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 March 31, 2020

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)

Securities registered pursuant to Section 12(b) of the Act

Title of each class	Trading symbol(s)	Name of each exchange on which registered
Common stock, par value $0.01 per share	CLSN	Nasdaq Capital Market

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 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 May 14, 2020, the Registrant had 29,257,101 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), uncertainties and assumptions regarding the impact of the COVID-19 pandemic on our business, operations, clinical trials, supply chain, strategy, goals and anticipated timelines, 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

	March 31, 2020 (Unaudited)	December 31, 2019
ASSETS		
Current assets:		
Cash and cash equivalents	$ 5,746,184	$ 6,875,273
Investment in debt securities - available for sale, at fair value	9,887,455	7,985,886
Accrued interest receivable on investment securities	22,713	21,369
Receivable on sale of net operating losses	1,819,324	—
Advances and deposits on clinical programs and other current assets	1,401,024	1,352,670
Total current assets	**18,876,700**	**16,235,198**
Property and equipment (at cost, less accumulated depreciation of $3,135,681 and $3,096,681, respectively)	**374,598**	**405,363**
Other assets:		
Deferred tax asset	—	1,819,324
In-process research and development, net	15,736,491	15,736,491
Goodwill	1,976,101	1,976,101
Operating lease right-of-use assets, net	1,339,140	1,431,640
Other intangible assets, net	284,147	340,976
Deposits and other assets	349,447	333,274
Total other assets	**19,685,326**	**21,637,806**
Total assets	**$ 38,936,624**	**$ 38,278,367**

See accompanying notes to the condensed consolidated financial statements.

CELSION CORPORATION

CONDENSED CONSOLIDATED
BALANCE SHEETS
(Continued)

	March 31, 2020 (Unaudited)	December 31, 2019
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable ─ trade	$ 2,856,378	$ 2,862,949
Other accrued liabilities	1,399,070	2,303,547
Notes payable – current portion, net of deferred financing costs	2,276,005	1,840,228
Operating lease liability - current portion	398,731	387,733
Deferred revenue - current portion	500,000	500,000
Total current liabilities	**7,430,184**	**7,894,457**
Earn-out milestone liability	5,758,983	5,717,709
Note payable, net of deferred financing costs	7,623,738	7,963,449
Operating lease liability - non-current portion	1,040,183	1,143,717
Deferred revenue - non-current portion	875,000	1,000,000
Total liabilities	**22,728,088**	**23,719,332**
Commitments and contingencies	─	─
Stockholders' equity:		
Preferred stock - $0.01 par value (100,000 shares authorized, and no shares issued or outstanding at March 31, 2020 and December 31, 2019)	─	─
Common stock - $0.01 par value (112,500,000 shares authorized; 29,257,435 and 23,256,152 shares issued at March 31, 2020 and December 31, 2019, respectively, and 29,257,101 and 23,255,818 shares outstanding at March 31, 2020 and December 31, 2019, respectively)	292,574	232,562
Additional paid-in capital	311,570,995	304,885,663
Accumulated other comprehensive gain	3,813	42,778
Accumulated deficit	(295,573,658)	(290,516,780)
Total stockholders' equity before treasury stock	**16,293,724**	**14,644,223**
Treasury stock, at cost (334 shares at March 31, 2020 and December 31, 2019)	(85,188)	(85,188)
Total stockholders' equity	**16,208,536**	**14,559,035**
Total liabilities and stockholders' equity	**$ 38,936,624**	**$ 38,278,367**

See accompanying notes to the condensed consolidated financial statements.

CELSION CORPORATION

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(Unaudited)

	Three Months Ended March 31,	
	2020	**2019**
Technology development and licensing revenue	**$ 125,000**	**$ 125,000**
Operating expenses:		
Research and development	3,052,049	2,767,659
General and administrative	1,838,906	2,217,864
Total operating expenses	**4,890,995**	**4,985,523**
Loss from operations	**(4,765,955)**	**(4,860,523)**
Other income (expense):		
(Loss) gain from change in valuation of earn-out milestone liability	(41,274)	3,130,000
Fair value of warrants issued in connection with amendment to modify GEN-1 earn-out milestone payments	—	(400,000)
Investment income	88,309	113,791
Interest expense	(339,365)	(350,747)
Other income	1,407	27
Total other income (expense), net	**(290,923)**	**2,493,071**
Net loss	**$ (5,056,878)**	**$ (2,367,452)**
Net loss per common share		
Basic and diluted	**$ (0.20)**	**$ (0.12)**
Weighted average shares outstanding		
Basic and diluted	**25,804,349**	**19,104,785**

See accompanying notes to the condensed consolidated financial statements.

CELSION CORPORATION

CONDENSED CONSOLIDATED
STATEMENTS OF COMPREHENSIVE LOSS
(Unaudited)

	Three Months Ended March 31,	
	2020	**2019**
Other comprehensive (loss) gain		
Changes in:		
Reclassification of realized gain on investment securities recognized in investment income, net	$ (43,232)	$ (9,381)
Unrealized loss on investment securities	4,267	66,333
Change in unrealized (loss) gain, net, on available for sale securities	(38,965)	56,952
Net loss	(5,056,878)	(2,367,452)
Comprehensive loss	**$ (5,095,843)**	**$ (2,310,500)**

See accompanying notes to the condensed consolidated financial statements.

CELSION CORPORATION

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(Unaudited)

	Three Months Ended March 31,	
	2020	**2019**
Cash flows from operating activities:		
Net loss	$ (5,056,878)	$ (2,367,452)
Adjustments to reconcile net loss to net cash from operating activities:		
Depreciation and amortization	188,329	188,806
Change in fair value of earn-out milestone liability	41,274	(3,130,000)
Fair value of warrants issued in connection with amendment to modify the GEN-1 earn-out milestone payments	—	400,000
Recognition of deferred revenue	(125,000)	(125,000)
Stock-based compensation costs	451,965	691,145
Deferred income tax asset	1,819,324	—
Amortization of deferred finance charges and debt discount associated with notes payable	96,066	97,458
Net changes in:		
Accrued interest on investment securities	(1,344)	(9,761)
Receivable on sale of net operating losses	(1,819,324)	—
Advances, deposits and other current assets	(64,527)	(645,864)
Accounts payable and accrued liabilities	(504,952)	(635,190)
Net cash (used in) operating activities:	**(4,975,067)**	**(5,535,858)**
Cash flows from investing activities:		
Purchases of investment securities	(9,940,534)	(11,251,818)
Proceeds from sale and maturity of investment securities	8,000,000	5,400,000
Purchases of property and equipment	(8,235)	(145,162)
Net cash used in investing activities	**(1,948,769)**	**(5,996,980)**
Cash flows from financing activities:		
Proceeds from sale of common stock equity, net of issuance costs	5,794,747	1,754,885
Net cash provided by financing activities	**5,794,747**	**1,754,885**
Decrease in cash and cash equivalents	**(1,129,089)**	**(9,777,953)**
Cash and cash equivalents at beginning of period	**6,875,273**	**13,353,543**
Cash and cash equivalents at end of period	**$ 5,746,184**	**$ 3,575,590**

See accompanying notes to the condensed consolidated financial statements.

CELSION CORPORATION

CONDENSED CONSOLIDATED
STATEMENTS OF CASH FLOWS (continued)
(Unaudited)

	Three Months Ended March 31,	
	2020	**2019**
Supplemental disclosures of cash flow information:		
Interest paid	$ 243,299	$ 253,289
Cash paid for amounts included in measurement of lease liabilities:		
Operating cash flows from lease payments	$ 130,631	$ 106,000
Non-cash financing and investing activities		
Fair value of warrants issued in connection with amendment to modify the GEN-1 earn-out milestone payments	$ —	$ 400,000
Right of use assets obtained in exchange for lease liabilities		
Right of use assets	$ —	$ 1,797,561
Stock issued in lieu of cash bonuses	$ 498,632	$ —
Realized and unrealized (gains) losses, net, on investment securities	$ (38,965)	$ 56,952

See accompanying notes to the condensed consolidated financial statements.

CELSION CORPORATION

CONDENSED CONSOLIDATED
STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY
(Unaudited)

THREE MONTHS ENDED MARCH 31, 2020

	Common Stock Outstanding		Additional Paid in	Treasury Stock		Accumulated Other Comprehensive	Accumulated	
	Shares	Amount	Capital	Shares	Amount	Income	Deficit	Total
Balance at January 1, 2020	23,255,818	$ 232,562	$ 304,885,663	334	$ (85,188)	$ 42,778	$ (290,516,780)	$ 14,559,035
Net loss	-	-	-	-	-	-	(5,056,878)	(5,056,878)
Sale of equity through equity financing facilities	5,571,428	55,713	5,739,034	-	-	-	-	5,794,747
Realized and unrealized gains and losses, net, on investments securities	-	-	-	-	-	(38,965)	-	(38,965)
Stock-based compensation expense	-	-	451,965	-	-	-	-	451,965
Issuance of restricted stock in lieu of cash bonus	429,855	4,299	494,333	-	-	-	-	498,632
Balance at March 31, 2020	29,257,101	$ 292,574	$ 311,570,995	334	$ (85,188)	$ 3,813	$ (295,573,658)	$ 16,208,536

See accompanying notes to the condensed consolidated financial statements

CELSION CORPORATION

CONDENSED CONSOLIDATED
STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY (continued)
(Unaudited)

THREE MONTHS ENDED MARCH 31, 2019

	Common Stock Outstanding		Additional Paid in	Treasury Stock		Accum. OtherCompr.	Accumulated	
	Shares	Amount	Capital	Shares	Amount	Income	Deficit	Total
Balance at January 1, 2019	18,831,834	$ 188,322	$ 294,393,313	334	$ (85,188)	$ 29,872	$ (273,665,247)	$ 20,861,072
Net loss	-	-	-	-	-	-	(2,367,452)	(2,367,452)
Sale of equity through equity financing facilities	822,186	8,222	1,746,663	-	-	-	-	1,754,885
Common stock warrants issued in connection with amendment to modify earn-out milestone payments	-	-	400,000	-	-	-	-	400,000
Realized and unrealized gains and losses, net, on investments securities	-	-	-	-	-	56,952	-	56,952
Stock-based compensation expense	-	-	691,145	-	-	-	-	691,145
Issuance of restricted stock	8,000	80	(80)	-	-	-	-	-
Balance at March 31, 2019	19,662,020	$ 196,624	$ 297,231,041	334	$ (85,188)	$ 86,824	$ (276,032,699)	$ 21,396,602

See accompanying notes to the condensed consolidated financial statements

CELSION CORPORATION
NOTES TO THE CONDENSED CONSOLIDATED
FINANCIAL STATEMENTS
(UNAUDITED)

FOR THE THREE MONTHS ENDED MARCH 31, 2020

Note 1. Business Description

Celsion Corporation ("Celsion" and the "Company") 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 cancer. These investigational products are based on our two platform technologies which, in addition, provide the basis for the future development of a range of therapeutics for difficult-to-treat forms of cancer. Our first platform is Lysolipid Thermally Sensitive Liposomes, a heat sensitive liposomal based dosage form that targets disease with known therapeutics in the presence of mild heat. Our second is 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.

Note 2. Basis of Presentation

The accompanying unaudited condensed consolidated financial statements, which include the accounts of the Company 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 significant intercompany balances and transactions have been eliminated in consolidation. Certain information and disclosures normally included in financial statements prepared in accordance with GAAP have been condensed or omitted pursuant to such rules and regulations.

In the opinion of management, all adjustments, consisting only of normal recurring accruals considered necessary for a fair presentation, have been included in the accompanying unaudited condensed consolidated financial statements. Operating results for the three-month period March 31, 2020 and 2019 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, 2019 filed with the Securities and Exchange Commission (SEC) on March 25, 2020.

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. With the recent introduction of the COVID-19 pandemic to the United States, the Company continues to monitor the impact of this pandemic on its financial condition and results of operations, along with the valuation of its long-term assets, intangible assets, and goodwill. The effect of this matter could potentially have an impact on the valuation of such assets in the future. The COVID-19 matter is discussed in more detail in Note 3 to the financial statements.

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. The Company has not generated significant revenue and have incurred significant net losses in each year since our inception. As of March 31, 2020, the Company has incurred approximately $296 million of cumulative net losses and we had approximately $17.5 million in cash, investment securities, interest receivable and receivables from the sale of our State of New Jersey net operating losses. 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.

COVID-19 Pandemic

In January 2020, the World Health Organization (WHO) declared an outbreak of coronavirus, COVID-19, to be a "Public Health Emergency of International Concern," and the U.S. Department of Health and Human Services declared a public health emergency to aid the U.S. healthcare community in responding to COVID-19. This virus continues to spread globally and, as of mid-May 2020, has spread to over 100 countries, including the United States. Governments and businesses around the world have taken unprecedented actions to mitigate the spread of COVID-19, including, but not limited to, shelter-in-place orders, quarantines, significant restrictions on travel, as well as restrictions that prohibit many employees from going to work. Uncertainty with respect to the economic impacts of the pandemic has introduced significant volatility in the financial markets. The Company did not observe significant impacts on its business or results of operations for the three months ended March 31, 2020 due to the global emergence of COVID-19. While the extent to which COVID-19 impacts the Company's future results will depend on future developments, the pandemic and associated economic impacts could result in a material impact to the Company's future financial condition, results of operations and cash flows.

The Company's ability to raise additional capital may be adversely impacted by potential worsening global economic conditions and the recent disruptions to, and volatility in, financial markets in the United States and worldwide resulting from the ongoing COVID-19 pandemic.

The disruptions caused by COVID-19 may also disrupt the clinical trials process and enrollment of patients. This may delay commercialization efforts. The Company is currently monitoring its operating activities in light of these events and it is reasonably possible that the virus could have a negative effect on the Company's financial condition and results of operations, the specific impact is not readily determinable as of the date of these financial statements.

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 the Company's 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.

During 2019 and 2018, the Company submitted applications to sell a portion of the Company's State of New Jersey net operating losses as part of the Technology Business Tax Certificate Program sponsored by The New Jersey Economic Development Authority. Under the program, emerging biotechnology companies with unused NOLs and unused research and development credits are allowed to sell these benefits to other companies. As more fully discussed in Note 9, the Company received approval from the New Jersey Economic Development Authority to sell $1.9 million of its State of New Jersey net operating losses recognizing a tax benefit for the year ended December 31, 2019 for the net proceeds (approximately $1.8 million). In early 2020, the Company entered into an agreement to sell these net operating losses, In April of 2020, the Company completed the sale of the New Jersey net operating losses and received the $1.8 million net proceeds. In 2018, the Company completed the sale of a portion of its New Jersey net operating losses for 2011 - 2017 totaling approximately $11.1 for net proceeds of approximately $10.4 million in December 2018. The proceeds of $10.4 million were reflected as a tax benefit for the year ended December 31, 2018. The Company has approximately $2.0 million available in future tax benefits remaining under the NOL Program for future years.

In June 2018, the Company entered into the Horizon Credit Agreement with Horizon that provided $10 million in new capital. 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. Payments under the loan agreement are interest only (calculated based on one-month LIBOR plus 7.625%) for the first twenty-four (24) months after through July 2020, closing, followed by a 24-month amortization period of principal and interest starting on August 1, 2020 and ending through the scheduled maturity date. On May 13, 2020, the Company and Horizon agreed to defer the first two principal payments totaling $833,333 due in August and September 2020.

With $17.5 million in cash, investments, interest receivable and receivable from the sale of the New Jersey net operating losses at March 31, 2020, coupled with future sales of the Company's New Jersey NOL's as well as the remaining availability under the Capital-on-Demand Equity Facility with JonesTrading Institutional Services LLC, the Company believes it has sufficient capital resources to fund its operations through mid-2021.

Note 4. New Accounting Pronouncements

From time to time, new accounting pronouncements are issued by the 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 condensed consolidated financial position, results of operations, and cash flows, or do not apply to our operations.

In June 2016, the FASB issued Accounting Standard Update No. 2016-13, “Financial Instruments – Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments”, which modifies the measurement of expected credit losses on certain financial instruments. The Company will adopt ASU 2016-13 in its first quarter of 2021 utilizing the modified retrospective transition method. Based on the composition of the Company’s investment portfolio and current market conditions, the adoption of ASU 2016-13 is not expected to have a material impact on its condensed consolidated financial statements.

In August 2018, the FASB issued ASU No. 2018-13, *Fair Value Measurement: Disclosure Framework – Changes to the Disclosure Requirements for Fair Value Measurement*, which adds and modifies certain disclosure requirements for fair value measurements. Under the new guidance, entities will no longer be required to disclose the amount of and reasons for transfers between Level 1 and Level 2 of the fair value hierarchy, or valuation processes for Level 3 fair value measurements. However, public companies will be required to disclose the range and weighted average of significant unobservable inputs used to develop Level 3 fair value measurements, and related changes in unrealized gains and losses included in other comprehensive income. This update is effective for annual periods beginning after December 15, 2019, and interim periods within those periods, and early adoption is permitted. The adoption of this standard did not have an impact on the Company’s condensed consolidated financial statements.

