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 September 30, 2022

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

Imunon, Inc.
(Exact name of Registrant as specified in its charter)

Delaware	**52-1256615**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification Number)

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

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

Celsion Corporation
(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	IMNN	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 ☐	Accelerated filer ☐
Non-accelerated filer ☐	Smaller reporting company ☒
Emerging growth company ☐	

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

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

As of November 9, 2022, the Registrant had 7,434,309 shares of common stock, $0.01 par value per share, outstanding.

IMUNON, INC.

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 using 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, 2021, 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," "Imunon," "we," "us," and "our" refer to Imunon, Inc., a Delaware corporation and its wholly owned subsidiaries.

Trademarks

The Company's brand and product names contained in this document are trademarks, registered trademarks, or service marks of Imunon, Inc. 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

IMUNON, INC.

CONDENSED CONSOLIDATED BALANCE SHEETS

	September 30, 2022 (Unaudited)	December 31, 2021
ASSETS		
Current assets:		
Cash and cash equivalents	$ 26,938,090	$ 19,586,272
Investment in debt securities - available for sale, at fair value	10,414,395	29,803,095
Accrued interest receivable on investment securities	30,495	108,844
Advances and deposits on clinical programs and other current assets	2,810,787	2,447,413
Total current assets	**40,193,767**	**51,945,624**
Property and equipment (at cost, less accumulated depreciation and amortization)	**582,531**	**477,011**
Other assets:		
Money market investments, restricted cash	6,000,000	6,000,000
Deferred income tax asset	-	1,383,446
In-process research and development, net	13,366,234	13,366,234
Operating lease right-of-use assets, net	294,814	690,995
Deposits and other assets	93,761	183,489
Total other assets	**19,754,809**	**21,624,164**
Total assets	**$ 60,531,107**	**$ 74,046,799**

See accompanying notes to the unaudited condensed consolidated financial statements.

IMUNON, INC.

CONDENSED CONSOLIDATED BALANCE SHEETS (Continued)

	September 30, 2022 (Unaudited)	December 31, 2021
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable – trade	$ 3,369,913	$ 2,547,251
Other accrued liabilities	3,925,561	3,173,537
Operating lease liability - current portion	373,525	548,870
Note payable – current portion, net of deferred financing costs	670,513	-
Deferred revenue - current portion	125,000	500,000
Total current liabilities	**8,464,512**	**6,769,658**
Earn-out milestone liability	5,396,000	5,396,000
Notes payable – non-current portion, net of deferred financing costs	5,319,520	5,854,461
Operating lease liability - non-current portion	-	230,749
Total liabilities	**19,180,032**	**18,250,868**
Commitments and contingencies	-	–
Stockholders' equity:		
Preferred stock - $0.01 par value (100,000 shares authorized, and no shares issued or outstanding at September 30, 2022 and December 31, 2021)	-	–
Common stock - $0.01 par value (112,500,000 shares authorized; 7,098,763 and 5,770,538 shares issued at September 30, 2022 and December 31, 2021, respectively; and 7,098,741 and 5,770,516 shares outstanding at September 30, 2022 and December 31, 2021, respectively)	70,988	57,705
Additional paid-in capital	396,825,849	388,600,979
Accumulated other comprehensive loss	(25,424)	(7,974)
Accumulated deficit	(355,435,150)	(332,769,591)
Total stockholders' equity before treasury stock	**41,436,263**	**55,881,119**
Treasury stock, at cost (22 shares at September 30, 2022 and December 31, 2021)	(85,188)	(85,188)
Total stockholders' equity	**41,351,075**	**55,795,931**
Total liabilities and stockholders' equity	**$ 60,531,107**	**$ 74,046,799**

See accompanying notes to the unaudited condensed consolidated financial statements.

IMUNON, INC.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(Unaudited)

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2022	**2021**	**2022**	**2021**
Licensing revenue	$ 125,000	$ 125,000	$ 375,000	$ 375,000
Operating expenses:				
Research and development	2,408,680	2,468,066	8,730,395	7,633,051
General and administrative	3,890,886	2,718,510	9,639,419	8,258,271
Total operating expenses	6,299,566	5,186,576	18,369,814	15,891,322
Loss from operations	(6,174,566)	(5,061,576)	(17,994,814)	(15,516,322)
Other (expense) income:				
Loss from change in valuation of earn-out milestone liability	-	(257,000)	-	(327,000)
Investment income	153,301	3,552	205,760	5,614
Interest expense	(127,025)	(95,520)	(4,878,306)	(474,361)
Recognized loss on extinguishment of debt	-	-	-	(234,419)
Other income (expense)	-	-	1,801	(1,456)
Total other income (expense), net	26,276	(348,968)	(4,670,745)	(1,031,622)
Net loss	$ (6,148,290)	$ (5,410,544)	$ (22,665,559)	$ (16,547,944)
Net loss per common share				
Basic and diluted	$ (0.87)	$ (0.94)	$ (3.42)	$ (3.12)
Weighted average shares outstanding				
Basic and diluted	7,098,741	5,770,516	6,621,925	5,311,174

See accompanying notes unaudited to the condensed consolidated financial statements.

IMUNON, INC.

CONDENSED CONSOLIDATED
STATEMENTS OF COMPREHENSIVE LOSS
(Unaudited)

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2022	**2021**	**2022**	**2021**
Other comprehensive loss				
Changes in:				
Realized gains on debt securities recognized in investment income, net	$ 10,369	$ 2,736	$ 34,303	$ 4,521
Unrealized gains (losses) on debt securities, net	34,241	3,173	(51,753)	(2,382)
Change in realized and unrealized gains (losses) on available for sale securities, net	44,610	5,909	(17,450)	2,139
Net loss	(6,148,290)	(5,410,544)	(22,665,559)	(16,547,944)
Total Comprehensive loss	$ (6,103,680)	$ (5,404,635)	$ (22,683,009)	$ (16,545,805)

See accompanying notes unaudited to the condensed consolidated financial statements.

IMUNON, INC.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(Unaudited)

	For the Nine Months Ended September 30,	
	2022	**2021**
Cash flows from operating activities:		
Net loss	$ (22,665,559)	$ (16,547,944)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	513,552	542,740
Change in fair value of earn-out milestone liability	-	327,000
Recognition of deferred revenue	(375,000)	(375,000)
Stock-based compensation	1,962,807	3,073,569
Realization of deferred income tax asset	1,383,446	1,845,823
Amortization of deferred finance charges and debt discount associated with notes payable	135,572	191,571
Net changes in:		
Accrued interest on investment securities	78,349	(38,404)
Advances, deposits, and other current assets	(273,646)	(552,567)
Accounts payable and accrued liabilities	1,168,592	397,701
Net cash used in operating activities	**(18,071,887)**	**(11,135,511)**
Cash flows from investing activities:		
Purchases of investment securities	(8,403,750)	(40,862,225)
Proceeds from sale and maturity of investment securities	27,775,000	12,000,000
Purchases of property and equipment	(222,891)	(285,971)
Net cash provided by (used in) investing activities	**19,148,359**	**(29,148,196)**
Cash flows from financing activities:		
Proceeds from redeemable convertible preferred stock offering	28,500,000	-
Payment upon redemption of redeemable convertible preferred stock	(28,500,000)	-
Proceeds from sale of common stock equity, net of issuance costs	6,275,346	52,688,945
Proceeds from exercise of common stock warrants	-	1,508,666
Proceeds from exercise of options to purchase common stock	-	4,725
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)
Net cash provided by financing activities	**6,275,346**	**54,768,379**
Net change in cash, cash equivalents and restricted cash	**7,351,818**	**14,484,672**
Cash, cash equivalents and restricted cash at beginning of period	**25,586,272**	**17,164,177**
Cash, cash equivalents and restricted cash at end of period	**$ 32,938,090**	**$ 31,648,849**

See accompanying notes unaudited to the condensed consolidated financial statements.

IMUNON, INC.

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

	For the Nine Months Ended September 30,	
	2022	**2021**
Supplemental disclosures of cash flow information:		
Interest paid	$ (4,742,734)	$ (307,985)
Cash paid for amounts included in measurement of lease liabilities:		
Operating cash flows for lease payments	$ 450,721	$ 418,696
Realized and unrealized (losses) gains, net, on investment securities	$ (17,450)	$ 2,139

See accompanying notes unaudited to the condensed consolidated financial statements.

IMUNON, INC.

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

FOR THE THREE MONTHS ENDED SEPTEMBER 30, 2022 AND 2021

	Common Stock Outstanding		Additional Paid-in	Treasury Stock		Accumulated Other Comprehensive	Accumulated	Total Stockholders'
	Shares	Amount	Capital	Shares	Amount	(Loss)/Income	Deficit	Equity
Balance at July 1, 2022	7,098,741	$ 70,988	$396,413,587	22	$(85,188)	$ (70,034)	$(349,286,860)	$ 47,042,493
Net loss	-	-	-	-	-	-	(6,148,290)	(6,148,290)
Fees incurred from registered direct offering	-	-	(64,023)	-	-	-	-	(64,023)
Realized and unrealized gains (losses), net, on investments securities	-	-	-	-	-	44,610	-	44,610
Stock-based compensation expense	-	-	476,285	-	-	-	-	476,285
Balance at September 30, 2022	7,098,741	$ 70,988	$396,825,849	22	$(85,188)	$ (25,424)	$(355,435,150)	$ 41,351,075

	Common Stock Outstanding		Additional Paid-in	Treasury Stock		Accumulated Other Comprehensive	Accumulated	Total Stockholders'
	Shares	Amount	Capital	Shares	Amount	(Loss)/Income	Deficit	Equity
Balance at July 1, 2021	5,770,516	$ 57,705	$387,222,506	22	$(85,188)	$ (3,770)	$(323,137,741)	$ 64,053,512
Net loss	-	-	-	-	-	-	(5,410,544)	(5,410,544)
Fees incurred from registered direct offering	-	-	(8,320)	-	-	-	-	(8,320)
Realized and unrealized gains (losses), net, on investments securities	-	-	-	-	-	5,909	-	5,909
Stock-based compensation expense	-	-	700,624	-	-	-	-	700,624
Balance at September 30, 2021	5,770,516	$ 57,705	$387,914,810	22	$(85,188)	$ 2,139	$(328,548,285)	$ 59,341,181

See accompanying notes unaudited to the condensed consolidated financial statements.

