedness, bankruptcy and insolvency defaults and material judgment defaults.

As a fee in connection with the Horizon Credit Agreement, Celsion issued Horizon warrants exercisable for a total of 190,114 shares of Celsion's common stock (the "Horizon Warrants") at a per share exercise price of $2.63. The Horizon Warrants are immediately exercisable for cash or by net exercise from the date of grant and will expire after ten years from the date of grant. Celsion is required to register the common stock underlying the Horizon Warrants within 90 days from the date of grant and use its best efforts to keep it effective. The Company valued the Horizon Warrants issued using the Black-Scholes option pricing model and recorded a total of $507,116 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.

In connection with the Horizon Credit Agreement, the Company incurred financing fees and expenses totaling $175,000 which are recorded and classified as debt discount. In addition, the Company paid loan origination fees of $100,000 which has been recorded and classified as debt discount. These debt discount amounts totaling $782,116 are being amortized as interest expense using the effective interest method over the life of the loan. Also, in connection with each of the Horizon Credit Agreements, the Company is required to pay an end of term charge equal to 4.0% of the original loan amount at time of maturity. Therefore, these amounts totaling $400,000 are being amortized as interest expense using the effective interest method over the life of the loan.

For the three and nine-month periods ended September 30, 2018 the Company incurred $248,270 and $259,064, respectively, in interest expense and amortized $97,458 and $101,695, respectively, as interest expense for debt discounts and end of term charges in connection with the Horizon Credit Agreement.

Following is a schedule of future principle payments, net of unamortized debt discounts and amortized end of term charges, due on the Horizon Credit Agreement:

	For the year ending September 30
2019	$-
2020	-
2021	4,583,333
2022	5,000,000
2023 and thereafter	416,667
Subtotal of future principle payments	10,000,000
Unamortized debt issuance costs, net	(680,421)
Total	$9,319,579

Hercules Credit Agreement

In November 2013, the Company entered into a loan agreement with Hercules Technology Growth Capital, Inc. (Hercules) which permits up to $20 million in capital to be distributed in multiple tranches (the Hercules Credit Agreement). The Company drew the first tranche of $5 million upon closing of the Hercules Credit Agreement in November 2013 and used approximately $4 million of the proceeds to repay the outstanding obligations under its loan agreement with Oxford Finance LLC and Horizon Technology Finance Corporation as discussed further below. On June 10, 2014, the Company closed the second $5 million tranche under the Hercules Credit Agreement. The proceeds were used to fund the $3.0 million upfront cash payment associated with Celsion's acquisition of EGEN, as well as the Company's transaction costs associated with the EGEN acquisition. Upon the closing of 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 were in the form of secured indebtedness bearing interest at a calculated prime-based variable rate (11.25% per annum since inception through December 17, 2015, 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. The loan balance and end of term charges on the Hercules Credit Agreement was paid in full in June 2017. For the three-month period ended September 30, 2017 the Company did not incur any interest expense and it did not amortize any interest expense for deferred fees, debt discount and end of term charges in connection with the Hercules Credit Agreement. For the nine-month period ended September 30, 2017, the Company incurred $56,386 in interest expense and amortized $35,370 as interest expense for deferred fees, debt discount and end of term charges in connection with the Hercules Credit Agreement

Note 11. Stockholders' Equity

In September 2015, the Company filed with 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. The 2015 Shelf Registration Statement expired on September 25, 2018.

In September 2018, the Company filed with the SEC a new $75 million shelf registration statement on Form S-3 (the 2018 Shelf Registration Statement) (File No. 333-227236) 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 October 12, 2018 and will expire three years from that date.

Increase in the Number of Authorized Shares

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 "October 2017 Underwritten 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. The October 2017 Underwritten Offering was made pursuant to the 2015 Shelf Registration Statement 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 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 2017 Public Offering.

In connection with the February 2017 Public Offering, the Company filed with the SEC 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, the Company 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.

Aspire Purchase Agreement

On August 31, 2018, we entered into a common stock purchase agreement (the “Aspire Purchase Agreement”) with Aspire Capital Fund, LLC (“Aspire Capital”) which provides that, upon the terms and subject to the conditions and limitations set forth therein, Aspire Capital is committed to purchase up to an aggregate of $15.0 million of shares of the Company’s common stock over the 24-month term of the Aspire Purchase Agreement. On October 12, 2018, the Company filed with the SEC a prospectus supplement to the 2018 Shelf Registration Statement registering all of the shares of common stock that may be offered to Aspire Capital from time to time.

Under the Aspire Purchase Agreement, on any trading day selected by the Company, the Company has the right, in its sole discretion, to present Aspire Capital with a purchase notice (each, a “Purchase Notice”), directing Aspire Capital (as principal) to purchase up to 100,000 shares of the Company’s common stock per business day, up to $15.0 million of the Company’s common stock in the aggregate at a per share price (the “Purchase Price”) equal to the lesser of:

- the lowest sale price of the Company’s common stock on the purchase date; or
- the arithmetic average of the three (3) lowest closing sale prices for the Company’s common stock during the ten (10) consecutive trading days ending on the trading day immediately preceding the purchase date.

