

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549**

FORM 10-Q

(Mark One)

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

For the quarterly period ended June 30, 2021

OR

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from _____ to _____

Commission file number: 001-15911

CELSION CORPORATION

(Exact name of Registrant as specified in its charter)

Delaware

(State or other jurisdiction of
incorporation or organization)

52-1256615

(I.R.S. Employer
Identification Number)

**997 Lenox Drive, Suite 100,
Lawrenceville, NJ 08648**
(Address of principal executive offices)

(609) 896-9100
(Registrant's telephone number, including area code)

NA

(Former name, former address and former fiscal year, if changed since last report)

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 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 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
Non-accelerated filer
Emerging growth company

Accelerated filer
Smaller reporting company

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

Indicate by check mark whether the Registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes No

As of August 11, 2021, the Registrant had 86,557,736 shares of common stock, \$0.01 par value per share, outstanding.

CELSION CORPORATION
QUARTERLY REPORT ON
FORM 10-Q

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Cautionary Note Regarding Forward-Looking Statements

This report includes “forward-looking statements” within the meaning of Section 27A of the Securities Act of 1933, as amended (the “Securities Act”), and Section 21E of the Securities Exchange Act of 1934, as amended (the “Exchange Act”). 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, 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 inherent uncertainty in the drug development process, our ability to raise additional capital to fund our planned future operations, our ability to obtain or maintain FDA and foreign regulatory approvals for our drug candidates, potential impact of the outbreak, duration and severity of the COVID-19 pandemic on our business, our ability to enroll patients in our clinical trials, risks relating to third parties conduct of our clinical trials, risks relating to government, private health insurers and other third-party payers coverage or reimbursement, risks relating to commercial potential of a drug candidate in development, changes in technologies for the treatment of cancer, impact of development of competitive drug candidates by others, risks relating to intellectual property, volatility in the market price of our common stock, potential inability to maintain compliance with The Nasdaq Marketplace Rules and the impact of adverse capital and credit market conditions. These and other risks, assumptions are described in Item 1A. Risk Factors in our Annual Report on Form 10-K for the fiscal year ended December 31, 2020 and in other documents that we file or furnish with the SEC. Should one or more of these risks or uncertainties materialize, or should underlying assumptions prove incorrect, actual results may vary materially from those indicated or anticipated by such forward-looking statements. All forward-looking statements speak only as of the date they are made and we do not intend to update any forward-looking statements, except as required by law or applicable regulations. 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

	<u>June 30, 2021</u> (Unaudited)	<u>December 31, 2020</u>
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 26,437,424	\$ 17,164,177
Investment in debt securities - available for sale, at fair value	31,923,285	-
Accrued interest on investment in debt securities	105,000	-
Advances and deposits on clinical programs and other current assets	1,844,451	1,660,695
Total current assets	60,310,160	18,824,872
Property and equipment (at cost, less accumulated depreciation and amortization)	458,551	294,551
Other assets:		
Money market investments, restricted cash	6,000,000	-
Deferred income tax asset	-	1,845,823
In-process research and development, net	13,366,234	13,366,234
Goodwill	1,976,101	1,976,101
Operating lease right-of-use assets, net	840,195	1,047,336
Other intangible assets, net	-	113,660
Deposits and other assets	58,761	58,761
Total other assets	22,241,291	18,407,915
Total assets	\$ 83,010,002	\$ 37,527,338

See accompanying notes to the condensed consolidated financial statements.

CELSION CORPORATION
CONDENSED CONSOLIDATED
BALANCE SHEETS
(Continued)

	<u>June 30, 2021</u> (Unaudited)	<u>December 31, 2020</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable – trade	\$ 2,109,479	\$ 2,244,847
Other accrued liabilities	2,312,705	2,458,532
Notes payable – current portion, net of deferred financing costs	–	1,116,663
Operating lease liability - current portion	458,168	433,413
Deferred revenue - current portion	500,000	500,000
Total current liabilities	5,380,352	6,753,455
Earn-out milestone liability	7,088,000	7,018,000
Notes payable – non-current portion, net of deferred financing costs	5,763,087	3,934,497
Operating lease liability - non-current portion	475,051	710,305
Deferred revenue - non-current portion	250,000	500,000
Total liabilities	18,956,490	18,916,257
Commitments and contingencies	–	–
Stockholders' equity:		
Preferred Stock - \$0.01 par value (100,000 shares authorized, and no shares issued or outstanding at June 30, 2021 and December 31, 2020)	–	–
Common stock - \$0.01 par value (112,500,000 shares authorized; 86,558,070 and 40,701,356 shares issued at June 30, 2021 and December 31, 2020, respectively, and 86,557,736 and 40,701,022 shares outstanding at June 30, 2021 and December 31, 2020, respectively)	865,581	407,014
Additional paid-in capital	386,414,630	330,289,596
Accumulated other comprehensive loss	(3,770)	–
Accumulated deficit	(323,137,741)	(312,000,341)
Total stockholders' equity before treasury stock	64,138,700	18,696,269
Treasury stock, at cost (334 shares at June 30, 2021 and December 31, 2020)	(85,188)	(85,188)
Total stockholders' equity	64,053,512	18,611,081
Total liabilities and stockholders' equity	\$ 83,010,002	\$ 37,527,338

See accompanying notes to the condensed consolidated financial statements.

CELSION CORPORATION
CONDENSED CONSOLIDATED
STATEMENTS OF OPERATIONS
(Unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
Licensing revenue	\$ 125,000	\$ 125,000	\$ 250,000	\$ 250,000
Operating expenses:				
Research and development	2,593,412	2,990,861	5,164,985	6,042,910
General and administrative	2,602,990	1,901,136	5,539,761	3,740,042
Total operating expenses	<u>5,196,402</u>	<u>4,891,997</u>	<u>10,704,746</u>	<u>9,782,952</u>
Loss from operations	<u>(5,071,402)</u>	<u>(4,766,997)</u>	<u>(10,454,746)</u>	<u>(9,532,952)</u>
Other (expense) income:				
Gain (loss) from change in valuation of earn-out milestone liability	81,000	(256,296)	(70,000)	(297,570)
Investment income	(349)	20,960	2,062	109,269
Interest expense	(221,227)	(340,602)	(378,841)	(679,967)
Recognized loss on extinguishment of debt	(234,419)	–	(234,419)	–
Other (expense) income	(2,000)	–	(1,456)	1,407
Total other (expense) income, net	<u>(376,995)</u>	<u>(575,938)</u>	<u>(682,654)</u>	<u>(866,861)</u>
Net loss	<u>\$ (5,448,397)</u>	<u>\$ (5,342,935)</u>	<u>\$ (11,137,400)</u>	<u>\$ (10,399,813)</u>
Net loss per common share				
Basic and diluted	<u>\$ (0.06)</u>	<u>\$ (0.18)</u>	<u>\$ (0.15)</u>	<u>\$ (0.37)</u>
Weighted average shares outstanding				
Basic and diluted	<u>85,923,755</u>	<u>29,887,329</u>	<u>76,165,451</u>	<u>27,830,573</u>

See accompanying notes to the condensed consolidated financial statements.

CELSION CORPORATION
CONDENSED CONSOLIDATED
STATEMENTS OF COMPREHENSIVE LOSS
(Unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
Other comprehensive (loss) gain				
Changes in:				
Realized gains (losses) on debt securities recognized in investment income, net	\$ 1,785	\$ (2,865)	\$ 1,785	\$ (46,097)
Unrealized (losses) gains on debt securities, net	<u>(7,340)</u>	<u>6,918</u>	<u>(5,555)</u>	<u>11,185</u>
Change in unrealized (losses) gains on available for sale securities, net	(5,555)	4,053	(3,770)	(34,912)
Net loss	<u>(5,448,397)</u>	<u>(5,342,935)</u>	<u>(11,137,400)</u>	<u>(10,399,813)</u>
Comprehensive loss	<u>\$ (5,453,952)</u>	<u>\$ (5,338,882)</u>	<u>\$ (11,141,170)</u>	<u>\$ (10,434,725)</u>

See accompanying notes to the condensed consolidated financial statements.

CELSION CORPORATION
CONDENSED CONSOLIDATED
STATEMENTS OF CASH FLOWS
(Unaudited)

	Six Months Ended June 30,	
	2021	2020
Cash flows from operating activities:		
Net loss	\$ (11,137,400)	\$ (10,399,813)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	383,801	378,990
Change in fair value of earn-out milestone liability	70,000	297,570
Recognition of deferred revenue	(250,000)	(250,000)
Stock-based compensation costs	2,372,945	1,030,726
Deferred income tax asset	1,845,823	1,819,324
Amortization of deferred finance charges and debt discount associated with notes payable	145,884	192,793
Net changes in:		
Accrued interest on investment securities	(105,000)	13,503
Advances, deposits, and other current assets	(183,756)	(60,104)
Accounts payable and accrued liabilities	(491,694)	(946,265)
Net cash used in operating activities	(7,349,397)	(7,923,276)
Cash flows from investing activities:		
Purchases of investment securities	(40,927,055)	(9,940,894)
Proceeds from sale and maturity of investment securities	9,000,000	15,100,000
Purchases of property and equipment	(227,000)	(11,837)
Net cash (used in) provided by investing activities	(32,154,055)	5,147,269
Cash flows from financing activities:		
Proceeds from sale of common stock equity, net of issuance costs	52,697,265	18,182,599
Proceeds from issuance of common stock upon conversion of stock warrants	1,508,666	-
Proceeds from issuance of common stock upon conversion of stock options	4,725	371,895
Proceeds from the SVB Loan Facility, net of issuance costs	5,756,630	-
Payoff of the Horizon Credit Agreement and accrued end of term fees	(5,190,587)	-
Proceeds from Payroll Protection Program (PPP) loans	-	1,324,750
Repayments on Payroll Protection Program (PPP) loans	-	(1,324,750)
Net cash provided by financing activities	54,776,699	18,554,494
Increase in cash, cash equivalents and restricted cash	15,273,247	15,778,487
Cash, cash equivalents and restricted cash at beginning of period	17,164,177	6,875,273
Cash, cash equivalents and restricted cash at end of period	\$ 32,437,424	\$ 22,653,760

See accompanying notes to the condensed consolidated financial statements.

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

	Six Months Ended June 30,	
	2021	2020
Supplemental disclosures of cash flow information:		
Interest paid	\$ (267,360)	\$ (487,174)
Cash paid for amounts included in measurement of lease liabilities:		
Operating cash flows from lease payments	\$ 264,546	\$ 262,084
Common stock issued to settle accrued bonuses	\$ –	\$ 498,632
Realized and unrealized gains (losses), net, on investment securities	\$ 3,770	\$ (34,912)

See accompanying notes to the condensed consolidated financial statements.

CELSION CORPORATION

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

THREE MONTHS ENDED JUNE 30, 2021 AND 2020

Three Months Ended June 30, 2021	Common Stock Outstanding		Additional Paid in Capital	Treasury Stock		Accumulated Other Comprehensive Income	Accumulated Deficit	Total
	Shares	Amount		Shares	Amount			
Balance at April 1, 2021	75,019,274	\$ 750,196	\$ 371,982,609	334	\$ (85,188)	\$ 1,785	\$ (317,689,344)	\$ 54,960,058
Net loss	-	-	-	-	-	-	(5,448,397)	(5,448,397)
Sale of equity through equity financing facilities	11,538,462	115,385	13,638,402	-	-	-	-	13,753,787
Realized and unrealized gains and losses, net, on investments securities	-	-	-	-	-	(5,555)	-	(5,555)
Stock-based compensation expense	-	-	793,619	-	-	-	-	793,619
Balance at June 30, 2021	<u>86,557,736</u>	<u>\$ 865,581</u>	<u>\$ 386,414,630</u>	<u>334</u>	<u>\$ (85,188)</u>	<u>\$ (3,770)</u>	<u>\$ (323,137,741)</u>	<u>\$ 64,053,512</u>
Three Months Ended June 30, 2020	Common Stock Outstanding		Additional Paid in Capital	Treasury Stock		Accumulated Other Comprehensive Income	Accumulated Deficit	Total
	Shares	Amount		Shares	Amount			
Balance at April 1, 2020	29,257,101	\$ 292,574	\$ 311,570,995	334	\$ (85,188)	\$ 3,813	\$ (295,573,658)	\$ 16,208,536
Net loss	-	-	-	-	-	-	(5,342,935)	(5,342,935)
Sale of equity through equity financing facilities	3,831,415	38,314	12,349,538	-	-	-	-	12,387,852
Issuance of common stock upon exercise of options	140,864	1,409	370,486	-	-	-	-	371,895
Realized and unrealized gains and losses, net, on investments securities	-	-	-	-	-	4,053	-	4,053
Stock-based compensation expense	-	-	578,761	-	-	-	-	578,761
Balance at June 30, 2020	<u>33,229,380</u>	<u>\$ 332,297</u>	<u>\$ 324,869,780</u>	<u>334</u>	<u>\$ (85,188)</u>	<u>\$ 7,866</u>	<u>\$ (300,916,593)</u>	<u>\$ 24,208,162</u>

