

**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, 2023

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)

NA

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

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

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

Non-accelerated filer

Emerging growth company

Accelerated filer

Smaller reporting company

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

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

As of November 9, 2023, the Registrant had 9,399,289 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 potential worsening global economic conditions and the recent disruptions to, and volatility in, financial markets in the U.S. and worldwide resulting from the COVID-19 pandemic, the Russian invasion of Ukraine and the unrest in the Middle East 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, 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, 2022, 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

	<u>September 30, 2023</u> (Unaudited)	<u>December 31, 2022</u>
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 12,884,199	\$ 11,492,841
Investment in debt securities - available for sale, at fair value	6,492,675	21,254,485
Accrued interest receivable on investment securities	97,103	128,932
Money market investments, restricted cash	-	1,500,000
Advances and deposits on clinical programs and other current assets	2,251,475	2,403,433
Total current assets	<u>21,725,452</u>	<u>36,779,691</u>
Property and equipment (at cost, less accumulated depreciation and amortization)	<u>823,551</u>	<u>548,301</u>
Other assets:		
Money market investments, restricted cash	-	4,500,000
Deferred income tax asset	-	1,567,026
Operating lease right-of-use assets, net	1,663,985	155,876
Deposits and other assets	441,440	425,000
Total other assets	<u>2,105,425</u>	<u>6,647,902</u>
Total assets	<u>\$ 24,654,428</u>	<u>\$ 43,975,894</u>

See accompanying notes to the unaudited condensed consolidated financial statements.

IMUNON, INC.

CONDENSED CONSOLIDATED
BALANCE SHEETS
(Continued)

	September 30, 2023 (Unaudited)	December 31, 2022
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable – trade	\$ 1,826,762	\$ 3,586,623
Other accrued liabilities	3,019,135	4,794,936
Note payable – current portion, net of deferred financing costs	-	1,424,774
Operating lease liabilities - current portion	470,613	230,749
Total current liabilities	5,316,510	10,037,082
Notes payable – non-current portion, net of deferred financing costs	-	4,610,946
Operating lease liabilities - non-current portion	1,266,176	-
Total liabilities	6,582,686	14,648,028
Commitments and contingencies	-	-
Stockholders' equity:		
Preferred stock - \$0.01 par value (100,000 shares authorized, and no shares issued or outstanding at September 30, 2023 and December 31, 2022)	-	-
Common stock - \$0.01 par value (112,500,000 shares authorized; 9,367,929 and 7,436,219 shares issued at September 30, 2023 and December 31, 2022, respectively; 9,367,907 and 7,436,197 shares outstanding at September 30, 2023 and December 31, 2022, respectively)	93,679	74,362
Additional paid-in capital	401,337,485	397,980,023
Accumulated other comprehensive income	20,435	26,494
Accumulated deficit	(383,294,669)	(368,667,825)
Total stockholders' equity before treasury stock	18,156,930	29,413,054
Treasury stock, at cost (22 shares at September 30, 2023 and December 31, 2022)	(85,188)	(85,188)
Total stockholders' equity	18,071,742	29,327,866
Total liabilities and stockholders' equity	\$ 24,654,428	\$ 43,975,894

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,	
	2023	2022	2023	2022
Licensing revenue	\$ -	\$ 125,000	\$ -	\$ 375,000
Operating expenses:				
Research and development	1,980,693	2,408,680	7,734,897	8,730,395
General and administrative	1,923,375	3,890,886	7,327,906	9,639,419
Total operating expenses	<u>3,904,068</u>	<u>6,299,566</u>	<u>15,062,803</u>	<u>18,369,814</u>
Loss from operations	<u>(3,904,068)</u>	<u>(6,174,566)</u>	<u>(15,062,803)</u>	<u>(17,994,814)</u>
Other income (expense):				
Investment income	427,454	153,301	962,197	205,760
Interest expense	-	(127,025)	(197,080)	(4,878,306)
Loss on extinguishment of debt	-	-	(329,158)	-
Other income	-	-	-	1,801
Total other income (expense), net	<u>427,454</u>	<u>26,276</u>	<u>435,959</u>	<u>(4,670,745)</u>
Net loss	<u>\$ (3,476,614)</u>	<u>\$ (6,148,290)</u>	<u>\$ (14,626,844)</u>	<u>\$ (22,665,559)</u>
Net loss per common share				
Basic and diluted	<u>\$ (0.37)</u>	<u>\$ (0.87)</u>	<u>\$ (1.64)</u>	<u>\$ (3.42)</u>
Weighted average shares outstanding				
Basic and diluted	<u>9,376,872</u>	<u>7,098,741</u>	<u>8,926,114</u>	<u>6,621,925</u>

See accompanying notes to the unaudited 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,	
	2023	2022	2023	2022
Other comprehensive loss				
Changes in:				
Realized gains (losses) on debt securities recognized in investment income, net	\$ 163,170	\$ 10,369	\$ (26,913)	\$ 34,303
Unrealized (losses) gains on debt securities, net	<u>(304,780)</u>	<u>34,241</u>	<u>20,854</u>	<u>(51,753)</u>
Change in realized and unrealized (losses) gains on available for sale securities, net	(141,610)	44,610	(6,059)	(17,450)
Net loss	<u>(3,476,614)</u>	<u>(6,148,290)</u>	<u>(14,626,844)</u>	<u>(22,665,559)</u>
Total comprehensive loss	<u>\$ (3,618,224)</u>	<u>\$ (6,103,680)</u>	<u>\$ (14,632,903)</u>	<u>\$ (22,683,009)</u>

See accompanying notes to the unaudited condensed consolidated financial statements.

IMUNON, INC.