IMUNON, INC.

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

FOR THE NINE MONTHS ENDED SEPTEMBER 30, 2022 AND 2021

	Series A & B Preferred		Common Stock Outstanding		Additional Paid-in	Treasury Stock		Accumulated Other Comprehensive	Accumulated	Total Stockholders'
	Shares	Amount	Shares	Amount	Capital	Shares	Amount	Loss	Deficit	Equity
Balance at January 1, 2022	-	$ -	5,770,516	$ 57,705	$388,600,979	22	$(85,188)	$ (7,974)	$(332,769,591)	$ 55,795,931
Net loss	-		-	-	-	-	-	-	(22,665,559)	(22,665,559)
Effect of reverse stock split	-	-	(49)	-	-	-	-	-	-	-
Issuance of preferred stock upon financing	100,000	28,500,000	-	-	-	-	-	-	-	-
Redemption of preferred stock	(100,000)	(28,500,000)	-	-	-	-	-	-	-	-
Sale of equity through equity financing facilities, net of costs	-	-	1,328,274	13,283	6,262,063	-	-	-	-	6,275,346
Realized and unrealized gains (losses), net, on investments securities	-	-	-	-	-	-	-	(17,450)	-	(17,450)
Stock-based compensation expense	-	-	-	-	1,962,807	-	-	-	-	1,962,807
Balance at September 30, 2022	-	$ -	7,098,741	$ 70,988	$396,825,849	22	$(85,188)	$ (25,424)	$(355,435,150)	$ 41,351,075

	Common Stock Outstanding		Additional Paid-in	Treasury Stock		Accumulated Other Comprehensive	Accumulated	Total Stockholders'
	Shares	Amount	Capital	Shares	Amount	Income	Deficit	Equity
Balance at January 1, 2021	2,713,402	$ 27,134	$330,669,476	22	$(85,188)	$ -	$(312,000,341)	$ 18,611,081
Net loss	-	-	-	-	-	-	(16,547,944)	(16,547,944)
Sale of equity through equity financing facilities, net of costs	2,975,503	29,755	52,659,190	-	-	-	-	52,688,945
Shares issued upon exercise of common stock warrants, net of fees	81,111	811	1,507,855	-	-	-	-	1,508,666
Shares issued upon exercise of options to purchase common stock	500	5	4,720	-	-	-	-	4,725
Realized and unrealized gains (losses), net, on investments securities	-	-	-	-	-	2,139	-	2,139
Stock-based compensation expense	-	-	3,073,569	-	-	-	-	3,073,569
Balance at September 30, 2021	5,770,516	$ 57,705	$387,914,810	22	$(85,188)	$ 2,139	$(328,548,285)	$ 59,341,181

See accompanying notes unaudited to the condensed consolidated financial statements.

Note 1. Business Description

On September 19, 2022, Celsion Corporation announced a corporate name change to Imunon, Inc., reflecting the evolution of the Company's business focus and its commitment to developing cutting-edge immunotherapies and next-generation vaccines to treat cancer and infectious diseases. The Company's common stock will continue to trade on the Nasdaq Stock Market under the new ticker symbol "IMNN" effective as of the opening of trading on September 21, 2022. The Company filed an amendment to its Articles of Incorporation to effect the new corporate name.

Imunon, Inc. ("Imunon" and the "Company") is a fully integrated, clinical stage biotechnology company focused on advancing a portfolio of innovative treatments that harness the body's natural mechanisms to generate safe, effective, and durable responses across a broad array of human diseases, constituting a differentiating approach from conventional therapies. Imunon has two platform technologies: Our TheraPlas® platform for the development of immunotherapies and other anti-cancer nucleic acid-based therapies, and our PLACCINE platform for the development of nucleic acid vaccines for infectious diseases and cancer. The Company's lead clinical program, GEN-1, is a DNA-based immunotherapy for the localized treatment of advanced ovarian cancer currently in Phase II development. GEN-1 works by instructing the body to produce safe and durable levels of powerful cancer fighting molecules, such as interleukin-12 and interferon gamma, at the tumor site. Additionally, the Company is conducting preclinical proof-of-concept studies on a nucleic acid vaccine candidate targeting SARS-CoV-2 virus in order to validate its PLACCINE platform. Imunon's platform technologies are based on the delivery of nucleic acids with novel synthetic delivery systems that are independent of viral vectors or devices. We will continue to leverage these platforms and to advance the technological frontier of plasmid DNA to better serve patients with difficult to treat conditions.

Note 2. Basis of Presentation

The accompanying unaudited condensed consolidated financial statements, which include the accounts of the Company and its wholly owned subsidiaries, 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. During the quarter, there have been no changes to the Company's accounting policies. Certain information and disclosures normally included in financial statements prepared in accordance with GAAP have been condensed or omitted pursuant to such rules and regulations.

In the opinion of management, all adjustments, consisting only of normal recurring accruals considered necessary for a fair presentation, have been included in the accompanying unaudited condensed consolidated financial statements. Operating results for the three-month and nine-month periods ended September 30, 2022 and 2021 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 consolidated financial statements and notes thereto included in the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2021, filed with the Securities and Exchange Commission ("SEC") on March 31, 2022.

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 and intangible assets. The effect of this matter could potentially have an impact on the valuation of such assets in the future.

Acquired in-process research and development ("IPR&D") in years prior to 2022 has been reviewed for impairment at least annually in the third quarter of each year, and whenever events or changes in circumstances indicate that the carrying value of the assets might not be recoverable. Starting in 2022, the Company will review its IPR&D annually in the fourth quarter of each year, and whenever events or changes in circumstances indicate that the carrying value of the assets might not be recoverable (see Note 8).

The Company has $37.4 million in cash and cash equivalents, short-term investments, and interest receivable to fund its operations. The Company also has $6.0 million in restricted cash to fund its financing activity. This is coupled with approximately $3.5 million of future planned sales of the Company's State of New Jersey net operating losses. The Company believes it has sufficient capital resources to fund its operations into 2025.

Note 3. 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 May 2021, the FASB issued ASU No. 2021-04, "Earnings Per Share (Topic 260), Debt-Modifications and Extinguishments (Subtopic 470-50), Compensation-Stock Compensation (Topic 718), and Derivatives and Hedging-Contracts in Entity's Own Equity (Subtopic 815-40): Issuer's Accounting for Certain Modifications or Exchanges of Freestanding Equity-Classified Written Call Options (a consensus of the FASB Emerging Issues Task Force)". This ASU is intended to clarify and reduce diversity in an issuer's accounting for modifications or exchanges of freestanding equity-classified written call options that remain equity classified after modification or exchange. The guidance clarifies whether an issuer should account for a modification or an exchange of a freestanding equity-classified written call option that remains equity classified after modification or exchange as: (1) an adjustment to equity and, if so, the related earnings per share effects, if any, or (2) an expense and, if so, the manner and pattern of recognition. The amendments in this ASU affect all entities that issue freestanding written call options that are classified in equity. The amendments do not apply to modifications or exchanges of financial instruments that are within the scope of another Topic and do not affect a holder's accounting for freestanding call options. The amendments in this ASU are effective for all entities for fiscal years beginning after December 15, 2021, including interim periods within those fiscal years. An entity should apply the amendments prospectively to modifications or exchanges occurring on or after the effective date of the amendments. Early adoption is permitted for all entities, including adoption in an interim period. The Company adopted this standard during the first quarter of 2022. The adoption of ASU 2021-04 did not have an impact on the Company's consolidated financial statements since the Company has not modified its freestanding call options.

Note 4. Restricted Cash

As a condition of the SVB Loan Facility entered into on June 18, 2021 as further discussed in Note 10, 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 (other than a lien in favor of SVB) 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 September 30, 2022 and December 31, 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 statements of cash flows:

	September 30, 2022	September 30, 2021
Cash and cash equivalents	$ 26,938,090	$ 25,648,849
Money market investments, restricted	6,000,000	6,000,000
Total	$ 32,938,090	$ 31,648,849

Note 5. Net Loss per Common Share

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

The total number of shares of common stock issuable upon exercise of warrants, stock option grants and equity awards were 1,346,472 and 616,690 shares for the periods ended September 30, 2022 and 2021, respectively. For the three-month and nine-month periods ended September 30, 2022 and 2021, 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 nine months of 2022 or 2021.

Note 6. Investment in Debt Securities-Available for Sale

Investments in debt securities available for sale with a fair value of $10,414,395 and $29,803,095 as of September 30, 2022 and December 31, 2021, respectively, which consisted of U.S. Treasury securities and corporate debt securities. These investments are valued at estimated fair value, with unrealized gains and losses reported as a separate component of stockholders' equity in accumulated other comprehensive loss.

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

	September 30, 2022		December 31, 2021	
	Cost	Fair Value	Cost	Fair Value
Short-term investments				
U.S. Treasury securities	$ -	$ -	$ 14,786,982	$ 14,778,705
Corporate debt securities	10,439,820	10,414,395	15,024,087	15,024,390
Total	$ 10,439,820	$ 10,414,395	$ 29,811,069	$ 29,803,095

	September 30, 2022		December 31, 2021	
	Cost	Fair Value	Cost	Fair Value
Short-term investment maturities				
Within 3 months	$ 5,995,105	$ 5,985,140	$ 19,798,177	$ 19,799,835
Between 3-12 months	4,444,715	4,429,255	10,012,892	10,003,260
Total	$ 10,439,820	$ 10,414,395	$ 29,811,069	$ 29,803,095

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 September 30, 2022 and December 31, 2021. The Company has reviewed individual securities to determine whether a decline in fair value below the amortizable cost basis is other than temporary.