See accompanying notes to the condensed consolidated financial statements

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

SIX MONTHS ENDED JUNE 30, 2021 AND 2020

Six Months Ended June 30, 2021	Common Stock Outstanding		Additional Paid in Capital	Treasury Stock		Accumulated Other Comprehensive Income	Accumulated Deficit	Total
	Shares	Amount		Shares	Amount			
Balance at January 1, 2021	40,701,022	\$ 407,014	\$ 330,289,596	334	\$ (85,188)	\$ -	\$ (312,000,341)	\$ 18,611,081
Net loss	-	-	-	-	-	-	(11,137,400)	(11,137,400)
Sale of equity through equity financing facilities	44,632,547	446,326	52,250,939	-	-	-	-	52,697,265
Shares issued upon exercise of common stock warrants, net of fees	1,216,667	12,166	1,496,500	-	-	-	-	1,508,666
Shares issued upon exercise of options to purchase common stock	7,500	75	4,650	-	-	-	-	4,725
Realized and unrealized gains and losses, net, on investments securities	-	-	-	-	-	(3,770)	-	(3,770)
Stock-based compensation expense	-	-	2,372,945	-	-	-	-	2,372,945
Balance at June 30, 2021	<u>86,557,736</u>	<u>\$ 865,581</u>	<u>\$ 386,414,630</u>	<u>334</u>	<u>\$ (85,188)</u>	<u>\$ (3,770)</u>	<u>\$ (323,137,741)</u>	<u>\$ 64,053,512</u>

Six Months Ended June 30, 2020	Common Stock Outstanding		Additional Paid in Capital	Treasury Stock		Accumulated Other Comprehensive Income	Accumulated Deficit	Total
	Shares	Amount		Shares	Amount			
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	-	-	-	-	-	-	(10,399,813)	(10,399,813)
Sale of equity through equity financing facilities	9,402,843	94,027	18,088,572	-	-	-	-	18,182,599
Issuance of common stock upon exercise of options	140,864	1,409	370,486	-	-	-	-	371,895
Realized and unrealized gains and losses, net, on investments securities	-	-	-	-	-	(34,912)	-	(34,912)
Stock-based compensation expense	-	-	1,030,726	-	-	-	-	1,030,726
Common stock issued to settle accrued bonuses	429,855	4,299	494,333	-	-	-	-	498,632
Balance at June 30, 2020	<u>33,229,380</u>	<u>\$ 332,297</u>	<u>\$ 324,869,780</u>	<u>334</u>	<u>\$ (85,188)</u>	<u>\$ 7,866</u>	<u>\$ (300,916,593)</u>	<u>\$ 24,208,162</u>

See accompanying notes to the condensed consolidated financial statements

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

FOR THE THREE AND SIX MONTHS ENDED JUNE 2021 AND 2020

Note 1. Business Description

Celsion Corporation (“Celsion” and the “Company”) is a fully integrated, clinical stage biotechnology company focused on advancing a portfolio of innovative treatments including DNA-based immunotherapies, next generation vaccines and directed chemotherapies through clinical trials and eventual commercialization. The Company’s product pipeline includes GEN-1, a DNA-based immunotherapy for the localized treatment of ovarian cancer and ThermoDox[®], a proprietary heat-activated liposomal encapsulation of doxorubicin, currently under investigator-sponsored development for several cancer indications. Celsion has two feasibility stage platform technologies for the development of novel nucleic acid-based immunotherapies and next generation vaccines and other anti-cancer DNA or RNA therapies. Both are novel synthetic, non-viral vectors with demonstrated capability in nucleic acid cellular transfection.

Note 2. Basis of Presentation

The accompanying unaudited condensed consolidated financial statements, which include the accounts of the Company and its wholly owned subsidiaries, CLSN Laboratories, Inc. and Celsion, GmbH, have been prepared in accordance with generally accepted accounting principles in the United States (GAAP) for interim financial information and with the instructions to Form 10-Q and Article 10 of Regulation S-X. All 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 and six-month periods June 30, 2021 and 2020 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, 2020 filed with the Securities and Exchange Commission (SEC) on March 19, 2021.

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. The Company continues to monitor the impact of the COVID-19 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 pandemic 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 has incurred significant net losses in each year since our inception. As of June 30, 2021, the Company has incurred approximately \$323 million of cumulative net losses and had approximately \$64.5 million in cash and cash equivalents, restricted cash, short-term investments and interest receivable. We have substantial future capital requirements to continue our research and development activities and advance our product candidates through various development stages. The Company believes these expenditures are essential for the commercialization of its technologies.

The Company expects its operating losses to continue for the foreseeable future as it continues its product development efforts, and when it undertakes marketing and sales activities. The Company’s ability to achieve profitability is dependent upon its ability to obtain governmental approvals, manufacture, and market and sell its 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 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 has spread to over 100 countries, including the U.S. 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 during 2020 and into 2021 due to 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 U.S. and worldwide resulting from the ongoing COVID-19 pandemic. The disruptions caused by COVID-19 may also disrupt the clinical trials process and enrolment of patients. This may delay commercialization efforts. The Company continues to monitor its operating activities in light of these events. The specific impact, if any, 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.

On July 13, 2020, the Company announced that it has received a recommendation from the independent DMC to consider stopping the global Phase III OPTIMA Study of ThermoDox[®] in combination with RFA for the treatment of HCC, or primary liver cancer. The recommendation was made following the second pre-planned interim safety and efficacy analysis by the DMC on July 9, 2020. The DMC’s analysis found that the pre-specified boundary for stopping the trial for futility of 0.900 was crossed with an actual value of 0.903. The Company followed the advice of the DMC and considered its options to either stop the study or continue to follow patients after a thorough review of the data, and an evaluation of the probability of success. On February 11, 2021, the Company issued a letter to shareholders stating that the Company was notifying all clinical sites to discontinue following patients in the OPTIMA Study.

During 2020, 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 New Jersey-based companies. In 2018 and 2019, the Company sold NOLs totaling \$13 million receiving net proceeds of \$12.2 million. In June 2020 and as updated in September 2020, the Company filed an application with the New Jersey Economic Development Authority to sell substantially all of its remaining State of New Jersey net operating losses totaling \$2.0 million available under the program. On February 12, 2021, the New Jersey Economic Development Authority approved the full amount of the Company’s application. In February of 2021, the Company entered into an agreement to sell the net operating losses from the 2020 application and the Company received net proceeds of approximately \$1.85 million on May 10, 2021. During 2021, the New Jersey State Legislature increased the maximum lifetime benefit per company from \$15 million to \$20 million, which will allow the Company to participate in this innovative funding program in future years. On June 16, 2021, the Company filed another application to sell approximately \$1.6 million of net operating losses during 2021 and expects to receive up to approximately \$1.4 million under the current year program.

In June 2018, the Company entered into a Credit Agreement with Horizon Technology Finance Corporation (“Horizon”) that provided \$10 million in capital (the “Horizon Credit Agreement”). 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 24 months through July 2020, followed by a 21-month amortization period of principal and interest starting on August 1, 2020 and ending through the scheduled maturity date on April 1, 2023. On August 28, 2020, in connection with an Amendment to the Horizon Credit Agreement, Celsion repaid \$5 million of the \$10 million loan and \$0.2 million in related end of term charges, and the remaining \$5 million in obligations were restructured. As more fully discussed in Note 11 to these financial statements, in June 2021, the Company entered into a \$10 million loan facility with Silicon Valley Bank. The Company immediately used \$6 million from this facility to retire all outstanding indebtedness with Horizon Technology Finance Corporation. The remaining \$4 million will be available to be drawn down up to 12 months after closing and will be used for working capital and to fund the advancement of the Company’s product pipelines. The funding is in the form of money market secured indebtedness bearing interest at a calculated WSJ Prime-based variable rate (currently 3.25%). Payments under the loan agreement are interest only for the first 24 months after loan closing, followed by a 24-month amortization period of principal and interest through the scheduled maturity date.

As more fully discussed in Note 12, during 2021 through the date of the filing of this Quarterly Report on Form 10-Q, the Company has raised approximately \$6.9 million in gross proceeds from the use of its JonesTrading Capital on DemandTM financing facility, \$35 million from a registered direct financing completed in January 2021, \$15 million from a registered direct financing completed on April 5, 2021, and \$1.5 million from warrant exercises. With \$64.5 million in cash and cash equivalents, restricted cash, short-term investments and interest receivable, the Company believes it has sufficient capital resources to fund its operations through the end of 2024.

The Company has based its estimates 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.

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 ASU 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 adopted ASU 2016-13 in the 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 did not have a material impact on its 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. The Company adopted this standard during the first quarter of 2021. The adoption of ASU 2019-12 did not have a material impact on its consolidated financial statements.

In connection with the upcoming elimination of the London Inter-bank Offered Rate, (“LIBOR”) and other reference interest rates, the FASB issued ASU 2020-04, Reference Rate Reform (Topic 848) Facilitation of the Effects of Reference Reform on Financial Reporting. ASU 2020-04, which is available for contract modifications and hedging relationship modifications entered into or evaluated before December 31, 2022, provides certain practical expedients related to simplifying the accounting for contract modifications resulting from the change in terms from LIBOR to a new required interest rate benchmark. The Company is currently evaluating the effects of adopting this accounting standards update.

Note 5. Restricted Cash

As a condition of the \$10 million loan facility with Silicon Valley Bank (“SVB”) entered into on June 18, 2021 as further discussed in Note 11, the Company is required at all times to maintain on deposit with SVB as cash collateral in a segregated money market bank account in the name of the Company, unrestricted and unencumbered cash in an amount of at least 100% of the aggregate outstanding amount of the SVB loan facility. SVB may restrict withdrawals or transfers by or on behalf of the Company that would violate this requirement. The required reserve totaled \$6.0 million as of June 30, 2021. This amount is presented in part as restricted cash in other non-current assets on the accompanying condensed consolidated balance sheets.

The following table reconciles cash and cash equivalents and restricted cash per the balance sheet to the condensed statement of cash flows:

	June 30, 2021	June 30, 2020
Cash and cash equivalents	\$ 26,437,424	\$ 22,653,760
Money market investments, restricted	6,000,000	-
Total	<u>\$ 32,437,424</u>	<u>\$ 22,653,760</u>

Note 6. 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 9,325,228 and 8,560,124 shares for the three and six-month periods ended June 30, 2021 and 2020, respectively. Warrants with an exercise price of \$0.01 exercisable for 200,000 shares of common stock were considered issued in calculating basic loss per share during the first six-months of 2020. These warrants were exercised in October 2020. For the three and six-month periods ended June 30, 2021 and 2020, 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 first six months of 2021 or 2020.

Note 7. Investment in Debt Securities Available for Sale

Investments in debt securities available for sale with a fair value of \$31,923,285 as of June 30, 2021, consisted of government backed debt securities and commercial paper. 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. The Company only had investments in cash and cash equivalents on December 31, 2020.

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:

	June 30, 2021		December 31, 2020	
	Cost	Fair Value	Cost	Fair Value
Short-term investments				
Commercial paper	\$ 7,795,035	\$ 7,792,785	\$ -	-
Government backed debt securities	24,132,020	24,130,500	-	-
Total	<u>\$ 31,927,055</u>	<u>\$ 31,923,285</u>	<u>\$ -</u>	<u>\$ -</u>
	June 30, 2021		December 31, 2020	
	Cost	Fair Value	Cost	Fair Value
Short-term investment maturities				
Within 3 months	\$ 2,999,420	\$ 7,792,785	\$ -	\$ -
Between 3-12 months	28,927,635	24,130,500	-	-
Total	<u>\$ 31,927,055</u>	<u>\$ 31,923,285</u>	<u>\$ -</u>	<u>\$ -</u>

The following table shows the Company's investment in debt securities available for sale 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 June 30, 2021 and December 31, 2020. The Company has reviewed individual securities to determine whether a decline in fair value below the amortizable cost basis is other than temporary.

Available for sale securities (all unrealized holding gains and losses are less than 12 months at date of measurement)	June 30, 2021		December 31, 2020	
	Fair Value	Unrealized Holding Gains (Losses)	Fair Value	Unrealized Holding Gains (Losses)
Investments with unrealized gains	\$ 5,998,980	\$ 1,073	\$ -	\$ -
Investments with unrealized losses	25,924,305	(4,843)	-	-
Total	\$ 31,923,285	\$ (3,770)	\$ -	\$ -

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

	Three Months Ended June 30,	
	2021	2020
Interest and dividends accrued and paid	\$ 1,436	\$ 18,095
Realized (losses) gains	(1,785)	2,865
Investment (loss) income, net	<u>\$ (349)</u>	<u>\$ 20,960</u>

	Six Months Ended June 30,	
	2021	2020
Interest and dividends accrued and paid	\$ 3,847	\$ 63,172
Realized (losses) gains	(1,785)	46,097
Investment income, net	<u>\$ 2,062</u>	<u>\$ 109,269</u>

Note 8. Fair Value Measurements

FASB 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, other current assets, accounts payable and other accrued liabilities are reflected in the condensed consolidated balance sheet at their approximate estimated fair values primarily due to their short-term nature. The fair values of securities available for sale is determined by relying on the securities' relationship to other benchmark quoted securities and classified its investments as Level 2 items in both 2021 and 2020. 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 six-months ended June 30, 2021 or during the year ended December 31, 2020. 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 14).