CONDENSED CONSOLIDATED
STATEMENTS OF CASH FLOWS
(Unaudited)

	For the Nine Months Ended September 30,	
	2023	2022
Cash flows from operating activities:		
Net loss	\$ (14,626,844)	\$ (22,665,559)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	176,509	117,371
Amortization of right-of-use assets	402,940	396,181
Recognition of deferred revenue	-	(375,000)
Realized and unrealized losses, net, on investment securities	(6,059)	(17,450)
Stock-based compensation	625,589	1,962,807
Realization of deferred income tax asset	1,567,026	1,383,446
Loss on extinguishment of debt	329,158	-
Amortization of deferred finance charges and debt discount associated with notes payable	55,122	135,572
Net changes in:		
Accrued interest receivable on investment securities	31,829	78,349
Advances, deposits, and other current assets	135,517	(273,646)
Accounts payable and accrued liabilities	(3,940,670)	1,168,592
Net cash used in operating activities	(15,249,883)	(18,089,337)
Cash flows from investing activities:		
Purchases of investment securities	(3,738,190)	(8,386,300)
Proceeds from sale and maturity of investment securities	18,500,000	27,775,000
Purchases of property and equipment	(451,759)	(222,891)
Net cash provided by investing activities	14,310,051	19,165,809
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	2,751,190	6,275,346
Payoff of the SVB loan and accrued end-of-term fees	(6,420,000)	-
Net cash (used in) provided by financing activities	(3,668,810)	6,275,346
Net change in cash, cash equivalents and restricted cash	(4,608,642)	7,351,818
Cash, cash equivalents and restricted cash at beginning of period	17,492,841	25,586,272
Cash, cash equivalents and restricted cash at end of period	\$ 12,884,199	\$ 32,938,090

See accompanying notes to the unaudited condensed consolidated financial statements.

IMUNON, INC.

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

	For the Nine Months Ended September 30,	
	2023	2022
Supplemental disclosures of cash flow information:		
Interest paid	\$ 179,542	\$ 4,742,734
Recognition of right of use asset and liability	<u>\$ 1,911,049</u>	<u>\$ -</u>
Cash paid for amounts included in measurement of lease liabilities:		
Operating cash flows for lease payments	<u>\$ 510,779</u>	<u>\$ 450,721</u>

See accompanying notes to the unaudited condensed consolidated financial statements.

IMUNON, INC.

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

FOR THE THREE MONTHS ENDED SEPTEMBER 30, 2023 AND 2022

	Common Stock Outstanding		Additional Paid-in Capital	Treasury Stock		Accum. Other Compr. Income (Loss)	Accumulated Deficit	Total
	Shares	Amount		Shares	Amount			
Balance at July 1, 2023	9,252,003	\$ 92,520	\$ 401,163,818	22	\$ (85,188)	\$ 162,045	\$ (379,818,055)	\$ 21,515,140
Net loss	-	-	-	-	-	-	(3,476,614)	(3,476,614)
Sale of equity through equity financing facilities	62,904	629	77,103	-	-	-	-	77,732
Issuance of common stock upon exercise of options	53,000	530	-	-	-	-	-	530
Realized and unrealized gains (losses), net, on investment securities	-	-	-	-	-	(141,610)	-	(141,610)
Stock-based compensation expense	-	-	96,564	-	-	-	-	96,564
Balance at September 30, 2023	<u>9,367,907</u>	<u>\$ 93,679</u>	<u>\$ 401,337,485</u>	<u>22</u>	<u>\$(85,188)</u>	<u>\$ 20,435</u>	<u>\$ (383,294,669)</u>	<u>\$ 18,071,742</u>
	Common Stock Outstanding		Additional Paid-in Capital	Treasury Stock		Accum. Other Compr. Income (Loss)	Accumulated Deficit	Total
	Shares	Amount		Shares	Amount			
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 investment securities	-	-	-	-	-	44,610	-	44,610
Stock-based compensation expense	-	-	476,285	-	-	-	-	476,285
Balance at September 30, 2022	<u>7,098,741</u>	<u>\$ 70,988</u>	<u>\$ 396,825,849</u>	<u>22</u>	<u>\$ (85,188)</u>	<u>\$ (25,424)</u>	<u>\$ (355,435,150)</u>	<u>\$ 41,351,075</u>

IMUNON, INC.

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

FOR THE NINE MONTHS ENDED SEPTEMBER 30, 2023 AND 2022

	Common Stock Outstanding		Additional Paid-in Capital	Treasury Stock		Accum. Other Compr. (Loss)	Accumulated Deficit	Total
	Shares	Amount		Shares	Amount			
Balance at January 1, 2023	7,436,219	\$ 74,362	\$ 397,980,023	22	\$ (85,188)	\$ 26,494	\$ (368,667,825)	\$ 29,327,866
Net loss	-	-	-	-	-	-	(14,626,844)	(14,626,844)
Sale of equity through equity financing facilities	1,878,488	18,785	2,731,873	-	-	-	-	2,750,658
Issuance of common stock upon exercise of options	53,200	532	-	-	-	-	-	532
Realized and unrealized gains (losses), net, on investment securities	-	-	-	-	-	(6,059)	-	(6,059)
Stock-based compensation expense	-	-	625,589	-	-	-	-	625,589
Balance at September 30, 2023	9,367,907	\$ 93,679	\$ 401,337,485	22	\$ (85,188)	\$ 20,435	\$ (383,294,669)	\$ 18,071,742

	Series A & B Preferred		Common Stock Outstanding		Additional Paid-in Capital	Treasury Stock		Accum. Other Compr. Income (Loss)	Accumulated Deficit	Total
	Shares	Amount	Shares	Amount		Shares	Amount			
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 investment 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

See accompanying notes to the unaudited condensed consolidated financial statements.

IMUNON, INC.

NOTES TO THE CONDENSED CONSOLIDATED
FINANCIAL STATEMENTS
(UNAUDITED)

SEPTEMBER 30, 2023

Note 1. Business Description

On September 19, 2022, Celsion Corporation announced a corporate name change to Imunon, Inc. (“Imunon” or the “Company”) 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 continues to trade on the Nasdaq Stock Market under the ticker symbol “IMNN.”

Imunon 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 is developing its non-viral DNA technology across four modalities. The first modality, TheraPlas[®], is developed for the coding of proteins and cytokines in the treatment of solid tumors where an immunological approach is deemed promising. The second modality, PlaCCine[®], is developed for the coding of viral antigens that can elicit a strong immunological response. This technology may represent a promising platform for the development of vaccines in infectious diseases. The third modality, FixPlas[®], concerns the application of Imunon’s DNA technology to produce universal cancer vaccines, also called tumor associated antigen cancer vaccines. The fourth modality, IndiPlas[®], is in the discovery phase and will focus on the development of personalized cancer vaccines, or neoepitope cancer vaccines.