The Company and Aspire Capital also may mutually agree to increase the number of shares that may be sold to as much as an additional 2,000,000 shares per business day.

In addition, on any date on which the Company submits a Purchase Notice to Aspire Capital in an amount equal to at least 100,000 shares, the Company also has the right, in its sole discretion, to present Aspire Capital with a volume-weighted average price purchase notice (each, a “VWAP Purchase Notice”) directing Aspire Capital to purchase an amount of stock equal to up to 30% of the aggregate shares of the Company’s common stock traded on its principal market on the next trading day (the “VWAP Purchase Date”), subject to a maximum number of shares the Company may determine. The purchase price per share pursuant to such VWAP Purchase Notice is generally 97% of the volume-weighted average price for the Company’s common stock traded on its principal market on the VWAP Purchase Date.

The Purchase Price will be adjusted for any reorganization, recapitalization, non-cash dividend, stock split, or other similar transaction occurring during the period(s) used to compute the Purchase Price. The Company may deliver multiple Purchase Notices and VWAP Purchase Notices to Aspire Capital from time to time during the term of the Purchase Agreement, so long as the most recent purchase has been completed.

There are no trading volume requirements or restrictions under the Purchase Agreement, and the Company will control the timing and amount of sales of the Company's common stock to Aspire Capital. Aspire Capital has no right to require any sales by the Company but is obligated to make purchases from the Company as directed by the Company in accordance with the Purchase Agreement. There are no limitations on use of proceeds, financial or business covenants, restrictions on future fundings, rights of first refusal, participation rights, penalties or liquidated damages in the Purchase Agreement. In consideration for entering into the Purchase Agreement, concurrently with the execution of the Purchase Agreement, the Company issued to Aspire Capital 164,835 shares of the Company's common stock (the "Commitment Shares"). The Company's policy is to record specific incremental costs directly attributable to an offering as a charge against the gross proceeds, if any, when the offering becomes effective. These Commitment Shares valued at $450,000 were recorded in September 2018 as costs of equity financing and charged against additional paid-in capital. The Aspire Purchase Agreement may be terminated by the Company at any time, at its discretion, without any cost to the Company. Aspire Capital has agreed that neither it nor any of its agents, representatives and affiliates shall engage in any direct or indirect short-selling or hedging of the Company's common stock during any time prior to the termination of the Purchase Agreement. Any proceeds from the Company receives under the Aspire Purchase Agreement are expected to be used for working capital and general corporate purposes.

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 could 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 2015 Shelf Registration Statement. Under the ATM Agreement, Cantor may sell ATM Shares by any method deemed to be an “at-the-market” offering as defined in Rule 415 promulgated under the Securities Act of 1933, as amended, including sales made directly on The NASDAQ Capital Market, on any other existing trading market for our common stock or to or through a market maker. On October 10, 2018, the Company delivered notice to Cantor terminating the ATM effective as of October 20, 2018. The Company has no further obligations under the Sales Agreement. From February 1, 2013 through September 30, 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.

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, other stock awards, and performance awards.

At the 2018 Annual Stockholders Meeting of the Company held on May 15, 2018, stockholders approved the Celsion Corporation 2018 Stock Incentive Plan (the “2018 Plan”). The 2018 Plan, as adopted, permits the granting of 2,700,000 shares of Celsion common stock as equity awards in the form of incentive stock options, nonqualified stock options, restricted stock, restricted stock units, stock appreciation rights, other stock awards, performance awards, or in any combination of the foregoing. Prior to the adoption of the 2018 Plan, the Company had maintained the Celsion Corporation 2007 Stock Incentive Plan (the 2007 Plan). The 2007 Plan permitted the granting of 688,531 shares of Celsion common stock as equity awards in the form of incentive stock options, nonqualified stock options, restricted stock, restricted stock units, stock appreciation rights, phantom stock, performance awards, or in any combination of the foregoing. The 2018 Plan replaced the 2007 Plan although the 2007 Plan remains in effect for awards previously granted under the 2007 Plan. Under the terms of the 2018 Plan, any shares subject to an award under the 2007 Plan which are not delivered because of the expiration, forfeiture, termination or cash settlement of the award will become available for grant under the 2018 Plan.

The Company has issued stock awards to employees and directors in the form of stock options and restricted stock. Options are generally granted with strike prices equal to the fair market value of a share of Celsion common stock on the date of 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 of Celsion must be at least 110% of such fair market value on the date of grant. Only officers and key employees may receive incentive stock options.