	September 30, 2022		December 31, 2021	
Available for sale securities (all unrealized holding gains and losses are less than 12 months at date of measurement)	Fair Value	Unrealized Holding Gains (Losses)	Fair Value	Unrealized Holding Gains (Losses)
Investments in debt securities with unrealized gains	$ 3,991,260	$ 1,310	$ 8,999,580	$ 3,499
Investments in debt securities with unrealized losses	6,423,135	(26,734)	20,803,515	(11,473)
Total	$ 10,414,395	$ (25,424)	$ 29,803,095	$ (7,974)

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:

	For the Three Months Ended September 30,	
	2022	2021
Interest and dividends accrued and paid	$ 163,670	$ 6,288
Realized losses	(10,369)	(2,736)
Investment income, net	$ 153,301	$ 3,552

	For the Nine Months Ended September 30,	
	2022	2021
Interest and dividends accrued and paid	$ 240,063	$ 10,135
Realized losses	(34,303)	(4,521)
Investment income, net	$ 205,760	$ 5,614

Note 7. 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 sheets 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 2022 and 2021. There were no transfers of assets or liabilities between Level 1 and Level 2 and no transfers in or out of Level 3 during the nine-month period ended September 30, 2022 or during the year ended December 31, 2021. The change in Level 3 liabilities in the first quarter of 2022 was the result of a change in the fair value of the earn-out milestone liability which is included in earnings and in-process R&D. During the third quarter and first nine months of 2022, there was no change in the fair value of the earn-out milestone liability. The earnout milestone liability is valued using a risk-adjusted assessment of the probability of payment of each milestone, discounted to present value using an estimated time to achieve the milestone (see Note 13).

Assets and liabilities measured at fair value are summarized below:

	Total Fair Value	Quoted Prices in Active Markets for Identical Assets/Liabilities (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Assets:				
Recurring items as of September 30, 2022				
Corporate debt securities, available for sale	$ 10,414,395	$ –	$ 10,414,395	$ –
Non-recurring items as of September 30, 2022				
In-process R&D (Note 8)	$ 13,366,234	$ –	$ –	$ 13,366,234
Recurring items as of December 31, 2021				
Corporate debt securities, available for sale	$ 29,803,095	$ –	$ 29,803,095	$ –
Non-recurring items as of December 31, 2021				
In-process R&D (Note 8)	$ 13,366,234	$ –	$ –	$ 13,366,234
Liabilities:				
Recurring items as of September 30, 2022				
Earn-out milestone liability (Note 13)	$ 5,396,000	$ –	$ –	$ 5,396,000
Recurring items as of December 31, 2021				
Earn-out milestone liability (Note 13)	$ 5,396,000	$ –	$ –	$ 5,396,000

Note 8. Intangible Assets

In June 2014, the Company completed the acquisition of substantially all of the assets of EGEN, Inc., an Alabama corporation ("EGEN"), which changed its company name to EGWU, Inc. after the closing of the acquisition (the "EGEN Acquisition"). 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 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 has been reviewed for impairment at least annually and whenever events or changes in circumstances indicate that the carrying value of the assets might not be recoverable. As a result of the Company's review for impairment, the IPR&D was impaired over the past 8 years by $10.8 million to its current stated value of $13.4 million. Starting in 2022, the Company will review its IPR&D annually in the fourth quarter of each year, and whenever events or changes in circumstances indicate that the carrying value of the assets might not be recoverable (see Note 2). The Company's IPR&D consisted of three core elements, its RNA delivery system, its glioblastoma multiform cancer ("GBM") product candidate and its ovarian cancer indication.

The Company's ovarian cancer indication, with an original value of $13.4 million, has not been impaired since its acquisition. At September 30, 2022, the Company evaluated the IPR&D for the ovarian cancer indication. As part of the valuation analysis, the fair value of the intangible assets was estimated by discounting forecasted risk adjusted cash flows at a rate that approximated the cost of capital of a market participant. Management's forecast of future cash flows was based on the income approach. Significant estimates, all of which are considered Level 3 inputs, were used in the fair value methodology, including the Company's forecast regarding its future operations and likeliness of obtaining approval to sell its products, as well as other market conditions. Changes in these estimates could change the forecasted cash flows attributed to the IPR&D which could have a significant impact on the fair value of these assets. Based on this valuation analysis, the Company concluded that it is not more than likely that the asset is impaired as of September 30, 2022. As such, no impairment charges for IPR&D related to the ovarian cancer indication were recorded during the three-month and nine-month periods ended September 30, 2022 and 2021.

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 would it contact, solicit or approach any of the employees of the Company for purposes of offering employment. The Covenant Not to Compete which was valued at approximately $1.6 million at the date of the EGEN Acquisition has a definitive life and is amortized on a straight-line basis over its life of 7 years. The Company recognized amortization expense of $56,829 during each of the three-month and nine-month periods ended September 30, 2021. The carrying value of the Covenant Not to Compete was fully amortized as of June 30, 2021.

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 the Company's third quarter ended September 30 or sooner if the Company believes indicators of impairment exist. Due to the continuing slowdown in investment in 2021 by public capital markets in the biotech industry and its impact on market capitalization rates in this sector, Goodwill was reviewed for impairment as of December 31, 2021. Based on this assessment, Company concluded that Goodwill was impaired. As of December 31, 2021, the Company wrote off the $2.0 million carrying value of this asset, thereby recognizing a non-cash charge of $2.0 million in the fourth quarter of 2021.

Following is a summary of the net fair value of the assets acquired in the EGEN asset acquisition for the nine-month period ended September 30, 2022:

	IPR&D
For the nine months ended September 30, 2022	
Balance at January 1, 2022, net	$ 13,366,234
Impairment	-
Balance at September 30, 2022, net	$ 13,366,234

Note 9. Accrued Liabilities

Other accrued liabilities at September 30, 2022 and December 31, 2021 include the following:

	September 30, 2022	December 31, 2021
Amounts due to contract research organizations and other contractual agreements	$ 2,094,811	$ 1,401,356
Accrued payroll and related benefits	1,276,882	1,636,727
Accrued interest	28,625	16,792
Accrued professional fees	505,831	87,250
Other	19,412	31,412
Total	$ 3,925,561	$ 3,173,537

Note 10. 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"). The Company immediately used $6 million from the SVB Loan Facility to retire all outstanding indebtedness with Horizon Technology Finance Corporation as further discussed below. Concurrently 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 SVB Loan Facility is in the form of money market secured indebtedness bearing interest at a calculated WSJ Prime-based variable rate (currently 6.25%). 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 are being amortized as interest expense using the effective interest method over the life of the loan. During the three-month period ended September 30, 2022, the Company incurred interest expense of $82,083 and amortized $44,942 as interest expense for debt discounts and end-of-term fee in connection with the SVB Financing Facility. During the nine-month period ended September 30, 2022, the Company incurred interest expense of $191,167 and amortized $135,572 as interest expense for debt discounts and end-of-term fee in connection with the SVB Financing Facility. During the three-month and nine-month periods ended September 30, 2021, the Company incurred interest expense of $49,883 and $56,875, respectively, and amortized $45,687 and $52,144, respectively, 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 September 30,
2023	$ 750,000
2024	3,000,000
2025	2,250,000
2026 and thereafter	–
Subtotal of future principal payments	6,000,000
Unamortized debt premium, net	(9,967)
Total	$ 5,990,033

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 "Horizon Amendment") whereby the Company repaid $5 million of the loan's principal with $5 million of the loan remaining outstanding.

On June 18, 2021, as a condition of entering into the SVB Loan Facility, the Company paid the remaining 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	$	5,425,000

As an initial fee in connection with the Horizon Credit Agreement, the Company issued Horizon warrants exercisable for a total of 12,674 shares of the Company's common stock (the "Existing Warrants") at a per share exercise price of $39.45. The Existing 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. Pursuant to the Horizon Amendment, one-half of the aggregate Existing Warrants, exercisable for a total of 6,337 shares of the Company's common stock, were cancelled, and the Company issued Horizon new warrants exercisable at a per share exercise price equal to $15.15 for a total of 16,501 shares of the Company's common stock (the "New Warrants"). 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. The remaining 6,337 Existing Warrants issued in connection with the Horizon Credit Agreement remain outstanding at a per share exercise price of $39.45.

The Company valued the warrants issued to Horizon using the Black-Scholes option pricing model and recorded as of the respective issuance dates a total of $507,116 for the Existing Warrants and $247,548 for the New Warrants as a direct deduction from the debt liability, consistent with the presentation of debt discounts, which was amortized as interest expense using the effective interest method over the life of the loan until the loan was terminated on June 18, 2021.

During the three months ended September 30, 2021, no interest expense was recognized as the amounts owed under the Horizon Credit agreement were paid off in June 2021. During the nine month ended September 30, 2021, the Company incurred $225,920 in interest expense and amortized $139,428 as interest expense for debt discounts and end of term charges in connection with the Horizon Credit Agreement.

Note 11. Stockholders' Equity

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.

On September 19, 2022, the Company announced a corporate name change to Imunon, Inc. The Company's common stock will continue to trade on the Nasdaq Stock Market under the new ticker symbol "IMNN" effective as of the opening of trading on September 21, 2022, and its CUSIP number (15117N602) remained unchanged. The Company filed an amendment to its Articles of Incorporation to effect the new corporate name.

Reverse Stock Split

On February 28, 2022, the Company effected a 15-for-1 reverse stock split of its common stock which was made effective for trading purposes as of the commencement of trading on March 1, 2022. As of that date, each 15 shares of issued and outstanding common stock and equivalents was consolidated into one share of common stock. All shares have been restated to reflect the effects of the 15-for-1 reverse stock split. In addition, at the market open on March 1, 2022, the Company's common stock started trading under a new CUSIP number 15117N602 although the Company's ticker symbol, CLSN, remained unchanged.