The Company’s lead clinical program, IMNN-001, is a DNA-based immunotherapy for the localized treatment of advanced ovarian cancer currently in Phase 2 development. IMNN-001 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 IND-enabling preclinical studies for the development of a COVID-19 booster vaccine (IMNN-101) and a treatment for the LASSA virus (IMNN-102). The Company has also initiated preclinical work to develop a Trp2 tumor associated antigen cancer vaccine in melanoma (IMNN-201). Imunon will continue to leverage these modalities 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 accounting principles generally accepted in the United States of America (“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 ended September 30, 2023, 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 nine months ended September 30, 2023 and 2022, 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, 2022, filed with the Securities and Exchange Commission (“SEC”) on March 30, 2023.

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 condensed consolidated 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 unaudited condensed consolidated financial statements and accompanying notes.

The Company has \$19.5 million in cash and cash equivalents, short-term investments, and interest receivable to fund its operations. The Company also has approximately \$1.8 million of future planned sales of the Company’s State of New Jersey net operating losses (\$1.5 million in 2023 and \$0.3 million in 2024). The Company believes it has sufficient capital resources to fund its operations for twelve months from the issuance of these condensed consolidated financial statements.

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 the Company as of the specified effective date. Unless otherwise discussed, the Company believes 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 its operations.

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 was 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 loan was repaid in full during the quarter ended June 30, 2023, thus removing this requirement. The required reserve totaled \$6.0 million as of December 31, 2022. This amount is presented in part as restricted cash in current and other non-current assets on the accompanying condensed consolidated balance sheets.

The following table reconciles cash and cash equivalents and restricted cash per the condensed consolidated balance sheets to the condensed consolidated statements of cash flows:

	<u>September 30, 2023</u>	<u>December 31, 2022</u>
Cash and cash equivalents	\$ 12,884,199	\$ 11,492,841
Money market investments, restricted cash	-	6,000,000
Total	<u>\$ 12,884,199</u>	<u>\$ 17,492,841</u>

Note 5. Net Loss per Common Share

Basic loss per share is calculated based upon the net loss available to common stockholders 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 was 1,147,960 and 1,346,472 shares for the three-month and nine-month periods ended September 30, 2023 and 2022, respectively. For the three-month and nine-month periods ended September 30, 2023 and 2022, diluted loss per common share was the same as basic loss per common share as the other warrants and equity awards that were convertible into shares of the Company’s common stock were excluded from the calculation of diluted loss per common share as their effect would have been anti-dilutive. The Company did not pay any dividends during the three-month and nine-month periods ended September 30, 2023 and 2022.

Note 6. Investment in Debt Securities-Available for Sale

Investments in debt securities available for sale with a fair value of \$6,492,675 and \$21,254,485 as of September 30, 2023 and December 31, 2022, respectively, 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 income (loss).

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

	September 30, 2023		December 31, 2022	
	Cost	Fair Value	Cost	Fair Value
Short-term investments				
U.S. Treasury securities	\$ 2,464,960	\$ 2,498,335	\$ -	\$ -
Corporate debt securities	4,007,280	3,994,340	21,227,991	21,254,485
Total	\$ 6,472,240	\$ 6,492,675	\$ 21,227,991	\$ 21,254,485

	September 30, 2023		December 31, 2022	
	Cost	Fair Value	Cost	Fair Value
Short-term investment maturities				
Within 3 months	\$ 6,472,240	\$ 6,492,675	\$ 4,005,559	\$ 3,994,590
Between 3 and 12 months	-	-	17,222,432	17,259,895
Total	\$ 6,472,240	\$ 6,492,675	\$ 21,227,991	\$ 21,254,485

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, 2023 and December 31, 2022. The Company has reviewed individual securities to determine whether a decline in fair value below the amortizable cost basis is other than temporary.

Available for sale securities (all unrealized holding gains and losses are less than 12 months at date of measurement)	September 30, 2023		December 31, 2022	
	Fair Value	Unrealized Holding Gains (Losses)	Fair Value	Unrealized Holding Gains (Losses)
Investments in debt securities with unrealized gains	\$ 2,498,335	\$ 33,375	\$ 13,278,505	\$ 43,508
Investments in debt securities with unrealized gains (losses)	3,994,340	(12,940)	7,975,980	(17,014)
Total	\$ 6,492,675	\$ 20,435	\$ 21,254,485	\$ 26,494

Investment income, which includes net realized gains (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,	
	2023	2022
Interest and dividends accrued and paid	\$ 264,284	\$ 163,670
Realized gains (losses)	163,170	(10,369)
Investment income, net	\$ 427,454	\$ 153,301

	For the Nine Months Ended September 30,	
	2023	2022
Interest and dividends accrued and paid	\$ 935,284	\$ 240,063
Realized gains (losses)	26,913	(34,303)
Investment income, net	\$ 962,197	\$ 205,760

Note 7. Fair Value Measurements

FASB Accounting Standards Codification 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 and accounts payable 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 are determined by relying on the securities’ relationship to other benchmark quoted securities and classified its investments as Level 2 items in both 2023 and 2022. 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, 2023 or during the year ended December 31, 2022. 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, 2023				
Corporate debt securities and U.S. Treasury obligations, available for sale	\$ 6,492,675	\$ –	\$ –	\$ 6,492,675
Recurring items as of December 31, 2022				
Corporate debt securities, available for sale	\$ 21,254,485	\$ –	\$ –	\$ 21,254,485

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”). The Company acquired EGEN’s rights, title and interest in and to substantially all of the assets of EGEN, including cash and cash equivalents, patents, trademarks and other intellectual property rights, clinical data, certain contracts, licenses and permits, equipment, furniture, office equipment, furnishings, supplies and other tangible personal property. In addition, CLSN Laboratories assumed certain specified liabilities of EGEN, including the liabilities arising out of the acquired contracts and other assets relating to periods after the closing date.