Option and restricted stock awards vest upon terms determined by the Compensation Committee of the Board of Directors and are subject to accelerated vesting in the event of a change of control or certain terminations of employment. The Company issues new shares to satisfy its obligations from the exercise of options or the grant of restricted stock awards.

On September 28, 2018, the Compensation Committee of the Board of Directors approved the grant of (i) inducement stock options (the “Inducement Option Grants”) to purchase a total of 164,004 shares of Celsion common stock and (ii) inducement restricted stock awards (the “Inducement Stock Grants”) totaling 19,000 shares of Celsion common stock to three new employees. All awards have a grant date of September 28, 2018. Each of Inducement Option Grant has an exercise price per share equal to $2.77, the closing price of Celsion’s common stock as reported by Nasdaq on September 28, 2018. Each Inducement Option Grant will vest over three years, with one-third vesting on the one-year anniversary of the employee’s first day of employment with the Company and one-third vesting on the second and third anniversaries thereafter, subject to the new employee’s continued service relationship with the Company on each such date. Each Inducement Option Grant has a ten-year term and is subject to the terms and conditions of the applicable stock option agreement. Each of Inducement Stock Grant will vest on the one-year anniversary of the employee’s first day of employment with the Company and are subject to the new employee’s continued service relationship with the Company through such date and is subject to the terms and conditions of the applicable restricted stock agreement.

As of September 30, 2018, there were a total of 3,399,893 shares of Celsion common stock reserved for issuance under the 2018 Plan, which were comprised of 3,064,741 shares of Celsion common stock subject to equity awards previously granted under the 2018 Plan and 2007 Plan and 335,152 shares of Celsion common stock available for future issuance under the 2018 Plan. As of September 30, 2018, there were a total of 183,004 of Celsion common stock subject to outstanding inducement awards.

Total compensation cost charged related to stock options and restricted stock awards amounted to $614,528 and $146,896 for the three-month periods ended September 30, 2018 and 2017, respectively. Total compensation cost charged related to stock options and restricted stock awards amounted to $3,985,829 and $951,488 for the nine-month periods ended September 30, 2018 and 2017, respectively. As of September 30, 2018, there was $2.5 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 1.1 years. The weighted average grant date fair values of the stock options granted during then nine-month periods ended September 30, 2018 and 2017 was $2.36 and $2.69, respectively.

A summary of stock option awards and restricted stock grants for the nine-months ended September 30, 2018 is presented below:

Equity Awards	Stock Options		Restricted Stock Awards		**Weighted Average**
	Options Outstanding	**Weighted Average Exercise Price**	Non-vested Restricted Stock Outstanding	**Weighted Average Grant Date Fair Value**	Contractual Terms of Equity Awards (in years)
Equity awards outstanding at January 1, 2018	703,442	$ 10.34	-	$ -	
Equity awards granted	2,629,004	$ 2.26	35,000	$ 2.71	
Vested and issued	-	$ -	(6,000)	$ 2.64	
Equity awards forfeited, cancelled or expired	(113,701)	$ 40.23	-	$ -	
Equity awards outstanding at September 30, 2018	3,218,745	$ 2.67	29,000	$ 2.72	9.4
Aggregate intrinsic value of outstanding equity awards at September 30, 2018	$1,384,245		$1,700		
Equity awards exercisable at September 30, 2018	1,677,998	$ 2.94			9.3
Aggregate intrinsic value of equity awards exercisable at September 30, 2018	$706,552				

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

	Nine Months Ended September 30,			
	2018		2017	
Risk-free interest rate	2.82 – 3.02	%	2.21	%
Expected volatility	99.9 -102.1	%	90.4	%
Expected life (in years)	8.0 - 10.0		10.00	
Expected dividend yield	-	%	-	%

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

Note 13. Earn-out Milestone Liability

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

As of September 30, 2018, June 30, 2018 and December 31, 2017, the Company fair valued these milestones at $9.0 million, $13.1 million and $12.5 million, respectively, and recognized a non-cash gain of $4,114,995 and $3,567,671 during the three and nine months ended September 30, 2018 as a result of the change in the fair value of these milestones from the beginning of each period, respectively.

As of September 30, 2017, June 30, 2017 and December 31, 2016, the Company fair valued these milestones at $12.5 million, $13.8 million and $13.2 million, respectively, and recognized a non-cash gain of $1,246,151 and $670,172 during the three and nine months ended September 30, 2017 as a result of the change in the fair value of these milestones from the beginning of each period, respectively

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

Balance at January 1, 2018	$12,538,525
Non-cash gain from the adjustment for the change in fair value	(3,567,671)
Balance at September 30, 2018	$8,970,854

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**
September 30, 2018	0% to 80%	9%	0.00 to 1.17 year
June 30, 2018	35% to 80%	9%	0.83 to 1.00 years
December 31, 2017	35% to 80%	9%	1.33 to 1.50 years
September 30, 2017	35% to 80%	9%	1.25 to 1.75 years
June 30, 2017	50% to 80%	9%	1.50 to 2.00 years
December 31, 2016	50% to 80%	9%	2.00 to 2.50 years