The reverse stock split was previously approved by the Company's stockholders at the 2022 Special Meeting held on February 24, 2022, and the Company subsequently filed a Certificate of Amendment to its Certificate of Incorporation to effect the stock consolidation.

Immediately prior to the reverse stock split, the Company had 86,557,736 shares of common stock outstanding which consolidated into 5,770,467 shares of the Company's common stock. No fractional shares were issued in connection with the reverse stock split. Holders of fractional shares have been paid out in cash for the fractional portion with the Company's overall exposure for such payouts consisting of a nominal amount. The amount of the Company's outstanding convertible preferred stock was not affected by the reverse stock split. The number of outstanding options, stock awards and warrants were adjusted accordingly, with outstanding options and stock awards being reduced from approximately 6.6 million to approximately 0.4 million and outstanding warrants being reduced from approximately 2.5 million to approximately 0.2 million.

At the Market Offering Agreement

On May 25, 2022, the Company entered into an At the Market Offering Agreement (the "Agreement") with H.C. Wainwright & Co., LLC, as sales agent ("Wainwright"), pursuant to which the Company may offer and sell, from time to time, through Wainwright, shares of the Company's common stock having an aggregate offering price of up to $7,500,000. The Company intends to use the net proceeds from the offering, if any, for general corporate purposes, including research and development activities, capital expenditures and working capital. The Company did not sell any shares under the Agreement with Wainwright in the first nine months of 2022. From October 1, 2022 through the date of November 7, 2022, the Company sold 329,511 shares of stock for net proceeds of $494,445.

Capital on Demand™ 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 the Company's common stock having an aggregate offering price of up to $16.0 million. During the first nine months of 2021, the Company has sold 477,877 shares under the Capital on Demand Agreement, receiving approximately $6.9 million in gross proceeds. The Capital on Demand Agreement with JonesTrading was terminated in the first quarter of 2021.

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 issued and sold, in a registered direct offering (the "January 2021 Offering"), an aggregate of 1,728,395 shares of the Company's common stock at an offering price of $20.25 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 with A.G.P./Alliance Global Partners ("AGP," and 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 issued and sold, in a registered direct offering (the "March 2021 Offering"), an aggregate of 769,231 shares of the Company's common stock, at an offering price of $19.50 per share for gross proceeds of approximately $15 million before the deduction of the placement agents fee and offering expenses. The closing of the offering occurred on April 5, 2021 and was accounted for 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 AGP, as lead placement agent (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.

Series A and Series B Convertible Redeemable Preferred Stock Offering

On January 10, 2022, the Company entered into a Securities Purchase Agreement (the "Preferred Stock Purchase Agreement") with several institutional investors, pursuant to which the Company agreed to issue and sell, in concurrent registered direct offerings (the "Preferred Offerings"), (i) 50,000 shares of the Company's Series A Convertible Redeemable Preferred Stock, par value $0.01 per share (the "Series A Preferred Stock"), and (ii) 50,000 shares of the Company's Series B Convertible Redeemable Preferred Stock, par value $0.01 per share (the "Series B Preferred Stock" and together with the Series A Preferred Stock, the "Preferred Stock"), in each case at an offering price of $285 per share, representing a 5% original issue discount to the stated value of $300 per share, for gross proceeds of each Preferred Offering of $14.25 million, or approximately $28.50 million in the aggregate for the Preferred Offerings, before the deduction of the Placement Agent's (as defined below) fee and offering expenses. The shares of Series A Preferred Stock had a stated value of $300 per share and were convertible, at a conversion price of $13.65 per share, into 1,098,901 shares of common stock (subject in certain circumstances to adjustments). The shares of Series B Preferred Stock had a stated value of $300 per share and were convertible, at a conversion price of $15.00 per share, into 1,000,000 shares of common stock (subject in certain circumstances to adjustments). The closing of the Preferred Offerings occurred on January 13, 2022.

The Company held a special meeting of stockholders to consider an amendment (the "Amendment") to the Company's Certificate of Incorporation, as amended, to effect a reverse stock split of the outstanding shares of common stock ("Common Stock") by a ratio to be determined by the Board of Directors of the Company (the "Reverse Stock Split"). The investors of the Preferred Stock Purchase Agreement had agreed to not transfer, offer, sell, contract to sell, hypothecate, pledge or otherwise dispose of the shares of the Preferred Stock until the Reverse Stock Split, to vote the shares of the Series A Preferred Stock purchased in the Preferred Offerings in favor of such Amendment and to vote the shares of the Series B Preferred Stock purchased in the Preferred Offerings in a manner that "mirrors" the proportions on which the shares of Common Stock (excluding any shares of Common Stock that are not voted) and Series A Preferred Stock are voted on the Reverse Stock Split and the Amendment.

Pursuant to the Preferred Stock Purchase Agreement, the Company filed two certificates of designation (the "Certificates of Designation") with the Secretary of the State of Delaware designating the rights, preferences, and limitations of the shares of Preferred Stock. The Certificates of Designation provided, in particular, that the Preferred Stock had no voting rights, other than the right to vote as a class on certain specified matters, except that (i) each share of Series A Preferred Stock had the right to vote, on an as converted basis, on the Reverse Stock Split (together with the Company's Common Stock and the Series B Preferred Stock as a single class), and (ii) each share of Series B Preferred Stock had the right to cast 3,000 votes per share of Series B Preferred Stock on the Reverse Stock Split.

The holders of Preferred Stock were entitled to dividends, on an as-if converted basis, equal to dividends actually paid, if any, on shares of Common Stock. The Preferred Stock was convertible into shares of Common Stock at a rate of $13.65 per share for the Series A Preferred Stock and $15.00 per share for the Series B Preferred Stock, subject to adjustment. The Preferred Stock was convertible at the option of the holder at any time after the Company had received stockholder approval for the Reverse Stock Split and filed the requisite Amendment with the Delaware Secretary of State's office to effectuate the Reverse Stock Split (the "Reverse Stock Split Date"), subject to beneficial ownership limitations set forth in the applicable Certificate of Designation. In addition, on or after the Reverse Stock Split Date, and subject to the satisfaction of certain conditions, the Company had the right to cause the holders of the Preferred Stock to convert their shares of Preferred Stock, subject to such beneficial ownership limitations.

Each holder of the Preferred Stock had the right to cause the Company to redeem all or part of their shares of the Preferred Stock from the earlier of receipt of stockholder approval of the Reverse Stock Split or of 90 days following the original issue date until 120 days following the original issue date, the "Redemption Date," in cash at a redemption price equal to 105% of the stated value plus an amount equal to accumulated but unpaid dividends, if any, on such shares (whether or not earned or declared, but excluding interest on such dividends) up to, but excluding, the Redemption Date. In connection with the Preferred Offerings, the Company entered into a placement agent agreement (the "Placement Agent Agreement") with AGP in which the Company paid $1,000,000 as a placement agent fee and $110,000 to reimburse AGP for certain expenses related to the Preferred Stock offering.

On March 3, 2022, the Company redeemed for cash at a price equal to 105% of the $300 stated value per share all of its 50,000 outstanding shares of Series A Preferred Stock and all of its 50,000 shares of Series B Preferred Stock. As a result, all shares of the Preferred Stock have been retired and are no longer outstanding and the Company's only class of outstanding stock is its common. Each share of common stock entitles the holder to one vote.

The Series A Preferred Stock and Series B Preferred Stock were recorded as a liability on the condensed consolidated balance sheet during the first quarter of 2022 until the preferred shares were redeemed during the same quarter. The Company recognized $4,551,567 as interest expense for the preferred shares during the first quarter of 2022, which was composed of: (a) $3,000,000 as the difference between the redemption price for the preferred shares and the net proceeds received from the issuance of the preferred shares, (b) $1,110,000 paid to AGP as a placement agent fee and reimbursement for certain expenses, and (c) $441,567 in legal fees recognized in the first quarter that were attributed to the preferred shares.

April 2022 Registered Direct Offering

On April 6, 2022, the Company entered into a Securities Purchase Agreement (the "April 2022 Purchase Agreement") with several institutional investors, pursuant to which the Company agreed to issue and sell, in a registered direct offering (the "April 2022 Offering"), an aggregate of 1,328,274 shares of the Company's common stock at an offering price of $5.27 per share for gross proceeds of $7.0 million before the deduction of the April 2022 Placement Agent (as defined below) fees and offering expenses. The April 2022 Purchase Agreement contains customary representations, warranties and agreements by the Company and customary conditions to closing. The closing of the April 2022 Offering occurred on April 8, 2022.

In connection with the April 2022 Offering, the Company entered into a placement agent agreement with A.G.P./Alliance Global Partners (the "April 2022 Placement Agent") pursuant to which the Company agreed to pay the April 2022 Placement Agent a cash fee equal to 6.5% of the aggregate gross proceeds raised from the sale of the securities sold in the April 2022 Offering and reimburse the April 2022 Placement Agent for certain of their expenses in an amount not to exceed $50,000.

Note 12. Stock-Based Compensation

The Company has long-term compensation plans that permit the granting of equity-based awards in the form of stock options, restricted stock, restricted stock units, stock appreciation rights, other stock awards, and performance awards.