Assets and liabilities measured at fair value are summarized below:

	<u>Total Fair Value</u>	<u>Quoted Prices in Active Markets for Identical Assets/Liabilities (Level 1)</u>	<u>Significant Other Observable Inputs (Level 2)</u>	<u>Significant Unobservable Inputs (Level 3)</u>
Assets:				
Recurring items as of June 30, 2021				
Investment in debt securities - available for sale, at fair value	\$ 31,923,285	\$ -	\$ 31,923,285	\$ -
Non-recurring items as of June 30, 2021				
In-process R&D (Note 9)	\$ 13,366,234	\$ -	\$ -	\$ 13,366,234
Non-recurring items as of December 31, 2020				
In-process R&D (Note 9)	\$ 13,366,234	\$ -	\$ -	\$ 13,366,234
Liabilities:				
Recurring items as of June 30, 2021				
Earn-out milestone liability (Note 14)	\$ 7,088,000	\$ -	\$ -	\$ 7,088,000
Recurring items as of December 31, 2020				
Earn-out milestone liability (Note 14)	\$ 7,018,000	\$ -	\$ -	\$ 7,018,000

Note 9. 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, 2020, 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 2020 or first half of 2021, no impairment charges were recorded during the three or six-months ended June 30, 2021 and 2020.

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. On September 30, 2020, the Company evaluated its IPR&D for the (GBM) product candidate and concluded that it is more likely than not that the asset is further impaired. After this assessment on September 30, 2020, the Company wrote off the remaining \$2.4 million of this asset, thereby recognizing a non-cash charge of \$2.4 million in the third quarter of 2020.

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 \$56,830 in each of the three and six-month periods ended June 30, 2021 and 2020. The carrying value of the Covenant Not to Compete was fully amortized as of June 30, 2021 and \$113,660, net of \$1,477,554 accumulated amortization, as of December 31, 2020.

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 June 30, 2021, 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 six-month period ended June 30, 2021:

	IPR&D	Goodwill	Covenant Not To Compete
For the six-months ended June 30, 2021			
Balance at January 1, 2021, net	\$ 13,366,234	\$ 1,976,101	\$ 113,660
Amortization	-	-	(113,660)
Balance at June 30, 2021, net	<u>\$ 13,366,234</u>	<u>\$ 1,976,101</u>	<u>\$ -</u>

Note 10. Accrued Liabilities

Other accrued liabilities at June 30, 2021 and December 31, 2020 include the following:

	<u>June 30, 2021</u>	<u>December 31, 2020</u>
Amounts due to contract research organizations and other contractual agreements	\$ 1,189,017	\$ 636,000
Accrued payroll and related benefits	1,016,610	1,736,271
Accrued professional fees	80,625	66,850
Accrued interest	7,042	-
Other	19,411	19,411
Total	<u>\$ 2,312,705</u>	<u>\$ 2,458,532</u>

Note 11. Notes Payable

The SVB Loan Facility

On June 18, 2021, the Company entered into a \$10 million loan facility (the “SVB Loan Facility”) with Silicon Valley Bank (“SVB”). Celsion immediately used \$6 million from the SVB Loan Facility to retire all outstanding indebtedness with Horizon Technology Finance Corporation as further discussed below. Simultaneously with this transaction, the Company used \$6.0 million of other available funds to establish a restricted cash account which serves as security for the SVB Loan Facility. The remaining \$4 million will be available to be drawn down up to 12 months after closing and will be used for working capital and to fund the advancement of the Company’s product pipeline, including GEN-1 for the treatment of newly diagnosed advanced ovarian cancer, as well as other strategic initiatives intended to broaden its product pipeline.

The SVB Loan Facility is in the form of money market secured indebtedness bearing interest at a calculated WSJ Prime-based variable rate (currently 3.25%). A final payment equal to 3% of the total \$10 million commitment amount is due upon maturity or prepayment of the SVB Loan Facility. There was no facility commitment fee and no stock or warrants were issued to SVB. Payments under the loan agreement are interest only for the first 24 months after loan closing, followed by a 24-month amortization period of principal and interest through the scheduled maturity date.

In connection with the SVB Loan Facility, the Company incurred financing fees and expenses totaling \$243,370 which is recorded and classified as debt discount and are being amortized as interest expense using the effective interest method over the life of the loan. Also, in connection with the SVB Loan Facility, the Company is required to pay an end-of-term fee equal to 3.0% of the original loan amount at time of maturity. Therefore, these amounts totaling \$300,000 were being amortized as interest expense using the effective interest method over the life of the loan. During the three and six-month periods ended June 30, 2021, the Company incurred \$7,042 in interest expense and amortized \$6,457 as interest expense for debt discounts and end-of-term fee in connection with the SVB Financing Facility.

Following is a schedule of future principal payments, net of unamortized debt discounts and amortized end-of-term fee, due on the SVB Loan Facility:

	As of June 30,
2022	\$ —
2023	—
2024	3,000,000
2025 and thereafter	3,000,000
Subtotal of future principal payments	<u>6,000,000</u>
Unamortized debt premium, net	(236,913)
Total	<u>\$ 5,763,087</u>

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. On August 28, 2020, Horizon and the Company amended the Horizon Credit Agreement (the “Amendment”) whereby Celsion repaid \$5 million of the \$10 million loan and \$0.2 million in related end of term charges, and the remaining \$5 million in obligations were restructured as set forth below.

Pursuant to the Amendment, the remaining \$5 million in obligations of Celsion under the Horizon Credit Agreement was secured by a first-priority security interest in substantially all assets of Celsion other than intellectual property assets. The obligations bore interest at a rate calculated based an amount by which the one-month LIBOR exceeds 2% plus 7.625%. In no event shall the interest rate be less than 9.625%. Payments pursuant to the Amendment were interest only for the first twelve (12) months after August 1, 2020, followed by a 21-month amortization period of principal and interest through the scheduled maturity date on April 1, 2023. In addition, the remaining \$5 million in obligations was subject to an end of term fee equal, in the aggregate, to \$275,000, which amount was payable upon the maturity of the obligations or upon the date of final payment or default, as applicable. In connection with the Amendment, Celsion agreed to a liquidity covenant which provides that, at all times, Celsion shall maintain unrestricted cash and/or cash equivalents on deposit in accounts over which the applicable Lenders maintain an account control agreement in an amount not less than \$2.5 million. In addition, pursuant to the Amendment, Celsion agreed to provide evidence to Horizon on or before March 31, 2021, that it received aggregate cash proceeds of not less than \$5 million from the sale of equity, debt, its New Jersey net operating losses, or a combination thereof, subsequent to the date of the Amendment. The Company met this requirement during the fourth quarter of 2020.

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

As a fee in connection with the Horizon Credit Agreement, Celsion issued Horizon warrants exercisable for a total of 190,114 shares of Celsion’s common stock (the “Existing Warrants”) at a per share exercise price of \$2.63. The Horizon Warrants were immediately exercisable for cash or by net exercise from the date of grant and will expire after ten years from the date of grant. The Company valued the Horizon Warrants issued using the Black-Scholes option pricing model and recorded a total of \$507,116 as a direct deduction from the debt liability, consistent with the presentation of debt discounts, and are being amortized as interest expense using the effective interest method over the life of the loan. Pursuant to the Amendment, one-half of the aggregate Existing Warrants, exercisable for a total of 95,057 shares of Celsion’s common stock, have been canceled, and, in connection with the Amendment, Celsion issued Horizon new warrants exercisable at a per share exercise price equal to \$1.01 for a total of 247,525 shares of Celsion’s common stock (the “New Warrants” and, together with the Existing Warrants, the “Warrants”). The remaining 95,057 Existing Warrants issued in connection with the Horizon Credit Agreement remain outstanding at a per share exercise price of \$2.63.

The New Warrants were immediately exercisable for cash or by net exercise from the date of grant and will expire after ten years from the date of grant. Effective October 27, 2020. The Horizon Credit Agreement contains customary representations, warranties and affirmative and negative covenants including, among other things, covenants that limit or restrict Celsion’s ability to grant liens, incur indebtedness, make certain restricted payments, merge, or consolidate and make dispositions of assets.

The Amendment was evaluated in accordance with FASB ASC 470-50, *Debt-Modifications and Extinguishments*, for debt modification and extinguishment accounting. We accounted for the \$5 million we repaid as a debt extinguishment thereby reducing the principal obligations accordingly. Also, in connection with the \$5 million repayment, we recognized as interest expense, approximately \$0.2 million of unamortized debt discount, deferred financing and end of term fees related to the repaid obligation in August 2020.

We accounted for the remaining \$5 million of obligation under the Amendment as a debt modification to the initial agreement with respect to the minor changes in cash flows. Also, in connection with the \$5 million remaining obligations, we recorded \$5,000 of financing fees and the New Warrant fair value of \$247,548 as additional debt discount on the \$5 million remaining obligation. Therefore, approximately \$109,706 of unamortized debt discount will be amortized over the remaining life of the new obligations. The \$275,000 of end of term fees, net of previously amortized end of term fees totaling \$142,605 previously accrued on the original note associated with the \$5 million remaining obligation, will be amortized as interest expense over the remaining life of the new obligations.

During the three and six-month periods ended June 30, 2021, the Company incurred \$105,607 and \$225,920, respectively, in interest expense and amortized \$102,126 and \$139,428 as interest expense for debt discounts and end of term charges in connection with the Horizon Credit Agreement. During the three and six-month periods ended June 30, 2020, the Company incurred \$243,299 and \$486,597, respectively, in interest expense and amortized \$96,727 and \$192,793, respectfully, as interest expense for debt discounts and end of term charges in connection with the Horizon Credit Agreement.

On June 18, 2021, as a condition of entering into the SVB Loan Facility, the Company paid the outstanding principal balance, an early termination fee and the end of term charges in full satisfaction of the Horizon Credit Agreement, as amended. Following is a schedule of the amounts paid to Horizon on June 18, 2021.

Principal balance at June 18, 2021	\$ 5,000,000
Early termination fees	150,000
End of term charges	275,000
Total	<u>\$ 5,425,000</u>

During the three and six months ended June 30, 2021, the Company recorded a loss of \$234,419 on the termination of the Horizon Credit Agreement, as amended, which represented the early termination fee and the end of term fees, net of previously amortized interest expense totaling \$190,581 on the date of its payoff.

Note 12. Stockholders’ Equity

In September 2018, the Company filed with the SEC a \$75 million shelf registration statement on Form S-3 (the 2018 Shelf Registration Statement) 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 was fully utilized by the end of January 2021.

On March 19, 2021, the Company filed with the SEC a new \$100 million shelf registration statement on Form S-3 (the “2021 Registration Statement”) 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 March 30, 2021.

Capital on DemandTM Sales Agreement

On December 4, 2018, the Company entered into the Capital on Demand Agreement with 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.

During 2020 through June 30, 2020, the Company sold and issued an aggregate of 1.2 million shares under the Capital on Demand Agreement, receiving approximately \$3.5 million in gross proceeds. During the first half of 2021, the Company sold 7.2 million shares under the Capital on Demand Agreement, receiving approximately \$6.9 million in gross proceeds under the Capital on Demand Agreement.

Registered Direct Offering

On February 27, 2020, we entered into a Securities Purchase Agreement (the “February 2020 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 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. In a concurrent private placement (the “Private Placement”), the Company issued to the investors that participated in the February 2020 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 Original 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 of the Original 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. On July 31, 2020, the Company filed a Form S-3 Registration Statement to register the shares of common stock issuable under the Exchange Warrants; the Registration Statement was declared effective by the SEC on August 13, 2020. No Exchange Warrants were exercised during 2020. During 2021 through the date of this Quarterly Report on Form 10-Q, the Company issued 1.2 million shares pursuant to investors exercising Exchange Warrants, receiving approximately \$1.5 million in net proceeds.

Underwritten Offering

On June 22, 2020, the Company entered into an underwriting agreement (the “Underwriting Agreement”) with Oppenheimer & Co. Inc. (the “Underwriter”), relating to the issuance and sale (the “Underwritten Offering”) of 2,666,667 shares of the Company’s common stock. Pursuant to the terms of the Underwriting Agreement, the Underwriter agreed to purchase the shares at a price of \$3.4875 per share. The Underwriter offered the shares at a public offering price of \$3.75 per share, reflecting an underwriting discount equal to \$0.2625, or 7.0% of the public offering price. The net proceeds to the Company from the Underwritten Offering, after deducting the underwriting discount and estimated offering expenses payable by the Company, were approximately \$9.1 million.

Pursuant to the Underwriting Agreement, until December 31, 2020, the Underwriter had a right of first refusal to act as sole underwriter, initial purchaser, placement/selling agent, or arranger, as the case may be, on any new financing for the Company (excluding equipment lease financings, loans or grants from governmental authorities or in connection with government programs and financings relating to or sales of tax attributes) during such period. The Underwriter common stock the sole right to determine whether or not any other broker dealer shall have the right to participate in any such offering and the economic terms of any such participation.

January 2021 Registered Direct Offering

On January 22, 2021, the Company entered into a Securities Purchase Agreement (the “January 2021 Purchase Agreement”) with several institutional investors, pursuant to which the Company agreed to issue and sell, in a registered direct offering (the “January 2021 Offering”), an aggregate of 25,925,925 shares of the Company’s common stock at an offering price of \$1.35 per share for gross proceeds of approximately \$35 million before the deduction of the January 2021 Placement Agents (as defined below) fee and offering expenses. The January 2021 Purchase Agreement contains customary representations, warranties and agreements by the Company and customary conditions to closing. The closing of the January 2021 Offering occurred on January 26, 2021.

In connection with the January 2021 Offering, the Company entered into a placement agent agreement (the “January 2021 Placement Agent Agreement”) with A.G.P./Alliance Global Partners (together with Brookline Capital Markets, the “January 2021 Placement Agents”) pursuant to which the Company agreed to pay the January 2021 Placement Agents a cash fee equal to 7% of the aggregate gross proceeds raised from the sale of the securities sold in the January 2021 Offering and reimburse the January 2021 Placement Agents for certain of their expenses in an amount not to exceed \$82,500.