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Note 14. Warrants

Common Stock Warrants

Following is a summary of all warrant activity for the nine months ended September 30, 2018:

Warrants	Number of Warrants Issued	Weighted Average Exercise Price
Warrants outstanding at December 31, 2017	3,058,402	$ 5.29
Warrants issued during the nine months ended September 30, 2018 (see Note 10)	190,114	$ 2.63
Warrants outstanding at September 30, 2018	3,248,516	$ 5.14
Aggregate intrinsic value of outstanding warrants at September 30, 2018	$69,229	
Weighted average remaining contractual terms at September 30, 2018 (in years)	3.24	

On October 29, 2018, the Company and certain investors holding warrants to collectively purchase 1.6 million shares of the Company's common stock, which were received in the February 2017 Public Offering and the October 2017 Underwritten Offering, entered into warrant exchange agreements whereby the Company issued 820,714 shares of its common stock in exchange for the warrants. After the warrant exchange, warrants outstanding totaled 1.6 million with a weighted average exercise price of $5.75 per share. Approximately 1.2 million of these outstanding warrants with a strike price of $6.20 per share will expire on April 4, 2019.

Note 15. Contingent Liabilities and Commitments

In July 2011, the Company executed a lease (the "Lease") with Brandywine Operating Partnership, L.P. ("Brandywine"), a Delaware limited partnership for a 10,870 square foot premises located in Lawrenceville, New Jersey. In October 2011, the Company relocated its offices to Lawrenceville, New Jersey from Columbia, Maryland. The lease has a term of 66 months and provides for 6 months of rent free, with the first monthly rent payment of approximately $23,000 due and paid in April 2012. Also, as required by the Lease, the Company provided Brandywine with an irrevocable and unconditional standby letter of credit for $250,000, which the Company secured with an escrow deposit at its banking institution of this same amount. The standby letter of credit 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 16. Technology Development and Licensing Agreements

On May 7, 2012, the Company entered into a long-term commercial supply agreement with Zhejiang Hisun Pharmaceutical Co. Ltd. (Hisun) for the production of ThermoDox® in mainland China, Hong Kong and Macau (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 (the “CFDA”). 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 ® 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 CFDA; 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 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 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 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 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 U.S, Canada, European Union (“EU”), China and other countries in the Asia-Pacific region, and will evaluate ThermoDox® in combination with standardized RFA for a minimum of 45 minutes 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 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.

On September 5, 2018, the Company announced that it reached its enrollment objective of 550 patients for the OPTIMA Study. The primary endpoint for the study is overall survival (OS). The OPTIMA Study’s design and statistical plan incorporates two pre-planned interim efficacy analyses by the study’s Data Monitoring Committee (DMC), and the first interim analysis is expected to occur in mid-2019. The DMC’s interim analyses will evaluate safety, efficacy and futility to determine if there is significant evidence of clinical benefit.

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, in the 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 I/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, which has changed its company name to EGWU, Inc. after the closing of the acquisition, pursuant to an asset purchase agreement (the “Asset Purchase Agreement”) dated as of June 6, 2014, by and between EGEN and Celsion. 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 issued the Holdback Shares 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.

At September 30, 2017 and 2018, after the Company’s annual assessments of the totality of the events that could impair IPR&D, the Company determined certain IPR&D assets related to the development of its 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 and 2018 using the MPEEM. After its assessment on September 30, 2017, 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 on September 30, 2017, incurring a non-cash charge of $2.5 million in the third quarter of 2017. In connection with the write down of this IPR&D asset on September 30, 2017, the Company concluded there was a reduced probability of payments of the earn-out milestones associated with the GBM asset and therefore reduced the earn-out milestone liability from $13.8 million to $12.5 million, recording a non-cash benefit of approximately $1.3 million in the third quarter of 2017. After its assessment on September 30, 2018, the Company concluded that the GBM asset, valued at $6.9 million, was partially impaired and wrote down the GBM asset to $2.4 million on September 30, 2018, incurring a non-cash charge of $4.5 million in the third quarter of 2018. In connection with the write down of this IPR&D asset, the Company concluded there was a reduced probability of payments of the earn-out milestones associated with the GBM asset and therefore reduced the earn-out milestone liability from $13.1 million to $9.0 million, recording a non-cash benefit of approximately $4.1 million in the third quarter of 2018.

As no other indicators of impairment existed during the first nine months of 2018, the Company concluded none of the other IPR&D assets were impaired at September 30, 2018.

GEN-1

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

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

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

Ideal for long-term maintenance therapy.