At the 2018 Annual Stockholders Meeting of the Company held on May 15, 2018, stockholders approved the 2018 Stock Incentive Plan (the "2018 Plan"). The 2018 Plan, as adopted, permits the granting of 180,000 shares of 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 80,000 to a total of 260,000 under the 2018 Plan, as amended. Prior to the adoption of the 2018 Plan, the Company had maintained the 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 166,667 to a total of 426,667 under the 2018 Plan, as amended. At the 2021 Annual Stockholders Meeting of the Company held on June 10, 2021, stockholders approved an amendment to the 2018 Plan, as previously amended, whereby the Company increased the number of shares of common stock available by 513,333 to a total of 940,000 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 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 the Company 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, February 19, 2019 and again on July 19, 2022 and September 27, 2022, 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 4,668 shares, 4,668 shares, 177,000 shares, and 8,501 shares of common stock, respectively and (ii) inducement restricted stock awards (the "Inducement Stock Grants") totaling 1,266 shares, 8,666 shares, 53,000 shares and 2,250 shares of common stock, respectively to eight new employees. Each award has a grant date of the date of grant. Each Inducement Option Grant has an exercise price per share equal to $41.55, $32.70, $1.95, and $1.65 which represents the closing price of the Company's common stock as reported by Nasdaq on September 28, 2018, February 19, 2019, July 19, 2022 and September 27, 2022, respectively. Each Inducement Option Grant vests over three to four years, with one-third or one-fourth vesting on the one-year anniversary of the employee's first day of employment with the Company and one-third or one-fourth vesting on the second thru fourth 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 September 30, 2022, there were a total of 194,837 shares of the Company's common stock subject to outstanding inducement awards.

As of September 30, 2022, there were a total of 946,454 shares of the Company's common stock reserved for issuance under the 2018 Plan, which were comprised of 926,085 shares of the Company's common stock subject to equity awards previously granted under the 2018 Plan and 2007 Plan and 18,088 shares of the Company's common stock available for future issuance under the 2018 Plan.

A summary of stock option awards and restricted stock grants, inclusive of awards granted under the 2018 Stock Plan and Inducement Option Grants for the nine-months ended September 30, 2022 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, 2022	441,425	$ 38.50	1,481	$ 12.36	
Equity awards granted	697,156	$ 2.79	55,650	$ 1.96	
Equity awards terminated	(17,659)	$ 35.28	(100)	$ 9.45	
Equity awards outstanding at September 30, 2022	1,120,922	$ 16.33	57,031	$ 2.23	8.1
Aggregate intrinsic value of outstanding equity awards at September 30, 2022	$ 335		$ -		
Equity awards exercisable at September 30, 2022	521,723	$ 27.72			7.5
Aggregate intrinsic value of equity awards exercisable at September 30, 2022	$ -				

Total compensation cost related to stock options and restricted stock awards amounted to approximately $0.4 million and $0.7 million for the three-month periods ended September 30, 2022 and 2021, respectively. Of these amounts, $0.1 million and $0.2 million was charged to research and development during the three-month periods ended September 30, 2022 and 2021, respectively, and $0.3 million and $0.5 million was charged to general and administrative expenses during the three-month periods ended September 30, 2022 and 2021, respectively.

Total compensation cost related to stock options and restricted stock awards amounted to approximately $2.0 million and $3.1 million for the nine-month periods ended September 30, 2022 and 2021, respectively. Of these amounts, $0.7 million and $1.1 million was charged to research and development during the nine-month periods ended September 30, 2022 and 2021, respectively, and $1.3 million and $2.0 million was charged to general and administrative expenses during the nine-month periods ended September 30, 2022 and 2021, respectively.

As of September 30, 2022, there was $1.9 million of total unrecognized compensation cost related to non-vested stock-based compensation arrangements. That cost is expected to be recognized over a period of 4 years. The weighted average grant date fair values of the stock options granted was $2.23 and $1.97 during the nine-month periods ended September 30, 2022 and 2021, respectively.

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 the Company'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:

	For the Nine Months Ended September 30,	
	2022	**2021**
Risk-free interest rate	1.74 to 4.14%	1.54 to 1.74%
Expected volatility	107.6 to 113.95%	106.8 to 113.2%
Expected life (in years)	7.5 to 9.0	7.5 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 13. 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 September 30, 2022 and December 31, 2021, the Company fair valued the earn-out milestone liability at $5.4 million. In assessing the fair value of the earnout milestone liability as of September 30, 2022 and December 31, 2021, the Company considered each of the settlement provisions per the Amended Asset Purchase Agreement and equally weighted the probability of a cash or cash and common stock payment.

Note 14. Warrants

Following is a summary of all warrant activity for the nine-month period ended September 30, 2022:

Warrants	Number of Warrants Issued	Weighted Average Exercise Price
Warrants outstanding at December 31, 2021	175,792	$ 20.96
Warrants expired during the nine months ended September 30, 2022	(7,273)	$ 48.30
Warrants outstanding at September 30, 2022	168,519	$ 19.78
Aggregate intrinsic value of outstanding warrants at September 30, 2022	$ -	
Weighted average remaining contractual terms at September 30, 2022	3.3 years	

Note 15. Leases

In 2011, the Company executed a lease (the "Lease") with Brandywine Operating Partnership, L.P. ("Brandywine"), a Delaware limited partnership, for a 10,870 square foot premises located in Lawrenceville, New Jersey and relocated its offices to Lawrenceville, New Jersey from Columbia, Maryland. The Lease had an initial term of 66 months. In late 2015, Lenox Drive Office Park LLC purchased the real estate and office building and assumed the Lease. This Lease was set to expire on April 30, 2017. In April 2017, the Company and the landlord amended the Lease effective May 1, 2017. The 1st Lease Amendment extended the term of the agreement for an additional 64 months, reduced the premises to 7,565 square feet, reduced the monthly rent and provided four months free rent. The monthly rent ranged from approximately $18,900 in the first year to approximately $20,500 in the final year of the 1st Lease Amendment. 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. On June 9, 2021 and, as amended on July 7, 2021, the Company and the Huntsville landlord entered into a 22-month lease for an additional 2,197 square foot premises with rent payments of approximately $5,500 per month.

The Company 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.

Following is a table of the lease payments and maturity of our operating lease liabilities as of September 30, 2022:

Remainder of 2022	$	150,774
2023		238,609
and thereafter		–
Subtotal future lease payments		389,383
Less imputed interest		(15,858)
Total lease liabilities	$	373,525
Weighted average remaining life		0.8
Weighted average discount rate		9.98%

For the three-month and nine-month periods ended September 30, 2022, operating lease expense was $146,936 and $440,808, respectively, and cash paid for operating leases included in operating cash flows was $150,774 and $450,721, respectively.

For the three-month and nine-month periods ended September 30, 2021, operating lease expense was $146,936 and $413,577, respectively, and cash paid for operating leases included in operating cash flows was $149,115 and $418,696, respectively.

Note 16. Technology Development and Licensing Agreements

On May 7, 2012, the Company entered into a long-term commercial supply agreement with Zhejiang Hisun Pharmaceutical Co. Ltd. (“Hisun”) for the production of ThermoDox® in the China territory. In accordance with the terms of the agreement, Hisun will be responsible for providing all of the technical and regulatory support services, including the costs of all technical transfer, registration and bioequivalence studies, technical transfer costs, the Company’s consultative support costs and the purchase of any necessary equipment and additional facility costs necessary to support capacity requirements for the manufacture of ThermoDox®. The Company 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 the Company 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, the Company 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 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, the Company 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, the Company'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 the Company 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;
- The Company 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 the Company 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 the Company around the regulatory approval activities for GEN-1 with the CHINA FDA. A local China partner affords the Company access to accelerated CHINA FDA review and potential regulatory exclusivity for the approved indication.

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

Note 17. Commitments and Contingencies

On 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 Individual Defendants. The Company believes that the case is without merit and intends to defend it vigorously. At this 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. At this 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 August 2021, a complaint regarding a corporate books and records demand was filed against the Company in the Court of Chancery of the State of Delaware, captioned *Pacheco v. Celsion Corporation*, Case No. 2021-0705. The plaintiff alleges he is entitled to inspect the Company's books and records concerning the OPTIMA Study and other materials. The Company believes that the scope of the demand is without merit and intends to defend it vigorously. At this 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 October 2021, an arbitration was commenced against the Company before the CPR Institute for Conflict Prevention & Resolution, captioned Curia New Mexico, LLC v. Celsion Corp., Case No. G-22-85-S. The plaintiff alleges that the Company failed to pay invoices for the manufacture of ThermoDox®. The Company believes it has a meritorious defense to these claims and is vigorously contesting this allegation. At this 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, 2021.

Strategic and Clinical Overview

On September 19, 2022, Celsion Corporation announced a corporate name change to Imunon, Inc., reflecting the evolution of the Company's business focus and its commitment to developing cutting-edge immunotherapies and next-generation vaccines to treat cancer and infectious diseases. The Company's common stock will continue to trade on the Nasdaq Stock Market under the new ticker symbol "IMNN" effective as of the opening of trading on September 21, 2022. The Company has filed an amendment to its Articles of Incorporation to effect the new corporate name.

Imunon, Inc. ("Imunon" and the "Company") is a fully integrated, clinical stage biotechnology company focused on advancing a portfolio of innovative treatments that harness the body's natural mechanisms to generate safe, effective, and durable responses across a broad array of human diseases, constituting a differentiating approach from conventional therapies. Imunon has two platform technologies: Our TheraPlas® platform for the development of immunotherapies and other anti-cancer nucleic acid-based therapies, and our PLACCINE platform for the development of nucleic acid vaccines for infectious diseases and cancer. The Company's lead clinical program, GEN-1, is a DNA-based immunotherapy for the localized treatment of advanced ovarian cancer currently in Phase II development. GEN-1 works by instructing the body to produce safe and durable levels of powerful cancer fighting molecules, such as interleukin-12 and interferon gamma, at the tumor site. Additionally, the Company is conducting preclinical proof-of-concept studies on a nucleic acid vaccine candidate targeting SARS-CoV-2 virus in order to validate its PLACCINE platform. Imunon's platform technologies are based on the delivery of nucleic acids with novel synthetic delivery systems that are independent of viral vectors or devices. We will continue to leverage these platforms and to advance the technological frontier of plasmid DNA to better serve patients with difficult to treat conditions.