In December 2019, the FASB issued ASU No. 2019-12, Income Taxes (Topic 740). The standard simplifies the accounting for incomes taxes by removing certain exceptions to the general principles in Topic 740 related to the approach for intra-period tax allocation and the recognition of deferred tax liabilities for outside basis differences. The standard also clarifies the accounting for transactions that result in a step-up in the tax basis of goodwill. The standard also improves consistent application of and simplifies GAAP for other areas of Topic 740 by clarifying and amending existing guidance. The amendment is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2020. Early adoption is permitted. The Company is currently evaluating the impact that the adoption of this standard will have on its condensed consolidated financial statements.

Note 5. Net Loss per Common Share

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

The total number of shares of common stock issuable upon exercise of warrants, stock option grants and equity awards were 7,982,990 and 5,412,554 shares for the three-month periods ended March 31, 2020 and 2019, respectively. Warrants with an exercise price of $0.01 (as more fully described in Note 13) exercisable for 200,000 shares of common stock were considered issued in calculating basic loss per share. For the three-month periods ended March 31, 2020 and 2019, diluted loss per common share was the same as basic loss per common share as the other warrants and equity awards that were convertible into shares of the Company’s common stock were excluded from the calculation of diluted loss per common share as their effect would have been anti-dilutive.

The Company did not pay any dividends during the three-month periods ended March 31, 2020 and 2019.

Note 6. Investment in Debt Securities Available for Sale

Investments in debt securities available for sale with a fair value of $9,887,455 and $7,985,886 as of March 31, 2020 and December 31, 2019, respectively, consist of corporate 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.

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

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

	March 31, 2020		December 31, 2019	
	Cost	Fair Value	Cost	Fair Value
Short-term investments				
Investments in debt securities	$ 9,883,642	$ 9,887,455	$ 7,943,108	$ 7,985,886
Total	$ 9,883,642	$ 9,887,455	$ 7,943,108	$ 7,985,886

	March 31, 2020		December 31, 2019	
	Cost	Fair Value	Cost	Fair Value
Short-term investment maturities				
Within 3 months	$ 5,592,801	$ 5,592,490	$ 7,943,108	$ 7,985,886
Between 3-12 months	4,290,841	4,294,965	-	-
Total	$ 9,883,642	$ 9,887,455	$ 7,943,108	$ 7,985,886

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 March 31, 2020 and December 31, 2019. The Company has reviewed individual securities to determine whether a decline in fair value below the amortizable cost basis is other than temporary.

	March 31, 2020		December 31, 2019	
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 in debt securities with unrealized gains	$ 6,591,505	$ 10,323	$ 7,985,886	$ 42,778
Investments in debt securities with unrealized losses	3,295,950	(6,510)	-	-
Total	$ 9,887,455	$ 3,813	$ 7,985,886	$ 42,778

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

	Three Months Ended March 31,	
	2020	2019
Interest and dividends accrued and paid	$ 45,077	$ 104,410
Realized gains	43,232	9,381
Investment income, net	$ 88,309	$ 113,791

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.

Cash and cash equivalents, 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. The fair values of securities available for sale are determined by relying on the securities' relationship to other benchmark quoted securities and classified its investments as Level 2 items at March 31, 2020 and December 31, 2019. 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 thee-month period ended March 31, 2020 or during the year ended December 31, 2019. The changes in Level 3 liabilities were the result of changes in the fair value of the earn-out milestone liability included in earnings and in-process R&D. The earnout milestone liability is valued using a risk-adjusted assessment of the probability of payment of each milestone, discounted to present value using an estimated time to achieve the milestone (see Note 13). The in-process R&D is valued using a multi-period excess earnings method (see Note 8).

Assets and liabilities measured at fair value are summarized below:

	Total Fair Value	Quoted Prices in Active Markets for Identical Assets/Liabilities (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Assets:				
Recurring items as of March 31, 2020				
Corporate debt securities, available for sale	$ 9,887,455	$ —	$ 9,887,455	$ —
Recurring items as of December 31, 2019				
Corporate debt securities, available for sale	$ 7,985,886	$ —	$ 7,985,886	$ —
Liabilities:				
Recurring items as of March 31, 2020				
Earn-out milestone liability (Note 13)	$ 5,758,983	$ —	$ —	$ 5,758,983
Recurring items as of December 31, 2019				
Earn-out milestone liability (Note 13)	$ 5,717,709	$ —	$ —	$ 5,717,709

Note 8. Intangible Assets

In June 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"). 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.

Acquired In-process Research and Development

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. The Company's IPR&D consisted of three core elements, its RNA delivery system, its glioblastoma multiforme cancer (GBM) product candidate and its ovarian cancer indication.

The Company's ovarian cancer indication, with original value of $13.3 million has not been impaired since its acquisition. At September 30, 2019 the Company evaluated its IPR&D of the ovarian cancer indication and concluded that it is not more likely than not that the asset is impaired. As no other indicators of impairment existed during the fourth quarter of 2019 or first quarter of 2020, no impairment charges were recorded during the three months ended March 31, 2020 and 2019.

The Company's GBM candidate, with original value of $9.4 million had cumulative impairments through 2018 of $7 million, with remaining carrying value of $2.4 million at December 31, 2019 and March 31, 2020, On September 30, 2019, the Company evaluated its IPR&D of the (GBM) product candidate and concluded that it is not more likely than not that the asset is further impaired. As no other indicators of impairment existed during the fourth quarter of 2019 and in the first quarter of 2020, no impairment charges were recorded during the three months ended March 31, 2020 and 2019.

The Company's RNA delivery system, with an initial value of $1.5 million was previously fully impaired.

Covenants Not to Compete

Pursuant to the EGEN Purchase Agreement, EGEN provided certain covenants ("Covenant Not To Compete") to the Company whereby EGEN agreed, during the period ending on the seventh anniversary of the closing date of the acquisition on June 20, 2014, not to enter into any business, directly or indirectly, which competes with the business of the Company nor will it contact, solicit or approach any of the employees of the Company for purposes of offering employment. The Covenant Not to Compete which was valued at approximately $1.6 million at the date of the EGEN acquisition has a definitive life and is amortized on a straight-line basis over its life of 7 years. The Company recognized amortization expense of $56,829 in each of the three-month periods ended March 31, 2020 and 2019. The carrying value of the Covenant Not to Compete was $284,147, net of $1,307,067 accumulated amortization as of March 31, 2020 and $340,976, net of $1,250,238 accumulated amortization, as of December 31, 2019.

Following is a schedule of future amortization amounts during the remaining life of the Covenant Not to Compete.

	Year Ended March 31,
2020	$ 227,318
2021	56,829
2022 and thereafter	-
Total	$ 284,147

Goodwill

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 March 31, 2020, 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.

Following is a summary of the net fair value of the assets acquired in the EGEN asset acquisition for the three-month period ended March 31, 2020:

	IPR&D	Goodwill	Covenant Not To Compete
For the three-months ended March 31, 2020			
Balance at January 1, 2020, net	$ 15,736,491	$ 1,976,101	$ 340,976
Amortization	-	-	(56,829)
Balance at March 31, 2020, net	$ 15,736,491	$ 1,976,101	$ 284,147

Note 9. Accrued Liabilities

Other accrued liabilities at March 31, 2020 and December 31, 2019 include the following:

	March 31, 2020	December 31, 2019
Amounts due to contract research organizations and other contractual agreements	$ 305,000	$ 475,440
Accrued payroll and related benefits	924,659	1,604,541
Accrued professional fees	150,000	204,155
Other	19,411	19,411
Total	$ 1,399,070	$ 2,303,547

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.

During the three-month period ended March 31, 2020, the Company incurred $243,299 in interest expense and amortized $96,066 as interest expense for debt discounts and end of term charges in connection with the Horizon Credit Agreement. During the three-month period ended March 31, 2019, the Company incurred $253,289 in interest expense and amortized $97,458 as interest expense for debt discounts and end of term charges in connection with the Horizon Credit Agreement.

On May 13, 2020, the Company and Horizon agreed to defer the first two principle payments totaling a $833,333 due in August and September 2020. Following is a schedule of future principal payments, net of unamortized debt discounts and amortized end of term charges, due on the Horizon Credit Agreement:

	As of March 31,
2020	$ 2,500,000
2021	4,583,333
2022	2,916,667
2023 and thereafter	-
Subtotal of future principle payments	10,000,000
Unamortized debt issuance costs, net	(100,257)
Total	$ 9,899,743

Note 11. Stockholders' Equity

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.

Aspire Purchase Agreement

On October 28, 2019, Company, entered into a common stock purchase agreement (the "2019 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 $10.0 million of shares of the Company's common stock over the 24-month term of the 2019 Aspire Purchase Agreement.

During 2019, the Company sold and issued an aggregate of 0.5 million shares under the 2019 Aspire Purchase Agreement, receiving approximately $0.7 million. During the first quarter of 2020 through March 5, 2020 when the Company delivered notice to Aspire terminating the 2019 Aspire Purchase Agreement, the Company sold 1.0 million shares of common stock under the Aspire Purchase Agreement, receiving approximately $1.6 million in additional gross proceeds.

Capital on Demand™ Sales Agreement

On December 4, 2018, the Company entered into a Capital on Demand™ Sales Agreement (the "Capital on Demand Agreement") with JonesTrading Institutional Services LLC, as sales agent ("JonesTrading"), pursuant to which the Company may offer and sell, from time to time, through JonesTrading shares of Common Stock having an aggregate offering price of up to $16.0 million.

The Shares will be issued pursuant to Celsion's previously filed and effective Registration Statement on Form S-3 (File No. 333-227236), the base prospectus dated October 12, 2018, filed as part of such Registration Statement, and the prospectus supplement dated December 4, 2018, filed by Celsion with the Securities and Exchange Commission. During 2019, the Company sold and issued an aggregate of 0.5 million shares under the Capital on Demand Agreement, receiving approximately $1.0 million in gross proceeds. The Company did not sell any shares under the Capital on Demand Agreement during 2020. As of March 31, 2020, the Company has approximately $15 million available under the Capital on Demand Agreement.

Registered Direct Offering

On February 27, 2020, we entered into a Securities Purchase Agreement (the "Purchase Agreement") with several institutional investors, pursuant to which we agreed to issue and sell, in a registered direct offering (the "February 2020 Offering"), an aggregate of 4,571,428 shares (the "Shares") of our common stock at an offering price of $1.05 per share for gross proceeds of approximately $4.8 million before the deduction of the Placement Agent fees and offering expenses. The Shares were offered by the Company pursuant to a registration statement on Form S-3 (File No. 333-227236). The Purchase Agreement contains customary representations, warranties and agreements by the Company and customary conditions to closing. In a concurrent private placement (the "Private Placement"), the Company agreed to issue to the investors that participated in the Offering, for no additional consideration, warrants, to purchase up to 2,971,428 shares of Common Stock (the "Original Warrants"). The Original Warrants were initially exercisable six months following their date of issue and were set to expire on the five-year anniversary of such initial exercise date. The Warrants had an exercise price of $1.15 per share subject to adjustment as provided therein. On March 12, 2020 the Company entered into private exchange agreements (the "Exchange Agreements") with holders the Warrants. Pursuant to the Exchange Agreements, in return for a higher exercise price of $1.24 per share of Common Stock, the Company issued new warrants to the Investors to purchase up to 3,200,000 shares of Common Stock (the "Exchange Warrants") in exchange for the Original Warrants. The Exchange Warrants, like the Original Warrants, are initially exercisable six months following their issuance (the "Initial Exercise Date") and expire on the five-year anniversary of their Initial Exercise Date. Other than having a higher exercise price, different issue date, Initial Exercise Date and expiration date, the terms of the Exchange Warrants are identical to those of the Original Warrants.

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. At the 2019 Annual Stockholders Meeting of the Company held on May 14, 2019, stockholders approved an amendment to the 2018 Plan whereby the Company increased the number of common stock shares available by 1,200,000 to a total of 3,900,000 under the 2018 Plan, as amended. 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 February 19, 2019, 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 140,004 shares of Celsion common stock, and (ii) inducement restricted stock awards (the "Inducement Stock Grants") totaling 13,000 shares of Celsion common stock to two new employees collectively. Each award has a grant date of the date of grant. Each Inducement Option Grant has an exercise price per share equal to $2.18 which represents the closing price of Celsion's common stock as reported by Nasdaq on the date of grant. 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 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 March 31, 2020, there was a total of 4,151,038 shares of Celsion common stock reserved for issuance under the 2018 Plan which were comprised of 4,146,886 shares of Celsion common stock subject to equity awards previously granted under the 2018 Plan and 2007 Plan and 4,152 shares of Celsion common stock available for future issuance under the 2018 Plan. As of March 31, 2020, there was a total of 210,006 of Celsion common stock subject to outstanding inducement awards.

Total compensation cost related to stock options and restricted stock awards amounted to $451,965 and $691,145 for the three-month periods ended March 31, 2020 and 2019, respectively. Of these amounts, $177,936 and $240,387 was charged to research and development during the three-month periods ended March 31, 2020 and 2019, respectively, and $274,029 and $450,758 was charged to general and administrative expenses during the three-month periods ended March 31, 2020 and 2019, respectively.

As of March 31, 2020, there was $1.2 million of total unrecognized compensation cost related to non-vested stock-based compensation arrangements. That cost is expected to be recognized over a weighted-average period of 0.9 years. The weighted average grant date fair values of the stock options granted was $1.01 and $1.90 during the three-month periods ended March 31, 2020 and 2019, respectively. In connection with the Company's annual 2019 bonus program, the Company issued 429,855 shares of common stock from the 2018 Stock Incentive Plan in lieu of paying cash for 50% of the annual bonus awards. These amounts were fully accrued for in 2019.

A summary of stock option awards and restricted stock grants for the three-months ended March 31, 2020 is presented below:

	Stock Options		Restricted Stock Awards		Weighted Average Contractual Terms of Equity Awards (in years)
	Options Outstanding	Weighted Average Exercise Price	Non-vested Restricted Stock Outstanding	Weighted Average Grant Date Fair Value	
Equity awards outstanding at January 1, 2020	4,332,142	$ 2.63	8,750	$ 1.59	
Equity awards granted	36,000	$ 1.16	429,855	$ 1.16	
Vested and issued	-	$ -	(429,855)	$ 1.16	
Equity awards forfeited, cancelled or expired	(20,000)	$ 2.27	-	$ -	
Equity awards outstanding at March 31, 2020	4,348,142	$ 2.62	8,750	$ 1.59	8.2
Aggregate intrinsic value of outstanding equity awards at March 31, 2020	$ -		$ 7,875		
Equity awards exercisable at March 31, 2020	2,591,536	$ 2.93			8.4
Aggregate intrinsic value of equity awards exercisable at March 31, 2020	$ -				

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

	Three Months Ended March 31,	
	2020	2019
Risk-free interest rate	1.33%	2.65%
Expected volatility	102.7%	101.3 -106.2%
Expected life (in years)	8.5	7.5 - 9.3
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.

Note 13. Earn-out Milestone Liability

As of March 31, 2020, and December 31, 2019, the Company fair valued the earn-out milestone liability at $5.8 million and $5.7 million, respectively and recognized a non-cash charge of $0.1 million for the three-months ended March 31, 2020. In assessing the earnout milestone liability at March 31, 2020, the Company fair valued each of the two payment options per the Amended Asset Purchase Agreement and weighted them at 80% and 20% probability for the $7.0 million and the $12.4 million payments, respectively.

As of March 31, 2019, and December 31, 2018, the Company fair valued the earn-out milestone liability at $5.8 million and $8.9 million, respectively and recognized a non-cash benefit of $3.1 million during the three months ended March 31, 2019. In assessing the earnout milestone liability at March 31, 2019, the Company fair valued each of the two payment options per the Amended Asset Purchase Agreement and weighted them at 80% and 20% probability for the $7.0 million and the $12.4 million payments, respectively.

The following is a summary of the changes in the earn-out milestone liability for the three-month period ended March 31, 2020:

Balance at January 1, 2020	$	(5,717,709)
Non-cash loss from the change in fair value		(41,274)
Balance at March 31, 2020	$	(5,758,983)

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

Date	**Risk-adjustment Assessment of achieving each Milestone**	Discount Rate	**Estimated Time to Achieve**
March 31, 2020	80%	9%	1.04 to 2.04 years
December 31, 2019	80%	9%	1.12 to 2.12 years
March 31, 2019	80%	9%	1.00 to 2.00 years
December 31, 2018	80%	9%	1.25 years

Note 14. Warrants

Common Stock Warrants

Following is a summary of all warrant activity for the three months ended March 31, 2020:

Warrants	**Number of Warrants Issued**	**Weighted Average Exercise Price**
Warrants outstanding at December 31, 2019	626,098	$ 1.87
Warrants issued during the three months ended March 31, 2020 (see Note 11)	3,200,000	$ 1.24
Warrants outstanding at March 31, 2020	3,826,098	$ 1.34
Aggregate intrinsic value of outstanding warrants at March 31, 2020	$ 178,000	

Schedule of weighted average remaining contractual terms at March 31, 2020	Number of Warrants Issued		Weighted Average Exercise Price	Weighted Average Contractual Terms Remaining
Warrants provided to EGWU, Inc (Note 13)	200,000	$	0.01	No expiration
All other warrants outstanding	3,626,098	$	1.42	5.3 years

Note 15. Leases

In 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 and relocated its offices to Lawrenceville, New Jersey from Columbia, Maryland. The Lease had an initial term of 66 months. 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 1st 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 ranged from approximately $18,900 in the first year to approximately $20,500 in the final year of the 1st Lease Amendment. The Company also had a one-time option to cancel the lease as of the 40th month after the commencement date of the 1st Lease Amendment and must provide the landlord notice by the 28th month of the lease. Effective January 9, 2019, the Company amended the current terms of the 1st Lease Amendment to increase the size of the premises by 2,285 square feet to 9,850 square feet and also extended the lease term by one year to September 1, 2023. In conjunction with this 2nd Lease Amendment, we agreed to modify our one-time option to cancel the lease as of the end of August 2021 and we must provide notice to the landlord by the end of August 2020. The monthly rent will range from approximately $25,035 in the first year to approximately $27,088 in the final year of the 2nd 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. In January 2018, the Company and the Huntsville 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.