GEN-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) identify a safe, tolerable and potentially therapeutically active dose of GEN-1 by recruiting and maximizing an immune response; (ii) to enroll three to six patients per dose level and will evaluate safety and efficacy and (iii) 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 a 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 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 and an 86% objective response rate ("ORR"). Of the five patients treated in the highest dose cohort, there was a 100% ORR with one complete response and four partial responses;

Fourteen patients had successful resections of their tumors, with nine patients (64%) having a complete tumor resection ("R0"), 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

On October 24, 2018, the Company announced final results from the OVATION Study. Median progression-free survival (PFS) in patients treated per protocol (n=13) was 24.3 months and was 17.1 months for the intent-to-treat population (n=18) for all dose cohorts, including three patients who dropped out of the study after 13 days or less, and two patients who did not receive full NAC and GEN-1 cycles. Under the current standard of care, in women with Stage III/IV ovarian cancer undergoing NAC, the disease progresses within about 12 months on average. Even with only limited GEN-1 plus standard NAC, treatment doubled PFS to an average of over 24 months for women in this small study. The results from the OVATION Study support continued evaluation of GEN-1 based on promising tumor response, as reported in the PFS data, and the ability for surgeons to completely remove visible tumor at debulking surgery. GEN-1 was well tolerated and no dose-limiting toxicities were detected. Intraperitoneal administration of GEN-1 was feasible with broad patient acceptance.

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 FDA 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 PFS comparing GEN-1 with neoadjuvant chemotherapy versus neoadjuvant chemotherapy alone.

On September 6, 2018, the Company announced it began dosing patients in the OVATION II Study.

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 the GEN-1 Agreement with Hisun to pursue an expanded partnership for the technology transfer relating to the clinical and commercial manufacture and supply of GEN-1, Celsion's proprietary gene mediated, IL-12 immunotherapy, for the 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 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.

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 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 FDA. We have not generated significant revenue and have incurred significant net losses in each year since our inception. As of September 30, 2018, we have incurred approximately $279 million of cumulated net losses. As of September 30, 2018, we had approximately $22.0 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.

Annually, the State of New Jersey enables approved technology and biotechnology businesses with New Jersey net operating tax losses the opportunity to sell these losses through the Technology Business Tax Certificate Program (the "NOL Program"), thereby providing cash to companies to help fund their operations. The Company determined it met the eligibility requirements of the NOL Program for 2018 and filed its application with the New Jersey Economic Development Authority (NJEDA) in June 2018. In this application, the Company requested authorization of up to $12.5 million in cumulative New Jersey net operating losses to be eligible for sale. In September 2018, the NJEDA notified the Company that its application received approval under the NOL Program for 2018. The Company expects that the successful transfer of these credits will result in receipt of approximately $10 million in net cash proceeds to the Company prior to the end of 2018.

With $22.0 million in cash, investment securities and interest receivable at September 30, 2018 and the impending sale of its New Jersey net operating losses, the Company believes it has sufficient capital resources to fund its operations into the fourth quarter of 2020. 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 $15.0 million available for future sale of equity securities under a common stock purchase agreement it has with Aspire Capital Fund, LLC.

Financing Overview

Equity and Debt Financings

During 2017 and thus far in 2018, we entered into a $10 million loan facility and we issued a total of 16.4 million shares of common stock in the following equity transactions for an aggregate $43.9 million in gross proceeds.

On June 27, 2018, the Company entered into the Horizon Credit Agreement with Horizon that provided $10 million in new capital. The Company drew down $10 million upon closing of the Horizon Credit Agreement on June 27, 2018. The Company anticipates that it will use the funding provided under the Horizon Credit Agreement for working capital and advancement of its product pipeline. The obligations under the Horizon Credit Agreement are secured by a first-priority security interest in substantially all assets of Celsion other than intellectual property assets. The obligations will bear interest at a rate calculated based on one-month LIBOR plus 7.625%. Payments under the loan agreement are interest only for the first twenty-four (24) months after loan closing, followed by a 24-month amortization period of principal and interest through the scheduled maturity date.

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 the Underwriting Agreement with the Underwriter, relating to the issuance and sale in the October 2017 Underwritten 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 an 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 Underwritten 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.

In the February 2017 Public Offering, the Company entered into a securities purchase agreement whereby it sold 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 to purchase up to 1,177,790 shares of common stock and 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 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℠ 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 10, 2018, the Company delivered notice to Cantor terminating the ATM effective as of October 20, 2018. From February 2013 through the date of termination, the Company sold 1,784,396 shares of Common Stock under the Sales Agreement generating gross proceeds of $12.8 million. The Company has no further obligations under the Sales Agreement.