March 2021 Registered Direct Offering

On March 31, 2021, the Company entered into a Securities Purchase Agreement (the “March 2021 Purchase Agreement”) with several institutional investors, pursuant to which the Company agreed to issue and sell, in a registered direct offering (the “March 2021 Offering”), an aggregate of 11,538,462 shares of the Company’s common stock, at an offering price of \$1.30 per share for gross proceeds of approximately \$15 million before the deduction of the placement agents fee and offering expenses. The shares were offered by the Company pursuant to the 2021 Registration Statement. The closing of the Offering occurred on April 5, 2021.

In connection with the March 2021 Offering, the Company entered into a placement agent agreement (the “March 2021 Placement Agent Agreement”) with A.G.P./Alliance Global Partners, as lead placement agent (“AGP,” and together with JonesTrading Institutional Services LLC and Brookline Capital Markets, a division of Arcadia Securities, LLC, serving as co-placement agents, the “March 2021 Placement Agents”) pursuant to which the Company agreed to pay the March 2021 Placement Agents an aggregate cash fee equal to 7% of the aggregate gross proceeds raised from the sale of the securities sold in the Offering and reimburse the Placement Agents for certain of their expenses in an amount not to exceed \$82,500.

Under the March 2021 Purchase Agreement and March 2021 Placement Agent Agreement, the Company and its subsidiaries are prohibited, for a period of 90 days after the closing, from entering into any agreement to issue or announcing any issuance or proposed issuance of common stock or any other securities that are at any time convertible into, or exercisable or exchangeable for, or otherwise entitle the holder thereof to receive common stock without the prior written consent of AGP or the investors participating in the offering. For purposes of this offering, AGP and the investors from the Company’s January 2021 Offering waived a similar 90-day restriction in the placement agent agreement and purchase agreement for that transaction.

LPC Purchase Agreement

On September 8, 2020, the Company entered into a purchase agreement (the “LPC Purchase Agreement”) and a Registration Rights Agreement (the “Registration Rights Agreement”) with Lincoln Park Capital Fund, LLC (“Lincoln Park”), pursuant to which, upon the terms and subject to the conditions and limitations set forth therein, the Company has the right to sell to Lincoln Park up to \$26.0 million of shares of the Company’s common stock at the Company’s discretion as described below (the “LPC Offering”). During 2020, the Company sold and issued an aggregate of 3.3 million shares, including the 437,828 commitment shares, under the LPC Purchase Agreement, receiving approximately \$2.2 million in gross proceeds. On January 21, 2021, the Company terminated the LPC Purchase Agreement. The Company did not sell any shares under the LPC Purchase Agreement in 2021.

Note 13. 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”). At the 2020 Annual Stockholders Meeting of the Company held on June 15, 2020, stockholders approved an amendment to the 2018 Plan, as previously amended, whereby the Company increased the number of shares of common stock available by 2,500,000 to a total of 6,400,000 under the 2018 Plan, as amended. At the 2021 Annual Stockholders Meeting of the Company held on June 10, 2020, stockholders approved an amendment to the 2018 Plan, as previously amended, whereby the Company increased the number of shares of common stock available by 7,700,000 to a total of 14,100,000 under the 2018 Plan, as amended.

The Company has issued stock awards to employees and directors in the form of stock options and restricted stock. Options are generally granted with strike prices equal to the fair market value of a share of Celsion common stock on the date of grant. Incentive stock options may be granted to purchase shares of common stock at a price not less than 100% of the fair market value of the underlying shares on the date of grant, provided that the exercise price of any incentive stock option granted to an eligible employee owning more than 10% of the outstanding stock of Celsion must be at least 110% of such fair market value on the date of grant. Only officers and key employees may receive incentive stock options.

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

On September 28, 2018, and again 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 164,004 and 140,004 shares of Celsion common stock, respectively and (ii) inducement restricted stock awards (the “Inducement Stock Grants”) totaling 19,000 and 13,000 shares of Celsion common stock to five 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 \$2.77 and \$2.18 which represents the closing price of Celsion’s common stock as reported by Nasdaq on September 28, 2018 and February 19, 2019, respectively. Each Inducement Option Grant will vest over three years, with one-third vesting on the one-year anniversary of the employee’s first day of employment with the Company and one-third vesting on the second and third anniversaries thereafter, subject to the new employee’s continued service relationship with the Company on each such date. Each Inducement Option Grant has a ten-year term and is subject to the terms and conditions of the applicable stock option agreement. Each of Inducement Stock Grant vested on the one-year anniversary of the employee’s first day of employment with the Company is 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 June 30, 2021, there were a total of 14,198,424 shares of Celsion common stock reserved for issuance under the 2018 Plan, which were comprised of 6,548,325 shares of Celsion common stock subject to equity awards previously granted under the 2018 Plan and 2007 Plan and 7,650,099 shares of Celsion common stock available for future issuance under the 2018 Plan. As of June 30, 2021, there were a total of 140,004 shares of Celsion common stock subject to outstanding inducement awards.

Total compensation cost related to stock options and restricted stock awards amounted to \$793,619 and \$578,761 for the three-month periods ended June 30, 2021 and 2020, respectively. Of these amounts, \$299,581 and \$200,186 was charged to research and development during the three-month periods ended June 30, 2021 and 2020, respectively, and \$494,038 and \$378,575 was charged to general and administrative expenses during the three-month periods ended June 30, 2021 and 2020, respectively.

Total compensation cost related to stock options and restricted stock awards amounted to \$2,372,945 and \$1,030,726 for the six-month periods ended June 30, 2021 and 2020, respectively. Of these amounts, \$882,088 and \$378,122 was charged to research and development during the six-month periods ended June 30, 2021 and 2020, respectively, and \$1,490,857 and \$652,604 was charged to general and administrative expenses during the six-month periods ended June 30, 2021 and 2020, respectively.

As of June 30, 2021, there was \$3.2 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 1.2 years. The weighted average grant date fair values of the stock options granted was \$1.98 and \$3.10 during the six-month periods ended June 30, 2021 and 2020, respectively. A summary of stock option awards and restricted stock grants for the three-months ended June 30, 2021 is presented below:

	Stock Options		Restricted Stock Awards		Weighted Average
	Options Outstanding	Weighted Average Exercise Price	Non-vested Restricted Stock Outstanding	Weighted Average Grant Date Fair Value	Contractual Terms of Equity Awards (in years)
Equity awards outstanding at January 1, 2021	4,624,725	\$ 2.77	2,750	\$ 0.89	
Equity awards granted	2,154,000	\$ 2.18	7,000	\$ 1.38	
Equity awards exercised or vested and issued	(7,500)	\$ 0.63	-	\$ -	
Equity awards forfeited, cancelled or expired	(92,646)	\$ 2.69	-	\$ -	
Equity awards outstanding at June 30, 2021	<u>6,678,579</u>	\$ 2.58	<u>9,750</u>	\$ 1.27	8.0
Aggregate intrinsic value of outstanding equity awards at June 30, 2021	<u>\$ 12,145</u>		<u>\$ 12,383</u>		
Equity awards exercisable at June 30, 2021	<u>4,329,286</u>	\$ 2.73			7.8
Aggregate intrinsic value of equity awards exercisable at June 30, 2021	<u>\$ 1,650</u>				

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:

	Six Months Ended June 30,	
	2021	2020
Risk-free interest rate	1.56 to 1.74%	0.71 to 1.33%
Expected volatility	106.8 to 113.0%	100.4 to 104.2%
Expected life (in years)	7.5 to 10.0	8.5 to 10.0
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 14. Earn-Out Milestone Liability

On March 28, 2019, the Company and EGWU, Inc, entered into an amendment to its purchase agreement ("Amended Asset Purchase Agreement"), whereby payment of the earnout milestone liability related to the Ovarian Cancer Indication of \$12.4 million had been modified. The Company has the option to make the payment as follows:

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

As of June 30, 2021, March 31, 2021, and December 31, 2020, the Company fair valued the earn-out milestone liability at \$7.1 million, \$7.2 million and \$7.0 million, respectively, and recognized a non-cash benefit of \$0.1 million for the three-months ended June 30, 2021 and a non-cash charge of \$0.1 million for the six-months ended June 30, 2021. In assessing the earnout milestone liability at June 30, 2021 and March 31, 2021, the Company fair valued each of the two payment options per the Amended Asset Purchase Agreement and weighted them at 50% / 50% probability for the \$7.0 million and the \$12.4 million payments, respectively.

As of June 30, 2020, March 31, 2020, and December 31, 2019, the Company fair valued the earn-out milestone liability at \$6.0 million, \$5.8 million, and \$5.7 million, respectively and recognized a non-cash charge of \$0.2 and \$0.3 million for the three-month and six-month periods ended June 30, 2020, respectively. In assessing the earnout milestone liability at June 30, 2020 and March 31, 2020, the Company fair valued each of the two payment options per the Amended Asset Purchase Agreement and weighted them at 80% / 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 six-month period ended June 30, 2021:

Balance at January 1, 2021	\$ (7,018,000)
Non-cash loss from the change in fair value	(70,000)
Balance at June 30, 2021	<u>\$ (7,088,000)</u>

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
June 30, 2021	80%	9%	0.42 to 1.42 years
March 31, 2021	80%	9%	0.29 to 1.29 years
December 31, 2020	80%	9%	0.54 to 1.54 years
June 30, 2020	80%	9%	0.54 to 1.54 years
March 31, 2020	80%	9%	1.04 to 2.04 years
December 31, 2019	80%	9%	1.12 to 2.12 years

Note 15. Warrants

Following is a summary of all warrant activity for the six months ended June 30, 2021:

Warrants	Number of Warrants Issued	Weighted Average Exercise Price
Warrants outstanding at December 31, 2020	3,853,566	\$ 1.35
Warrants exercised during the six months ended June 30, 2021 (see Note 12)	(1,216,667)	\$ 1.24
Warrants outstanding at June 30, 2021	<u>2,636,899</u>	\$ 1.40
Aggregate intrinsic value of outstanding warrants at June 30, 2021	<u>\$ 159,857</u>	
Weighted average remaining contractual terms at June 30, 2021	4.6 years	

Note 16. 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. 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. The monthly rent ranges 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 June 30, 2021:

	For the year ending June 30,
Remainder of 2021	\$ 266,188
2022	535,579
2023	233,116
2024 and thereafter	-
Subtotal future lease payments	<u>1,034,883</u>
Less imputed interest	<u>(101,664)</u>
Total lease liabilities	<u>\$ 933,219</u>
Weighted average remaining life	<u>2.0 years</u>
Weighted average discount rate	<u>9.98%</u>

For the three-month and six-month periods ended June 30, 2021, operating lease expense was \$130,595 and \$261,190, respectively and cash paid for operating leases included in operating cash flows was \$132,684 and \$264,546, respectively. For the three-month and six-month periods ended June 30, 2020, operating lease expense was \$130,595 and \$261,190, respectively and cash paid for operating leases included in operating cash flows was \$131,452 and \$262,084, respectively.

Note 17. 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 18. 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 Company was a defendant in this derivative and putative class action lawsuit in the Superior Court of New Jersey, Chancery Division, filed by a shareholder against the Company (as both a class action defendant and nominal defendant), and certain of its officers and directors (the “Individual Defendants”), with the caption *O’Connor v. Braun et al.*, Docket No. MER-C-000068-19 (the “Shareholder Action”). The Shareholder Action alleged breaches of the defendants’ fiduciary duties based on allegations that the defendants omitted or made improper statements when seeking shareholder approval of the 2018 Stock Incentive Plan. The Shareholder Action sought, 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.

On April 24, 2020, the Company, the Individual Defendants, and the plaintiff (the “Parties”) entered into a Settlement Agreement and Release (the “Settlement Agreement”), which memorializes the terms of the Parties’ settlement of the Shareholder Action (the “Settlement”). The Settlement calls for repricing of certain stock options and payment of plaintiff legal fees of \$187,500. On July 24, 2020, the Court issued an order approving the Parties’ proposed form of notice to shareholders regarding the Settlement. A hearing was held on September 8, 2020 whereby the Court issued a final approval approving the Settlement. Pursuant to the Settlement, the Company paid \$187,500 on October 1, 2020. Without admitting the validity of any of the claims asserted in the Shareholder Action, or any liability with respect thereto, and expressly denying all allegations of wrongdoing, fault, liability, or damage against the Company and the Individual Defendants arising out of any of the conduct, statements, acts or omissions alleged, or that could have been alleged, in the Shareholder Action, the Company and the Individual Defendants concluded that it was desirable that the claims be settled on the terms and subject to the conditions set forth in the Settlement Agreement. The Company and the Individual Defendants entered into the Settlement Agreement for settlement purposes only and solely to avoid the cost and disruption of further litigation.

On October 29, 2020, a putative securities class action was filed against the Company and certain of its officers and directors (the “Spar Individual Defendants”) in the U.S. District Court for the District of New Jersey, captioned *Spar v. Celsion Corporation, et al.*, Case No. 1:20-cv-15228. The plaintiff alleges that the Company and Individual Defendants made false and misleading statements regarding one of the Company’s product candidates, ThermoDox[®], and brings claims for damages under Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder against all Defendants, and under Section 20(a) of the Exchange Act of 1934 against the Spar Individual Defendants. The Company believes that the case is without merit and intends to defend it vigorously. Due to the early stage of the case neither the likelihood that a loss, if any, will be realized, nor an estimate of possible loss or range of loss, if any, can be determined.