We adopted ASC Topic 842 on January 1, 2019 using the modified retrospective transition method for all lease arrangements at the beginning of the period of adoption. Results for reporting periods beginning January 1, 2019 are presented under ASC 842, while prior period amounts were not adjusted and continue to be reported in accordance with our historic accounting under Topic 840, Leases. The standard had a material impact on our Condensed Consolidated Balance Sheet but had no impact on our condensed consolidated net earnings and cash flows. The most significant impact of adopting ASC Topic 842 was the recognition of the right-of-use (ROU) asset and lease liabilities for operating leases, which are presented in the following three-line items on the Consolidated Condensed Balance Sheet: (i) operating lease right-of-use asset; (ii) current operating lease liabilities; and (iii) operating lease liabilities. Therefore, on date of adoption of ASC Topic 842, the Company recognized a ROU asset of $1.4 million, operating lease liabilities, current and non-current collectively, of $1.5 million and reduced other liabilities by approximately $0.1 million. We elected the package of practical expedients for leases that commenced before the effective date of ASC Topic 842 whereby we elected to not reassess the following: (i) whether any expired or existing contracts contain leases; (ii) the lease classification for any expired or existing leases; and (iii) initial direct costs for any existing leases. In addition, we have lease agreements with lease and non-lease components, and we have elected the practical expedient for all underlying asset classes and account for them as a single lease component. We have no finance leases. We determine if an arrangement is a lease at inception. We have operating leases for office space and research and development facilities. Neither of our leases include options to renew, however, one contains an option for early termination. We considered the option of early termination in measurement of right-of-use assets and lease liabilities and we determined it is not reasonably certain to be terminated. In connection with the 2nd Lease Amendment for the New Jersey office lease in January 2019, the Company considered this as one modified lease and not as two separate leases. Therefore, in January 2019, the Company determined this lease was an operating lease and remeasured the ROU asset and lease liability. Therefore, the Company increased the ROU asset and operating lease liabilities by $0.4 million to $1.8 million and $1.9 million, respectively.

Following is a table of the lease payments and maturity of our operating lease liabilities as of March 31, 2020:

	For the year ending December 31,
Remainder of 2020	$ 395,178
2021	530,734
2022	535,579
2023	233,117
2024 and thereafter	-
Subtotal future lease payments	1,694,608
Less imputed interest	(255,694)
Total lease liabilities	$ 1,438,914
Weighted average remaining life	3.2 years
Weighted average discount rate	9.98%

For the three-month period ending March 31, 2020, operating lease expense was $130,595 and cash paid for operating leases included in operating cash flows was $130,631. For the three-month period ending March 31, 2019, operating lease expense was $130,595 and cash paid for operating leases included in operating cash flows was $106,000.

Note 16. Technology Development and Licensing Agreements

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

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

On July 19, 2013, the Company and Hisun entered into a Memorandum of Understanding to pursue ongoing cooperation 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 level of cooperation 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 internal resources necessary to complete the technology transfer of the Company's proprietary manufacturing process and the production of registration batches for the China territory;

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

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

On August 8, 2016, we signed a Technology Transfer, Manufacturing and Commercial Supply Agreement ("GEN-1 Agreement") with Hisun to pursue an expanded partnership for the technology transfer relating to the clinical and commercial manufacture and supply of GEN- 1, Celsion's proprietary gene mediated, IL- 12 immunotherapy, for the greater China territory, with the option to expand into other countries in the rest of the world after all necessary regulatory approvals are in effect. The GEN- 1 Agreement will help to support supply for both ongoing and planned clinical studies in the U.S., and for potential future studies of GEN- 1 in China. GEN- 1 is currently being evaluated by Celsion in first line ovarian cancer patients.

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

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

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

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

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

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

The Company evaluated the Hisun arrangement in accordance with ASC 606 and determined that its performance obligations under the agreement include the non-exclusive, royalty-free license, research and development services to be provided by the Company, and its obligation to serve on a joint committee. The Company concluded that the license was not distinct since its value is closely tied to the ongoing research and development activities. As such, the license and the research and development services are bundled as a single performance obligation. Since the provision of the license and research and development services are considered a single performance obligation, the $5,000,000 upfront payment is being recognized as revenue ratably through 2022.

Note 17. Commitments and Contingencies

On September 20, 2019, a purported stockholder of the Company filed a derivative and putative class action lawsuit against the Company and certain officers and directors (the "Shareholder Action"). The Shareholder Action alleges breaches of fiduciary duty in connection with the shareholder approval process associated with the 2018 Stock Incentive Plan. The matter is in the early stages and the ultimate outcome of this matter is not currently determinable at this time.

Note 18. Subsequent Events

As more fully discussed in Note 3, the Company completed the sale of its State of New Jersey net operating loss and received the $1.8 million in proceeds from the sale in April 2020.

On April 23, 2020, we filed a Current Report on Form 8-K announcing we entered into a loan agreement with Silicon Valley Bank (the "PPP Loan"), pursuant to the Paycheck Protection Program of the Coronavirus Aid, Relief, and Economic Security Act. We thereafter received proceeds of $632,220 under the PPP Loan. The PPP Loan application required Celsion to certify that there was economic uncertainty surrounding the Company and that, as such, the PPP Loan was necessary to support our ongoing operations. Celsion made this certification in good faith after analyzing, among other things, its financial situation and access to alternative forms of capital, and believes that the Company satisfied all eligibility criteria for the PPP Loan, and that our receipt of the PPP Loan proceeds was consistent with the broad objectives of the PPP of the CARES Act. The certification given with respect to the PPP Loan does not contain any objective criteria and is subject to interpretation. In light of subsequent guidance issued by the U.S. Small Business Administration in consultation with the U.S. Department of the Treasury, out of an abundance of caution we returned the proceeds of the PPP Loan in full on May 13, 2020. Celsion may choose to reapply for the loan if the SBA provides future applicable guidance.

As disclosed in Note 10, the Company and Horizon agreed to defer the first two principal payments totaling a $833,333 due in August and September 2020.

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, 2019 filed with the SEC on March 25, 2020, 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 clinical stage oncology drug company focused on advancing 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 cancer. These investigational products are based on technologies that provide the platform for the future development of a range of therapeutics for difficult-to-treat forms of cancer. The first technology is Lysolipid Thermally Sensitive Liposomes, a heat sensitive liposomal based dosage form that targets disease with known chemotherapeutics in the presence of mild heat. The second technology is TheraPlas, a novel nucleic acid-based treatment for local transfection of therapeutic DNA 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. 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, RFA, for newly diagnosed, intermediate stage HCC patients. HCC incidence globally is approximately 755,000 new cases per year and is the third largest cancer indication globally. Approximately 30% of newly diagnosed patients can be addressed with RFA.

On February 24, 2014, we announced that the United States Food and Drug Administration (the "FDA") 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 (the "HEAT Study"). The OPTIMA Study is supported by a hypothesis developed from an overall survival analysis of a large subgroup of patients from the HEAT Study.

Post-hoc data analysis from our 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, we 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).

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 subgroup. We commissioned an independent computational model at the University of South Carolina Medical School. The results unequivocally 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.

The OPTIMA Study was designed with extensive input from globally recognized HCC researchers and expert clinicians and after receiving formal written feedback from the FDA. The OPTIMA Study was designed to enroll up to 550 patients globally at approximately 65 clinical 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, which will require a minimum of 45 minutes across all investigators and clinical sites for treating lesions three to seven centimeters, versus standardized RFA alone. The primary endpoint for this clinical trial is overall survival ("OS"), and the secondary endpoints are progression free survival and safety. The statistical plan calls for two interim efficacy analyses by an independent Data Monitoring Committee ("DMC").

We completed enrollment of 556 patients in the Phase III OPTIMA Study in August 2018. Data for the study will be reviewed as it matures with two pre-planned interim analyses to be conducted in the fourth quarter of 2019 and in the first half of 2020. We expect that the final efficacy analysis, if necessary, will be completed in the first quarter of 2021. If the study proves to provide a clinically meaningful improvement in overall survival, Celsion will immediately apply for marketing authorization in the US, Europe and China. ThermoDox® has received U.S. FDA Fast Track Designation and has been granted orphan drug designation for primary liver cancer in both the U.S. and the EU. Additionally, the U.S. FDA has provided ThermoDox® with a 505(b)(2) registration pathway. Subject to a successful trial, the OPTIMA Study has been designed to support registration in all key primary liver cancer markets. We fully expect to submit registrational applications in the U.S., Europe and China. We expect to submit and believes that applications will be accepted in South Korea, Taiwan and Vietnam, three other significant markets for ThermoDox® if it were to receive approval in Europe, China or the U.S.

On December 18, 2018, we announced that the DMC for the OPTIMA Study completed its last scheduled review of all patients enrolled in the trial and 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 all patients randomized in the trial as of October 4, 2018. The DMC reviewed study data at regular intervals throughout the patient enrollment period, 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 all 556 patients enrolled into the trial, the DMC evaluated 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 August 5, 2019, the Company announced that the prescribed number of OS events had been reached for the first prespecified interim analysis of the OPTIMA Phase III Study. Following preparation of the data, the first interim analysis was conducted by the DMC on November 1, 2019. This timeline was consistent with the Company's stated expectations and is necessary to provide a full and comprehensive data set that may represent the potential for a successful trial outcome. In accordance with the statistical plan, this initial interim analysis has a target of 118 events, or 60% of the total number required for the final analysis. At the time of the data cutoff, the Company received reports of 128 events. The hazard ratio for success at 128 events is approximately 0.63, which represents a 37% reduction in the risk of death compared with RFA alone and is consistent with the 0.65 hazard ratio that was observed in the prospective HEAT Study subgroup, which demonstrated a two-year overall survival advantage and a median time to death of more than seven and a half years.

On November 4, 2019, the Company announced that the DMC unanimously recommended the OPTIMA Study continue according to protocol. The recommendation was based on a review of blinded safety and data integrity from 556 patients enrolled in the Company's multinational, double-blind, placebo-controlled pivotal Phase III OPTIMA Study. The DMC's pre-planned interim efficacy review followed 128 patient events, or deaths, which occurred in August 2019. Data presented demonstrated that PFS and OS data appear to be tracking with patient data observed at a similar point in the Company's subgroup of patients followed prospectively in the earlier Phase III HEAT Study, upon which the OPTIMA Study is based.

The data review demonstrated the following:

- The OPTIMA Study patient demographics and risk factors are consistent with what the Company observed in the HEAT Study subgroup with all data quality metrics meeting expectations.

- Median PFS for the OPTIMA Study reached 17 months as of August 2019. These blinded data compare favorably with 16 months median PFS for all 285 patients in the HEAT Study subgroup of patients treated with RFA >45 minutes.

- Median OS for the OPTIMA Study has not been reached as of August 5, 2019, however median OS appears to be consistent with the HEAT Study subgroup of patients treated with RFA >45 minutes and followed prospectively for overall survival.

- The OPTIMA Study has lost only 4 patients to follow-up from the initiation of the trial in September 2014 through August 2019 while the trial design allows for 3% risk for loss per year, which at this point would have exceeded 60 patients.

While the Company has not unblinded the study to report a hazard ratio, PFS and OS are tracking similarly to the subgroup of patients who received more than 45 minutes of RFA in our HEAT Study and followed prospectively for more than three years. This subgroup in the HEAT Study demonstrated a 2-year overall survival advantage and a median time to death of more than 7 ½ years. This tracking appears to bode well for success at the second of two pre-planned interim efficacy analysis, which is intended after a minimum of 158 patient deaths and is projected to occur during the second quarter of 2020. The hazard ratio for success at 158 events is 0.70. This is below the hazard ratio of 0.65 observed in the HEAT Study subgroup of patients treated with RFA > 45 minutes.

On April 15, 2020, the Company announced that the prescribed minimum number of events of 158 patient deaths has been reached for the second pre-specified interim analysis of the OPTIMA Phase III Study. Following preparation of the data, the Independent Data Monitoring Committee (iDMC) is expected to meet in July to conduct the second interim analysis. Celsion expects to announce iDMC recommendations as soon as possible after the meeting. The hazard ratio for success at 158 deaths is 0.70, which represents a 30% reduction in the risk of death compared with RFA alone. This compares favorably with the hazard ratio of 0.65 observed in the prospective HEAT Study subgroup upon which the OPTIMA Study is based.

On August 13, 2019, the Company announced that results from an independent analysis of the Company's ThermoDox® HEAT Study conducted by the National Institutes of Health (NIH) were published in the peer-reviewed publication, *Journal of Vascular and Interventional Radiology*. The analysis was conducted by the intramural research program of the NIH and the NIH Center for Interventional Oncology (CIO), with the full data set from the Company's HEAT Study. The analysis evaluated the full data set to determine if there was a correlation between baseline tumor volume and radiofrequency ablation (RFA) heating time (minutes/tumor volume in milliliters), with or without ThermoDox® treatment, for patients with HCC. The NIH analysis was conducted under the direction of Dr. Bradford Wood, MD, Director, NIH Center for Interventional Oncology and Chief, NIH Clinical Center Interventional Radiology.

The article titled, "*RFA Duration Per Tumor Volume May Correlate With Overall Survival in Solitary Hepatocellular Carcinoma Patients Treated With RFA Plus Lyso-thermosensitive Liposomal Doxorubicin*," discussed the NIH analysis of results from 437 patients in the HEAT Study (all patients with a single lesion representing 62.4% of the study population). The key finding was that increased RFA heating time per tumor volume significantly improved overall survival (OS) in patients with single-lesion HCC who were treated with RFA plus ThermoDox®, compared to patients treated with RFA alone. A one-unit increase in RFA duration per tumor volume was shown to result in about a 20% improvement in OS for patients administered ThermoDox®, compared to RFA alone. The authors conclude that increasing RFA heating time in combination with ThermoDox® significantly improves OS and establishes an improvement of over two years versus the control arm when the heating time per milliliter of tumor is greater than 2.5 minutes. This finding is consistent with the Company's own results, which defined the optimized RFA procedure as a 45-minute treatment for tumors with a diameter of 3 centimeters. Thus, the NIH analysis lends support to the hypothesis underpinning the OPTIMA Study.

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®.

GEN-1

GEN-1 is a DNA-based immunotherapeutic product candidate for the localized treatment of ovarian cancer 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 is based on the following.

- Loco-regional production of the potent cytokine IL-12 avoids toxicities and poor pharmacokinetics associated with systemic delivery of recombinant IL-12;
- Persistent local delivery of IL-12 lasts up to one week and dosing can be repeated; and
- Ideal for long-term maintenance therapy.

GEN-I OVATION Study. In February 2015, we announced that the FDA accepted, without objection, the Phase I dose-escalation clinical trial of GEN-1 in combination with the standard of care in neoadjuvant ovarian cancer (the "OVATION Study"). On September 30, 2015, we announced enrollment of the first patient in the OVATION Study. The OVATION Study was 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 was 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.

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-γ) 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 (88%) 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; and

- 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.

On March 2, 2019, the Company announced final PFS results from the OVATION Study. Median progression-free survival (PFS) in patients treated per protocol (n=14) was 21 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. 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 2 Study. The Company held an Advisory Board Meeting on September 27, 2017 with the clinical investigators and scientific experts including those from Roswell Park Cancer Institute, Vanderbilt University Medical School, and M.D. Anderson Cancer Center to review and finalize clinical, translational research and safety data from the Phase IB OVATION Study in order to determine the next steps forward for our GEN-1 immunotherapy program.

On November 13, 2017, the Company filed its Phase I/II clinical trial protocol with the U.S. Food and Drug Administration for GEN-1 for the localized treatment of ovarian cancer. The protocol is designed with a single dose escalation phase to 100 mg/m² to identify a safe and tolerable dose of GEN-1 while maximizing an immune response. The Phase I portion of the study will be followed by a continuation at the selected dose in 130 patients randomized Phase II study.