On August 31, 2018, we entered into the Aspire Purchase Agreement with Aspire Capital Fund which provides that, upon the terms and subject to the conditions and limitations set forth therein, Aspire Capital is committed to purchase up to an aggregate of $15.0 million of shares of the Company’s common stock over the 24-month term of the Aspire Purchase Agreement. On October 12, 2018, the Company filed with the SEC a prospectus supplement to the 2018 Shelf Registration Statement registering all of the shares of common stock that may be offered to Aspire Capital from time to time. The timing and amount of sales of the Company’s common stock to Aspire Capital. Aspire Capital has no right to require any sales by the Company but is obligated to make purchases from the Company as directed by the Company in accordance with the Purchase Agreement. There are no limitations on use of proceeds, financial or business covenants, restrictions on future fundings, rights of first refusal, participation rights, penalties or liquidated damages in the Purchase Agreement. In consideration for entering into the Purchase Agreement, concurrently with the execution of the Purchase Agreement, the Company issued to Aspire Capital 164,835 Commitment Shares. The Aspire Purchase Agreement may be terminated by the Company at any time, at its discretion, without any cost to the Company. Any proceeds from the Company receives under the Aspire Purchase Agreement are expected to be used for working capital and general corporate purposes. The Company has not sold any shares under the Aspire Purchase Agreement.

On October 29, 2018, the Company and certain investors holding warrants to purchase 1.6 million shares collectively of the Company’s common stock received in the February 27, 2017 Public Offering and the October 2017 Underwritten Offering, entered into warrant exchange agreements whereby the Company issued 820,714 shares collectively of common stock to these investors in exchange for the warrants. After the warrant exchange, warrants outstanding totaled 1.6 million with a weighted average exercise price of $5.75 per share. Approximately 1.2 million of these outstanding warrants with a strike price of $6.20 per share will expire on April 4, 2019.

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.

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 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 AND NINE MONTHS ENDED SEPTEMBER 30, 2018 AND 2017

Results of Operations

For the three months ended September 30, 2018, our net loss was $4.7 million compared to a net loss of $5.7 million for the same period of 2017. For the nine months ended September 30, 2018, our net loss was $17.4 million compared to a net loss of $16.1 million for the same period of 2017. In the third quarter and for the first nine months of 2018, the Company incurred $0.6 million and $4.0 million, respectively, of non-cash stock option expense compared to $0.2 million and $1.0 million, respectively, during the same periods of 2017. With $22.0 million in cash and investments on hand at September 30, 2018, the Company believes it has sufficient capital resources to fund its operations into the fourth quarter of 2020.

	Three Months Ended September 30, (In thousands)		**Change**	
			Increase (Decrease)	
	2018	2017		%
Licensing Revenue:	$125	$125	$-	- %
Operating Expenses:				
Clinical Research	2,033	2,951	(918)	(31.1)%
Chemistry, Manufacturing and Controls	154	398	(244)	(61.3)%
Research and development expenses	2,187	3,349	(1,162)	(34.7)%
General and administrative expenses	1,960	1,174	786	67.0 %
Total operating expenses	4,147	4,523	(376)	(8.3)%
Loss from operations	$(4,022)	$(4,398)	$376	8.6 %

	Nine Months September 30, (In thousands)		Change Increase (Decrease)	
	2018	2017	$	%
Licensing Revenue:	$375	$375	$-	- %
Operating Expenses:				
Clinical Research	8,670	8,859	(189)	(2.1)%
Chemistry, Manufacturing and Controls	852	1,012	(160)	(15.8)%
Research and development expenses	9,522	9,871	(349)	(3.5)%
General and administrative expenses	7,168	4,291	2,877	67.0 %
Total operating expenses	16,690	14,162	2,528	17.6 %
Loss from operations	$(16,315)	$(13,787)	$(2,528)	(18.3)%

Comparison of the Three Months ended September 30, 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 third quarters of 2018 and 2017.

Research and Development Expenses

Research and development (“R&D”) expenses decreased by $1.1 million to $2.2 million in the third quarter of 2018 from $3.3 million in the same period of 2017. Costs associated with the OPTIMA Study decreased by $1.1 million to $0.7 million in the third quarter of 2018 compared to $1.8 million in the same period of 2017. This decrease resulted from cost concessions negotiated with its lead contract research organization (CRO) for the OPTIMA Study as well as lower monthly CRO fees after completion of engagement of this Phase III study during the third quarter of 2018. Costs associated the OVATION II Study were $0.2 million in the third quarter of 2018. Preclinical and regulatory costs were $0.1 million in the third quarter of 2018 and were insignificant in the same period of 2017. Other clinical costs increased by $0.2 million to $0.6 million in the third quarter of 2018 compared to $0.4 million in the same period of 2017. This increase is mostly attributable to an increase of $0.1 million in non-cash stock compensation expense during the third quarter of 2018 compared to the same period of 2017. Costs associated with the production and distribution of ThermoDox® to support the OPTIMA Study decreased $0.2 million to $0.2 million in the third quarter of 2018 compared to $0.4 million in the same period of 2017. Enrollment for the OPTIMA Study was completed during the third quarter of 2018. R&D costs associated with the development of GEN-1 to support the OVATION Studies remained relatively unchanged at $0.5 million in each of the third quarters of 2018 and 2017.