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 the Company 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 50%. This poor outcome is due in part to the lack of effective prevention and early detection strategies. There were approximately 20,000 new cases of ovarian cancer in the U.S. in 2021 with an estimated 13,000 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. The five-year survival rates for Stages III and IV are 39% and 17%, respectively. First-line chemotherapy regimens are typically platinum-based combination therapies. Although this first line of treatment has an approximate 80% response rate, 55% to 75% 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% 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"). 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 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.

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.

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. The Company 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 the Company, 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 29, 2021, the Company announced final progression free survival ("PFS") results from the OVATION I Study published in the Journal of Clinical Cancer Research. Median PFS in patients treated per protocol (n=14) was 21 months and was 18.4 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 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 R0 Resections
0, 36, 47 mg/m² of GEN-1 plus NACT	N =12	42%
61, 79, 100 mg/m² of GEN-1 plus NACT	N = 17	82%

- The 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.

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. Of the 34 patients enrolled in the trial, 27 patients have had their interval debulking surgery with the following results:

- 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.

- 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.

In June 2022, the Company announced that following a pre-planned interim safety review of 87 as treated patients (46 patients in the experimental arm and 41 patients in the control arm) randomized in the OVATION 2 Study, the Data Safety Monitoring Board ("DSMB") unanimously recommended that the OVATION 2 Study continue treating patients with the dose of 100 mg/m^2. The DSMB also determined that safety is satisfactory with an acceptable risk/benefit, and that patients tolerate GEN-1 during a course of treatment that lasts up to six months. No dose-limiting toxicities were reported. Interim clinical data from patients who have undergone interval debulking surgery showed that the GEN-1 treatment arm is continuing to show improvement in R0 surgical resection rates and CRS 3 chemotherapy response scores over the control arm. A complete tumor resection (R0) is a microscopically margin-negative resection in which no gross or microscopic tumor remains in the tumor bed. The chemotherapy response score is a three-tier standardized scoring system for histological tumor regression into complete/near complete (CRS 3), partial (CRS 2) and no/minimal (CRS 1) response based on omental examination.

In September 2022, the Company announced that its Phase I/II OVATION 2 Study with GEN-1 in advanced ovarian cancer has completed enrollment with 110 patients. Topline results are expected in the first half of 2024.

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 TheraPlas platform technology.

The Company's PLACCINE DNA vaccine technology platform is characterized by a single multi-cistronic DNA plasmid vector expressing multiple pathogen antigens delivered with a synthetic delivery system. We believe it is 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 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. The Company'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. The Company's extensive experience with TheraPlas suggests that the PLACCINE-based nanoparticles are stable at storage temperatures of $4^{o}C$ to $25^{o}C$, making vaccines developed on this platform easily suitable for broad world-wide distribution.

The Company's vaccine approach is designed to optimize the quality of the immune response dictating the efficiency of pathogen clearance and patient recovery. The Company 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 the Company'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

The Company's vaccine candidate comprises a single plasmid vector containing the DNA sequence encoding multiple SARS-CoV-2 antigens. 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 the Company's vaccine candidates may offer several potential key advantages. 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. 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.

- **Durable Efficacy**: PLACCINE delivers a DNA plasmid-based antigen that could 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.

On September 2, 2021, the Company announced results from preclinical *in vivo* studies showing production of antibodies and cytotoxic T-cell response specific to the spike antigen of SARS-CoV-2 when immunizing BALB/c mice with the Company's next-generation PLACCINE DNA vaccine platform. Moreover, the antibodies to SARS-CoV-2 spike antigen prevented the infection of cultured cells in a viral neutralization assay. The production of antibodies predicts the ability of PLACCINE to protect against SARS-CoV-2 exposure, and the elicitation of cytotoxic T-cell response shows the vaccine's potential to eradicate cells infected with SARS-CoV-2. These findings demonstrate the potential immunogenicity of the Company's PLACCINE DNA vaccine, which is intended to provide broad-spectrum protection and resistance against variants by incorporating multiple viral antigens, to improve vaccine stability at storage temperatures of 4^{o} C and above, and to facilitate cheaper and easier manufacturing.

On January 31, 2022, the Company announced it had engaged BIOQUAL, Inc., a preclinical testing contract research organization, to conduct a non-human primate ("NHP") challenge study with the Company's DNA-based approach for a SARS-CoV-2 vaccine. The NHP pilot study follows the generation of encouraging mouse data and will evaluate the Company's lead vaccine formulations for safety, immunogenicity, and protection against SARS-CoV-2. In completed preclinical studies, the Company demonstrated safe and efficient immune responses including IgG response, neutralizing antibodies and T-cell responses that parallel the activity of commercial vaccines following intramuscular ("IM") administration of novel vaccine compositions expressing a single viral antigen. In addition, vector development has shown promise of neutralizing activity against a range of SARS-CoV-2 variants. The Company's novel DNA-based vaccines have been based on a simple intramuscular injection that does not require viral encapsulation or special equipment for administration.

In April 2022, the Company presented its PLACCINE platform technology at the 2022 World Vaccine Congress. In an oral presentation during a Session on Cancer and Immunotherapy, Dr. Khursheed Anwer, the Company's Chief Science Officer, highlighted the Company's technology platform in his presentation entitled: "*Novel DNA Approaches for Cancer Immunotherapies and Multivalent Infectious Disease Vaccines*." PLACCINE is demonstrating the potential to be a powerful platform that provides for rapid design capability for targeting two or more different variants of a single virus in one vaccine. There is a clear public health need for vaccines today that address more than one strain of viruses, like COVID-19, which have fast evolving variant capability to offer the widest possible protection. Murine model data has thus far been encouraging and suggests that the Company's approach provides not only flexibility, but also the potential for efficacy comparable to benchmark COVID-19 commercial vaccines with durability to protect for more than 6 months.

In September 2022, the Company provided an update on the progress made in the development of a DNA-based vaccine using its PLACCINE platform technology. The Company reported evidence of IgG, neutralizing antibody, and T-cell responses to its SARS-CoV-2 PLACCINE vaccines in normal mice. In this murine model, the Company's multivalent PLACCINE vaccine targeted against two different variants showed to be immunogenic as determined by the levels of IgG, neutralizing antibodies, and T-cell responses. Additionally, our multivalent vaccine was equally effective against two different variants of the COVID-19 virus while the commercial mRNA vaccine appeared to have lost some activity against the newer variant. The murine model data has thus far been encouraging and suggests that the Company's approach provides not only flexibility, but also the potential for efficacy comparable to benchmark COVID-19 commercial vaccines with durability to protect expected to be greater than 6 months.

Final data from its now completed proof-of-concept mouse challenge study confirmed that a PLACCINE DNA-based vaccine can produce robust levels of IgG, neutralizing antibodies, and T-cell responses. The data demonstrates the ability of the Company's PLACCINE vaccine to protect a SARS-CoV-2 mouse model in a live viral challenge. In the study, mice were vaccinated with a PLACCINE vaccine expressing the SARS-CoV-2 spike antigen from the D614G variant or the Delta variant, or a combination vaccine expressing both the D614G and Delta spike variants. The vaccination was administered by intramuscular injection on Day 0 and Day 14, followed by challenge with live SARS-CoV-2 virus on Day 42. All three vaccines, including the single and dual antigen vaccines, were found to be safe and elicited IgG responses and inhibited the viral load by 90-95%. The dual antigen vaccine was equally effective against both variants of the SARS CoV-2 virus.

In October 2022, the Company reported partial results from an ongoing non-human primate study designed to examine the immunogenicity of its proprietary PLACCINE vaccine which supports PLACCINE as a viable alternative to mRNA vaccines. The study examined a single plasmid DNA vector containing the SARS-CoV-2 Alpha variant spike antigen formulated with a synthetic DNA delivery system and administered by intramuscular injection. In the study, Cynomolgus monkeys were vaccinated with the PLACCINE vaccine or a commercial mRNA vaccine on Day 1, 28 and 84. Analysis of blood samples for IgG and neutralizing antibodies showed evidence of immunogenicity both in PLACCINE and mRNA vaccinated subjects. Analysis of bronchoalveolar lavage for viral load by quantitative PCR showed viral clearance by >90% of the non-vaccinated controls. Viral clearance from nasal swab followed a similar pattern in a majority of vaccinated animals and a similar clearance profile was observed when viral load was analyzed by the tissue culture infectious dose method.

Importantly, in a head-to-head comparison the protection efficiency as measured by viral clearance following challenge with the SARS-CoV-2 virus was similar between PLACCINE and a commercial mRNA vaccine. In an ongoing stability study, the physio-chemical properties and immunogenicity of PLACCINE vaccine did not change during storage at 4° C for up to three months.

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 39.5º to 42º 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.

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”).

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 the Company. 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. 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 is 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®

The Company continues working closely and supporting investigations by others to evaluate the use of ThermoDox for the treatment of various cancer. Following inquiries from the NIH, we renewed 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, the Company is developing a business model to support these investigator-sponsored studies in a manner that will not interfere with its current focus on our GEN-1 program and vaccine development initiative.

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 September 30, 2022, the Company has incurred approximately $355 million of cumulative net losses. As of September 30, 2022, the Company had $43.4 million in cash and cash equivalents, short-term investments, interest receivable and restricted cash. The Company has substantial future capital requirements to continue its research and development activities and advance its product candidates through various development stages. The Company believes these expenditures are essential for the commercialization of its technologies.

The Company expects its operating losses to continue for the foreseeable future as it continues its product development efforts, and when it undertakes marketing and sales activities. The Company's ability to achieve profitability is dependent upon its ability to obtain governmental approvals, manufacture, and market and sell its new product candidates. There can be no assurance that the Company will be able to commercialize its technology successfully or that profitability will ever be achieved. The operating results of the Company have fluctuated significantly in the past.