Acquired In-process Research and Development

Acquired in-process research and development (“IPR&D”) consists of EGEN’s drug technology platforms: TheraPlas and TheraSilence. The fair value of the IPR&D drug technology platforms was estimated to be \$24.2 million as of the acquisition date. As of the closing of the acquisition, the IPR&D was considered indefinite lived intangible assets and will not be amortized. IPR&D is reviewed for impairment at least annually and whenever events or changes in circumstances indicate that the carrying value of the assets might not be recoverable. The Company’s IPR&D consisted of three core elements, its RNA delivery system, its glioblastoma multiforme cancer drug candidate and its ovarian cancer indication.

As of December 31, 2022, the Company assessed whether there were indicators of impairment for the Company’s IPR&D and determined that the IPR&D asset was impaired during that period. Due to the continuing deterioration of public capital markets in the biotech industry in 2022 and its impact on market capitalization rates in this sector, IPR&D was reviewed for impairment. Having conducted a quantitative analysis of its IPR&D assets, the Company concluded the IPR&D asset was impaired during the fourth quarter of 2022. As of December 31, 2022, the Company wrote off the \$13.4 million carrying value of this asset, thereby recognizing a non-cash charge of \$13.4 million in the fourth quarter of 2022.

Note 9. Accrued Liabilities

Other accrued liabilities at September 30, 2023 and December 31, 2022 include the following:

	<u>September 30, 2023</u>	<u>December 31, 2022</u>
Amounts due to contract research organizations and other contractual agreements	\$ 1,556,511	\$ 2,196,711
Accrued payroll and related benefits	1,416,024	2,139,927
Accrued interest	-	37,583
Accrued professional fees	26,600	215,402
Other	20,000	205,313
Total	<u>\$ 3,019,135</u>	<u>\$ 4,794,936</u>

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 served 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. 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 are 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 periods ended September 30, 2023 and 2022, the Company incurred interest expense of \$0 and \$82,083, respectively, and amortized \$0 and \$44,942, respectively, as interest expense for debt discounts and end-of-term fee in connection with the SVB Financing Facility. During the nine-month periods ended September 30, 2023 and 2022, the Company incurred interest expense of \$141,958 and \$191,167, respectively, and amortized \$55,122 and \$135,572, respectively, as interest expense for debt discounts and end-of-term fee in connection with the SVB Financing Facility.

On April 21, 2023, the Company repaid the outstanding principal balance, an early termination fee and the end-of-term charges in full satisfaction of the SVB Loan Facility. The following is a schedule of the amounts paid to SVB on April 21, 2023:

Principal balance at April 21, 2023	\$	6,000,000
Early termination fee		120,000
End-of-term charges		300,000
Total	\$	<u>6,420,000</u>

During the nine months ended September 30, 2023, the Company recorded a loss of \$329,158 on the early termination of the SVB Loan Facility which represented the early termination fee and the end of the term fees, net of previously amortized interest expense totaling \$334,212 on the date of its payoff.

Note 11. Stockholders' Equity

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 ticker symbol "IMNN" and its CUSIP number (15117N602) remained unchanged.

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 of the 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. In 2022, the Company sold 336,075 shares of common stock for net proceeds of \$503,798. During the first nine months of 2023, the Company sold 1,878,488 shares of common stock for net proceeds of \$2,750,658.

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 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.

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 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. 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. At the 2023 Annual Stockholders Meeting of the Company held on June 14, 2023, stockholders approved an amendment to the 2018 Plan, as previously amended, whereby the Company increased the number of shares of common stock available by 1,030,000 to a total of 1,970,000 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”).

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 July 19, 2022, September 27, 2022, December 13, 2022, March 17, 2023 and June 26, 2023, 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 177,000 shares, 8,501 shares, 19,000 shares, 5,230 shares and 5,000 shares of common stock, respectively, and (ii) inducement restricted stock awards (the “Inducement Stock Grants”) totaling 63,000 shares, 2,250 shares, 4,000 shares, 1,100 shares and 1,000 shares of common stock, respectively, to eleven employees. Each Inducement Option Grant has an exercise price per share equal to \$1.95, \$1.65, \$1.40, \$1.32, and \$1.28 which represents the closing price of the Company’s common stock as reported by Nasdaq on July 19, 2022, September 27, 2022, December 13, 2022, March 17, 2023, and June 26, 2023, 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, 2023, there were a total of 214,751 shares of the Company’s common stock subject to outstanding inducement awards.

As of September 30, 2023, there were a total of 1,975,073 shares of the Company’s common stock reserved for issuance under the 2018 Plan, which were comprised of 802,363 shares of the Company’s common stock subject to equity awards previously granted under the 2018 Plan and 2007 Plan and 1,172,710 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, 2023 is presented below.

	<u>Stock Options</u>		<u>Restricted Stock Awards</u>		<u>Weighted</u>
	<u>Options Outstanding</u>	<u>Weighted Average Exercise Price</u>	<u>Non-vested Restricted Stock Outstanding</u>	<u>Weighted Average Grant Date Fair Value</u>	<u>Contractual Terms of Equity Awards (in years)</u>
Equity awards outstanding at January 1, 2023	760,220	\$ 4.55	69,650	\$ 1.92	
Equity awards granted	335,000	\$ 1.32	2,100	\$ 1.30	
Equity awards vested and issued	-	-	(53,200)	1.96	
Equity awards terminated	(125,672)	\$ 8.99	(200)	\$ 4.60	
Equity awards outstanding at September 30, 2023	<u>969,548</u>	\$ 2.86	<u>18,350</u>	\$ 1.70	8.9
Aggregate intrinsic value of outstanding equity awards at September 30, 2023	<u>\$ -</u>		<u>\$ -</u>		
Equity awards exercisable at September 30, 2023	<u>400,879</u>	\$ 4.03			8.7
Aggregate intrinsic value of equity awards exercisable at September 30, 2023	<u>\$ -</u>				

Total compensation cost related to stock options and restricted stock awards amounted to approximately \$0.6 million and \$2.0 million for the nine-month periods ended September 30, 2023 and 2022, respectively. Of these amounts, \$0.2 million and \$0.7 million were charged to research and development during the nine-month periods ended September 30, 2023 and 2022, respectively, and \$0.4 million and \$1.3 million were charged to general and administrative expenses during the nine-month periods ended September 30, 2023 and 2022, respectively.