General and Administrative Expenses

General and administrative (“G&A”) expenses increased to $2.0 million in the third quarter of 2018 compared to $1.2 million in the same period of 2017. This increase is mostly attributable to an increase in professional fees of approximately $0.2 million and an increase in personnel costs of approximately $0.1 million coupled with a $0.4 million in non-cash stock compensation expense in the third quarter of 2018 compared to the same period of 2017.

Impairment of IPR&D Liability

At September 30, 2018, after our 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 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 concluded that the GBM asset, valued at $6.9 million, was partially impaired and wrote down the GBM asset to $2.5 million incurring a non-cash charge of $4.5 million in the third quarter of 2018.

At September 30, 2017, after our 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 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 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.

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 is recognized in the condensed consolidated financial statements.

In connection with the write down of the IPR&D asset discussed above, the Company concluded there was a reduced probability of payments of the earn-out milestones associated with the GBM asset as of September 30, 2018, therefore, the Company fair valued these milestones at $9.0 million and recognized a non-cash benefit of $4.1 million in the third quarter of 2018 as a result of the change in the fair value of these milestones from $13.1 million at June 30, 2018.

In connection with the write down of the IPR&D asset discussed above, the Company concluded there was a reduced probability of payments of the earn-out milestones associated with the GBM asset as of September 30, 2017, therefore, the Company fair valued these milestones at $12.5 million and recognized a non-cash benefit of $1.2 million in the third quarter of 2017 as a result of the change in the fair value of these milestones from $13.7 million at June 30, 2017.

Investment income and interest expense

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

The Company entered into a new loan facility with Horizon Technology Finance Corporation on June 27, 2018. In connection with this debt facility the Company incurred $0.1 million and $0.6 million in interest expense in the third quarter of 2018. In connection with its debt facilities, the Company interest expense was insignificant in the third quarter of 2017.

Comparison of the Nine Months ended September 30, 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 $375,000 in each of the first nine months of 2018 and 2017.

Research and Development Expenses

Research and development (R&D) expenses decreased by $0.4 million to $9.5 million in the first nine months of 2018 from $9.9 million in the same period of 2017. Costs associated with the OPTIMA Study were $4.0 million in the first nine months of 2018 compared to $4.9 million in the same period of 2017. This decrease resulted from cost concessions negotiated with its lead contract research organization (CRO) for the OPTIMA Study as well as lower monthly CRO fees after completion of engagement of this Phase III study during the third quarter of 2018. Costs associated with the OVATION studies were $0.4 million in the first nine months of 2018 compared to $0.2 million in the same period of 2017. The Company announced the completion of enrollment of all cohorts of the OVATION I Study in 2017. The Company initiated the OVATION II Study during 2018. Other clinical costs were $2.0 million in the first nine months of 2018 compared to $1.9 million in the same period of 2017. In the nine months of 2018, the other clinical costs included an increase of $0.5 million in non-cash stock compensation expense compared to the same period of 2017. In early 2017, the Company executed a cost reduction plan by reducing the costs associated with the support of the ThermoDox® studies in Europe. The majority of the $0.5 million in 2017 costs were realized in the first quarter of 2017. ThermoDox® preclinical and regulatory R&D costs were $0.2 million in the first nine months of 2018 compared to $0.1 million in the same period of 2017. Costs associated with the production of ThermoDox® to support the OPTIMA Study were $0.9 million in the first nine months of 2018 compared to $1.0 million in the same period of 2017. Costs associated with the research and development of GEN-1 increased by $0.3 million to $2.1 million in the first nine months of 2018 compared to $1.8 million in the same period of 2017.

General and Administrative Expenses

General and administrative expenses increased by $2.9 million to $7.2 million in the first nine months of 2018 compared to $4.3 million in the same nine-month period of 2017. This increase is primarily attributable to increases in professional fees of approximately $0.7 million and compensation expenses totaling $2.0 million in non-cash stock compensation expense in the first nine months of 2018 compared to the same period of 2017.

Impairment of IPR&D Liability

At September 30, 2018, after our 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 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 concluded that the GBM asset, valued at $6.9 million, was partially impaired and wrote down the GBM asset to $2.5 million incurring a non-cash charge of $4.5 million in the third quarter and first nine months of 2018.

At September 30, 2017, after our 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 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 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 and first nine months 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 is recognized in the condensed consolidated financial statements.

In connection with the write down of the IPR&D asset mentioned above, the Company concluded there was a reduced probability of payments of the earn-out milestones associated with the GBM asset as of September 30, 2018, therefore, the Company fair valued these milestones at $9.0 million and recognized a non-cash benefit of $3.5 million in the first nine months of 2018 as a result of the change in the fair value of these milestones from $12.5 million at December 31, 2018.