In January 2020, the World Health Organization declared an outbreak of coronavirus, COVID-19, to be a "Public Health Emergency of International Concern," and the U.S. Department of Health and Human Services declared a public health emergency to aid the U.S. healthcare community in responding to COVID-19. This virus continues to evolve and may have an adverse effect on our operations and product development timelines. Uncertainty with respect to the economic impacts of the pandemic has introduced significant volatility in the financial markets. 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 and the geopolitical turmoil caused by the war in Ukraine. These disruptions may have a negative impact on the Company's clinical trials process and enrollment of patients. The ongoing geopolitical turmoil caused by the war in Ukraine has contributed to highly volatile financial markets which may impact our ability to access the capital markets and rising levels of inflation which may impact our expenditures and supply chain. The Company continues to monitor its operating activities in light of these events, and it is reasonably possible that these events could have a negative effect on the Company's financial condition and results of operations. The specific impact, if any, is not readily determinable as of the date of the 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.

Since 2018, the Company has annually 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 New Jersey 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 cumulative New Jersey NOLs from 2011 to 2018 totaling $13 million and received net proceeds of $12.2 million. As part of the Technology Business Tax Certificate Program, the Company sold $1.5 million and $2.0 million of its New Jersey NOLs in 2021 and 2020, respectively. The sale of these net operating losses resulted in net proceeds to the Company of approximately $1.4 million in 2021 and $1.9 million in 2020. 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 funding program in future years for up to an additional $3.5 million in net operating losses under this maximum lifetime benefit. In June 2022, the Company filed an application with The New Jersey Economic Development Authority to sell $1.7 million of its New Jersey NOL's for the tax year 2021 which is expected to generate net proceeds to the Company of approximately $1.6 million.

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 the Company 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, the Company 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 10 to the Financial Statements, in June 2021, the Company entered into a $10 million loan facility with Silicon Valley Bank ("SVB"). The Company immediately used $6 million from this facility to retire all outstanding indebtedness with Horizon and deposited $6 million with SVB as restricted cash as discussed in more detail in Note 4. The remaining $4 million under the SVB loan facility ("SVB Loan Facility") 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.

With $43.4 million in cash and cash equivalents, short-term investments, interest receivable and restricted cash, coupled with approximately $3.5 million of future planned sales of the Company's State of New Jersey net operating losses, the Company believes it has sufficient capital resources to fund its operations into 2025.

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 New Jersey NOLs 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

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 2021 and 2022 through the date of this Quarterly Report filed on Form 10-Q, we issued a total of 4.5 million shares of common stock as discussed below for an aggregate $65.6 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 2021, the Company sold 0.5 million shares under the Capital on Demand Agreement, receiving approximately $6.9 million in gross proceeds under the Capital on Demand Agreement.

- 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 1,728,395 shares of the Company's common stock at an offering price of $20.25 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 with A.G.P./Alliance Global Partners ("AGP" and 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 769,230 shares of the Company's common stock, at an offering price of $19.50 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 with AGP, as lead placement agent (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.

- On January 10, 2022, the Company entered into the Preferred Stock Purchase Agreement with several institutional investors, pursuant to which the Company agreed to issue and sell, in the Preferred Offerings, (i) 50,000 shares of Series A Preferred Stock, and (ii) 50,000 shares of Series B Preferred Stock, in each case at an offering price of $285 per share, representing a 5% original issue discount to the stated value of $300 per share, for gross proceeds of each Preferred Offering of $14.25 million, or approximately $28.50 million in the aggregate for the Preferred Offerings, before the deduction of the Placement Agent's (as defined below) fee and offering expenses. The shares of Series A Preferred Stock had a stated value of $300 per share and were convertible, at a conversion price of $13.65 per share, into 1,098,901 shares of common stock (subject in certain circumstances to adjustments). The shares of Series B Preferred Stock had a stated value of $300 per share and were convertible, at a conversion price of $15.00 per share, into 1,000,000 shares of common stock (subject in certain circumstances to adjustments). The closing of the Preferred Offerings occurred on January 13, 2022.

  The Company held a special meeting of stockholders to consider an amendment (the "Amendment") to the Company's Certificate of Incorporation, as amended, to effect a reverse stock split of the outstanding shares of common stock ("Common Stock") by a ratio to be determined by the Board of Directors of the Company (the "Reverse Stock Split"). The investors have agreed in the Purchase Agreement to not transfer, offer, sell, contract to sell, hypothecate, pledge or otherwise dispose of the shares of the Preferred Stock until the Reverse Stock Split, to vote the shares of the Series A Preferred Stock purchased in the Preferred Offerings in favor of such Amendment and to vote the shares of the Series B Preferred Stock purchased in the Preferred Offerings in a manner that "mirrors" the proportions on which the shares of Common Stock (excluding any shares of Common Stock that are not voted) and Series A Preferred Stock are voted on the Reverse Stock Split and the Amendment.

The holders of Preferred Stock were entitled to dividends, on an as-if converted basis, equal to dividends actually paid, if any, on shares of Common Stock. The Preferred Stock was convertible into shares of Common Stock at a rate of $13.65 per share for the Series A Preferred Stock and $15.00 per share for the Series B Preferred Stock, subject to adjustment. The Preferred Stock was convertible at the option of the holder at any time after the Company had received stockholder approval for the Reverse Stock Split and filed the requisite Amendment with the Delaware Secretary of State's office to effectuate the Reverse Stock Split (the "Reverse Stock Split Date"), subject to beneficial ownership limitations set forth in the applicable Certificate of Designation. In addition, on or after the Reverse Stock Split Date, and subject to the satisfaction of certain conditions, the Company had the right to cause the holders of the Preferred Stock to convert their shares of Preferred Stock, subject to such beneficial ownership limitations.

Each holder of the Preferred Stock had the right to cause the Company to redeem all or part of their shares of the Preferred Stock from the earlier of receipt of stockholder approval of the Reverse Stock Split or of 90 days following the original issue date until 120 days following the original issue date, the "Redemption Date," in cash at a redemption price equal to 105% of the stated value plus an amount equal to accumulated but unpaid dividends, if any, on such shares (whether or not earned or declared, but excluding interest on such dividends) up to, but excluding, the Redemption Date. In connection with the Preferred Offerings, the Company entered into a placement agent agreement (the "Placement Agent Agreement") with AGP in which the Company paid $1,000,000 as a placement agent fee and $110,000 to reimburse AGP for certain expenses related to the Preferred Stock offering.

On March 3, 2022, the Company redeemed for cash at a price equal to 105% of the $300 stated value per share all of its 50,000 outstanding shares of Series A Preferred Stock and all of its 50,000 shares of outstanding Series B Preferred Stock. As a result, all shares of the Preferred Stock have been retired and are no longer outstanding and the Company's only class of outstanding stock is its common stock.

The Series A Preferred Stock and Series B Preferred Stock were recorded as a liability on the condensed consolidated balance sheet during the first quarter of 2022 until the preferred shares were redeemed during the same quarter. The Company recognized $4,551,567 as interest expense for the preferred shares during the first quarter of 2022, which was composed of: (a) $3,000,000 as the difference between the redemption price for the preferred shares and the net proceeds received from the issuance of the preferred shares, (b) $1,110,000 paid to AGP as a placement agent fee and reimbursement for certain expenses, and (c) $441,567 in legal fees recognized in the first quarter that were attributed to the preferred shares.

- On April 6, 2022, the Company entered into a Securities Purchase Agreement (the "April 2022 Purchase Agreement") with several institutional investors, pursuant to which the Company agreed to issue and sell, in a registered direct offering (the "April 2022 Offering"), an aggregate of 1,328,274 shares of the Company's common stock at an offering price of $5.27 per share for gross proceeds of $7.0 million before the deduction of the April 2022 Placement Agent (as defined below) fees and offering expenses. The closing of the April 2022 Offering occurred on April 8, 2022.

  In connection with the April 2022 Offering, the Company entered into a placement agent agreement with A.G.P./Alliance Global Partners (the "April 2022 Placement Agent") pursuant to which the Company agreed to pay the April 2022 Placement Agent a cash fee equal to 6.5% of the aggregate gross proceeds raised from the sale of the securities sold in the April 2022 Offering and reimburse the April 2022 Placement Agent for certain of their expenses in an amount not to exceed $50,000.

Significant Accounting Policies

Our significant accounting policies are more fully described in Note 1 to our consolidated financial statements included in our 2021 Annual Report on Form 10-K for the year ended December 31, 2021 filed with the SEC on March 31, 2022. See Note 3 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 MONTHS ENDED SEPTEMBER 30, 2022 AND 2021

Results of Operations

For the three months ended September 30, 2022 our net loss was $6.1 million compared to a net loss of $5.4 million for the same three-month period of 2021.

With $43.4 million in cash and cash equivalents, short-term investments, interest receivable and restricted cash, coupled with approximately $3.5 million of future planned sales of the Company's State of New Jersey net operating losses, the Company believes it has sufficient capital resources to fund its operations into 2025.

	For the Three Months Ended September 30,			
	(In thousands)		Change Increase (Decrease)	
	2022	2021		
Licensing Revenue:	$ 125	$ 125	$ –	–%
Operating Expenses:				
Clinical Research	982	1,036	(54)	(5.2)%
Chemistry, Manufacturing and Controls (CMC)	1427	1,432	(5)	(0.3)%
Research and development expenses	2,409	2,468	(59)	(2.4)%
General and administrative expenses	3,891	2,719	1,172	43.1%
Total operating expenses	6,300	5,187	1,113	21.5%
Loss from operations	$ (6,175)	$ (5,062)	$ 1,113	22.0%

Licensing Revenue

In January 2013, we entered into a technology development contract with Hisun, pursuant to which Hisun paid us a non-refundable technology transfer fee of $5.0 million to support our development of ThermoDox® in the China territory. The $5.0 million received as a non-refundable payment from Hisun in the first quarter 2013 has been recorded to deferred revenue and will be amortized over the ten-year term of the agreement; therefore, we recorded deferred revenue of $125,000 in each of the third quarters of 2022 and 2021.