In the OVATION 2 Study, patients in the GEN-1 treatment arm will receive GEN-1 plus chemotherapy pre- and post-interval debulking surgery. The OVATION 2 Study will include up to 130 patients with Stage III/IV ovarian cancer, with 12 to 15 patients in the Phase I portion and up to 118 patients in Phase II. The study is powered to show a 33% improvement in the primary endpoint, PFS, when comparing GEN-1 with neoadjuvant + adjuvant chemotherapy versus neoadjuvant + adjuvant chemotherapy alone. The PFS primary analysis will be conducted after at least 80 events have been observed or after all patients have been followed for at least 16 months, whichever is later.

On November 5, 2019, the Company announced that the independent Data Safety Monitoring Board (DSMB) completed its safety review of data from the first eight patients enrolled in the ongoing Phase I/II OVATION 2 Study. Based on the DSMB's recommendation, the study will continue as planned and the Company will proceed with completing enrollment in the Phase I portion of the trial.

In March 2020, the Company announced highly encouraging initial clinical data from the first 15 patients enrolled in the ongoing Phase I/II OVATION 2 Study for patients newly diagnosed with Stage III and IV ovarian cancer. The OVATION 2 Study combines GEN-1, the Company's IL-12 gene-mediated immunotherapy, with standard-of-care neoadjuvant chemotherapy (NACT). Following NACT, patients undergo interval debulking surgery (IDS), followed by three additional cycles of chemotherapy.

GEN-1 plus standard NACT produced positive dose-dependent efficacy results, with no dose-limiting toxicities, which correlates well with successful surgical outcomes as summarized below:

- Of the 15 patients treated in the Phase I portion of the OVATION 2 Study, nine patients were treated with GEN-1 at a dose of 100 mg/m² plus NACT and six patients were treated with NACT only. All 15 patients had successful resections of their tumors, with seven out of nine patients (78%) in the GEN-1 treatment arm having an R0 resection, which indicates a microscopically margin-negative resection in which no gross or microscopic tumor remains in the tumor bed. Only three out of six patients (50%) in the NACT only treatment arm had a R0 resection.

- When combining these results with the surgical resection rates observed in the Company's prior Phase Ib dose-escalation trial (the OVATION 1 Study), a population of patients with inclusion criteria identical to the OVATION 2 Study, the data reflect the strong dose-dependent efficacy of adding GEN-1 to the current standard of care NACT:

		% of Patients with R0 Resections
0, 36, 47 mg/m² of GEN-1 plus NACT	n=12	42%
61, 79, 100 mg/m² of GEN-1 plus NACT	n=17	82%

- The objective response rate (ORR) as measured by Response Evaluation Criteria in Solid Tumors (RECIST) criteria for the 0, 36, 47 mg/m² dose GEN-1 patients were comparable, as expected, to the higher (61, 79, 100 mg/m²) dose GEN-1 patients, with both groups demonstrating an approximate 80% ORR.

On March 23, 2020, the Company announced that the European Medicines Agency (EMA) Committee for Orphan Medicinal Products (COMP) has recommended that GEN-1 be designated as an orphan medicinal product for the treatment of ovarian cancer. GEN-1, designed using Celsion's proprietary TheraPlas platform technology, is an interleukin-12 (IL-12) DNA plasmid vector encased in a non-viral nanoparticle delivery system, which enables cell transfection followed by persistent, local secretion of the IL-12 protein. GEN-1 previously received orphan designation from the U.S. Food and Drug Administration and is currently being evaluated in a Phase I/II clinical trial (the OVATION 2 Study) for the treatment of newly diagnosed patients with Stage III and IV ovarian cancer.

On March 26, 2020, the Company announced leading oncology drug development company, today jointly announced with Medidata, a Dassault Systèmes company, that examining matched patient data provided by Medidata in a synthetic control arm (SCA) with results from the Company's completed Phase Ib dose-escalating OVATION I Study with GEN-1 in Stage III/IV ovarian cancer patients showed positive results in progression-free survival (PFS). The hazard ratio (HR) was 0.53 in the intent-to-treat (ITT) group, showing strong signals of efficacy. GEN-1, designed using Celsion's proprietary TheraPlas platform technology, is an interleukin-12 (IL-12) DNA plasmid vector encased in a non-viral nanoparticle delivery system, which enables cell transfection followed by persistent, local secretion of the IL-12 protein. Celsion believes these data may warrant consideration of strategies to accelerate the clinical development program for GEN-1 in newly diagnosed, advanced ovarian cancer patients by the U.S. Food and Drug Administration (FDA). In its March 2019 discussion with Celsion, the FDA noted that preliminary findings from the Phase Ib OVATION I Study were exciting but lacked a control group to evaluate GEN-1's independent impact on impressive tumor response, surgical results and PFS. The Agency encouraged the Company to continue its GEN-1 development program and consult with FDA with new findings that may have a bearing on designations such as Fast Track and Breakthrough Therapy. SCAs have the potential to revolutionize clinical trials in certain oncology indications and some other diseases where a randomized control is not ethical or practical. SCAs are formed by carefully selecting control patients from historical clinical trials to match the demographic and disease characteristics of the patients treated with the new investigational product. SCAs have been shown to mimic the results of traditional randomized controls so that the treatment effects of an investigational product can be visible by comparison to the SCA. SCAs can help advance the scientific validity of single arm trials, and in certain indications, reduce time and cost, and expose fewer patients to placebos or existing standard-of-care treatments that might not be effective for them.

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 U.S. Food and Drug Administration. The Company has not generated significant revenue and have incurred significant net losses in each year since our inception. As of March 31, 2020, the Company has incurred approximately $296 million of cumulative net losses and we had approximately $17.5 million in cash, investment securities, interest receivable and receivables on the sale of is State of New Jersey net operating losses. 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. In January 2020, the World Health Organization (WHO) declared an outbreak of coronavirus, COVID-19, to be a "Public Health Emergency of International Concern," and the U.S. Department of Health and Human Services declared a public health emergency to aid the U.S. healthcare community in responding to COVID-19. This virus continues to spread globally and, as of mid-May 2020, has spread to over 100 countries, including the United States. Our ability to raise additional capital may be adversely impacted by potential worsening global economic conditions and the recent disruptions to, and volatility in, financial markets in the United States and worldwide resulting from the ongoing COVID-19 pandemic.

The disruptions caused by COVID-19 may also disrupt the clinical trials process and enrollment of patients. This may delay commercialization efforts. The Company is currently monitoring its operating activities in light of these events and it is reasonably possible that the virus could have a negative effect on the Company's financial condition and results of operations, the specific impact is not readily determinable as of the date of these financial statements.

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 the Company's 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.

During 2019 and 2018, the Company submitted applications to sell a portion of the Company's State of New Jersey net operating losses as part of the Technology Business Tax Certificate Program sponsored by The New Jersey Economic Development Authority. Under the program, emerging biotechnology companies with unused NOLs and unused research and development credits are allowed to sell these benefits to other companies. As more fully discussed in Note 9, the Company received approval from the New Jersey Economic Development Authority to sell $1.9 million of its State of New Jersey net operating losses recognizing a tax benefit for the year ended December 31, 2019 for the net proceeds (approximately $1.8 million). In early 2020, the Company entered into an agreement to sell these net operating losses, In April of 2020, the Company completed the sale of the New Jersey net operating losses and received the $1.8 million net proceeds. In 2018, the Company completed the sale of a portion of its New Jersey net operating losses for 2011 - 2017 totaling approximately $11.1 for net proceeds of approximately $10.4 million in December 2018. The proceeds of $10.4 million were reflected as a tax benefit for the year ended December 31, 2018. The Company has approximately $2.0 million in future tax benefits remaining under the NOL Program for future years.

On April 23, 2020, we filed a Current Report on Form 8-K announcing we entered into a loan agreement with Silicon Valley Bank (the "PPP Loan"), pursuant to the Paycheck Protection Program of the Coronavirus Aid, Relief, and Economic Security Act. We thereafter received proceeds of $632,220 under the PPP Loan. The PPP Loan application required Celsion to certify that there was economic uncertainty surrounding the Company and that, as such, the PPP Loan was necessary to support our ongoing operations. Celsion made this certification in good faith after analyzing, among other things, its financial situation and access to alternative forms of capital, and believes that the Company satisfied all eligibility criteria for the PPP Loan, and that our receipt of the PPP Loan proceeds was consistent with the broad objectives of the PPP of the CARES Act. The certification given with respect to the PPP Loan does not contain any objective criteria and is subject to interpretation. In light of subsequent guidance issued by the U.S. Small Business Administration in consultation with the U.S. Department of the Treasury, out of an abundance of caution we returned the proceeds of the PPP Loan in full on May 13, 2020.. Celsion may choose to reapply for the loan if the SBA provides future applicable guidance.

In June 2018, the Company entered into the Horizon Credit Agreement with Horizon that provided $10 million in new capital. 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. Payments under the loan agreement are interest only (calculated based on one-month LIBOR plus 7.625%) for the first twenty-four (24) months after through July 2020, closing, followed by a 24-month amortization period of principal and interest starting on August 1, 2020 and ending through the scheduled maturity date. On May 13, 2020, the Company and Horizon agreed to defer the first two principal payments totaling a $833,333 due in August and September 2020.

With $17.5 million in cash, investments, interest receivable and receivable from the sale of the New Jersey net operating losses at March 31, 2020, coupled with future sales of the Company's State of New Jersey NOL's as well as the remaining availability under the Capital-on-Demand Equity Facility with JonesTrading Institutional Services LLC, the Company believes it has sufficient capital resources to fund its operations through mid-2021.

Financing Overview

Equity, Debt and Other Forms of Financing

As more fully discussed in Note 3of the Financial Statement included in this Quarterly Report, during the fourth quarter of 2018, the Company received eligibility from the New Jersey Economic Development Authority to sell, and did sell, $11.1 million of its unused New Jersey net operating losses under the Technology Business Tax Certificate Program, receiving $10.4 million of non-dilutive funding in the process. During the fourth quarter of 2019, the Company received approval from the New Jersey Economic Development Authority to sell $1.9 million of its New Jersey net operating losses. In early 2020, the Company entered into an agreement to sell these net operating losses. In April 2020, the Company completed the sale of its New Jersey net operating losses and received $1.8 million in net proceeds.

On April 23, 2020, we filed a Current Report on Form 8-K announcing we entered into a loan agreement with Silicon Valley Bank (the "PPP Loan"), pursuant to the Paycheck Protection Program of the Coronavirus Aid, Relief, and Economic Security Act. We thereafter received proceeds of $632,220 under the PPP Loan. The PPP Loan application required Celsion to certify that there was economic uncertainty surrounding the Company and that, as such, the PPP Loan was necessary to support our ongoing operations. Celsion made this certification in good faith after analyzing, among other things, its financial situation and access to alternative forms of capital, and believes that the Company satisfied all eligibility criteria for the PPP Loan, and that our receipt of the PPP Loan proceeds was consistent with the broad objectives of the PPP of the CARES Act. The certification given with respect to the PPP Loan does not contain any objective criteria and is subject to interpretation. In light of subsequent guidance issued by the U.S. Small Business Administration in consultation with the U.S. Department of the Treasury, out of an abundance of caution we returned the proceeds of the PPP Loan in full on May 13, 2020.. Celsion may choose to reapply for the loan if the SBA provides future applicable guidance.

In June 2018, the Company entered into the Horizon Credit Agreement with Horizon that provided $10 million in new capital. 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. Payments under the loan agreement are interest only (calculated based on one-month LIBOR plus 7.625%) for the first twenty-four (24) months after through July 2020, closing, followed by a 24-month amortization period of principal and interest starting on August 1, 2020 and ending through the scheduled maturity date. On May 13, 2020, the Company and Horizon agreed to defer the first two principal payments totaling a $833,333 due in August and September 2020.

During 2019 and thus far in 2020, we issued a total of 10.0 million shares of common stock in the following equity transactions for an aggregate of approximately $14.4 million in gross proceeds.

- On February 27, 2020, we entered into a Securities Purchase Agreement (the "Purchase Agreement") with several institutional investors, pursuant to which we agreed to issue and sell, in a registered direct offering (the "February 2020 Offering"), an aggregate of 4.6 million shares (the "Shares") of our common stock at an offering price of $1.05 per share for gross proceeds of approximately $4.8 million before the deduction of the Placement Agent fees and offering expenses. The Shares were offered by the Company pursuant to a registration statement on Form S-3 (File No. 333-227236). The Purchase Agreement contains customary representations, warranties and agreements by the Company and customary conditions to closing. In a concurrent private placement (the "Private Placement"), the Company agreed to issue to the investors that participated in the Offering, for no additional consideration, warrants, to purchase up to 3.0 million shares of Common Stock (the "Original Warrants"). The Original Warrants were initially exercisable six months following their and were set to expire on the five-year anniversary of such initial exercise date. The Warrants had an exercise price of $1.15 per share subject to adjustment as provided therein. On March 12, 2020 the Company entered into private exchange agreements (the "Exchange Agreements") with holders the Warrants. Pursuant to the Exchange Agreements, in return for a higher exercise price of $1.24 per share of Common Stock, the Company issued new warrants to the Investors to purchase up to 3.2 million shares of Common Stock (the "Exchange Warrants") in exchange for the Original Warrants. The Exchange Warrants, like the Original Warrants, are initially exercisable six months following their issuance (the "Initial Exercise Date") and expire on the five-year anniversary of their Initial Exercise Date. Other than having a higher exercise price, different issue date, Initial Exercise Date and expiration date, the terms of the Exchange Warrants are identical to those of the Original Warrants.

- On August 31, 2018, the Company entered into the 2018 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 2018 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 funding, 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 in 2018, the Company issued to Aspire Capital 164,835 Commitment Shares. The 2018 Aspire Purchase Agreement may be terminated by the Company at any time, at its discretion, without any cost to the Company. During 2019 the Company sold and issued an aggregate of 3.3 million shares under the Purchase Agreement, receiving approximately $6.3 million. All proceeds from the Company received under the 2018 Aspire Purchase Agreement were used for working capital and general corporate purposes. As a result of the Company and Aspire Capital entering into a new purchase agreement on October 28, 2019 discussed in the next paragraph, the 2018 Aspire Purchase Agreement was terminated. The Company sold a total of 3.4 million shares receiving $6.5 million under the 2018 Aspire Agreement during 2018 through its termination in 2019

- On October 28, 2019, Company entered into the 2019 Aspire Purchase Agreement with Aspire Capital. The terms and conditions pursuant to the 2019 Aspire Purchase Agreement are substantially similar to the 2018 Aspire Purchase Agreement. Pursuant to the new 2019 Aspire Purchase Agreement, Aspire Capital is committed to purchase up to an aggregate of $10.0 million of shares of the Company's common stock over the 24-month term of the 2019 Aspire Purchase Agreement. Concurrently with entering into the 2019 Aspire Purchase Agreement, the Company also entered into a registration rights agreement with Aspire Capital (the "Registration Rights Agreement"), in which the Company agreed to file one or more registration statements, as permissible and necessary to register under the Securities Act of 1933, as amended (the "Securities Act"), registering the sale of the shares of the Company's common stock that have been and may be issued to Aspire Capital under the 2019 Aspire Purchase Agreement. In consideration for entering into the 2019 Aspire Purchase Agreement, the Company issued to Aspire Capital an additional 0.1 million Commitment Shares. On November 8, 2019, the Company filed with the SEC a Registration Statement on Form S-1 registering all the shares of common stock that may be offered to Aspire Capital from time to time under the 2019 Aspire Purchase Agreement. During 2019, the Company sold 0.5 million shares of common stock under the 2019 Aspire Purchase Agreement, receiving approximately $0.7 million in gross proceeds. On March 5, 2020, the Company delivered notice to Aspire Capital terminating the 2019 Aspire Purchase Agreement effective as of March 6, 2020. During the first quarter of 2020 though the date of termination, the Company sold 1.0 million shares of common stock under the 2019 Aspire Purchase Agreement and received $1.6 million in gross proceeds.

- On December 4, 2018, the Company entered into a new Capital on Demand™ Sales Agreement (the "Capital on Demand Agreement") with JonesTrading Institutional Services LLC, as sales agent ("JonesTrading"), pursuant to which the Company may offer and sell, from time to time, through JonesTrading shares of common stock having an aggregate offering price of up to $16.0 million. The Company intends to use the net proceeds from the offering, if any, for general corporate purposes, including research and development activities, capital expenditures and working capital. The Company is not obligated to sell any Common Stock under the Capital on Demand Agreement and, subject to the terms and conditions of the Capital on Demand Agreement, JonesTrading will use commercially reasonable efforts, consistent with its normal trading and sales practices and applicable state and federal law, rules and regulations and the rules of The Nasdaq Capital Market, to sell common stock from time to time based upon Celsion's instructions, including any price, time or size limits or other customary parameters or conditions the Company may impose. Under the Capital on Demand Agreement, JonesTrading may sell common stock 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. The Capital on Demand Agreement will terminate upon the earlier of (i) the sale of all shares of our common stock subject to the Sales Agreement, and (ii) the termination of the Capital on Demand Agreement by JonesTrading or Celsion. The Capital on Demand Agreement may be terminated by JonesTrading or the Company at any time upon 10 days' notice to the other party, or by JonesTrading at any time in certain circumstances, including the occurrence of a material adverse change in the Company. The Company did not sell any shares under the Capital on Demand Agreement thus far in 2020. During 2019, the Company sold 0.5 million shares of common stock under the Capital on Demand Agreement, receiving approximately $1.0 million.