In February 2021, a derivative shareholder lawsuit was filed against the Company, as the nominal defendant, and certain of its directors and officers as defendants in the U.S. District Court for the District of New Jersey, captioned *Fidler v. Michael H. Tardugno et al.*, Case No. 3:21-cv-02662. The plaintiff alleges breach of fiduciary duty and other claims arising out of alleged statements made by certain of the Company’s directors and/or officers regarding ThermoDox[®]. The Company believes it has meritorious defenses to these claims and intends to vigorously contest this suit. Due to the early stage of the case neither the likelihood that a loss, if any, will be realized, nor an estimate of possible loss or range of loss, if any, can be determined.

Item 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS.

The following discussion and analysis of our financial condition and results of operations This discussion contains forward-looking statements that involve risks and uncertainties. Our actual results may differ materially from those discussed in forward-looking statements. Factors that might cause a difference include, but are not limited to, those discussed above under "Cautionary Note Regarding Forward-Looking Statements", and in Item 1A. Risk factors in our Annual Report on Form 10-K for the fiscal year ended December 31, 2020.

Strategic and Clinical Overview

Celsion Corporation ("Celsion" and the "Company") is a fully integrated, clinical stage biotechnology company focused on advancing a portfolio of innovative treatments including DNA-based immunotherapies, next generation vaccines and directed chemotherapies through clinical trials and eventual commercialization. The Company's product pipeline includes GEN-1, a DNA-based immunotherapy for the localized treatment of ovarian cancer and ThermoDox[®], a proprietary heat-activated liposomal encapsulation of doxorubicin, currently under investigator-sponsored development for several cancer indications. Celsion has two feasibility stage platform technologies for the development of novel nucleic acid-based immunotherapies and next generation vaccines and other anti-cancer DNA or RNA therapies. Both are novel synthetic, non-viral vectors with demonstrated capability in nucleic acid cellular transfection.

IMMUNO-ONCOLOGY Program

On June 20, 2014, the Company completed the acquisition of substantially all of the assets of EGEN, a private company located in Huntsville, Alabama. Pursuant to the Asset Purchase Agreement, CLSN Laboratories acquired all of EGEN's right, title and interest in 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. A key asset acquired from EGEN was the TheraPlas technology platform. The first drug candidate developed from this technology platform is GEN-1.

THERAPLAS Technology Platform

TheraPlas is a technology platform for the delivery of DNA and 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/mRNA 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 that TheraPlas may be a viable alternative to current approaches to gene delivery due to several distinguishing characteristics, including enhanced molecular versatility that allows for complex modifications to potentially improve activity and safety.

The design of the TheraPlas delivery system is based on molecular functionalization of polyethyleneimine (PEI), a cationic delivery polymer with a distinct ability to escape from the endosomes due to heavy protonation. The transfection activity and toxicity of PEI is tightly coupled to its molecular weight; therefore, the clinical application of PEI is limited. We have used molecular functionalization strategies to improve the activity of low molecular weight PEIs without augmenting their cytotoxicity. In one instance, chemical conjugation of a low molecular weight branched BPEI1800 with cholesterol and polyethylene glycol (PEG) to form PEG-PEI-Cholesterol (PPC) dramatically improved the transfection activity of BPEI1800 following in vivo delivery. Together, the cholesterol and PEG modifications produced approximately 20-fold enhancement in transfection activity. Biodistribution studies following intraperitoneal or subcutaneous administration of DNA/PPC nanocomplexes showed DNA delivery localized primarily at the injection site with only small amount escaping into the systemic circulation. PPC is the delivery component of our lead TheraPlas product, GEN-1, which is in clinical development for the treatment of ovarian cancer. The PPC manufacturing process has been scaled up from bench scale (1-2 g) to 0.6Kg, and several current Good Manufacturing Practice ("cGMP") lots have been produced with reproducible quality.

We believe that TheraPlas has emerged as a viable alternative to current approaches due to several distinguishing characteristics such as strong molecular versatility that may allow for complex modifications to potentially improve activity and safety with little difficulty. The biocompatibility of these polymers reduces the risk of adverse immune response, thus allowing for repeated administration. Compared to naked DNA or cationic lipids, TheraPlas is generally safer, more efficient, and cost effective. We believe that these advantages place Celsion in a strong position to capitalize on this technology platform.

Ovarian Cancer Overview

Ovarian cancer is the most lethal of gynecological malignancies among women with an overall five-year survival rate of 45%. This poor outcome is due in part to the lack of effective prevention and early detection strategies. There were approximately 22,000 new cases of ovarian cancer in the U.S. in 2014 with an estimated 14,000 deaths. Mortality rates for ovarian cancer declined very little in the last forty years due to the unavailability of detection tests and improved treatments. Most women with ovarian cancer are not diagnosed until Stages III or IV, when the disease has spread outside the pelvis to the abdomen and areas beyond causing swelling and pain, where the five-year survival rates are 25 - 41 percent and 11 percent, respectively. First-line chemotherapy regimens are typically platinum-based combination therapies. Although this first line of treatment has an approximate 80 percent response rate, 55 to 75 percent of women will develop recurrent ovarian cancer within two years and ultimately will not respond to platinum therapy. Patients whose cancer recurs or progresses after initially responding to surgery and first-line chemotherapy have been divided into one of the two groups based on the time from completion of platinum therapy to disease recurrence or progression. This time period is referred to as platinum-free interval. The platinum-sensitive group has a platinum-free interval of longer than six months. This group generally responds to additional treatment with platinum-based therapies. The platinum-resistant group has a platinum-free interval of shorter than six months and is resistant to additional platinum-based treatments. Pegylated liposomal doxorubicin, topotecan, and Avastin are the only approved second-line therapies for platinum-resistant ovarian cancer. The overall response rate for these therapies is 10 to 20 percent with median overall survival (“OS”) of eleven to twelve months. Immunotherapy is an attractive novel approach for the treatment of ovarian cancer particularly since ovarian cancers are considered immunogenic tumors. IL-12 is one of the most active cytokines for the induction of potent anti-cancer immunity acting through the induction of T-lymphocyte and natural killer cell proliferation. The precedence for a therapeutic role of IL-12 in ovarian cancer is based on epidemiologic and preclinical data.

GEN-1 Immunotherapy

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
- Local therapy is ideal for long-term maintenance therapy.

OVATION I Study. In February 2015, we announced that the U.S. Food and Drug Administration (“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 I Study”). On September 30, 2015, we announced enrollment of the first patient in the OVATION I Study. The OVATION I Study was designed to:

- (i) identify a safe, tolerable and therapeutically active dose of GEN-1 by recruiting and maximizing an immune response;
- (ii) enroll three to six patients per dose level and evaluate safety and efficacy; and
- (iii) attempt to define an optimal dose for a follow-on Phase I/II study.

In addition, the OVATION I Study established 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 ovarian cancer 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 I 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 I Study. On October 3, 2017, we announced final translational research and clinical data from the OVATION I 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 NACT 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 OS; 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 I Study. GEN-1 plus standard chemotherapy produced 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 progression free survival ("PFS") results from the OVATION I Study. Median PFS in patients treated per protocol (n=14) was 21 months and was 17.1 months for the intent-to-treat ("ITT") 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, their disease progresses within about 12 months on average. The results from the OVATION I 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 interval 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.

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 OVATION I Study in order to determine the next steps forward for our GEN-1 immunotherapy program.

On November 13, 2017, the Company filed its Phase I/II clinical trial protocol with the FDA for GEN-1 for the localized treatment of ovarian cancer. The protocol is designed with a single dose escalation phase to 100 mg/m² to identify a safe and tolerable dose of GEN-1 while maximizing an immune response. The Phase I portion of the study will be followed by a continuation at the selected dose in approximately 110 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 (“IDS”). The OVATION 2 Study will include up to 110 patients with Stage III/IV ovarian cancer, with 12 to 15 patients in the Phase I portion and up to 95 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.

In March 2020, the Company announced encouraging initial clinical data from the first 15 patients enrolled in the Phase I portion of the 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 eight out of nine patients (88%) in the GEN-1 treatment arm having an R0 resection, which indicates a microscopically margin-negative complete 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/m ² of GEN-1 plus NACT	n=12	42%
61, 79, 100 mg/m ² of GEN-1 plus NACT	n=17	82%

- The 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 (the “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 is an 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 FDA.

On March 26, 2020, the Company 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 showed positive results in progression-free survival (“PFS”). The hazard ratio (“HR”) was 0.53 in the ITT group, showing strong signals of efficacy. 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 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 FDA 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.

On July 27, 2020, the Company announced the randomization of the first two patients in the Phase II portion of the OVATION 2 Study with GEN-1 in advanced ovarian cancer. The Company anticipates completing enrollment of up to 110 patients in the second half of 2021. Because this is an open-label study, the Company intends to provide clinical updates throughout the course of treatment including response rates and surgical resection scores.

In February 2021, the Company announced that it has received Fast Track designation from the FDA for GEN-1, its DNA-mediated IL-12 immunotherapy currently in Phase II development for the treatment of advanced ovarian cancer and also provided an update on the OVATION 2 Study. The Company reported that approximately one-third, or 34 patients, of the anticipated 110 patients had been enrolled into the OVATION 2 Study, of which 20 are in the treatment arm and 14 are in the control. Currently, 27 patients have had their interval debulking surgery with the following results:

- 12 of 15, or 80%, of patients treated with GEN-1 had a R0 resection, which indicates a microscopically margin-negative complete resection in which no gross or microscopic tumor remains in the tumor bed.
- 7 of 12 patients, or 58%, of patients in the control arm had an R0 resection.
- This interim data represents a 38% improvement in R0 resection rates for GEN-1 patients compared with control arm patients and is consistent with the reported improvement in resection scores noted in the encouraging Phase I OVATION I Study, the manuscript of which has been submitted for peer review publication.

The Company further reported that 22 clinical sites in the U.S. and Canada have been initiated, with three more sites expected to be added by the end of the first quarter. Clinical investigators met in early February 2021 in a virtual meeting and expressed excitement about the potential for GEN-1 to treat advanced ovarian cancer and, despite the challenges and earlier delays posed by the COVID-19 pandemic, they remain committed to completing enrollment in the study during the second half of 2021.

PLACCINE DNA VACCINE TECHNOLOGY PLATFORM

In January 2021, the Company announced the filing of a provisional U.S. patent application for a novel DNA-based, investigational vaccine for preventing or treating infections from a broad range of infectious agents including the coronavirus disease using its PLACCINE DNA vaccine technology platform (“PLACCINE”). The provisional patent covers a family of novel composition of multi-cistronic vectors and polymeric nanoparticles that comprise the PLACCINE DNA vaccine platform technology for preventing or treating infectious agents that have the potential for global pandemics, including the SARS-CoV-2 virus and its variations, using the Company’s platform technology.

Celsion’s PLACCINE DNA vaccine technology platform is characterized by a single multi-cistronic DNA plasmid vector expressing multiple pathogen antigens along with a potent immune modifier and delivered with a synthetic delivery system. It is easily adaptable to creating vaccines for a multitude of pathogens, including emerging pathogens leading to pandemics as well as infectious diseases that have yet to be effectively addressed with current vaccine technologies. This flexible vaccine platform is well supported by an already established supply chain to produce any plasmid vector and its assembly into a respective vaccine formulation.

PLACCINE is an extension of the Company’s synthetic, non-viral TheraPlas delivery technology currently in a Phase II trial for the treatment of late-stage ovarian cancer with GEN-1. Celsion’s proprietary multifunctional DNA vaccine technology concept is built on the flexible PLACCINE technology platform that is amenable to rapidly responding to the SARS-CoV-2 virus, as well as possible future mutations of SARS-CoV-2, other future pandemics, emerging bioterrorism threats, and novel infectious diseases. Celsion’s extensive experience with TheraPlas suggests that the PLACCINE-based nanoparticles are stable at storage temperatures of 4°C to 25°C, making vaccines developed on this platform easily suitable for broad world-wide distribution.

Celsion’s vaccine approach is designed to optimize the quality of the immune response dictating the efficiency of pathogen clearance and patient recovery. Celsion has taken a multivalent approach in an effort to generate an even more robust immune response that not only results in a strong neutralizing antibody response, but also a more robust and durable T-cell response. Delivered with Celsion’s synthetic polymeric system, the proprietary DNA plasmid is protected from degradation and its cellular uptake is facilitated.

COVID-19 Vaccine Overview

Emerging data from the recent literature indicates that the quality of the immune response as opposed to its absolute magnitude is what dictates SARS-CoV-2 viral clearance and recovery and that an ineffective or non-neutralizing enhanced antibody response might actually exacerbate disease. The first-generation COVID-19 vaccines were developed for rapid production and deployment and were not optimized for generating cellular responses that result in effective viral clearance. Though early data has indicated some of these vaccines to be over 95% effective, these first-generation vaccines were primarily designed to generate a strong antibody response and, while they have been shown to provide prophylactic protection against disease, the durability of this protection is currently unclear. The vast majority of these vaccines have been specifically developed to target the SARS-CoV-2 Spike (S) protein (antigen), though it is known that restricting a vaccine to a sole viral antigen creates selection pressure that can serve to facilitate the emergence of viral resistance. Indeed, even prior to full vaccine rollout, it has been observed that the S protein is a locus for rapid evolutionary and functional change as evidenced by the D614G, Y453F, 501Y.V2, and VUI-202012/01 mutations/deletions. This propensity for mutation of the S protein leads to future risk of efficacy reduction over time as these mutations accumulate.