As of September 30, 2023, there was \$0.4 million of total unrecognized compensation cost related to non-vested stock-based compensation arrangements. That cost is expected to be recognized over a period of 3 to 4 years. The weighted average grant date fair values of the stock options granted were \$2.03 and \$4.16 during the nine-month periods ended September 30, 2023 and 2022, 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,	
	2023	2022
Risk-free interest rate	3.72%	1.74 to 4.14%
Expected volatility	107.03 to 113.64%	107.6 to 113.95%
Expected life (in years)	9.0 to 10.0	7.5 to 9.0
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

The total aggregate purchase price for the EGEN Acquisition (see Note 8) included potential future earn-out payments contingent upon achievement of certain milestones. The difference between the aggregate \$30.4 million in future earn-out payments and the \$13.9 million included in the fair value of the acquisition consideration at June 20, 2014 was based on the Company's risk-adjusted assessment of each milestone (10% to 67%) and utilizing a discount rate based on the estimated time to achieve the milestone (1.5 to 2.5 years). The earn-out milestone liability is fair valued at the end of each quarter and any change in their value will be recognized in the condensed consolidated financial statements.

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.

At December 31, 2022, the Company wrote off the carrying value of the earn-out milestone liability as a result of the requirements not being achieved and recognized a non-cash gain of \$5.4 million during 2022 as a result of the change in the fair value of the earn-out milestone liability.

Note 14. Warrants

The following is a summary of all warrant activity for the nine-month period ended September 30, 2023:

Warrants	Number of Warrants Issued	Weighted Average Exercise Price
Warrants outstanding at December 31, 2022	168,519	\$ 19.78
Warrants expired during the nine months ended September 30, 2023	<u>(8,459)</u>	\$ 37.29
Warrants outstanding at September 30, 2023	<u>160,060</u>	\$ 18.86
Aggregate intrinsic value of outstanding warrants at September 30, 2023	<u>\$ -</u>	
Weighted average remaining contractual terms at September 30, 2023	2.4 years	

Note 15. Leases

In August 2023, the Company renewed its Lawrenceville office lease for a 24-month agreement for 9,850 square feet with monthly rent payments of approximately \$22,983 to \$23,394.

In January 2023, the Company renewed its Huntsville facility lease for a 60-month lease agreement for 11,420 square feet with monthly rent payments of approximately \$28,550 to \$30,903.

The following is a table of the lease payments and maturity of the Company's operating lease liabilities as of September 30, 2023:

2023	\$ 154,600
2024	626,323
2025	543,009
2026	362,976
2027	370,236
Thereafter	<u>30,903</u>
Subtotal future lease payments	2,088,047
Less imputed interest	<u>(351,258)</u>
Total lease liabilities	<u>\$ 1,736,789</u>
Weighted average remaining life	3.72
Weighted average discount rate	9.98%

For the three-month and nine-month periods ended September 30, 2023, operating lease expense was \$163,201 and \$487,923, respectively, and cash paid for operating leases included in operating cash flows was \$162,808 and \$489,993, respectively.

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.

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, Imunon consultative support costs and the purchase of any necessary equipment and additional facility costs necessary to support capacity requirements for the manufacture of ThermoDox®. Imunon 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 meet 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 Imunon around the regulatory approval activities for ThermoDox® with the China State Food and Drug Administration.

On January 18, 2013, the Company entered into a technology development contract with Hisun, pursuant to which Hisun paid it a non-refundable research and development fee of \$5 million to support development of ThermoDox® in mainland China, Hong Kong and Macau (the China territory). Following the Company’s announcement on January 31, 2013 that the HEAT study failed to meet its primary endpoint, Imunon 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 HCC 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 was 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. As of December 31, 2022, this contract has been fully amortized and recognized as revenue.

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 Spar Action”). The plaintiff alleged that the Company and Individual Defendants made false and misleading statements regarding one of the Company’s drug 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. 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. On February 6, 2023, the U.S. District Court granted a Motion to Dismiss filed by the Company and Spar Individual Defendants and granted Plaintiff leave to file an amended complaint within 30 days. Plaintiff did not file an amended complaint within the 30-day deadline. In September 2023, the U.S. District Court Issued an Order for Dismissal without prejudice.

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. The U.S. District Court has stayed the action pending an appeal in the Spar Action or until the time to appear has run in the Spar Action without any decision being made.

Note 18. Related Party Transaction

On November 16, 2022, the Company entered into a Convertible Note Purchase Agreement with Transomic Technologies, Inc. (“Transomic”) whereby the Company purchased \$375,000 of convertible notes secured by certain assets held by Transomic and warrants. The Notes, which are included in deposits and other assets, bear interest at 5% per annum, with interest and principal due on December 31, 2026. The Notes are classified as available for sale. The warrants are exercisable upon closing and expire 36 months from the date of issuance or November 22, 2025. As a result of Mr. Tardugno’s appointment to the Board of Transomic, the Company is disclosing the notes receivable as a related party transaction.

Note 19. Subsequent Events

The Company has evaluated its subsequent events from September 30, 2023, through the date these condensed consolidated financial statements were issued.

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, 2022.

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 continues to trade on the Nasdaq Stock Market under the ticker symbol “IMNN.”

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 is developing its non-viral DNA technology across four modalities. The first modality, TheraPlas[®], is developed for the coding of proteins and cytokines in the treatment of solid tumors where an immunological approach is deemed promising. The second modality, PlaCCine[®], is developed for the coding of viral antigens that can elicit a strong immunological response. This technology may represent a promising platform for the development of vaccines in infectious diseases. The third modality, FixPlas[®], concerns the application of our DNA technology to produce universal cancer vaccines, also called tumor associated antigen cancer vaccines. The fourth modality, IndiPlas[®], is in the discovery phase and will focus on the development of personalized cancer vaccines, or neoepitope cancer vaccines.