Significant Accounting Policies

Our significant accounting policies are more fully described in Note 1 to our consolidated financial statements included in our 2018 Annual Report on Form 10-K for the year ended December 31, 2019 filed with the SEC on March 25, 2020.

In June 2016, the FASB issued Accounting Standard Update No. 2016-13, "Financial Instruments – Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments", which modifies the measurement of expected credit losses on certain financial instruments. The Company will adopt ASU 2016-13 in its first quarter of 2021 utilizing the modified retrospective transition method. Based on the composition of the Company's investment portfolio and current market conditions, the adoption of ASU 2016-13 is not expected to have a material impact on its consolidated financial statements.

In August 2018, the FASB issued ASU No. 2018-13, *Fair Value Measurement: Disclosure Framework – Changes to the Disclosure Requirements for Fair Value Measurement*, which adds and modifies certain disclosure requirements for fair value measurements. Under the new guidance, entities will no longer be required to disclose the amount of and reasons for transfers between Level 1 and Level 2 of the fair value hierarchy, or valuation processes for Level 3 fair value measurements. However, public companies will be required to disclose the range and weighted average of significant unobservable inputs used to develop Level 3 fair value measurements, and related changes in unrealized gains and losses included in other comprehensive income. This update is effective for annual periods beginning after December 15, 2019, and interim periods within those periods, and early adoption is permitted. The adoption of this standard did not have an impact on the Company's financial statements.

In December 2019, the FASB issued ASU No. 2019-12, Income Taxes (Topic 740). The standard simplifies the accounting for incomes taxes by removing certain exceptions to the general principles in Topic 740 related to the approach for intra-period tax allocation and the recognition of deferred tax liabilities for outside basis differences. The standard also clarifies the accounting for transactions that result in a step-up in the tax basis of goodwill. The standard also improves consistent application of and simplifies GAAP for other areas of Topic 740 by clarifying and amending existing guidance. The amendment is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2020. Early adoption is permitted. The Company is currently evaluating the impact that the adoption of this standard will have on its consolidated financial statements.

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. 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. Please refer to Note 3 of the Financial Statements contained in this Form 10-Q. Also refer to **Item IA, Risk Factors**, including, but not limited to, *"We will need to raise substantial additional capital to fund our planned future operations, and we may be unable to secure such capital without dilutive financing transactions. If we are not able to raise additional capital, we may not be able to complete the development, testing and commercialization of our product candidates."*

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

FINANCIAL REVIEW FOR THE THREE MONTHS ENDED MARCH 31, 2020 AND 2019

Results of Operations

For the three months ended March 31, 2020 our net loss was $5.1 million compared to a net loss of $2.4 million for the same three-month period of 2019.

With $17.5 million in cash, investments, interest receivable and income tax receivable at March 31, 2020, coupled with future sales of the Company's State of New Jersey net operating losses well as the remaining availability under the Capital on Demand Equity Facility with JonesTrading Institutional Services LLC, the Company believes it has sufficient capital resources to fund its operations through mid-2021.

	Three Months Ended March 31,			
	(In thousands)		Change Increase (Decrease)	
	2020	2019		%
Licensing Revenue:	$ 125	$ 125	$ -	-%
Operating Expenses:				
Clinical Research	1,819	1,780	39	2.2%
Chemistry, Manufacturing and Controls	1,233	988	245	24.7%
Research and development expenses	3,052	2,768	284	10.3%
General and administrative expenses	1,839	2,218	(379)	(17.0)%
Total operating expenses	4,891	4,986	(95)	(4.2)%
Loss from operations	$ (4,766)	$ (4,861)	$ (95)	1.9%

Comparison of the Three Months Ended March 31, 2020 and 2019

Licensing Revenue

In January 2013, we entered into a technology development contract with Hisun, pursuant to which Hisun paid us a non-refundable technology transfer fee of $5.0 million to support our development of ThermoDox® in the China territory. The $5.0 million received as a non-refundable payment from Hisun in the first quarter 2013 has been recorded to deferred revenue and will be amortized over the ten-year term of the agreement; therefore, we recorded deferred revenue of $125,000 in each of the first quarters of 2020 and 2019.

Research and Development Expenses

Research and development ("R&D") expenses increased by $0.3 million to $3.1 million in the first quarter of 2020 from $2.8 million in the same period of 2019. Costs associated with the OPTIMA Study decreased to $0.7 million in the first quarter of 2020 compared to $0.9 million in the same period of 2019. Costs associated the OVATION 2 Study increased to $0.3 million in the first quarter of 2020 compared to $0.1 million in the same period of 2019. Regulatory costs were $0.2 million in each of the first quarters of 2020 and 2019. Other clinical costs were consistent at $0.6 million in each of the first quarters of 2020 and 2019. Costs associated with the production of GEN-1 clinical supplies were consistent at $0.3 million in each of the first quarters of 2020 and 2019. R&D costs associated with the development of GEN-1 to support the OVATION 2 Study increased to $0.9 million in the first quarter of 2020 compared to $0.6 million in the same period of 2019.

General and Administrative Expenses

General and administrative expenses decreased to $1.8 million in the first quarter of 2020 compared to $2.2 million in the same period of 2019. This decrease is primarily attributable to lower personnel costs of approximately $0.3 million which included a $0.2 million decrease in non-cash stock compensation expense and a decrease in professional fees of $0.2 million in the first quarter of 2020 when compared to the same period of 2019. The decrease was partially offset by an increase in premiums for directors' and officers' insurance for 2020.

Change in Earn-out Milestone Liability and Warrant Expense

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.

On March 28, 2019, the Company and EGWU, Inc, entered into the Amended Asset Purchase Agreement discussed in Note 8. Pursuant to the Amended Asset Purchase Agreement, payment of the earnout milestone liability related to the Ovarian Cancer Indication of $12.4 million has been modified. The Company has the option to make the payment as follows:

- $7.0 million in cash within 10 business days of achieving the milestone; or
- $12.4 million in cash, common stock of the Company, or a combination of either, within one year of achieving the milestone.

The Company provided EGWU, Inc. 200,000 warrants to purchase common stock at a strike price of $0.01 per warrant share as consideration for entering into the amended agreement. These warrant shares have no expiration and were fair valued at $2.00 using the closing price of a share of Celsion stock on the date of issuance offset by the exercise price and recorded as an expense in the income statement and were classified as equity on the balance sheet.

As of March 31, 2020, and December 31, 2019, the Company fair valued the earn-out milestone liability at $5.8 million and $5.7 million, respectively and recognized a non-cash charge of $0.1 million for the three-months ended March 31, 2020. In assessing the earnout milestone liability at March 31, 2020, the Company fair valued each of the two payment options per the Amended Asset Purchase Agreement and weighted them at 80% and 20% probability for the $7.0 million and the $12.4 million payments, respectively.

As of March 31, 2019, and December 31, 2018, the Company fair valued the earn-out milestone liability at $5.8 million and $8.9 million, respectively and recognized a non-cash benefit of $3.1 million during the three months ended March 31, 2019. In assessing the earnout milestone liability at March 31, 2019, the Company the fair valued each of the two payment options per the Amended Asset Purchase Agreement and weighted them at 80% and 20% probability for the $7.0 million and the $12.4 million payments, respectively.

Investment income and interest expense

The Company realized $0.1 million of interest income from its short-term investments during each of the first quarters of 2020 and 2019.

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 $0.3 million in interest expense in each of the first quarters of 2020 and 2019.

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 $296 million at March 31, 2020.

At March 31, 2020 we had total current assets of $18.9 million (including cash, cash equivalents and short-term investments, related interest receivable on short-term investments and receivable from sale of its New Jersey net operating losses of $17.5 million) and current liabilities of $7.4 million, resulting in net working capital of $11.5 million. At December 31, 2019 we had total current assets of $16.2 million (including cash, cash equivalents, short-term investment, interest receivable of $14.9 million) and current liabilities of $7.9 million, resulting in net working capital of $8.3 million. We have substantial future capital requirements to continue our research and development activities and advance our product candidates through various development stages. The Company believes these expenditures are essential for the commercialization of its technologies.

Net cash used in operating activities for the first three months of 2020 was $5.0 million. Net cash used in investing activities was $1.9 million during the first three months of 2020. Net cash provided by financing activities was $5.8 million during the first three months of 2020 from net proceeds received through the sale of our common stock.

We expect to seek additional capital through further public or private equity offerings, debt financing, additional strategic alliance and licensing arrangements, collaborative arrangements, potential sales of our net operating losses, 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, collaborators, or sales of our net operating losses, 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

None.

Item 3. QUANTITATIVE AND QUALITATIVE DISCLOSURE ABOUT MARKET RISK

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

Item 4. CONTROLS AND PROCEDURES

We have carried out an evaluation, under the supervision and with the participation of management, including our principal executive officer and principal financial officer, of the effectiveness of the design and operation of our disclosure controls and procedures, as that term is defined in Rule 13a-15(e) under the Securities Exchange Act of 1934, as amended. Based on that evaluation, our principal executive officer and principal financial officer have concluded that, as of March 31, 2020, 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 control over financial reporting identified in connection with the evaluation that occurred during the period covered by this report that have materially affected, or are reasonably likely to materially affect, our internal control 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

On September 20, 2019, a purported stockholder of the Company filed a derivative and putative class action lawsuit in the Superior Court of New Jersey, Chancery Division, against the Company (as both a class action defendant and nominal defendant), certain officers and directors), with the caption *O'Connor v. Braun et al.*, Docket No. MER-C-000068-19 (the "Shareholder Action"). The Shareholder Action alleges breaches of the defendants' fiduciary based on allegations that the Defendants made or approved improper statements when seeking shareholder approval of the 2018 Stock Incentive Plan. The Shareholder Action seeks, among other things, any damages sustained by the Company as a result of the defendants' alleged wrongdoing, a declaratory judgment against all defendants invalidating the 2018 Stock Incentive Plan and declaring any awards made under the Plan invalid, rescinded, and subject to disgorgement, an order disgorging the equity awards granted to the individual defendants under the 2018 Stock Incentive Plan, and attorneys' fees and costs.

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, 2019 filed on March 25, 2020 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 $296 million at March 31, 2020. For the year ended December 31, 2019 and the three months ended March 31, 2020, we incurred net losses of $16.9 million and $5.1 million, respectively. We currently have no product revenue and do not expect to generate any product revenue for the foreseeable future. Because we are committed to continuing our product research, development, clinical trial and commercialization programs, we will continue to incur significant operating losses unless and until we complete the development of ThermoDox®, GEN-1 and other new product candidates and these product candidates have been clinically tested, approved by the United States Food and Drug Administration (FDA) and successfully marketed. The amount of future losses is uncertain. Our ability to achieve profitability, if ever, will depend on, among other things, us or our collaborators successfully developing product candidates, obtaining regulatory approvals to market and commercialize product candidates, manufacturing any approved products on commercially reasonable terms, delays or setbacks we may experience associated with our preclinical studies, clinical trials, third parties, or supply chain due to the COVID-19 pandemic, 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.

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, including GEN-1, are still in various stages of development and trials and cannot be marketed until we have completed clinical testing and obtained necessary governmental approval. Following our announcement on January 31, 2013 that the HEAT Study failed to meet its primary endpoint of progression free survival, we continued to follow the patients enrolled in the HEAT Study to the secondary endpoint, overall survival. Based on the overall survival data from the post-hoc analysis of results from the HEAT Study, we launched a pivotal, double-blind, placebo-controlled Phase III trial of ThermoDox® in combination with RFA in primary liver cancer, known as the OPTIMA Study, in the first half of 2014. 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 completing enrollment in 2017. We also expanded our ovarian cancer development program to include a Phase I/II dose escalating trial evaluating GEN-1 in ovarian cancer patients. Our delivery technology platforms, TheraPlas and TheraSilence, are in preclinical stages of development. Accordingly, our revenue sources are, and will remain, extremely limited until our product candidates are clinically tested, approved by the FDA or foreign regulatory agencies and successfully marketed. We cannot guarantee that any of our product candidates will be approved by the FDA or any foreign regulatory agency or marketed, successfully or otherwise, at any time in the foreseeable future or at all.

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 our earlier Phase III clinical trial.

On January 31, 2013, we announced that our lead product ThermoDox® in combination with radiofrequency ablation (RFA) failed to meet the primary endpoint of the Phase III clinical trial for primary liver cancer, known as the HEAT study. We have not completed our final analysis of the data and do not know the extent to which, if any, the failure of ThermoDox® to meet its primary endpoint in the Phase III trial could impact our other ongoing studies of ThermoDox® including a pivotal, double-blind, placebo-controlled Phase III trial of ThermoDox® in combination with RFA in primary liver cancer, known as the OPTIMA study, which we launched in the first half of 2014. The trial design of the OPTIMA study is based on the overall survival data from the post-hoc analysis of results from the HEAT study. ThermoDox® is also being evaluated in a Phase II clinical trial for recurrent chest wall breast cancer and other preclinical studies. In addition, we have initiated a Phase I dose-escalation clinical trial of GEN-1 in combination with the standard of care in neo-adjuvant ovarian cancer, known as the OVATION Study, and plan to expand our ovarian cancer development program to include a Phase I/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. For the year ended December 31, 2019 and the three months ended March 31, 2020, we incurred net losses of $16.9 million and $5.1 million, respectively. We have incurred approximately $296 million of cumulative net losses. As of March 31, 2020, cash, cash equivalents and short-term investments, related interest receivable on short-term investments and receivable on sale of its New Jersey net operating losses of $17.5 million.

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 expanded our clinical development program for GEN-1 into a follow-on Phase I/II trial for newly diagnosed ovarian cancer in 2018.

To complete the development and commercialization of our product candidates, we will need to raise substantial amounts of additional capital to fund our operations. Our future capital requirements will depend upon numerous unpredictable factors, including, without limitation, the cost, timing, progress and outcomes of clinical studies and regulatory reviews of our proprietary drug candidates, including any unforeseen delays or increased costs we may incur as a result of the COVID-19 pandemic or other causes, our efforts to implement new collaborations, licenses and strategic transactions, general and administrative expenses, capital expenditures and other unforeseen uses of cash. We do not have any committed sources of financing and cannot assure you that alternate funding will be available in a timely manner, on acceptable terms or at all. We may need to pursue dilutive equity financings, such as the issuance of shares of common stock, convertible debt or other convertible or exercisable securities. Such dilutive equity financings could dilute the percentage ownership of our current common stockholders and could significantly lower the market value of our common stock. In addition, a financing could result in the issuance of new securities that may have rights, preferences or privileges senior to those of our existing stockholders.

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

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

To obtain regulatory approvals from the FDA and foreign regulatory agencies, we must conduct clinical trials demonstrating that our products are safe and effective. We may need to amend ongoing trials, or the FDA and/or foreign regulatory agencies may require us to perform additional trials beyond those we planned. The testing and approval process require substantial time, effort and resources, and generally takes a number of years to complete. The time to complete testing and obtaining approvals is uncertain, and the FDA and foreign regulatory agencies have substantial discretion, at any phase of development, to terminate clinical studies, require additional clinical studies or other testing, delay or withhold approval, and mandate product withdrawals, including recalls. In addition, our drug candidates may have undesirable side effects or other unexpected characteristics that could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restricted label or the delay or denial of regulatory approval by regulatory authorities.

Even if we receive regulatory approval of a product, the approval may limit the indicated uses for which the drug may be marketed. The failure to obtain timely regulatory approval of product candidates, the imposition of marketing limitations, or a product withdrawal would negatively impact our business, results of operations and financial condition. Even if we receive approval, we will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense and subject us to restrictions, withdrawal from the market, or penalties if we fail to comply with applicable regulatory requirements or if we experience unanticipated problems with our product candidates, when and if approved. Finally, even if we obtain FDA approval of any of our product candidates, we may never obtain approval or commercialize such products outside of the United States, given that we may be subject to additional or different regulatory burdens in other markets. This could limit our ability to realize their full market potential.

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

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

- factors related to the COVID-19 pandemic, including regulators or institutional review boards, or IRBs, or ethics committees may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site
- any preclinical test or clinical trial may fail to produce safety and efficacy results satisfactory to the FDA or comparable foreign regulatory authorities;
- preclinical and clinical data can be interpreted in different ways, which could delay, limit or prevent marketing approval;
- negative or inconclusive results from a preclinical test or clinical trial or adverse events during a clinical trial could cause a preclinical study or clinical trial to be repeated or a development program to be terminated, even if other studies relating to the development program are ongoing or have been completed and were successful;
- the FDA or comparable foreign regulatory authorities can place a clinical hold on a trial if, among other reasons, it finds that subjects enrolled in the trial are or would be exposed to an unreasonable and significant risk of illness or injury;
- the facilities that we utilize, or the processes or facilities of third-party vendors, including without limitation the contract manufacturers who will be manufacturing drug substance and drug product for us or any potential collaborators, may not satisfactorily complete inspections by the FDA or comparable foreign regulatory authorities; and
- we may encounter delays or rejections based on changes in FDA policies or the policies of comparable foreign regulatory authorities during the period in which we develop a product candidate, or the period required for review of any final marketing approval before we are able to market any product candidate.