Our Next Generation Vaccine Initiative

Celsion's next generation vaccine initiative stands at the confluence of immunotherapy and immunogenicity and envisions delivery, on a single plasmid, multiple SARS-CoV-2 antigens in conjunction with a potent immune modifier, interleukin-12 (IL-12), which directs a TH-1 immune response, stimulates T-cell immunity, and also promises the promotion of humoral immunity (antibody response). While most COVID-19 vaccines in late-stage clinical development are monovalent (S protein antigen only), Celsion has taken this multivalent approach in an effort to generate an even more robust immune response that not only results in a strong neutralizing antibody response, but also a more robust and durable T-cell response.

Celsion's vaccine candidate approach comprises a single plasmid vector containing the DNA sequence encoding the cytokine IL-12 and multiple SARS-CoV-2 antigens, including S antigen in combination with the membrane (M) or nucleocapsid (N) antigen. Delivery will be evaluated intramuscularly, intradermally, or subcutaneously with a non-viral synthetic DNA delivery carrier that facilitates vector delivery into the cells of the injected tissue and has potential immune adjuvant properties. Unique designs and formulations of Celsion vaccine candidates may offer several potential key advantages.

- While the antibodies against S antigen would prevent virus entry into cells, the M and N antibodies could help virus clearance through antibody-mediated opsonization and phagocytosis. The presentation of multiple antigens on the cell surface of vaccine-injected tissue produces a broad variety of killer T-cells which could potentially produce more efficient viral clearance than a single antigen vaccine.
- Since IL-12 is an essential regulator of the differentiation, proliferation, and maintenance of T helper 1 (TH-1) cells that generate killer T-cells and memory T-cells against virally infected cells, its simultaneous expression could boost the viral clearance by the vaccine and improve the immune system's memory against any future exposure of the same virus.
- Finally, the synthetic polymeric DNA carrier is an important component of the vaccine composition as it has the potential to facilitate the vaccine immunogenicity by improving vector delivery and, due to potential adjuvant properties, attract professional immune cells to the site of vaccine delivery.

Future vaccine technology will need to address viral mutations and the challenges of efficient manufacturing, distribution, and storage. We believe an adaptation of our TheraPlas technology, PLACCINE, has the potential to meet these challenges. Our approach is described in our provisional patent filing and is summarized as a DNA vaccine technology platform characterized by a single plasmid DNA with multiple coding regions. The plasmid vector is designed to express multiple pathogen antigens along with a potent immune modifier. It is delivered via a synthetic delivery system and has the potential to be easily modified to create vaccines against a multitude of infectious diseases, addressing:

- **Viral Mutations:** PLACCINE may offer broad-spectrum and mutational resistance (variants) by targeting multiple antigens on a single plasmid vector.
- **Enhanced Efficacy:** The potent immune modifier IL-12 may improve humoral and cellular responses to viral antigens and can be incorporated in the plasmid.
- **Durable Efficacy:** PLACCINE delivers a DNA plasmid-based antigen that can result in durable antigen exposure and a robust vaccine response to viral antigens.
- **Storage & Distribution:** PLACCINE allows for stability that is compatible with manageable vaccine storage and distribution.
- **Simple Dosing & Administration:** PLACCINE is a synthetic delivery system that should require a simple injection that does not require viruses or special equipment to deliver its payload.

We are conducting preliminary research associated with our recently announced proprietary DNA vaccine platform provisional patent filing. At the same time, we are redoubling our efforts and R&D resources in our immuno-oncology and next generation vaccine program.

THERMODOX[®] - DIRECTED CHEMOTHERAPY

Liposomes are manufactured submicroscopic vesicles consisting of a discrete aqueous central compartment surrounded by a membrane bilayer composed of naturally occurring lipids. Conventional liposomes have been designed and manufactured to carry drugs and increase residence time, thus allowing the drugs to remain in the bloodstream for extended periods of time before they are removed from the body. However, the current existing liposomal formulations of cancer drugs and liposomal cancer drugs under development do not provide for the immediate release of the drug and the direct targeting of organ specific tumors, two important characteristics that are required for improving the efficacy of cancer drugs such as doxorubicin. A team of research scientists at Duke University developed a heat-sensitive liposome that rapidly changes its structure when heated to a threshold minimum temperature of 39.5° to 42° Celsius. Heating creates channels in the liposome bilayer that allow an encapsulated drug to rapidly disperse into the surrounding tissue. This novel, heat-activated liposomal technology is differentiated from other liposomes through its unique low heat-activated release of encapsulated chemotherapeutic agents. We are able to use several available focused-heat technologies, such as radiofrequency ablation (“RFA”), microwave energy and high intensity focused ultrasound (“HIFU”), to activate the release of drugs from our novel heat sensitive liposomes.

THERMODOX[®] for the Treatment of Primary Liver Cancer

Primary Liver Cancer Overview

Hepatocellular carcinoma (“HCC”) is one of the most common and deadliest forms of cancer worldwide. It ranks as the third most common solid tumor cancer. It is estimated that up to 90% of liver cancer patients will die within five years of diagnosis. The incidence of primary liver cancer is approximately 35,000 cases per year in the U.S., approximately 65,000 cases per year in Europe and is increasing at approximately 2-3% per year worldwide. Global incidence (per 2017 GLOBALCAN statistics) is reported at 755,000 cases. The World Health Organization (the “WHO”) has projected that HCC will be the most prevalent form of cancer by 2030. HCC is commonly diagnosed in patients with longstanding hepatic disease and cirrhosis (primarily due to hepatitis C in the U.S., Japan and Europe and hepatitis B in Asia).

At an early stage, the standard first line treatment for liver cancer is surgical resection of the tumor. Up to 80% of patients are ineligible for surgery or transplantation at time of diagnosis because early-stage liver cancer generally has few symptoms and when finally detected the tumor frequently is too large for surgical resection. There are few alternative treatments since radiation therapy and chemotherapy are largely ineffective in treating liver cancer. For tumors generally up to 5 centimeters in diameter, RFA has emerged as the standard of care treatment which directly destroys the tumor tissue through the application of high temperatures administered by a probe inserted into the core of the tumor. Local recurrence rates after RFA directly correlate to the size of the tumor. For tumors 3 cm or smaller in diameter the recurrence rate has been reported to be 10 – 20%; however, for tumors greater than 3 cm, local recurrence rates of 40% or higher have been observed.

Celsion’s Approach

While RFA uses extremely high temperatures (greater than 90° Celsius) to ablate the tumor, it may fail to treat micro-metastases in the outer margins of the ablation zone because temperatures in the periphery may not be high enough to destroy cancer cells. Our ThermoDox[®] treatment approach is designed to utilize the ability of RFA devices to ablate the center of the tumor while simultaneously thermally activating our ThermoDox[®] liposome to release its encapsulated doxorubicin to kill any remaining viable cancer cells throughout the heated region, including the ablation margins. This novel treatment approach is intended to deliver the drug directly to those cancer cells that survive RFA. This approach is designed to increase the delivery of the doxorubicin at the desired tumor site while potentially reducing drug exposure distant to the tumor site.

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. 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 the OPTIMA Study is OS, and the secondary endpoints are progression free survival and safety. The statistical plan calls for two interim efficacy analyses by an independent Data Monitoring Committee (“DMC”).

On February 24, 2014, we announced that 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 Phase III clinical trial called the HEAT Study (the “HEAT Study”). The OPTIMA Study is supported by a hypothesis developed from an OS analysis of a large subgroup of patients from the HEAT Study.

Post-hoc data analysis from our earlier Phase III HEAT Study suggests 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 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). 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.

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, 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 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 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 was 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 lent support to the hypothesis underpinning the OPTIMA Study.

In August 2018, the Company announced that the OPTIMA Study was fully enrolled. 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. The DMC’s pre-planned interim efficacy review followed 128 patient events, or deaths, which occurred in August 2019. 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 OPTIMA Study. Data presented demonstrated that PFS and OS data appeared 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 was based.

On April 15, 2020, the Company announced that the prescribed minimum number of events of 158 patient deaths had been reached for the second pre-specified interim analysis of the OPTIMA Phase III Study. 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. On July 13, 2020, the Company announced that it has received a recommendation from the DMC to consider stopping the global OPTIMA Study. The recommendation was made following the second pre-planned interim safety and efficacy analysis by the DMC on July 9, 2020. The DMC analysis found that the pre-specified boundary for stopping the trial for futility of 0.900 was crossed with an actual value of 0.903. However, the 2-sided p-value of 0.524 for this analysis provides uncertainty, subsequently, the DMC left the final decision of whether or not to stop the OPTIMA Study to Celisio. There were no safety concerns noted during the interim analysis. The Company followed the advice of the DMC considered its options either to stop the study or continue to follow patients after a thorough review of the data, and an evaluation of our probability of success.

On August 4, 2020, the Company issued a press release announcing it would continue following patients for OS, noting that the unexpected and marginally crossed futility boundary, suggested by the Kaplan-Meier analysis at the second interim analysis on July 9, 2020, may be associated with a data maturity issue. On October 12, 2020, the Company provided an update on the ongoing data analysis from its Phase III OPTIMA Study with ThermoDox[®] as well as growing interest among clinical investigators in conducting studies with ThermoDox[®] as a monotherapy or in combination with other therapies.

- Celsion engaged a global biometrics contract research organization, with forensic statistical analysis capability that specializes in data management, statistical consulting, statistical analysis and data sciences, with particular expertise in evaluating unusual data from clinical trials and experience with associated regulatory issues. The primary objective of the CRO's work was to determine the basis and reasoning behind continuing to follow patients for survival, and if there were outside influences that may have impacted the forecast of futility.
- In parallel, the Company submitted all OPTIMA Study clinical trial data to the National Institutes of Health (NIH) and with the expectation of receiving a report on the following:
 - A Cox Regression Analysis for single solitary lesions including minimum burn time per tumor volume, evaluating similarities to the hypothesis generated from the NIH paper published in the *Journal of Vascular and Interventional Radiology*, in which the key finding was that increased RFA heating time per tumor volume significantly improved OS in patients with single lesion HCC who were treated with RFA plus ThermoDox[®], compared with patients treated with RFA alone.
 - A site-by-site evaluation for RFA heating time-based anomalies that may have contributed to the treatment arm performance.
 - An image-based evaluation comparing results from the OPTIMA Study to the data from the HEAT Study that led to the RFA heating time hypothesis.

On February 11, 2021, the Company provided a final update on the Phase III OPTIMA Study and the decision to stop following patients in the Study. Independent analyses conducted by a global biometrics contract research organization and the NIH, did not find any evidence of significance or factors that would justify continuing to follow patients for OS. Therefore, the Company notified all clinical sites to discontinue following patients. The OPTIMA Study database of 556 patients will now be frozen at 185 patient deaths. While the analyses did identify certain patient subgroups that appear to have had a clinical benefit, the Company concluded that it would not be in its best interest to pursue these retrospective findings as the regulatory hurdles supporting further discussion will be significant.

Investigator-Sponsored Studies with ThermoDox[®]

Celsion continues working closely and supporting investigations by others throughout the world in breast cancer, pancreatic cancer and in solid tumors in children. Following inquiries from the NIH, we intend to renew our Cooperative Research and Development Agreement (CRADA) with the Institute at a nominal cost, one goal of which is to pursue their interest in a study of ThermoDox[®] to treat patients with bladder cancer. Importantly, Celsion is developing a business model to support these investigator-sponsored studies in a manner that will not interfere with the Company's focus on our GEN-1 program and vaccine development initiative.

Below are summaries of several investigator-sponsored studies using ThermoDox[®]:

- Oxford University commenced enrolling patients in a Phase I pancreatic cancer study with ThermoDox[®] in combination with High Intensity Focused Ultrasound (HIFU) in July of 2021. The primary objective of this trial, the *PanDox Study: Targeted Doxorubicin in Pancreatic Tumors*, is to quantify the enhancement in intratumoral doxorubicin concentration when delivered with ThermoDox[®] and HIFU, versus doxorubicin monotherapy. This study is being undertaken pursuant to promising data in a mouse model of pancreatic cancer, which was published in the *International Journal of Hyperthermia* in 2018. That preclinical study showed a 23x increase in intratumoral doxorubicin concentration with ThermoDox[®] + HIFU, compared with a 2x increase in intratumoral doxorubicin concentration with free doxorubicin plus HIFU.
- Utrecht University in the Netherlands continues to enroll patients in a Phase I breast cancer study to determine the safety, tolerability and feasibility of ThermoDox[®] in combination with Magnetic Resonance Guided High Intensity Focused Ultrasound (MR-HIFU) hyperthermia and cyclophosphamide therapy for the local treatment of the primary tumor in metastatic breast cancer (mBC). This investigator-sponsored study, which is being funded by the Dutch Cancer Society, the Center for Translational Molecular Medicine (a public-private partnership in the Netherlands), will be conducted at University Medical Center Utrecht and will enroll up to 12 newly diagnosed mBC patients. Celsion will supply ThermoDox[®] clinical product for the trial.
- As evidence of the ongoing support Celsion enjoys from the NIH, they have organized a clinical project to evaluate ThermoDox[®] plus the chemotherapy drug mitomycin in bladder cancer. Depending on the NIH timelines, this study may commence as early as 2021.