The Company’s lead clinical program, IMNN-001, is a DNA-based immunotherapy for the localized treatment of advanced ovarian cancer currently in Phase 2 development. IMNN-001 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 IND-enabling preclinical studies for the development of a COVID-19 booster vaccine (IMNN-101) and a treatment for the LASSA virus (IMNN-102). The Company has also initiated preclinical work to develop a Trp2 tumor associated antigen cancer vaccine in melanoma (IMNN-201). We will continue to leverage these modalities and to advance the technological frontier of plasmid DNA to better serve patients with difficult-to-treat conditions.

Technology Platform

Imunon’s technology platform is optimized 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 to the system, a backbone with plasmid DNA or mRNA payload encoding therapeutic proteins, or pathogen antigens or tumor associated antigens or cancer neoantigens 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 by chemically modifying the low molecular weight polymer to improve its gene transfer activity without increasing toxicity. We believe that our non-viral DNA technology 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 biocompatibility of these polymers reduces the risk of adverse immune response, thus allowing for repeated administration. Compared to naked DNA or cationic lipids, our delivery systems are generally safer, more efficient, and cost effective. We believe that these advantages place Imunon in a position to capitalize on this technology platform.

THERAPLAS MODALITY: IMNN-001 DEVELOPMENT PROGRAM

Ovarian Cancer Overview

Ovarian cancer is the most lethal of gynecological malignancies among women with an overall five-year survival rate of 45%. This poor outcome is due in part to the lack of effective prevention and early detection strategies. There were approximately 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 percent and 17 percent, respectively. Firstline chemotherapy regimens are typically platinum-based combination therapies. Although this first line of treatment has an approximate 80 percent response rate, 55 to 75 percent of women will develop recurrent ovarian cancer within two years and ultimately will not respond to platinum therapy. Patients whose cancer recurs or progresses after initially responding to surgery and first-line chemotherapy have been divided into one of the two groups based on the time from completion of platinum therapy to disease recurrence or progression. This time period is referred to as platinum-free interval. The platinum-sensitive group has a platinum-free interval of longer than six months. This group generally responds to additional treatment with platinum-based therapies. The platinum-resistant group has a platinum-free interval of shorter than six months and is resistant to additional platinum-based treatments. Pegylated liposomal doxorubicin, topotecan, and Avastin are the only approved second-line therapies for platinum-resistant ovarian cancer. The overall response rate for these therapies is 10 to 20 percent with median overall survival (“OS”) of eleven to twelve months. Additionally, 10% to 15% of ovarian cancer cases nationwide are a result of germline or somatic BRCA mutations. With cognizance of tumor genetics, practice has shifted to include targeted agents in ovarian cancer treatment.

PARP enzymes are responsible for detecting and repairing single-stranded and double-stranded DNA breaks during cell replication. BRCA1/2 mutations hinder the homologous recombination repair pathway, and tumor cells utilize PARP enzymes to repair DNA. For this reason, these tumors are particularly sensitive to the mechanism of PARP inhibitors. PARP inhibitors have expanded treatment options in ovarian cancer, but few treatment options are left for women who are not eligible to receive PARP inhibitors.

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.

IMNN-001 Immunotherapy

IMNN-001 is a DNA-based immunotherapeutic drug 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 IL12 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 IMNN-001 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 IMNN-001 in combination with the standard of care in neoadjuvant ovarian cancer (the “OVATION I Study”). On September 30, 2015, we announced enrollment of the first patient in the OVATION I Study. The OVATION I Study was designed to:

- (i) identify a safe, tolerable, and therapeutically active dose of IMNN-001 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 IMNN-001, 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 IMNN-001 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 immune-suppressive cytokines associated with tumor suppression and growth, respectively; and
- Expression profile of a comprehensive panel of immune related genes in pre-treatment and IMNN-001-treated tumor tissue.

We initiated the OVATION I Study at four clinical sites at the University of Alabama at Birmingham, Oklahoma University Medical Center, Washington University in St. Louis, and the Medical College of Wisconsin. During 2016 and 2017, we announced data from the first fourteen patients in the OVATION I Study. On October 3, 2017, we announced final translational research and clinical data from the OVATION I Study.

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

- The intraperitoneal treatment of IMNN-001 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 IMNN-001. An increase in CD8+ to immunosuppressive T-cell populations is a leading indicator and believed to be a good predictor of improved OS; and
- Analysis of peritoneal fluid by cell sorting, not reported before, shows a treatment-related decrease in the percentage of immunosuppressive T-cell (Foxp3+), which is consistent with the reduction of Foxp3+ T-cells in the primary tumor tissue, and a shift in tumor naïve CD8+ cell population to more efficient tumor killing memory effector CD8+ cells.

The Company also reported encouraging clinical data from the first fourteen patients who completed treatment in the OVATION I Study. IMNN-001 plus standard chemotherapy produced no dose limiting toxicities and positive dose dependent efficacy signals which correlate well with positive surgical outcomes as summarized below:

- Of the fourteen patients treated in the entire study, two patients demonstrated a complete response, ten patients demonstrated a partial response and two patients demonstrated stable disease, as measured by RECIST criteria. This translates to a 100% disease control rate and an 86% objective response rate (“ORR”). Of the five patients treated in the highest dose cohort, there was a 100% ORR with one complete response and four partial responses;
- Fourteen patients had successful resections of their tumors, with nine patients (64%) having a complete tumor resection (“R0”), which indicates a microscopically margin-negative resection in which no gross or microscopic tumor remains in the tumor bed. Seven out of eight (88%) patients in the highest two dose cohorts experienced a R0 surgical resection. All five patients treated at the highest dose cohort experienced a R0 surgical resection; and
- All patients experienced a clinically significant decrease in their CA-125 protein levels as of their most recent study visit. CA-125 is used to monitor certain cancers during and after treatment. CA-125 is present in greater concentrations in ovarian cancer cells than in other cells.