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

Separately, in response to the COVID-19 global pandemic, on March 10, 2020, the FDA announced its intention to postpone most inspections of foreign manufacturing facilities and products through at least April 2020, though no set end date has been determined. On March 18, 2020, the FDA announced its intention to temporarily postpone routine surveillance inspections of domestic manufacturing facilities. Regulatory authorities outside the United States may adopt similar restrictions or other policy measures in response to the COVID-19 pandemic and provide guidance regarding the conduct of clinical trials , which guidance continues to evolve. In April 2020, the FDA stated that its New Drug Program was continuing to meet program user fee performance goals, but due to many agency staff working on COVID-19 activities, it was possible that the FDA would not be able to sustain that level of performance indefinitely. If global health concerns continue to prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews or other regulatory activities, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business

The outbreak of the novel coronavirus disease, COVID-19, could adversely impact our business, including our preclinical studies and clinical trials.

In December 2019, a novel strain of coronavirus, severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), was identified in Wuhan, China. This disease resulting from SARS-CoV-2, COVID-19, has now become a global pandemic. The outbreak and government measures taken in response have had a significant impact, both directly and indirectly, on businesses and commerce throughout the world generally: worker shortages have occurred; supply chains have been disrupted; facilities and production have been suspended; and demand for certain goods and services, such as medical services and supplies, has spiked, while demand for other goods and services, such as travel, has fallen. In response to the spread of COVID-19, our personnel have mainly been continuing their work outside of our offices. While, as of the date of this report, we have not experienced any material disruptions to the execution of the clinical trials and the research and development activities that we currently have underway, as a result of the pandemic we may experience disruptions that could severely impact research and development timelines and outcomes, including, but not limited to:

- delays or difficulties in enrolling patients in our clinical trials;
- delays or difficulties in clinical site initiation, including difficulties in recruiting clinical site investigators and clinical site staff;
- diversion of healthcare resources away from the conduct of clinical trials, including the diversion of hospitals serving as our clinical trial sites and hospital staff supporting the conduct of our clinical trials;
- interruption of key clinical trial activities, such as clinical trial site data monitoring, due to limitations on travel imposed or recommended by federal, state or foreign governments, employers and others or interruption of clinical trial subject visits and study procedures (such as procedures that are deemed non-essential under law, regulation or institutional policies), which may impact the integrity of subject data and clinical study endpoints;
- interruption or delays in the operations of the FDA or other regulatory authorities, which may impact review and approval timelines;
- interruption of, or delays in receiving, supplies of our product candidates from our contract manufacturing organizations due to staffing shortages, production slowdowns or stoppages and disruptions in delivery systems;
- interruptions in preclinical studies due to restricted or limited operations at our contracted research facilities;
- unforeseen costs we may incur as a result of the impact of the COVID-19 pandemic, including the costs of mitigation efforts;
- deterioration of worldwide credit and financial markets that could limit our ability to obtain external financing to fund our operations and capital expenditures;
- investment-related risks, including difficulties in liquidating investments due to current market conditions and adverse investment performance;
- limitations on employee resources that would otherwise be focused on the conduct of our research and development activities, including because of sickness of employees or their families or the desire of employees to avoid contact with large groups of people; or
- interruptions or limitations of the types described affecting our service providers and collaboration partners, including contract research organizations running clinical trials and collaboration partners sponsoring clinical trials in which we are supplying our product candidates or otherwise participating.

In addition, the trading prices for common stock of other biopharmaceutical companies have been highly volatile as a result of the COVID-19 pandemic. The COVID-19 pandemic continues to rapidly evolve. The extent to which the outbreak impacts our business, preclinical studies and clinical trials will depend on future developments, which are highly uncertain and cannot be predicted with confidence, such as the ultimate geographic spread of the disease, the duration of the pandemic, travel restrictions and social distancing in the United States and other countries, business closures or business disruptions and the effectiveness of actions taken in the United States and other countries to diagnose, contain and treat the disease. If we or any of the third parties with whom we engage were to experience shutdowns or other business disruptions, our ability to conduct our business and development activities in the manner and on the timelines presently planned could be materially and negatively impacted. There can be no assurance that any such disruptions or delays will not materially adversely impact our business, results of operations, access to financial resources and our financial condition.

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

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

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

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

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

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

Even if our product candidates initially show promise in these early clinical trials, the side effects of drugs are frequently only detectable after they are tested in large, Phase 3 clinical trials or, in some cases, after they are made available to patients on a commercial scale after approval. Sometimes, it can be difficult to determine if the serious adverse or unexpected side effects were caused by the product candidate or another factor, especially in oncology subjects who may suffer from other medical conditions and be taking other medications. If serious adverse or unexpected side effects are identified during development and are determined to be attributed to our product candidate, we may be required to develop a Risk Evaluation and Mitigation Strategy (REMS) to mitigate those serious safety risks, which could impose significant distribution and use restrictions on our products.

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

If we encounter difficulties enrolling patients in our clinical trials, our clinical development activities could be delayed or otherwise adversely affected.

We may experience difficulties in patient enrollment in our clinical trials for a variety of reasons. The timely completion of clinical trials in accordance with their protocols depends, among other things, on our ability to enroll a sufficient number of patients who remain in the trial until its conclusion. The enrollment of patients depends on many factors, including:

- the patient eligibility and exclusion criteria defined in the protocol;
- the size of the patient population required for analysis of the trial's primary endpoints and the process for identifying patients;
- delays in our research programs resulting from factors related to the COVID-19 pandemic;
- the willingness or availability of patients to participate in our trials;
- the proximity of patients to trial sites;
- the design of the trial;
- our ability to recruit clinical trial investigators with the appropriate competencies and experience;
- clinicians' and patients' perceptions as to the potential advantages and risks of the product candidate being studied in relation to other available therapies, including any new products that may be approved for the indications we are investigating;
- the availability of competing commercially available therapies and other competing drug candidates' clinical trials;
- our ability to obtain and maintain patient informed consents; and
- the risk that patients enrolled in clinical trials will drop out of the trials before completion.

In addition, our clinical trials will compete with other clinical trials for product candidates that are in the same therapeutic areas as our product candidates, and this competition will reduce the number and types of patients available to us, because some patients who might have opted to enroll in our trials may instead opt to enroll in a trial being conducted by one of our competitors. Since the number of qualified clinical investigators is limited, we expect to conduct some of our clinical trials at the same clinical trial sites that some of our competitors use, which will reduce the number of patients who are available for our clinical trials in such clinical trial site. Certain of our planned clinical trials may also involve invasive procedures, which may lead some patients to drop out of trials to avoid these follow-up procedures.

Further, timely enrollment in clinical trials is reliant on clinical trial sites which may be adversely affected by global health matters, including, among other things, pandemics. For example, our clinical trial sites may be located in regions currently being affected by the COVID-19 coronavirus. Some factors from the COVID-19 coronavirus outbreak that we believe may adversely affect enrollment in our trials include:

- the diversion of healthcare resources away from the conduct of clinical trial matters to focus on pandemic concerns, including the attention of infectious disease physicians serving as our clinical trial investigators, hospitals serving as our clinical trial sites and hospital staff supporting the conduct of our clinical trials;

- patients who would otherwise be candidates for enrollment in our clinical trials, may become infected with the COVID-19 coronavirus, which may kill some patients and render others too ill to participate, limiting the available pool of participants for our trials;

- limitations on travel that interrupt key trial activities, such as clinical trial site initiations and monitoring;

- interruption in global shipping affecting the transport of clinical trial materials, such as investigational drug product and comparator drugs used in our trials; and

- employee furlough days that delay necessary interactions with local regulators, ethics committees and other important agencies and contractors.

These and other factors arising from the COVID-19 coronavirus could worsen in countries that are already afflicted with the virus or could continue to spread to additional countries, each of which may further adversely impact our clinical trials. The global outbreak of the COVID-19 coronavirus continues to evolve and the conduct of our trials may continue to be adversely affected, despite efforts to mitigate this impact.

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

In the future, we may consider strategic alternatives intended to further the development of our business, which may include acquiring businesses, technologies or products, out- or in-licensing product candidates or technologies or entering into a business combination with another company. Any strategic transaction may require us to incur non-recurring or other charges, increase our near- and long-term expenditures and pose significant integration or implementation challenges or disrupt our management or business. These transactions would entail numerous operational and financial risks, including exposure to unknown liabilities, disruption of our business and diversion of our management's time and attention in order to manage a collaboration or develop acquired products, product candidates or technologies, incurrence of substantial debt or dilutive issuances of equity securities to pay transaction consideration or costs, higher than expected collaboration, acquisition or integration costs, write-downs of assets or goodwill or impairment charges, increased amortization expenses, difficulty and cost in facilitating the collaboration or combining the operations and personnel of any acquired business, impairment of relationships with key suppliers, manufacturers or customers of any acquired business due to changes in management and ownership and the inability to retain key employees of any acquired business. Accordingly, although there can be no assurance that we will undertake or successfully complete any transactions of the nature described above, any transactions that we do complete may be subject to the foregoing or other risks and have a material adverse effect on our business, results of operations, financial condition and prospects. Conversely, any failure to enter any strategic transaction that would be beneficial to us could delay the development and potential commercialization of our product candidates and have a negative impact on the competitiveness of any product candidate that reaches market.

Strategic transactions, such as acquisitions, partnerships and collaborations, including the EGEN asset 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 asset 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 asset 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 another's claimed proprietary rights.

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

The patent positions of pharmaceutical and biotechnology companies, such as ours, are uncertain and involve complex legal and factual issues. We own various U.S. and international patents and have pending U.S. and international patent applications that cover various aspects of our technologies. There can be no assurance that patents that have issued will be held valid and enforceable in a court of law through the entire patent term. Even for patents that are held valid and enforceable, the legal process associated with obtaining such a judgment is time consuming and costly. Additionally, issued patents can be subject to opposition, interferences or other proceedings that can result in the revocation of the patent or maintenance of the patent in amended form (and potentially in a form that renders the patent without commercially relevant or broad coverage). Further, our competitors may be able to circumvent and otherwise design around our patents. Even if a patent is issued and enforceable, because development and commercialization of pharmaceutical products can be subject to substantial delays, patents may expire early and provide only a short period of protection, if any, following the commercialization of products encompassed by our patents. We may have to participate in interference proceedings declared by the U.S. Patent and Trademark Office, which could result in a loss of the patent and/or substantial cost to us.

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

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

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

We rely on trade secrets and confidential information that we seek to protect, in part, by confidentiality agreements with our corporate partners, collaborators, employees and consultants. We cannot assure you that these agreements are adequate to protect our trade secrets and confidential information or will not be breached or, if breached, we will have adequate remedies. Furthermore, others may independently develop substantially equivalent confidential and proprietary information or otherwise gain access to our trade secrets or disclose such technology. Any loss of trade secret protection or other unpatented proprietary rights could harm our business, results of operations and financial condition.

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

Our commercial success depends on our ability to operate without infringing the patents and other proprietary rights of third parties. There may be third party patents that relate to our products and technology. We may unintentionally infringe upon valid patent rights of third parties. Although we currently are not involved in any material litigation involving patents, a third-party patent holder may assert a claim of patent infringement against us in the future. Alternatively, we may initiate litigation against the third-party patent holder to request that a court declare that we are not infringing the third party's patent and/or that the third party's patent is invalid or unenforceable. If a claim of infringement is asserted against us and is successful, and therefore we are found to infringe, we could be required to pay damages for infringement, including treble damages if it is determined that we knew or became aware of such a patent and we failed to exercise due care in determining whether or not we infringed the patent. If we have supplied infringing products to third parties or have licensed third parties to manufacture, use or market infringing products, we may be obligated to indemnify these third parties for damages they may be required to pay to the patent holder and for any losses they may sustain.

We can also be prevented from selling or commercializing any of our products that use the infringing technology in the future, unless we obtain a license from such third party. A license may not be available from such third party on commercially reasonable terms or may not be available at all. Any modification to include a non-infringing technology may not be possible, or if possible, may be difficult or time-consuming to develop, and require revalidation, which could delay our ability to commercialize our products. Any infringement action asserted against us, even if we are ultimately successful in defending against such action, would likely delay the regulatory approval process of our products, harm our competitive position, be expensive and require the time and attention of our key management and technical personnel.

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

We do not independently conduct clinical trials for our drug candidates. We rely, and expect to continue to rely, on third-party clinical investigators, clinical research organizations (CROs), clinical data management organizations and consultants to design, conduct, supervise and monitor our clinical trials.

Because we do not conduct our own clinical trials, we must rely on the efforts of others and have reduced control over aspects of these activities, including, the timing of such trials, the costs associated with such trials and the procedures that are followed for such trials. We do not expect to significantly increase our personnel in the foreseeable future and may continue to rely on third parties to conduct all of our future clinical trials. If we cannot contract with acceptable third parties on commercially reasonable terms or at all, if these third parties are unable to carry out their contractual duties or obligations in a manner that is consistent with our expectations or meet expected deadlines, if they do not carry out the trials in accordance with budgeted amounts, if the quality or accuracy of the clinical data they obtain is compromised due to their failure to adhere to our clinical protocols or for other reasons, or if they fail to maintain compliance with applicable government regulations and standards, our clinical trials may be extended, delayed or terminated or may become significantly more expensive, we may not receive development milestone payments when expected or at all, and we may not be able to obtain regulatory approval for or successfully commercialize our product candidates.

Despite our reliance on third parties to conduct our clinical trials, we are ultimately responsible for ensuring that each of our clinical trials is conducted in accordance with the general investigational plan and protocols for the trial. Moreover, the FDA requires clinical trials to be conducted in accordance with good clinical practices for conducting, recording and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of clinical trial participants are protected. We also are required to register ongoing clinical trials and post the results of completed clinical trials on a government-sponsored database, ***ClinicalTrials.gov***, within certain timeframes. Failure to do so can result in fines, adverse publicity and civil and criminal sanctions. Our reliance on third parties that we do not control does not relieve us of these responsibilities and requirements. If we or a third party we rely on fails to meet these requirements, we may not be able to obtain, or may be delayed in obtaining, marketing authorizations for our drug candidates and will not be able to, or may be delayed in our efforts to, successfully commercialize our drug candidates. This could have a material adverse effect on our business, financial condition, results of operations and prospects.

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

We rely on third party supply and manufacturing partners to supply the materials and components for, and manufacture, our research and development, preclinical and clinical trial drug supplies. We do not own manufacturing facilities or supply sources for such components and materials. There can be no assurance that our supply of research and development, preclinical and clinical development drugs and other materials will not be limited, interrupted, restricted in certain geographic regions or of satisfactory quality or continue to be available at acceptable prices. Suppliers and manufacturers must meet applicable manufacturing requirements and undergo rigorous facility and process validation tests required by FDA and foreign regulatory authorities in order to comply with regulatory standards, such as current Good Manufacturing Practices. In the event that any of our suppliers or manufacturers fails to comply with such requirements or to perform its obligations to us in relation to quality, timing or otherwise, or if our supply of components or other materials becomes limited or interrupted for other reasons, we may be forced to manufacture the materials ourselves, for which we currently do not have the capabilities or resources, or enter into an agreement with another third party, which we may not be able to do on reasonable terms, if at all.

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

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

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

We are subject to the periodic inspection of our clinical trials, facilities, procedures and operations and/or the testing of our products by the FDA to determine whether our systems and processes, or those of our vendors and suppliers, are in compliance with FDA regulations. Following such inspections, the FDA may issue notices on Form 483 and warning letters that could cause us to modify certain activities identified during the inspection.

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

We are also subject to recordkeeping and reporting regulations. These regulations require, among other things, the reporting to the FDA of adverse events alleged to have been associated with the use of a product or in connection with certain product failures. Labeling and promotional activities also are regulated by the FDA. We must also comply with record keeping requirements as well as requirements to report certain adverse events involving our products. The FDA can impose other post-marketing controls on us as well as our products including, but not limited to, restrictions on sale and use, through the approval process, regulations and otherwise.

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

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

We have obtained Orphan Drug Designation for ThermoDox® and may seek Orphan Drug Designation for other product candidates, but we may be unsuccessful or may be unable to maintain the benefits associated with Orphan Drug Designation, including the potential for market exclusivity.

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

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

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

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

Our relationships with healthcare providers and physicians and third-party payors will be subject to applicable anti-kickback, fraud and abuse and other healthcare laws and regulations, which could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm and diminished profits and future earnings.