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 has incurred significant net losses in each year since our inception. As of June 30, 2021, the Company has incurred approximately \$323 million of cumulative net losses and we had approximately \$64.5 million in cash and cash equivalents, restricted cash, short-term investments, and receivable on sale of 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 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 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 has spread to over 100 countries, including the U.S. Governments and businesses around the world undertook 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 has prohibited many employees from going to work. Uncertainty with respect to the economic impacts of the pandemic introduced significant volatility in the financial markets. The Company did not observe significant impacts on its business or results of operations during 2020 and thus far in 2021 due to 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 U.S. and worldwide resulting from the ongoing COVID-19 pandemic. The disruptions caused by COVID-19 may also disrupt the clinical trials process and enrolment of patients. This may delay commercialization efforts. The Company continues to monitor its operating activities in light of these events. The specific impact, if any, 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.

On July 13, 2020As discussed earlier in this Quarterly Report on Form 10Q, the Company announced that it has received a recommendation from the independent DMC to consider stopping the global Phase III OPTIMA Study of ThermoDox® in combination with RFA for the treatment of HCC, or primary liver cancer on July 13, 2020. On February 11, 2021, the Company issued a letter to shareholders stating that the Company was notifying all clinical sites to discontinue following patients in the OPTIMA Study.

During 2020, 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 New Jersey-based companies. In 2018 and 2019, the Company sold NOLs totaling \$13 million receiving net proceeds of \$12.2 million. In June 2020 and as updated in September 2020, the Company filed an application with the New Jersey Economic Development Authority to sell substantially all of its remaining State of New Jersey net operating losses totaling \$2.0 million available under the program. On February 12, 2021, the New Jersey Economic Development Authority approved the full amount of the Company's application. In February of 2021, the Company entered into an agreement to sell the net operating losses from the 2020 application and the Company received net proceeds of approximately \$1.85 million on May 10, 2021. During 2021, the New Jersey State Legislature increased the maximum lifetime benefit per company from \$15 million to \$20 million, which will allow the Company to participate in this innovative funding program in future years (see additional disclosure on next page).

In June 2018, the Company entered into a Credit Agreement with Horizon Technology Finance Corporation ("Horizon") that provided \$10 million in capital (the "Horizon Credit Agreement"). 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 24 months through July 2020, followed by a 21-month amortization period of principal and interest starting on August 1, 2020 and ending through the scheduled maturity date on April 1, 2023. On August 28, 2020, in connection with an Amendment to the Horizon Credit Agreement, Celsion repaid \$5 million of the \$10 million loan and \$0.2 million in related end of term charges, and the remaining \$5 million in obligations were restructured as more fully discussed in Note 11 to the financial statements. As more fully discussed in Note 11, in June 2021, the Company entered into a \$10 million loan facility with Silicon Valley Bank. The Company immediately used \$6 million from this facility to retire all outstanding indebtedness with Horizon Technology Finance Corporation. The remaining \$4 million will be available to be drawn down up to 12 months after closing and will be used for working capital and to fund the advancement of the Company's product pipelines. The funding is in the form of money market secured indebtedness bearing interest at a calculated WSJ Prime-based variable rate (currently 3.25%).

Payments under the loan agreement are interest only for the first 24 months after loan closing, followed by a 24-month amortization period of principal and interest through the scheduled maturity date.

As more fully discussed in Note 12, during 2021 through the date of the filing of this Quarterly Report on Form 10-Q, the Company raised approximately \$6.9 million in gross proceeds from the use of its JonesTrading Capital on Demand™ financing facility, \$35 million from a registered direct financing completed in January 2021, \$15 million from a registered direct financing completed in April 2021, and \$1.5 million from warrant exercises. With \$64.5 million in cash and cash equivalents, restricted cash, short-term investments and interest receivable at June 30, 2021, the Company believes it has sufficient capital resources to fund its operations through the end of 2024.

The Company has based its estimates 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.

Financing Overview

Equity, Debt and Other Forms of Financing

During 2020, 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 New Jersey-based companies. In 2018 and 2019, the Company sold NOLs totaling \$13 million receiving net proceeds of \$12.2 million. In June 2020 and as updated in September 2020, the Company filed an application with the New Jersey Economic Development Authority to sell substantially all of its remaining State of New Jersey net operating losses totaling \$2.0 million available under the program. On February 12, 2021, the New Jersey Economic Development Authority approved the full amount of the Company's application. In February of 2021, the Company entered into an agreement to sell the net operating losses from the 2020 application and the Company received net proceeds of approximately \$1.85 million on May 10, 2021. During 2021, the New Jersey State Legislature increased the maximum lifetime benefit per company from \$15 million to \$20 million, which will allow the Company to participate in this innovative funding program in future years. On June 16, 2021, the Company filed another application to sell approximately \$1.6 million of net operating losses during 2021 and expects to receive up to approximately \$1.4 million under the current year program.

As previously discussed, the Company entered into a Credit Agreement with Horizon Technology Finance Corporation (“Horizon”) that provided \$10 million in capital (the “Horizon Credit Agreement”) in June 2018. In August, 2020, in connection with an Amendment to the Horizon Credit Agreement, Celsion repaid \$5 million of the \$10 million loan and \$0.2 million in related end of term charges, and the remaining \$5 million in obligations were restructured. In June 2021, the Company entered into a \$10 million loan facility with Silicon Valley Bank. The Company immediately used \$6 million from this facility to retire all outstanding indebtedness with Horizon Technology Finance Corporation. The remaining \$4 million will be available to be drawn down up to 12 months after closing. Payments under the loan agreement are interest only for the first 24 months after loan closing, followed by a 24-month amortization period of principal and interest through the scheduled maturity date.

In September 2018, the Company filed with the SEC a \$75 million shelf registration statement on Form S-3 (the 2018 Shelf Registration Statement) 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 was fully utilized by the end of January 2021.

On March 19, 2021, the Company filed with the SEC a new \$100 million shelf registration statement on Form S-3 (File No. 333-254515) (the “2021 Registration Statement”) 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 March 30, 2021.

During 2020 and 2021 through the date of this Quarterly Report filed on Form 10-Q, we issued a total of 62.5 million shares of common stock as discussed below for an aggregate \$83.2 million in gross proceeds.

- On December 4, 2018, the Company entered into the Capital on Demand Agreement with 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. 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. During 2020, the Company sold and issued an aggregate of 5.2 million shares under the Capital on Demand Agreement, receiving approximately \$6.2 million in gross proceeds. During 2021 through the date of this Quarterly Report on Form 10-Q, the Company sold 7.2 million shares under the Capital on Demand Agreement, receiving approximately \$6.9 million in gross proceeds under the Capital on Demand Agreement.
- On February 27, 2020, we entered into a Securities Purchase Agreement (the “February 2020 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 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. In a concurrent private placement (the “Private Placement”), the Company issued to the investors that participated in the February 2020 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 Original 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 of the Original 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. On July 31, 2020, the Company filed a Form S-3 Registration Statement to register the shares of common stock issuable under the Exchange Warrants; the Registration Statement was declared effective by the SEC on August 13, 2020. No Exchange Warrants were exercised during 2020. During 2021 through the date of this Quarterly Report on Form 10-Q, the Company issued 1.2 million shares pursuant to investors exercising Exchange Warrants, receiving approximately \$1.5 million.

- On June 22, 2020, the Company entered into an underwriting agreement (the “Underwriting Agreement”) with Oppenheimer & Co. Inc. (the “Underwriter”), relating to the issuance and sale (the “Underwritten Offering”) of 2,666,667 shares of the Company’s common stock. Pursuant to the terms of the Underwriting Agreement, the Underwriter agreed to purchase the shares at a price of \$3.4875 per share. The Underwriter offered the shares at a public offering price of \$3.75 per share, reflecting an underwriting discount equal to \$0.2625, or 7.0% of the public offering price. The net proceeds to the Company from the Underwritten Offering, after deducting the underwriting discount and estimated offering expenses payable by the Company, were approximately \$9.1 million.
- On September 8, 2020, the Company entered into a purchase agreement (the “LPC Purchase Agreement”) and a Registration Rights Agreement (the “Registration Rights Agreement”) with Lincoln Park Capital Fund, LLC (“Lincoln Park”), pursuant to which, upon the terms and subject to the conditions and limitations set forth therein, the Company has the right to sell to Lincoln Park up to \$26.0 million of shares of the Company’s Common Stock at the Company’s discretion as described below (the “LPC Offering”). During 2020, the Company sold and issued an aggregate of 3.3 million shares, including the LPC Commitment Shares, under the LPC Purchase Agreement, receiving approximately \$2.2 million in gross proceeds. The Company sent a letter to Lincoln Park terminating the LPC Offering effective January 21, 2021. The Company did not sell any shares under the LPC Purchase Agreement in 2021.
- On January 22, 2021, the Company entered into a Securities Purchase Agreement (the “January 2021 Purchase Agreement”) with several institutional investors, pursuant to which the Company agreed to issue and sell, in a registered direct offering (the “January 2021 Offering”), an aggregate of 25,925,925 shares of the Company’s common stock at an offering price of \$1.35 per share for gross proceeds of approximately \$35 million before the deduction of the January 2021 Placement Agents (as defined below) fee and offering expenses. The closing of the January 2021 Offering occurred on January 26, 2021. In connection with the January 2021 Offering, the Company entered into a placement agent agreement (the “January 2021 Placement Agent Agreement”) with A.G.P./Alliance Global Partners (together with Brookline Capital Markets, the “January 2021 Placement Agents”) pursuant to which the Company agreed to pay the January 2021 Placement Agents a cash fee equal to 7% of the aggregate gross proceeds raised from the sale of the securities sold in the January 2021 Offering and reimburse the January 2021 Placement Agents for certain of their expenses in an amount not to exceed \$82,500.
- On March 31, 2021, the Company entered into a Securities Purchase Agreement (the “March 2021 Purchase Agreement”) with several institutional investors, pursuant to which the Company agreed to issue and sell, in a registered direct offering (the “March 2021 Offering”), an aggregate of 11,538,462 shares of the Company’s common stock, at an offering price of \$1.30 per share for gross proceeds of approximately \$15 million before the deduction of the placement agents fee and offering expenses. The shares were offered by the Company pursuant to the 2021 Registration Statement. The March 2021 Purchase Agreement contains customary representations, warranties and agreements by the Company and customary conditions to closing. The closing of the Offering occurred on April 5, 2021. The Company will account for the March 31, 2021 Offering in the second quarter of 2021. In connection with the March 2021 Offering, the Company entered into a placement agent agreement (the “March 2021 Placement Agent Agreement”) with A.G.P./Alliance Global Partners, as lead placement agent (“AGP,” and together with JonesTrading Institutional Services LLC and Brookline Capital Markets, a division of Arcadia Securities, LLC, serving as co-placement agents, the “March 2021 Placement Agents”) pursuant to which the Company agreed to pay the March 2021 Placement Agents an aggregate cash fee equal to 7% of the aggregate gross proceeds raised from the sale of the securities sold in the Offering and reimburse the Placement Agents for certain of their expenses in an amount not to exceed \$82,500.

Significant Accounting Policies

Our significant accounting policies are more fully described in Note 1 to our consolidated financial statements included in our 2020 Annual Report on Form 10-K for the year ended December 31, 2020 filed with the SEC on March 19, 2021. See Note 5 to the Condensed Consolidated Financial Statements contained in this Quarterly Report on Form 10-Q.

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

FINANCIAL REVIEW FOR THE THREE AND SIX MONTHS ENDED JUNE 30, 2021 AND 2020

Results of Operations

For the three months ended June 30, 2021 our net loss was \$5.4 million compared to a net loss of \$5.3 million for the same three-month period of 2020. For the six months ended June 30, 2021 our net loss was \$11.1 million compared to a net loss of \$10.4 million for the same three-month period of 2020.

With \$64.5 million in cash and cash equivalents, short-term investments, interest receivable and restricted cash, at June 30, 2021, coupled with approximately \$15 million of potential future sales of the Company’s State of New Jersey net operating losses, the Company believes it has sufficient capital resources to fund its operations through 2024.

	Three Months Ended June 30,			
	(In thousands)		Change Increase (Decrease)	
	2021	2020		%
Licensing Revenue:	\$ 125	\$ 125	\$ -	-%
Operating Expenses:				
Clinical Research	1,210	1,481	(271)	(18.3)%
Chemistry, Manufacturing and Controls (CMC)	1,383	1,510	(127)	(8.4)%
Research and development expenses	2,593	2,991	(398)	(13.3)%
General and administrative expenses	2,603	1,901	702	36.9%
Total operating expenses	5,196	4,892	304	6.2%
Loss from operations	\$ (5,071)	\$ (4,767)	\$ (304)	(6.4)%

	Six Months Ended June 30,			
	(In thousands)		Change Increase (Decrease)	
	2021	2020		%
Licensing Revenue:	\$ 250	\$ 250	\$ -	-%
Operating Expenses:				
Clinical Research	2,364	3,299	(935)	(28.3)%
Chemistry, Manufacturing and Controls (CMC)	2,801	2,744	57	2.1%
Research and development expenses	5,165	6,043	(878)	(14.5)%
General and administrative expenses	5,540	3,740	1,800	48.1%
Total operating expenses	10,705	9,783	922	9.4%
Loss from operations	\$ (10,455)	\$ (9,533)	\$ (922)	(9.7)%

Comparison of the Three Months Ended June 30, 2021 and 2020

Licensing Revenue

In January 2013, we entered into a technology development contract with Hisun, pursuant to which Hisun paid us a non-refundable technology transfer fee of \$5.0 million to support our development of ThermoDox® in the China territory. The \$5.0 million received as a non-refundable payment from Hisun in the first quarter 2013 has been recorded to deferred revenue and will be amortized over the ten-year term of the agreement; therefore, we recorded deferred revenue of \$125,000 in each of the second quarters of 2021 and 2020.