On March 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 IMNN-001 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 IMNN-001’s independent impact on impressive tumor response, surgical results and PFS. The FDA encouraged the Company to continue its IMNN-001 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 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 IMNN001 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 IMNN-001 based on promising tumor response, as reported in the PFS data, and the ability for surgeons to completely remove visible tumors at interval debulking surgery. IMNN-001 was well tolerated, and no dose-limiting toxicities were detected. Intraperitoneal administration of IMNN-001 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 IMNN-001 immunotherapy program. On November 13, 2017, the Company filed its Phase I/II clinical trial protocol with the FDA for IMNN-001 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 IMNN-001 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 IMNN-001 treatment arm will receive IMNN-001 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 IMNN-001 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 IMNN-001, 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.

IMNN-001 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 fifteen patients treated in the Phase I portion of the OVATION 2 Study, nine patients were treated with IMNN-001 at a dose of 100 mg/m² plus NACT and six patients were treated with NACT only. All fifteen patients had successful resections of their tumors, with eight out of nine patients (88%) in the IMNN-001 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 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 IMNN-001 to the current standard of care NACT:

		% of Patients R0 Resections
0, 36, 47 mg/m ² of IMNN-001 plus NACT	N = 12	42%
61, 79, 100 mg/m ² of IMNN-001 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 IMNN-001 patients were comparable, as expected, to the higher (61, 79, 100 mg/m²) dose IMNN-001 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 IMNN-001 be designated as an orphan medicinal product for the treatment of ovarian cancer. IMNN-001 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. IMNN-001 previously received orphan designation from the FDA.

In February 2021, the Company announced that it has received Fast Track designation from the FDA for IMNN-001, 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 IMNN-001 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 IMNN-001 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/m². The DSMB also determined that safety is satisfactory with an acceptable risk/benefit, and that patients tolerate IMNN-001 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 IMNN-001 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 IMNN-001 in advanced ovarian cancer has completed enrollment with 110 patients.

In April 2023, the Company presented a poster at the American Association for Cancer Research Annual Meeting Demonstrating Preclinical Immune Response of IMNN-001. The findings from a mouse model of peritoneally disseminated ovarian cancer suggest biweekly dosing regimen for further evaluation in human clinical studies. This research in mice will underpin the dosing frequency being investigated in our upcoming Phase 1/2 combination study with IMNN-001 and bevacizumab following neoadjuvant chemotherapy in advanced ovarian cancer.

In September 2023, the Company announced interim progression-free survival (PFS) and overall survival (OS) data with IMNN-001 in its Phase 1/2 OVATION 2 Study. Interim clinical data from the intent-to-treat (ITT) population showed efficacy trends in PFS, demonstrating a delay in disease progression in the treatment arm of approximately 33% compared with the control arm, with the hazard ratio nearing the required value. Preliminary OS data follows a similar trend, showing an approximate 9-month improvement in the treatment arm over the control arm.

Subgroup analyses show patients treated with a PARP inhibitor (PARPi) as maintenance therapy had longer PFS and OS if they were also treated with IMNN-001 compared with patients treated with NACT only. This was not a pre-specified subgroup as PARP inhibitors were approved after the OVATION 2 Study was initiated.

- The median PFS in the PARPi + NACT group and the PARPi + NACT + IMNN-001 group was 15.7 months and 23.7 months, respectively.
- The median OS in the PARPi + NACT group was 45.6 months and has not yet been reached in the PARPi + NACT + IMNN-001 group.

While the data is still preliminary, the Company believes that patients treated with a combination of NACT + PARPi + IMNN-001 appear to have the greatest benefit and should be the focus of on-going follow-up.

Imunon also continues to see benefits in other secondary endpoints including an approximately 20% higher R0 tumor resection score and a doubling of the CRS 3 chemotherapy response score to approximately 30% in the treatment arm versus 14% in 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. Chemotherapy response score is considered a good prognostic indicator in ovarian cancer. The DSMB determined that safety analyses continue to show good tolerability of IMNN-001 in this setting. Topline results from the OVATION 2 Study are expected in mid-2024.

IMNN-001 in Combination with bevacizumab. In February 2023, the Company and Break *Through* Cancer, a public foundation dedicated to supporting translational research in the most difficult-to-treat cancers that partners with top cancer research centers, announced the commencement of patient enrollment in a collaboration to evaluate IMNN-001 in combination with Avastin® (bevacizumab) in patients with advanced ovarian cancer in the frontline, neoadjuvant clinical setting.

This Phase 1/2 study, titled “Targeting Ovarian Cancer Minimal Residual Disease (MRD) Using Immune and DNA Repair Directed Therapies,” is expected to enroll 50 patients with Stage III/IV advanced ovarian cancer and is being led by principal investigator Amir Jazaeri, M.D., Vice Chair for Clinical Research and Director of the Gynecologic Cancer Immunotherapy Program in the Department of Gynecologic Oncology and Reproductive Medicine at MD Anderson. Dana-Farber Cancer Institute, The Sidney Kimmel Comprehensive Cancer Center at Johns Hopkins and Memorial Sloan Kettering Cancer Center will also be participating in the trial. In addition, The Koch Institute for Integrative Cancer Research at the Massachusetts Institute of Technology (MIT) will provide artificial intelligence services including biomarker and genomic analysis.

Patients will be randomized 1:1 in a two-arm trial. In October 2023, the first patient began treatment at University of Texas MD Anderson Cancer Center in the Phase 1/2 Clinical Trial Evaluating IMNN-001 in Combination with Bevacizumab in Advanced Ovarian Cancer. The trial’s primary endpoint is detection of minimal residual disease (MRD) by second look laparoscopy (SLL), and the secondary endpoint is PFS. Initial SLL data are expected within one year following the completion of enrollment and final PFS data are expected approximately three years following the completion of enrollment. This trial will also include a wealth of translational endpoints aimed at understanding the clonal evolution and immunogenomic features of the MRD phase of ovarian cancer that is currently undetectable by imaging or tumor markers.

PLACCINE DNA VACCINE MODALITY: IMNN-101

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.

Imunon’s PLACCINE DNA vaccine technology modality is characterized by a single mono-cistronic or multi-cistronic DNA plasmid vector expressing single or 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.

The need for new vaccine technologies is urgent. Since 1980 more than 80 pathogenic viruses have been discovered, yet fewer than 4% have a commercially available prophylactic vaccine. We have engaged with the Biomedical Advanced Research and Development Authority (BARDA), a division of the U.S. Department of Health and Human Services, to pursue certain pathogens BARDA has identified as the most urgent and the most important.