Healthcare providers, physicians and third-party payors in the United States and elsewhere play a primary role in the recommendation and prescription of biopharmaceutical products. Arrangements with third-party payors and customers can expose biopharmaceutical manufacturers to broadly applicable fraud and abuse and other healthcare laws and regulations, including, without limitation, the federal Anti-Kickback Statute and the federal False Claims Act, which may constrain the business or financial arrangements and relationships through which such companies sell, market and distribute biopharmaceutical products. In particular, the research of our product candidates, as well as the promotion, sales and marketing of healthcare items and services, as well as certain business arrangements in the healthcare industry, are subject to extensive laws designed to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, structuring and commission(s), certain customer incentive programs and other business arrangements generally. Activities subject to these laws also involve the improper use of information obtained in the course of patient recruitment for clinical trials. The applicable federal, state and foreign healthcare laws and regulations laws that may affect our ability to operate include, but are not limited to:

- the federal Anti-Kickback Statute, which prohibits, among other things, knowingly and willfully soliciting, receiving, offering or paying any remuneration (including any kickback, bribe, or rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual, or the purchase, lease, order or recommendation of any good, facility, item or service for which payment may be made, in whole or in part, under a federal healthcare program, such as the Medicare and Medicaid programs. A person or entity can be found guilty of violating the statute without actual knowledge of the statute or specific intent to violate it. In addition, a claim submitted for payment to any federal health care program that includes items or services that were made as a result of a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal False Claims Act, or FCA. The Anti-Kickback Statute has been interpreted to apply to arrangements between biopharmaceutical manufacturers on the one hand and prescribers, purchasers, and formulary managers, among others, on the other. There are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution;

- the federal civil and criminal false claims laws, including the FCA, and civil monetary penalty laws which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, false, fictious or fraudulent claims for payment to, or approval by Medicare, Medicaid, or other federal healthcare programs; knowingly making, using or causing to be made or used a false record or statement material to a false or fraudulent claim or an obligation to pay or transmit money or property to the federal government; or knowingly concealing or knowingly and improperly avoiding or decreasing or concealing an obligation to pay money to the federal government. A claim that includes items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim under the FCA. Manufacturers can be held liable under the FCA even when they do not submit claims directly to government payors if they are deemed to "cause" the submission of false or fraudulent claims. The FCA also permits a private individual acting as a "whistleblower" to bring qui tam actions on behalf of the federal government alleging violations of the FCA and to share in any monetary recovery;

- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which created additional federal criminal statutes that prohibit knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of the payor (e.g., public or private) and knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false statements in connection with the delivery of, or payment for, healthcare benefits, items or services relating to healthcare matters. Similar to the federal Anti-Kickback Statute, a person or entity can be found guilty of violating HIPAA without actual knowledge of the statute or specific intent to violate it;

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and their respective implementing regulations, which impose, among other things, requirements relating to the privacy, security and transmission of individually identifiable health information on certain covered healthcare providers, health plans, and healthcare clearinghouses, known as covered entities, as well as their respective "business associates," those independent contractors or agents of covered entities that perform services for covered entities that involve the creation, use, receipt, maintenance or disclosure of individually identifiable health information. HITECH also created new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorneys' fees and costs associated with pursuing federal civil actions;

- the federal Physician Payments Sunshine Act, created under the ACA, and its implementing regulations, which require some manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report annually to CMS information related to payments or other transfers of value made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members. Effective January 1, 2022, these reporting obligations will extend to include transfers of value made in the previous year to certain non-physician providers such as physician assistants and nurse practitioners;

- federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers; and

- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, which may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by third-party payors, including private insurers, and may be broader in scope than their federal equivalents; state and foreign laws that require biopharmaceutical companies to comply with the biopharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state and foreign laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers, marketing expenditures or drug pricing; state and local laws that require the registration of biopharmaceutical sales representatives; and state and foreign laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

The distribution of biopharmaceutical products is subject to additional requirements and regulations, including extensive record-keeping, licensing, storage and security requirements intended to prevent the unauthorized sale of biopharmaceutical products.

The scope and enforcement of each of these laws is uncertain and subject to rapid change in the current environment of healthcare reform, especially in light of the lack of applicable precedent and regulations. Ensuring business arrangements comply with applicable healthcare laws, as well as responding to possible investigations by government authorities, can be time- and resource-consuming and can divert a company's attention from the business.

It is possible that governmental and enforcement authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law interpreting applicable fraud and abuse or other healthcare laws and regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, reputational harm, possible exclusion from participation in federal and state funded healthcare programs, contractual damages and the curtailment or restricting of our operations, as well as additional reporting obligations and oversight if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with these laws. Further, if any of the physicians or other healthcare providers or entities with whom we expect to do business is found to be not in compliance with applicable laws, they may be subject to significant criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs. Any action for violation of these laws, even if successfully defended, could cause a biopharmaceutical manufacturer to incur significant legal expenses and divert management's attention from the operation of the business. Prohibitions or restrictions on sales or withdrawal of future marketed products could materially affect business in an adverse way.

Ongoing legislative and regulatory changes affecting the healthcare industry could have a material adverse effect on our business.

Political, economic and regulatory influences are subjecting the healthcare industry to potential fundamental changes that could substantially affect our results of operations by requiring, for example: (i) changes to our manufacturing arrangements; (ii) additions or modifications to product labeling; (iii) the recall or discontinuation of our products; or (iv) additional record-keeping requirements.

In the United States, there have been and continue to be a number of legislative initiatives to contain healthcare costs. For example, in March 2010, the ACA was passed, which substantially changed the way health care is financed by both governmental and private insurers, and significantly impacted the U.S. biopharmaceutical industry. The ACA, among other things, addressed a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected, increased the minimum Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program and extended the rebate program to individuals enrolled in Medicaid managed care organizations, established annual fees and taxes on manufacturers of certain branded prescription drugs, and created a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 70% (increased pursuant to the Bipartisan Budget Act of 2018, effective as of 2019) point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D.

Since its enactment, some of the provisions of the ACA have yet to be fully implemented, while certain provisions have been subject to judicial, congressional, and executive challenges. As a result, there have been delays in the implementation of, and action taken to repeal or replace, certain aspects of the ACA. Since January 2017, President Trump has signed two Executive Orders designed to delay the implementation of certain provisions of the ACA or otherwise circumvent some of the requirements for health insurance mandated by the ACA. One Executive Order directs federal agencies with authorities and responsibilities under the ACA to waive, defer, grant exemptions from, or delay the implementation of any provision of the ACA that would impose a fiscal or regulatory burden on states, individuals, healthcare providers, health insurers, or manufacturers of pharmaceuticals or medical devices. The second Executive Order terminates the cost-sharing subsidies that reimburse insurers under the ACA. Several state Attorneys General filed suit to stop the administration from terminating the subsidies, but their request for a restraining order was denied by a federal judge in California on October 25, 2017. The loss of the cost share reduction payments is expected to increase premiums on certain policies issued by qualified health plans under the ACA. Further, on June 14, 2018, U.S. Court of Appeals for the Federal Circuit ruled that the federal government was not required to pay more than $12 billion in ACA risk corridor payments to third-party payors who argued were owed to them. On December 10, 2019, the U.S. Supreme Court heard arguments in *Moda Health Plan, Inc. v. United States*, which will determine whether the government must make risk corridor payments. The U.S. Supreme Court's decision will be released in the coming months, but we cannot predict how the U.S. Supreme Court will rule. The effects of this gap in reimbursement on third-party payors, the viability of the ACA marketplace, providers, and potentially our business, are not yet known. While Congress has not passed comprehensive repeal legislation, it has enacted laws that modify certain provisions of the Affordable Care Act such as removing penalties, starting January 1, 2019, for not complying with the Affordable Care Act's individual mandate to carry health insurance, delaying the implementation of certain Affordable Care Act-mandated fees, and increasing the point-of-sale discount that is owed by pharmaceutical manufacturers who participate in Medicare Part D. On December 14, 2018, a Texas U.S. District Court Judge ruled that the ACA is unconstitutional in its entirety because the "individual mandate" was repealed by Congress as part of the Tax Cuts and Jobs Act of 2017. Additionally, on December 18, 2019, the U.S. Court of Appeals for the 5th Circuit upheld the District Court ruling that the individual mandate was unconstitutional and remanded the case back to the District Court to determine whether the remaining provisions of the ACA are invalid as well. On March 2, 2020, the United States Supreme Court granted the petitions for writs of certiorari to review this case, and has allotted one hour for oral arguments, which are expected to occur in the fall. We cannot predict what affect further changes to the ACA would have on our business.

Other legislative changes have been proposed and adopted in the United States since the ACA was enacted. The Budget Control Act of 2011, among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation's automatic reduction to several government programs, including aggregate reductions of Medicare payments to providers of 2% per fiscal year. These reductions went into effect on April 1, 2013 and, due to subsequent legislative amendments to the statute, including the Bipartisan Budget Act of 2018, or BBA, will remain in effect through 2030, unless additional congressional action is taken. The BBA also amended the ACA, effective January 1, 2019, by increasing the point-of-sale discount that is owed by pharmaceutical manufacturers who participate in Medicare Part D and closing the coverage gap in most Medicare drug plans, commonly referred to as the "donut hole". However, pursuant to the CARES Act, these reductions will be suspended from May 1, 2020 through December 31, 2020 due to the COVID-19 pandemic. On January 2, 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, further reduced Medicare payments to several types of providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

Moreover, increasing efforts by governmental and third-party payors in the United States and abroad to cap or reduce healthcare costs may cause such organizations to limit both coverage and the level of reimbursement for newly approved products and, as a result, they may not cover or provide adequate payment for our product candidates. There has been increasing legislative and enforcement interest in the United States with respect to specialty drug pricing practices. Specifically, there have been several recent U.S. Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under Medicare, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drugs. Several states have adopted price transparency requirements and those as well as any future federal price transparency requirements that may be implemented in the future could have a negative effect on our business. Additionally, we expect to experience pricing pressures in connection with the sale of any future approved product candidates due to the trend toward managed healthcare, the increasing influence of health maintenance organizations, cost containment initiatives and additional legislative changes.

At the federal level, the Trump administration's budget for fiscal year 2021 includes a $135 billion allowance to support legislative proposals seeking to reduce drug prices, increase competition, lower out-of-pocket drug costs for patients, and increase patient access to lower-cost generic and biosimilar drugs. The Trump administration previously released a "Blueprint" to lower drug prices and reduce out of pocket costs of drugs that contains additional proposals to increase manufacturer competition, increase the negotiating power of certain federal healthcare programs, incentivize manufacturers to lower the list price of their products and reduce the out of pocket costs of drug products paid by consumers. The U.S. Department of Health and Human Services, or HHS, has solicited feedback on some of these measures and has implemented others under its existing authority. For example, in May 2019, CMS issued a final rule that would allow Medicare Advantage Plans the option of using step therapy, a type of prior authorization, for Part B drugs beginning January 1, 2020. This final rule codified CMS's policy change that was effective January 1, 2019. Although a number of these and other measures may require additional authorization to become effective, Congress and the Trump administration have each indicated that it will continue to seek new legislative and/or administrative measures to control drug costs. For example, the Lower Drug Costs Now Act of 2019 was introduced in the House of Representatives on September 19, 2019 and would require HHS to directly negotiate drug prices with manufacturers. The Lower Drugs Costs Now Act of 2019 has passed out of the House and was delivered to the Senate on December 16, 2019. However, it is unclear whether this bill will make it through both chambers and be signed into law, and if enacted, what effect it would have on our business. Individual states in the United States have also increasingly passed legislation and implemented regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing

At the state level, legislatures are increasingly passing legislation and implementing regulations designed to control biopharmaceutical and biologic product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

We cannot predict what healthcare reform initiatives may be adopted in the future. Further, federal and state legislative and regulatory developments are likely, and we expect ongoing initiatives in the United States to increase pressure on drug pricing. Such reforms could have an adverse effect on anticipated revenues from reloxaliase and any other product candidates that we may successfully develop and for which we may obtain regulatory approval and may affect our overall financial condition and ability to develop product candidates.

We may fail to comply with evolving European and other privacy laws.

Since we conduct clinical trials in the European Economic Area ("EEA"), we are subject to additional European data-privacy laws. The General Data Protection Regulation, (EU) 2016/679 ("GDPR") became effective on May 25, 2018 and deals with the processing of personal data and on the free movement of such data. The GDPR imposes a broad range of strict requirements on companies subject to the GDPR, including requirements relating to having legal bases for processing personal information relating to identifiable individuals and transferring such information outside the EEA, including to the United States, providing details to those individuals regarding the processing of their personal information, keeping personal information secure, having data processing agreements with third parties who process personal information, responding to individuals' requests to exercise their rights in respect of their personal information, reporting security breaches involving personal data to the competent national data protection authority and affected individuals, appointing data protection officers, conducting data protection impact assessments, and record-keeping. The GDPR increases substantially the penalties to which we could be subject in the event of any non-compliance, including fines of up to 10,000,000 Euros or up to 2% of our total worldwide annual turnover for certain comparatively minor offenses, or up to 20,000,000 Euros or up to 4% of our total worldwide annual turnover for more serious offenses. Given the limited enforcement of the GDPR to date, we face uncertainty as to the exact interpretation of the new requirements on our trials and we may be unsuccessful in implementing all measures required by data protection authorities or courts in interpretation of the new law.

In particular, national laws of member states of the EU are in the process of being adapted to the requirements under the GDPR, thereby implementing national laws which may partially deviate from the GDPR and impose different obligations from country to country, so that we do not expect to operate in a uniform legal landscape in the EEA. Also, as it relates to processing and transfer of genetic data, the GDPR specifically allows national laws to impose additional and more specific requirements or restrictions, and European laws have historically differed quite substantially in this field, leading to additional uncertainty. Further, the impact of the impending "Brexit", (whereby the United Kingdom is planning to leave the EEA in March of 2019), either with or without a "deal" is uncertain and cannot be predicted at this time.

In the event we continue to conduct clinical trials in the EEA, we must also ensure that we maintain adequate safeguards to enable the transfer of personal data outside of the EEA, in particular to the United States, in compliance with European data protection laws. We expect that we will continue to face uncertainty as to whether our efforts to comply with our obligations under European privacy laws will be sufficient. If we are investigated by a European data protection authority, we may face fines and other penalties. Anype1 such investigation or charges by European data protection authorities could have a negative effect on our existing business and on our ability to attract and retain new clients or pharmaceutical partners. We may also experience hesitancy, reluctance, or refusal by European or multi-national clients or pharmaceutical partners to continue to use our products and solutions due to the potential risk exposure as a result of the current (and, in particular, future) data protection obligations imposed on them by certain data protection authorities in interpretation of current law, including the GDPR. Such clients or pharmaceutical partners may also view any alternative approaches to compliance as being too costly, too burdensome, too legally uncertain, or otherwise objectionable and therefore decide not to do business with us. Any of the foregoing could materially harm our business, prospects, financial condition and results of operations

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

Our ability to commercialize our new cancer treatment systems successfully will depend in part on the extent to which reimbursement for the costs of such products and related treatments will be available from third-party payors, which include government authorities such as Medicare, Medicaid, TRICARE, and the Veterans Administration, managed care providers, private health insurers, and other organizations. Patients who are provided medical treatment for their conditions generally rely on third-party payors to reimburse all or part of the costs associated with their treatment. Coverage and adequate reimbursement from governmental healthcare programs, such as Medicare and Medicaid, and commercial payors is critical to new product acceptance. Patients are unlikely to use our product candidates unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost. The reimbursement status of newly approved medical products is subject to significant uncertainty We cannot be sure that coverage and reimbursement will be available for, or accurately estimate the potential revenue from, our product candidates or assure that coverage and reimbursement will be available for any product that we may develop. Further, due to the COVID-19 pandemic, millions of individuals have lost or will be losing employer-based insurance coverage, which may adversely affect our ability to commercialize our product candidates even if there is adequate coverage and reimbursement from third-party payors.

Government authorities and other third-party payors decide which drugs and treatments they will cover and the amount of reimbursement. In the United States, the principal decisions about reimbursement for new medicines are typically made by the Centers for Medicare & Medicaid Services, or CMS, an agency within the U.S. Department of Health and Human Services. CMS decides whether and to what extent a new medicine will be covered and reimbursed under Medicare and private payors tend to follow CMS to a substantial degree. No uniform policy of coverage and reimbursement for drug products exists among third-party payors. Therefore, coverage and reimbursement for drug products can differ significantly from payor to payor. The process for determining whether a third-party payor will provide coverage for a product may be separate from the process for setting the price or reimbursement rate that the payor will pay for the product once coverage is approved. Coverage and reimbursement by a third-party payor may depend upon a number of factors, including the third-party payor's determination that use of a product is:

- a covered benefit under its health plan;
- safe, effective and medically necessary;
- appropriate for the specific patient;
- cost-effective; and
- neither experimental nor investigational.

In order to secure coverage and reimbursement for any product that might be approved for sale, a company may need to conduct expensive pharmacoeconomic studies in order to demonstrate the medical necessity and cost-effectiveness of the product, in addition to the costs required to obtain FDA or other comparable regulatory approvals. Additionally, companies may also need to provide discounts to purchasers, private health plans or government healthcare programs. Nonetheless, product candidates may not be considered medically necessary or cost effective. A decision by a third-party payor not to cover a product could reduce physician utilization once the product is approved and have a material adverse effect on sales, our operations and financial condition.