In connection with the write down of the IPR&D asset mentioned above, the Company concluded there was a reduced probability of payments of the earn-out milestones associated with the GBM asset as of September 30, 2017, therefore, the Company fair valued these milestones at $12.5 million and recognized a non-cash benefit of $0.7 million in the first nine months of 2017 as a result of the change in the fair value of these milestones from $13.2 million at December 31, 2017.

Investment income and interest expense

The Company realized $0.3 million of interest income from its short-term investments during the first nine months of 2018. Investment income was negligible in the first nine months of 2017.

In connection with its debt facilities, the Company incurred interest expense of $0.4 million in the first nine months of 2018 compared to $0.1 million in the same nine-month period of 2017. The Company entered a new loan facility with Horizon Technology Finance Corporation on June 27, 2018. In the second quarter of 2017, Company paid off its prior loan facility with Hercules Technology Growth Capital, Inc.

Deemed dividend

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

Financial Condition, Liquidity and Capital Resources

Since inception we have incurred significant losses and negative cash flows from operations. We have financed our operations primarily through the net proceeds from the sales of equity, credit facilities and amounts received under our product licensing agreement with Yakult and our technology development agreement with Hisun. The process of developing and commercializing ThermoDox®, GEN-1 and other product candidates and technologies requires significant research and development work and clinical trial studies, as well as significant manufacturing and process development efforts. We expect these activities, together with our general and administrative expenses to result in significant operating losses for the foreseeable future. Our expenses have significantly and regularly exceeded our revenue, and we had an accumulated deficit of $279 million at September 30, 2018.

At September 30, 2018 we had total current assets of $22.3 million (including cash, cash equivalents and short-term investments and related interest receivable on short-term investments of $22.0 million) and current liabilities of $5.8 million, resulting in net working capital of $16.7 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 nine months of 2018 was $13.1 million. Our 2018 net loss of $17.4 million for the first nine months of 2018 included $4.0 million in non-cash stock-based compensation expense.

Net cash provided by financing activities was $11.0 million during the first nine months of 2018 from $9.7 million in net proceeds from the Horizon Credit Facility and $1.2 million in net proceeds from the sale of our common stock through an ATM Facility with Cantor Fitzgerald.

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 and nine months ended September 30, 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 SEC.

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 September 30, 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 SEC.

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 and nine months ended September 30, 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 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 $279 million at September 30, 2018. For the years ended December 31, 2016 and 2017, and for the nine months ended September 30, 2018, we incurred a net loss of $22.1 million, $20.4 million and $17.4 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 FDA and successfully marketed. The amount of future losses is uncertain. Our ability to achieve profitability, if ever, will depend on, among other things, us or our collaborators successfully developing product candidates, obtaining regulatory approvals to market and commercialize product candidates, manufacturing any approved products on commercially reasonable terms, establishing a sales and marketing organization or suitable third party alternatives for any approved product and raising sufficient funds to finance business activities. If we or our collaborators are unable to develop and commercialize one or more of our product candidates or if sales revenue from any product candidate that receives approval is insufficient, we will not achieve profitability, which could have a material adverse effect on our business, financial condition, results of operations and prospects.

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

On January 31, 2013, we announced that our lead product ThermoDox® in combination with radiofrequency ablation (RFA) failed to meet the primary endpoint of the Phase III clinical trial for primary liver cancer, known as the HEAT Study. We have 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/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 $279 million at September 30, 2018. For the years ended December 31, 2016 and 2017 and the nine months ended September 30, 2018, we incurred a net loss of $22.1 million, $20.4 million and $17.4 million, respectively. As of September 30, 2018, we had approximately $22.0 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 we expanded our clinical development program for GEN-1 in ovarian cancer during 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 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 or may be unable to sell those products and our business, results of operations and financial condition will be negatively affected. Similarly, if we were unable to maintain FDA and foreign regulatory approvals for our drug candidates, our business and financial conditions will be negatively affected.

To obtain regulatory approvals from the FDA and foreign regulatory authorities, 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 authorities 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 authorities 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 U.S., 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 authorities. We must comply with extensive, strictly enforced regulatory requirements to develop product candidates and to obtain and maintain marketing approval for those 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:

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 regulations or policies or the regulations or policies of comparable foreign regulatory authorities during the period in which we develop a product candidate, or the period required for regulatory review of a product candidate or marketing application.

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 regulatory approval 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 foreign regulatory authorities. 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 EU 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 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 requirements or 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 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 to mitigate those serious safety risks, which could impose significant distribution and use restrictions on our products.

In addition, drug-related side effects could 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 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 authorities and successfully marketed. We cannot guarantee that any of our product candidates will be approved by the FDA or any foreign regulatory authorities 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, contract research organizations (CROs), clinical data management organizations and consultants to design, conduct, supervise and monitor our clinical trials.