Research and Development Expenses

Research and development ("R&D") expenses were $2.4 million in the third quarter of 2022 compared to $2.5 million in same period of 2021. Costs associated with the OVATION 2 Study were $0.4 million in the third quarter of 2022 compared to $0.2 million in the same period of 2021. Costs associated with the OPTIMA Study were $0.1 million in the third quarter of 2022 compared to $0.2 million in the same period of 2021. In July 2020, the Company unblinded the OPTIMA Study at the recommendation of the DMC to halt the study due to futility. Other clinical and regulatory costs were $0.5 million the third quarter of 2022 compared to $0.7 million in the same period of 2021. 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 $1.1 million in the third quarter of 2022 compared to $1.1 million in the same period of 2021. CMC costs increased to $0.3 million in the third quarter of 2022 compared to $0.3 million in the same period of 2021.

General and Administrative Expenses

General and administrative expenses were $3.9 million in the third quarter of 2022 compared to $2.7 million in the same period of 2021. The increase was primarily attributable to costs associated with higher legal fees partially offset by lower stock compensation costs.

Impairment of IPR&D Liability

Due to the continuing deterioration of public capital markets in the biotech industry and its impact on market capitalization rates in this sector, IPR&D related to the ovarian cancer indication was reviewed for impairment during the third quarter of 2022. Based on the Company's analysis of the IPR&D, the Company has concluded that it is not more than likely that the asset had been impaired as of September 30, 2022. As such, no impairment charges for IPR&D related to the ovarian cancer indication were recorded during the third quarter of 2022.

Change in Earn-out Milestone Liability

As of September 30, 2022 and June 30, 2022, the Company fair valued the earn-out milestone liability at $5.4 million with no change recorded to the fair value of the earn-out milestone during the third quarter of 2022.

Investment income and interest expense

The Company recognized interest expense of $0.1 million in the third quarter of 2022 compared to $0.1 million in the same period of 2021. As more fully discussed in Note 10, 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. In connection with this Horizon Technology Financing Facility, the Company incurred $0.2 million in interest expense in the third quarter of 2021. 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.

Investment income from its short-term investments was insignificant in the third quarter of 2021 and 2022.

FINANCIAL REVIEW FOR THE NINE MONTHS ENDED SEPTEMBER 30, 2022 AND 2021

Results of Operations

For the nine months ended September 30, 2022, our net loss was $22.7 million compared to a net loss of $16.5 million for the same nine-month period of 2021.

	For the Nine Months Ended September 30,			
	(In thousands)		Change Increase (Decrease)	
	2022	2021		
Licensing Revenue:	$ 375	$ 375	$ –	–%
Operating Expenses:				
Clinical Research	3,808	3,400	408	12.0%
Chemistry, Manufacturing and Controls (CMC)	4,922	4,233	689	16.3%
Research and development expenses	8,730	7,633	1,097	14.4%
General and administrative expenses	9,640	8,258	1,382	16.7%
Total operating expenses	18,370	15,891	2,479	15.6%
Loss from operations	$ (17,995)	$ (15,516)	$ 2,479	16.0%

Licensing Revenue

In January 2013, we entered into a technology development contract with Hisun, pursuant to which Hisun paid us a non-refundable technology transfer fee of $5.0 million to support our development of ThermoDox® in the China territory. The $5.0 million received as a non-refundable payment from Hisun in the first quarter 2013 has been recorded to deferred revenue and will be amortized over the ten-year term of the agreement; therefore, we recorded deferred revenue of $375,000 in the first nine months of 2022 and 2021.

Research and Development Expenses

Research and development ("R&D") expenses were $8.7 million in the first nine months of 2022 compared $7.6 million in same period of 2021. Costs associated with the OVATION 2 Study were $1.2 million in the first nine months of 2022 compared to $1.0 million in the same period of 2021. Costs associated with the OPTIMA Study were $1.0 million in the first nine months of 2022 compared to $0.6 million in the same period of 2021. In July 2020, the Company unblinded the OPTIMA Study at the recommendation of the DMC to halt the study due to futility. Other clinical and regulatory costs were $1.6 million the first nine months of 2022 compared to $1.8 million in the same period of 2021. 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 $4.1 million in the first nine months of 2022 compared to $3.1 million in the same period of 2021. CMC costs decreased to $0.8 million in the first nine months of 2022 compared to $1.1 million in the same period of 2021.

General and Administrative Expenses

General and administrative expenses were $9.6 million in the first nine months of 2022 compared to $8.3 million in the same period of 2021. The increase was primarily attributable to costs associated with higher professional fees partially offset by lower stock compensation costs.

Impairment of IPR&D Liability

Due to the continuing deterioration of public capital markets in the biotech industry and its impact on market capitalization rates in this sector, IPR&D related to the ovarian cancer indication was reviewed for impairment during the first nine months of 2022. Based on the Company's analysis of the IPR&D, the Company has concluded that it is not more than likely that the asset had been impaired as of September 30, 2022. As such, no impairment charges for IPR&D related to the ovarian cancer indication were recorded during the first nine months of 2022.

Change in Earn-out Milestone Liability

As of September 30, 2022 and December 31, 2021, the Company fair valued the earn-out milestone liability at $5.4 million with no change recorded to the fair value of the earn-out milestone liability during the first nine months of 2022.

Investment income and interest expense

The Company recognized interest expense of $4.9 million in the first nine months of 2022. As more fully discussed in Notes 10 and 11 of the financial statements, the Company expensed $0.3 million in interest due to the Silicon Valley Bank loan facility and $4.6 million in interest attributed to the Series A Preferred Stock and Series B Preferred Stock during the first quarter of 2022.

As more fully discussed in Note 10, 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. In connection with this Horizon Technology Financing Facility, the Company incurred $0.5 million in interest expense in the first nine months of 2021. 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.

Investment income from its short-term investments was insignificant in the first nine months of 2021 and 2022.

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 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 $355 million as of September 30, 2022.

At September 30, 2022, we had total current assets of $40.2 million and current liabilities of $8.5 million, resulting in net working capital of $31.7 million. At September 30, 2022, 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 $43.4 million. At December 31, 2021 we had total current assets of $51.9 million and current liabilities of $6.8 million, resulting in net working capital of $45.1 million. We have substantial future capital requirements to continue our research and development activities and advance our product candidates through various development stages. The Company believes these expenditures are essential for the commercialization of its technologies.

Net cash used in operating activities for the first nine months of 2022 was $18.1 million. Net cash provided by investing activities was $19.1 million during the first nine months of 2022. Cash provided by financing activities during the first nine months of 2022 totaled $6.3 million. With $43.4 million in cash and cash equivalents, short-term investments, interest receivable and restricted cash, coupled with approximately $3.5 million of future planned sales of the Company's State of New Jersey net operating losses, the Company believes it has sufficient capital resources to fund its operations into 2025.

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 DISCLOSURES ABOUT MARKET RISK

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

Item 4. CONTROLS AND PROCEDURES

We have carried out an evaluation, under the supervision and with the participation of management, including our principal executive officer and principal financial officer, of the effectiveness of the design and operation of our disclosure controls and procedures, as that term is defined in Rule 13a-15(e) under the Securities Exchange Act of 1934, as amended. Based on that evaluation, our principal executive officer and principal financial officer have concluded that, as of September 30, 2022, 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 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. 3:20-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 Individual Defendants. The Company believes that the case is without merit and intends to defend it vigorously. At this 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. At this 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 August 2021, a complaint regarding a corporate books and records demand was filed against the Company in the Court of Chancery of the State of Delaware, captioned *Pacheco v. Celsion Corporation*, Case No. 2021-0705. The plaintiff alleges he is entitled to inspect the Company's books and records concerning the OPTIMA Study and other materials. The Company believes that the scope of the demand is without merit and intends to defend it vigorously. At this 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 October 2021, an arbitration was commenced against the Company before the CPR Institute for Conflict Prevention & Resolution, captioned *Curia New Mexico, LLC v. Celsion Corp.*, Case No. G-22-85-S. The plaintiff alleges that the Company failed to pay invoices for the manufacture of ThermoDox®. The Company believes it has a meritorious defense to these claims and is vigorously contesting this allegation. At this 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 2021 Annual Report on Form 10-K. The risks and uncertainties described in our 2021 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.

3.1	Certificate of Amendment to Certificate of Incorporation of the Company, as filed with the Secretary of State of the State of Delaware, effective on September 19, 2022, incorporated by reference to Exhibit 3.1 to the Current Report on Form 8-K of the Company, filed on September 19, 2022 (SEC File No. 001-15911).
3.2	Certificate of Elimination of Series A Convertible Redeemable Preferred Stock and Series B Convertible Redeemable Preferred Stock of the Company, as filed with the Secretary of State of the State of Delaware, effective on September 16, 2022, incorporated by reference to Exhibit 3.2 to the Current Report on Form 8-K of the Company, filed on September 19, 2022 (SEC File No. 001-15911).
3.3	Amended and Restated Bylaws of the Company, effective on September 19, 2022, incorporated by reference to Exhibit 3.3 to the Current Report on Form 8-K of the Company, filed on September 19, 2022 (SEC File No. 001-15911).
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.
101**	The following materials from the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2022 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.
+	Filed herewith.
*	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.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

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.

November 14, 2022

IMUNON, INC.

Registrant

By: */s/ Corinne Le Goff*
Corinne Le Goff
President and Chief Executive Officer

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

Exhibit 31.1

IMUNON, INC.
CERTIFICATION

I, Corinne Le Goff, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Imunon, Inc.;

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.

Imunon, Inc.

November 14, 2022

By: */s/ Corinne Le Goff*
Corinne Le Goff
President and Chief Executive Officer

Exhibit 31.2

IMUNON, INC.
CERTIFICATION

I, Jeffrey W. Church, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Imunon, Inc.;

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.

Imunon, Inc.

November 14, 2022

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

Exhibit 32.1

IMUNON, INC.

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 September 30, 2022 of Imunon, Inc. (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.

November 14, 2022 By: */s/ Corinne Le Goff*
Corinne Le Goff
President and Chief Executive Officer

November 14, 2022 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.