Government, private health insurers and other third-party payors are increasingly attempting to contain healthcare costs by limiting both coverage and the level of reimbursement for new therapeutic products approved for marketing by the FDA. For example, Congress passed the Affordable Care Act in 2010 which enacted a number of reforms to expand access to health insurance while also reducing or constraining the growth of healthcare spending, enhancing remedies against fraud and abuse, adding new transparency requirements for healthcare industries, and imposing new taxes on fees on healthcare industry participants, among other policy reforms. Federal agencies, Congress and state legislatures have continued to show interest in implementing cost containment programs to limit the growth of health care costs, including price controls, price disclosures, restrictions on reimbursement and other fundamental changes to the healthcare delivery system. In addition, in recent years, Congress has enacted various laws seeking to reduce the federal debt level and contain healthcare expenditures, and the Medicare and other healthcare programs are frequently identified as potential targets for spending cuts. New government legislation or regulations related to pricing or other fundamental changes to the healthcare delivery system as well as a government or third-party payer decision not to approve pricing for, or provide adequate coverage or reimbursement of, our product candidates hold the potential to severely limit market opportunities of such products. Accordingly, even if coverage and reimbursement are provided by government, private health insurers and third-party payors for uses of our products, market acceptance of these products would be adversely affected if the reimbursement available proves to be unprofitable for health care providers.

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

The commercial success of our products will depend upon their acceptance by the medical community and third-party payors as clinically useful, cost effective and safe. Any of our drug candidates or similar product candidates being investigated by our competitors may prove not to be effective in trial or in practice, cause adverse events or other undesirable side effects. Our testing and clinical practice may not confirm the safety and efficacy of our product candidates or even if further testing and clinical practice produce positive results, the medical community may view these new forms of treatment as effective and desirable or our efforts to market our new products may fail. Market acceptance depends upon physicians and hospitals obtaining adequate reimbursement rates from third-party payors to make our products commercially viable. Any of these factors could have an adverse effect on our business, financial condition and results of operations.

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

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

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

Several of our current clinical trials are being conducted outside the United States. Although the FDA may accept data from clinical trials conducted outside the United States, acceptance of these data is subject to certain conditions imposed by the FDA. For example, the clinical trial must be well designed and conducted and performed by qualified investigators in accordance with ethical principles. The trial population must also adequately represent the U.S. population, and the data must be applicable to the U.S. population and U.S. medical practice in ways that the FDA deems clinically meaningful. In general, the patient population for any clinical trials conducted outside of the United States must be representative of the population for whom we intend to label the product in the United States. In addition, while these clinical trials are subject to the applicable local laws, FDA acceptance of the data will be dependent upon its determination that the trials also complied with all applicable U.S. laws and regulations. We cannot assure you that the FDA will accept data from trials conducted outside of the United States. If the FDA does not accept the data from such clinical trials, it would likely result in the need for additional trials, which would be costly and time-consuming and delay or permanently halt our development of our product candidates.

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

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

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

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

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

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

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

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

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

There are many companies and other institutions engaged in research and development of various technologies for cancer treatment products that seek treatment outcomes similar to those that we are pursuing. We believe that the level of interest by others in investigating the potential of possible competitive treatments and alternative technologies will continue and may increase. Potential competitors engaged in all areas of cancer treatment research in the U.S. and other countries include, among others, major pharmaceutical, specialized technology companies, and universities and other research institutions. Most of our current and potential competitors have substantially greater financial, technical, human and other resources, and may also have far greater experience than do we, both in pre-clinical testing and human clinical trials of new products and in obtaining FDA and other regulatory approvals. One or more of these companies or institutions could succeed in developing products or other technologies that are more effective than the products and technologies that we have been or are developing, or which would render our technology and products obsolete and non-competitive. Furthermore, if we are permitted to commence commercial sales of any of our products, we will also be competing, with respect to manufacturing efficiency and marketing, with companies having substantially greater resources and experience in these areas.

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

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

We or the third parties upon whom we depend may be adversely affected by earthquakes, global pandemics or other natural disasters and our business continuity and disaster recovery plans may not adequately protect us from a serious disaster, including earthquakes, outbreak of disease or other natural disasters.

Our current operations are located in our facilities in Lawrenceville, New Jersey. Any unplanned event, such as flood, fire, explosion, earthquake, extreme weather condition, medical epidemics, power shortage, telecommunication failure or other natural or manmade accidents or incidents that result in us being unable to fully utilize our facilities, or the manufacturing facilities of our third-party contract manufacturers, may have a material and adverse effect on our ability to operate our business, particularly on a daily basis, and have significant negative consequences on our financial and operating conditions. Loss of access to these facilities may result in increased costs, delays in the development of our product candidates or interruption of our business operations. Earthquakes or other natural disasters could further disrupt our operations and have a material and adverse effect on our business, financial condition, results of operations and prospects. If a natural disaster, power outage or other event occurred that prevented us from using all or a significant portion of our headquarters, that damaged critical infrastructure, such as our research facilities or the manufacturing facilities of our third-party contract manufacturers, or that otherwise disrupted operations, it may be difficult or, in certain cases, impossible, for us to continue our business for a substantial period of time. For example, in December 2019, an outbreak of a novel strain of coronavirus, or the COVID-19 coronavirus, originated in Wuhan, China. To date, this outbreak has already resulted in extended shutdowns of certain businesses in the Wuhan region and has had ripple effects to businesses around the world. An outbreak of communicable diseases in China or elsewhere, or the perception that such an outbreak could occur, and the measures taken by the governments of countries affected, could adversely affect our business, financial condition or results of operations by limiting our ability to manufacture products within or outside China, forcing temporary closure of facilities that we rely upon or increasing the costs associated with obtaining clinical supplies of our product candidates. The extent to which the COVID-19 coronavirus impacts our results will depend on future developments, which are highly uncertain and cannot be accurately predicted, including new information which may emerge concerning the severity of the COVID-19 coronavirus and the actions to contain the COVID-19 coronavirus or treat its impact, among others. Global health concerns, such as the COVID-19 coronavirus, could also result in social, economic, and labor instability in the countries in which we or the third parties with whom we engage operate.

The disaster recovery and business continuity plans we have in place may prove inadequate in the event of a serious disaster or similar event. We may incur substantial expenses as a result of the limited nature of our disaster recovery and business continuity plans, which, could have a material adverse effect on our business. As part of our risk management policy, we maintain insurance coverage at levels that we believe are appropriate for our business. However, in the event of an accident or incident at these facilities, we cannot assure you that the amounts of insurance will be sufficient to satisfy any damages and losses. If our facilities, or the manufacturing facilities of our third-party contract manufacturers, are unable to operate because of an accident or incident or for any other reason, even for a short period of time, any or all of our research and development programs may be harmed.

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

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

Pandemics such as the COVID-19 coronavirus could have an adverse impact on our developmental programs and our financial condition.

In December 2019, a novel strain of the COVID-19 coronavirus was first identified in Wuhan, Hubei Province, China. Any outbreak of contagious diseases, or other adverse public health developments, could have a material and adverse effect on our business operations. These could include disruptions or restrictions on our ability to travel, pursue partnerships and other business transactions, conduct clinical trials, make shipments of biologic materials, as well as be impacted by the temporary closure of the facilities of suppliers and clinical trial sites. Any disruption of suppliers, clinical trial sites or access to patients would likely impact our clinical trial enrollment progress and rates as well as our ability to access capital through the financial markets. The extent to which the COVID-19 coronavirus impacts our business will depend on future developments, which are highly uncertain and cannot be predicted, including new information which may emerge concerning the severity of the COVID-19 coronavirus and the actions to contain the COVID-19 coronavirus or treat its impact, among others.

RISKS RELATED TO OUR SECURITIES

The market price of our common stock has been, and may continue to be volatile and fluctuate significantly, which could result in substantial losses for investors and subject us to securities class action litigation.

The trading price for our common stock has been, and we expect it to continue to be, volatile. The price at which our common stock trades depends upon a number of factors, including our historical and anticipated operating results, our financial situation, announcements of technological innovations or new products by us or our competitors, our ability or inability to raise the additional capital we may need and the terms on which we raise it, and general market and economic conditions. Some of these factors are beyond our control. Broad market fluctuations may lower the market price of our common stock and affect the volume of trading in our stock, regardless of our financial condition, results of operations, business or prospect. The closing price of our common stock as reported on The Nasdaq Capital Market had a high price of $3.48 and a low price of $1.35 in the 52-week period ended December 31, 2018, a high price of $2.47 and a low price of $1.08 in the 52-week period ended December 31, 2019, and a high price of $1.73 and a low price of $0.72 from January 1, 2020 through May 14, 2020. Among the factors that may cause the market price of our common stock to fluctuate are the risks described in this "Risk Factors" section and other factors, including:

- results of preclinical and clinical studies of our product candidates or those of our competitors;
- regulatory or legal developments in the U.S. and other countries, especially changes in laws and regulations applicable to our product candidates;
- actions taken by regulatory agencies with respect to our product candidates, clinical studies, manufacturing process or sales and marketing terms;
- introductions and announcements of new products by us or our competitors, and the timing of these introductions or announcements;
- announcements by us or our competitors of significant acquisitions or other strategic transactions or capital commitments;
- fluctuations in our quarterly operating results or the operating results of our competitors;
- variance in our financial performance from the expectations of investors;
- changes in the estimation of the future size and growth rate of our markets;
- changes in accounting principles or changes in interpretations of existing principles, which could affect our financial results;
- failure of our products to achieve or maintain market acceptance or commercial success;
- conditions and trends in the markets we serve;
- changes in general economic, industry and market conditions;
- success of competitive products and services;
- changes in market valuations or earnings of our competitors;
- changes in our pricing policies or the pricing policies of our competitors;
- changes in legislation or regulatory policies, practices or actions;
- the commencement or outcome of litigation involving our company, our general industry or both;

- recruitment or departure of key personnel;
- changes in our capital structure, such as future issuances of securities or the incurrence of additional debt;
- actual or anticipated changes in earnings estimates or changes in stock market analyst recommendations regarding our common stock, other comparable companies or our industry generally;
- actual or expected sales of our common stock by our stockholders;
- acquisitions and financings, including the EGEN asset acquisition; and
- the trading volume of our common stock.

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

Future sales of our common stock in the public market could cause our stock price to fall.

Sales of a substantial number of shares of our common stock in the public market, or the perception that these sales might occur, could depress the market price of our common stock and could impair our ability to raise capital through the sale of additional equity securities. As of May 14, 2020, we had 29,257,435 shares of common stock outstanding, all of which, other than shares held by our directors and certain officers, were eligible for sale in the public market, subject in some cases to compliance with the requirements of Rule 144, including the volume limitations and manner of sale requirements. In addition, all of the shares of common stock issuable upon exercise of warrants will be freely tradable without restriction or further registration upon issuance.

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

In order to raise additional capital or pursue strategic transactions, we may in the future offer, issue or sell additional shares of our common stock or other securities convertible into or exchangeable for our common stock, including the issuance of common stock in relation to the achievement, if any, of milestones triggering our payment of earn-out consideration in connection with the EGEN asset acquisition. Our stockholders may experience significant dilution as a result of future equity offerings or issuances. Investors purchasing shares or other securities in the future could have rights superior to existing stockholders. As of May 14, 2020, we have a significant number of securities convertible into, or allowing the purchase of, our common stock, including 3,826,098 shares of common stock issuable upon exercise of warrants outstanding, 4,266,890 options to purchase shares of our common stock and restricted stock awards outstanding, and 24,152 shares of common stock reserved for future issuance under our stock incentive plan.

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

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

Changes in tax law could adversely affect our financial condition and results of operations.

The rules dealing with U.S. federal, state, and local income taxation are constantly under review by persons involved in the legislative process and by the Internal Revenue Service and the U.S. Treasury Department. Changes to tax laws (which changes may have retroactive application) could adversely affect us or holders of our common stock. In recent years, many such changes have been made and changes are likely to continue to occur in the future. For example, on March 27, 2020, President Trump signed into law the "Coronavirus Aid, Relief, and Economic Security Act" or the CARES Act, which included certain changes in tax law intended to stimulate the U.S. economy in light of the COVID-19 coronavirus outbreak, including temporary beneficial changes to the treatment of net operating losses, interest deductibility limitations and payroll tax matters. Future changes in tax laws could have a material adverse effect on our business, cash flow, financial condition or results of operations. We urge investors to consult with their legal and tax advisers regarding the implications of potential changes in tax laws on an investment in our common stock.

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

On December 22, 2017, the President of the United States signed into law the Tax Reform Act. The Tax Reform Act significantly changes U.S. tax law by, among other things, lowering corporate income tax rates, implementing a quasi-territorial tax system, providing a one-time transition toll charge on foreign earnings, creating a new limitation on the deductibility of interest expenses and modifying the limitation on officer compensation. The Tax Reform Act permanently reduces the U.S. corporate income tax rate from a maximum of 35% to a flat 21% rate, effective January 1, 2018. Net operating losses generated after December 31, 2017 are not subject to expiration, and generally ~~but~~ may not be carried back to prior taxable years except that, under the CARES Act, net operating losses generated in 2018, 2019 and 2020 may be carried back five taxable years. Additionally, for taxable years beginning after December 31, 2020, the deductibility of such federal net operating losses is limited to 80% of our taxable income in any future taxable year. We currently have significant net operating losses (NOLs) that may be used to offset future taxable income. In general, under Section 382 of the Internal Revenue Code of 1986, as amended (the Code), a corporation that undergoes an "ownership change" is subject to limitations on its ability to utilize its pre-change NOLs to offset future taxable income. During 2018, 2017 and years prior, we performed analyses to determine if there were changes in ownership, as defined by Section 382 of the Internal Revenue Code that would limit our ability to utilize certain net operating loss and tax credit carry forwards. We determined we experienced ownership changes, as defined by Section 382, in connection with certain common stock offerings in 2011, 2013, 2015, 2017 and 2018. As a result, the utilization of our federal tax net operating loss carry forwards generated prior to the ownership changes is limited. Future changes in our stock ownership, some of which are outside of our control, could result in an ownership change under Section 382 of the Code, which would significantly limit our ability to utilize NOLs to offset future taxable income.

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

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

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

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

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

None

Item 3. Defaults Upon Senior Securities.

None.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

None.

Item 6. Exhibits.

4.1	Form of Common Stock Purchase Warrant (incorporated herein by reference to Exhibit 4.1 to the Registrant's Current Report on Form 8-K filed with the Securities and Exchange Commission on March 3, 2020).
31.1+	Certification of Chief Executive Officer pursuant to Rule 13a-14(a)/15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2+	Certification of Chief Financial Officer pursuant to Rule 13a-14(a)/15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1*	Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
+	Filed herewith.
101**	The following materials from the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2020 formatted in XBRL (Extensible Business Reporting Language): (i) the unaudited Consolidated Balance Sheets, (ii) the unaudited Consolidated Statements of Operations, (iii) the unaudited Consolidated Statements of Comprehensive Loss, (iv) the unaudited Consolidated Statements of Cash Flows, (v) the unaudited Consolidated Statements of Change in Stockholders' Equity (Deficit), and (vi) Notes to Consolidated Financial Statements.
*	Exhibit 32.1 is being furnished and shall not be deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liability of that section, nor shall such exhibit be deemed to be incorporated by reference in any registration statement or other document filed under the Securities Act of 1933, as amended, or the Securities Exchange Act, except as otherwise stated in such filing.
**	XBRL information is filed herewith.

SIGNATURES

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

May 15, 2020

CELSION CORPORATION

Registrant

By: */s/ Michael H. Tardugno*

Michael H. Tardugno
Chairman, President and Chief Executive Officer

By: */s/ Jeffrey W. Church*

Jeffrey W. Church
Executive Vice President and Chief Financial Officer

Exhibit 31.1

CELSION CORPORATION
CERTIFICATION

I, Michael H. Tardugno, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Celsion Corporation;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)), and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15 (f)), for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Celsion Corporation

May 15, 2020

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

Exhibit 31.2

CELSION CORPORATION
CERTIFICATION

I, Jeffrey W. Church, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Celsion Corporation;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)), and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15 (f)), for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Celsion Corporation

May 15, 2020

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

Exhibit 32.1

CELSION CORPORATION

SECTION 1350 CERTIFICATIONS*

Pursuant to the requirement set forth in Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350), each of the undersigned hereby certifies that, to the best of his knowledge, (i) the Quarterly Report on Form 10-Q for the period ended March 31, 2020 of Celsion Corporation (the "Company") filed with the Securities and Exchange Commission on the date hereof fully complies with the requirements of Section 13(a) or 15(d) of the Exchange Act and (ii) the information contained in such report fairly presents, in all material respects, the financial condition and results of operations of the Company.

May 15, 2020

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

May 15, 2020

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

* This certification accompanies the Form 10-Q to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of the Company under the Securities Act of 1933, as amended, or the Exchange Act (whether made before or after the date of the Form 10-Q), irrespective of any general incorporation language contained in such filing.