Research and Development Expenses

Research and development (“R&D”) expenses decreased by \$0.4 million to \$2.6 million in the second quarter of 2021 from \$3.0 million in the same period of 2020. Costs associated with the OVATION 2 Study increased to \$0.4 million in the second quarter of 2021 compared to \$0.2 million in the same period of 2020. The Company initiated enrollment in the Phase 2 portion of the study during the third quarter of 2020. Costs associated with the OPTIMA Study decreased to \$0.2 million in the second quarter of 2021 compared to \$0.6 million in the same period of 2020. In July 2020, the Company unblinded the OPTIMA Study at the recommendation of the DMC to halt the study due to futility. Regulatory costs were \$0.1 million in the second quarter of 2021 compared to \$0.3 million in the same period of 2020. Other clinical costs were \$0.4 million the second quarter of 2021 compared to \$0.5 million in the same period of 2020. R&D costs associated with the development of GEN-1 to support the OVATION 2 Study as well as development of the PLACCINE DNA vaccine technology platform increased to \$1.0 million in the second quarter of 2021 compared to \$0.7 million in the same period of 2020. CMC costs decreased to \$0.4 million in the second quarter of 2021 compared to \$0.8 million in the same period of 2020.

General and Administrative Expenses

General and administrative expenses increased to \$2.6 million in the second quarter of 2021 compared to \$1.9 million in the same period of 2020. This increase is primarily attributable to higher non-cash stock compensation expense of approximately \$0.1 million, an increase in professional fees of \$0.4 million and an increase in premiums for directors’ and officers’ insurance of \$0.1 million in the second quarter of 2021 when compared to the same period of 2020.

Change in Earn-out Milestone Liability and Warrant Expense

On March 28, 2019, the Company and EGWU, Inc, entered into an amendment to its purchase agreement (“Amended Asset Purchase Agreement”), whereby payment of the earnout milestone liability related to the Ovarian Cancer Indication of \$12.4 million had been modified. The Company has the option to make the payment as follows:

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

As of June 30, 2021, and March 31, 2021, the Company fair valued the earn-out milestone liability at \$7.1 million and \$7.1 million, respectively, and recognized a non-cash benefit of \$0.1 million for the three-months ended June 30, 2021. In assessing the earnout milestone liability at June 30, 2021, the Company fair valued each of the two payment options per the Amended Asset Purchase Agreement and weighted them at 50% / 50% probability for the \$7.0 million and the \$12.4 million payments, respectively.

As of June 30, 2020, and March 31, 2020, the Company fair valued the earn-out milestone liability at \$6.1 million and \$5.8 million, respectively, and recognized a non-cash charge of \$0.3 million for the three-months ended June 30, 2020. In assessing the earnout milestone liability at June 30, 2020, the Company fair valued each of the two payment options per the Amended Asset Purchase Agreement and weighted them at 80% / 20% probability for the \$7.0 million and the \$12.4 million payments, respectively.

Investment income and interest expense

Investment income from its short-term investments was insignificant in each of the second quarters of 2021 and 2020.

As more fully discussed in Note 11, in June 2021, the Company entered into a \$10 million loan facility with Silicon Valley Bank. The Company immediately used \$6 million from this facility to retire all outstanding indebtedness with Horizon Technology Finance Corporation. The remaining \$4 million will be available to be drawn down up to 12 months after closing and will be used for working capital and to fund the advancement of the Company’s product pipelines. In connection with this Horizon Technology Financing Facility, the Company incurred \$0.2 million in interest expense in the second quarter of 2021 compared to \$0.3 million during the same period of 2020. In connection with the termination of the Horizon Technology Financing Facility in the second quarter of 2021, the Company paid early termination and end of term charges to Horizon and recognized \$0.2 million as a loss on debt extinguishment.

Comparison of the Six Months Ended June 30, 2021 and 2020

Licensing Revenue

In January 2013, we entered 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 second quarter 2013 has been recorded to deferred revenue and will be amortized over the ten-year term of the agreement; therefore, we recorded deferred revenue of \$250,000 in each of the first six months of 2021 and 2020.

Research and Development Expenses

R&D expenses decreased by \$0.9 million to \$5.2 million in the first half of 2021 from \$6.1 million in the same period of 2020. Costs associated with the OVATION 2 Study increased to \$0.9 million in the first half of 2021 compared to \$0.5 million in the same period of 2020. The Company initiated enrollment in the Phase 2 portion of the study during the third quarter of 2020. Costs associated with the OPTIMA Study decreased to \$0.4 million in the first half of 2021 compared to \$1.3 million in the same period of 2020. In July 2020, the Company unblinded the OPTIMA Study at the recommendation of the DMC to halt the study due to futility. Regulatory costs were \$0.2 million in the first half of 2021 compared to \$0.4 million in the same period of 2020. Regulatory costs were \$0.2 million in the first half of 2021 compared to \$0.4 million in the same period of 2020. Other clinical costs were \$0.9 million in the first half of 2021 compared to \$1.1 million in the same period of 2020. R&D costs associated with the development of GEN-1 to support the OVATION 2 Study as well as development of the PLACCINE DNA vaccine technology platform increased to \$2.0 million in the first half of 2021 compared to \$1.6 million in the same period of 2020. CMC costs decreased to \$0.8 million in the first half of 2021 compared to \$1.1 million in the same period of 2020.

General and Administrative Expenses

General and administrative expenses increased to \$5.5 million in the first half of 2021 compared to \$3.7 million in the same period of 2020. This increase is primarily attributable to higher non-cash stock compensation expense of approximately \$0.8 million, an increase in professional fees of \$0.7 million and an increase in premiums for directors' and officers' insurance of \$0.2 million in the first half of 2021 when compared to the same period of 2020.

Change in Earn-out Milestone Liability and Warrant Expense

On March 28, 2019, the Company and EGWU, Inc. entered into an amendment to its purchase agreement ("Amended Asset Purchase Agreement"), whereby payment of the earnout milestone liability related to the Ovarian Cancer Indication of \$12.4 million had been modified. The Company has the option to make the payment as follows:

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

As of June 30, 2021, and December 31, 2020, the Company fair valued the earn-out milestone liability at \$7.1 million and \$7.0 million, respectively and recognized a non-cash charge of \$0.1 million during the first half of 2021. In assessing the earnout milestone liability at June 30, 2021, the Company fair valued each of the two payment options per the Amended Asset Purchase Agreement and weighted them at 50% / 50% probability for the \$7.0 million and the \$12.4 million payments, respectively.

As of June 30, 2020, and December 31, 2019, the Company fair valued the earn-out milestone liability at \$6.0 million and \$5.7 million, respectively and recognized a non-cash charge of \$0.3 million during the first half of 2020. In assessing the earnout milestone liability at June 30, 2020, the Company fair valued each of the two payment options per the Amended Asset Purchase Agreement and weighted them at 80% / 20% probability for the \$7.0 million and the \$12.4 million payments, respectively.

Investment income and interest expense

Investment income from its short-term investments was insignificant in the first half of 2021. The Company realized \$0.1 million of investment income from its short-term investments during the first half of 2020.

As more fully discussed in Note 11, in June 2021, the Company entered into a \$10 million loan facility with Silicon Valley Bank. The Company immediately used \$6 million from this facility to retire all outstanding indebtedness with Horizon Technology Finance Corporation. The remaining \$4 million will be available to be drawn down up to 12 months after closing and will be used for working capital and to fund the advancement of the Company's product pipelines. In connection with this Horizon Technology Financing Facility, the Company incurred \$0.4 million in interest expense in the first half of 2021 compared to \$0.7 million during the same period of 2020. In connection with the termination of the Horizon Technology Financing Facility in the second quarter of 2021, the Company paid early termination and end of term charges to Horizon and recognized \$0.2 million as a loss on debt extinguishment.

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 \$323 million at June 30, 2021.

At June 30, 2021, we had total current assets of \$60.3 million and current liabilities of \$5.4 million, resulting in net working capital of \$54.9 million. At June 30, 2021, we had cash and cash equivalents, short-term investments, interest receivable on short term investments and money market investments (\$6.0 million of which is included in other assets) of \$64.5 million. At December 31, 2020, we had total current assets of \$18.8 million (including cash and cash equivalents of \$17.2 million) and current liabilities of \$6.8 million, resulting in net working capital of \$12.0 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 half of 2021 was \$7.3 million. Net cash used in investing activities was \$32.2 million during the first half of 2021. Net cash provided by financing activities was \$54.8 million during the first half of 2021 mostly from net proceeds received through the sale of our common stock. With \$64.5 million in cash and cash equivalents, short-term investments, interest receivable on short term investments and money market investments at June 30, 2021 and with potential future sales of the Company's State of New Jersey net operating losses, the Company believes it has sufficient capital resources to fund its operations through 2024.

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 June 30, 2021, 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 against the Company and certain officers and directors (the “Shareholder Action”). The Company was a defendant in this derivative and putative class action lawsuit in the Superior Court of New Jersey, Chancery Division, filed by a shareholder against the Company (as both a class action defendant and nominal defendant), and certain of its officers and directors (the “Individual Defendants”), with the caption *O’Connor v. Braun et al.*, Docket No. MER-C-000068-19 (the “Shareholder Action”). The Shareholder Action alleged breaches of the defendants’ fiduciary duties based on allegations that the defendants omitted or made improper statements when seeking shareholder approval of the 2018 Stock Incentive Plan. The Shareholder Action sought, 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.

On April 24, 2020, the Company, the Individual Defendants, and the plaintiff (the “Parties”) entered into a Settlement Agreement and Release (the “Settlement Agreement”), which memorializes the terms of the Parties’ settlement of the Shareholder Action (the “Settlement”). The Settlement calls for repricing of certain stock options and payment of plaintiff legal fees of \$187,500. On July 24, 2020, the Court issued an order approving the Parties’ proposed form of notice to shareholders regarding the Settlement. A hearing was held on September 8, 2020 whereby the Court issued a final approval approving the Settlement. Pursuant to the Settlement, the Company paid \$187,500 on October 1, 2020. Without admitting the validity of any of the claims asserted in the Shareholder Action, or any liability with respect thereto, and expressly denying all allegations of wrongdoing, fault, liability, or damage against the Company and the Individual Defendants arising out of any of the conduct, statements, acts or omissions alleged, or that could have been alleged, in the Shareholder Action, the Company and the Individual Defendants concluded that it was desirable that the claims be settled on the terms and subject to the conditions set forth in the Settlement Agreement. The Company and the Individual Defendants entered into the Settlement Agreement for settlement purposes only and solely to avoid the cost and disruption of further litigation.

On October 29, 2020, a putative securities class action was filed against the Company and certain of its officers and directors (the “Spar Individual Defendants”) in the U.S. District Court for the District of New Jersey, captioned *Spar v. Celsion Corporation, et al.*, Case No. 1:20-cv-15228. The plaintiff alleges that the Company and Individual Defendants made false and misleading statements regarding one of the Company’s product candidates, ThermoDox[®], and brings claims for damages under Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder against all Defendants, and under Section 20(a) of the Exchange Act of 1934 against the Spar Individual Defendants. The Company believes that the case is without merit and intends to defend it vigorously. Due to the early stage of the case neither the likelihood that a loss, if any, will be realized, nor an estimate of possible loss or range of loss, if any, can be determined.

In February 2021, a derivative shareholder lawsuit was filed against the Company, as the nominal defendant, and certain of its directors and officers as defendants in the U.S. District Court for the District of New Jersey, captioned *Fidler v. Michael H. Tardugno et al.*, Case No. 3:21-cv-02662. The plaintiff alleges breach of fiduciary duty and other claims arising out of alleged statements made by certain of the Company’s directors and/or officers regarding ThermoDox[®]. The Company believes it has meritorious defenses to these claims and intends to vigorously contest this suit. Due to the early stage of the case neither the likelihood that a loss, if any, will be realized, nor an estimate of possible loss or range of loss, if any, can be determined.

Item 1A. Risk Factors

There have been no material changes to our risk factors from those disclosed under “Risk Factors” in Part I, Item 1A of our 2020 Annual Report on Form 10-K. The risks and uncertainties described in our 2020 Annual Report on Form 10-K are not the only ones we face. Additional risks and uncertainties not presently known to us or that we currently deem immaterial may also materially adversely affect our business, financial condition or results of operations.

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

None

Item 3. Defaults Upon Senior Securities.

None.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

None.

Item 6. Exhibits.

31.1+ [Certification of Chief Executive Officer pursuant to Rule 13a-14\(a\)/15d-14\(a\), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.](#)

31.2+ [Certification of Chief Financial Officer pursuant to Rule 13a-14\(a\)/15d-14\(a\), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.](#)

32.1* [Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.](#)

+ Filed herewith.

101** The following materials from the Company's Quarterly Report on Form 10-Q for the quarter ended 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.

August 12, 2021

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

**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

August 12, 2021

By: /s/ Michael H. Tardugno

Michael H. Tardugno

Chairman, President and Chief Executive Officer

**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

August 12, 2021

By: /s/ Jeffrey W. Church

Jeffrey W. Church

Executive Vice President and Chief Financial Officer

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 June 30, 2021 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.

August 12, 2021

By: /s/ Michael H. Tardugno

Michael H. Tardugno
Chairman, President and Chief Executive Officer

August 12, 2021

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.