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 IMNN-001. Imunon’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. Imunon’s extensive experience with TheraPlas suggests that the PLACCINE-based nanoparticles are stable at storage temperatures of 4oC to 25oC, making vaccines developed on this platform easily suitable for broad world-wide distribution.

Imunon’s vaccine approach is designed to optimize the quality of the immune response dictating the efficiency of pathogen clearance and patient recovery. Imunon 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 Imunon’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 SARSCoV-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. Most 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

Imunon'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 Imunon 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 Imunon'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°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 nonhuman primate (NHP) challenge study with Imunon'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, Imunon 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. Imunon's 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.

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.

In March 2023, the Company announced final results from the non-human primate study involving three vaccine-treated non-human primates. The final data are consistent with the earlier data and show excellent immunological response and viral clearance. More specifically, in this NHP study, we examined PLACCINE activity against a more advanced SARS-CoV-2 variants and at a DNA dose that was not previously tested in NHP and demonstrated robust IgG responses, neutralizing antibody responses and complete clearance of virus following the challenge as seen in the previous study.

In a recent mouse study, a single dose of PLACCINE vaccine without a booster dose produced longer duration of IgG responses and higher T-cell activation than an mRNA vaccine. A 12-month PLACCINE stability study has now completed 9 months demonstrating continued drug stability at 4° C (standard refrigerated temperature).

In March 2023, these compelling data were presented at the Vaccine Technology Summit 2023 in Boston. All the generated data to date were presented. They showed: robust immunogenicity and protection in SARS-CoV-2 models, durable cellular or humoral responses detectable for more than 12 months, comparable protection activity to a commercial mRNA vaccine in a booster-dose comparison and superior immune quality versus the mRNA vaccine in a single-dose comparison.

In March 2023, the Company filed with the U.S. Food and Drug Administration (FDA) a pre-IND package in advance of beginning human testing of a SARS-CoV-2 seasonal booster vaccine. In July 2023, the FDA confirmed in a written response our plug and play strategy agreeing that a platform approach to pre-clinical toxicology testing with reference to updated SARS-CoV-2 genes that align with current variant of concern may be used without additional need for toxicology studies. This confirms the flexibility and versatility of our platform which allows for the rapid production and development of any vaccine by simply changing the antigen coding cassette.

The Company is on track to submit an Investigational New Drug (IND) application in the first quarter of 2024 for a Phase 1/2 trial with IMNN-101, a seasonal COVID-19 booster vaccine, following positive feedback from the FDA. Development of our PlaCCine modality reached important milestones with confirmation of its value across pathogens of interest by demonstrating the immunogenicity and safety of our vaccines in animals. The Company has generated compelling data in SARS-CoV-2 and with IMNN-101, a next-generation COVID-19 seasonal booster, and expects to begin patient enrollment in a Phase 1/2 trial in the second quarter of 2024.

During the third quarter, the Company chose the LASSA virus as the next pathogen target for its PLACCINE modality. In August 2023, the Company announced it has entered into a Cooperative Research and Development Agreement (CRADA) with the National Institute of Allergy and Infectious Diseases (NIAID) to evaluate the immunogenicity and efficacy of two Imunon DNA-based Lassa virus vaccine candidates. Under the three-year agreement, the NIAID will assess the efficacy of PlaCCine DNA constructs against Lassa virus in guinea pig and non-human primate disease models, including both prime and prime-boost vaccine strategies.

Lassa virus is typically spread by rodents and can cause Lassa fever, a viral hemorrhagic-fever disease that is a significant and growing public health concern with approximately 5,000 deaths annually. Nearly 60 million people throughout West Africa are estimated to be at risk of contracting Lassa fever. Several unusually large outbreaks have occurred over the past few years with fatality rates of up to 30%. Because of its lethality and increasing incidence, NIAID and the World Health Organization have categorized Lassa virus as a Category A Priority Pathogen. There is currently no vaccine or therapeutic for Lassa virus.

This collaboration with the Laboratory of Virology at NIAID to research a potential solution for combatting this life-threatening pathogen will evaluate the hypothesis that a DNA-based vaccine may be an excellent modality for a Lassa virus vaccine. With its durable antigen expression, longer shelf-life at workable, standard refrigerated temperatures and flexible manufacturing, the Company believes that PlaCCine is a potentially superior alternative that can address the limitations of current commercial products particularly in developing countries around the world.

This CRADA is an example of one of the Company's growth strategy pillars, namely, to help defray development costs through non-dilutive sources of capital. Incremental investments to generate novel vaccine designs with optimized antigens will allow Imunon to quickly generate early pre-clinical and clinical data against additional pathogen targets that position the Company to partner with large vaccine companies who Imunon expects may fund remaining clinical development.

The Company is eager to advance the FixPlas and IndiPlas modalities into universal and personalized cancer vaccines and have begun preclinical work in melanoma. The Company's consultants will provide invaluable assistance as we advance along the development pathway and into clinical testing. The FixPlas concerns the application of our DNA technology to produce universal cancer vaccines also called tumor associated antigen cancer vaccines. The IndiPlas modality is in the discovery phase and will focus on the development of personalized cancer vaccines or neoepitope cancer vaccines.

THERMODOX® - DIRECTED CHEMOTHERAPY

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 to evaluate ThermoDox® in combination with standardized RFA, which required 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 called 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 had 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 prespecified 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 provided 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 and 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 announced 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 has been 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.

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 drug 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, 2023, the Company has incurred approximately \$383 million of cumulative net losses and had approximately \$19.5 million in cash and cash equivalents, short-term investments, and interest receivable. We have substantial future capital requirements to continue our research and development activities and advance our drug 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 drug 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 March 2020, the World Health Organization declared COVID-19, to be a Global pandemic and recommended containment and mitigation measures worldwide. The Company's operations have not been materially affected by the COVID-19 outbreak, if not for delayed inclusions of patients in the OVATION 2 studies. The recruitment of the trial was fully completed in September 2022. The global COVID-19 pandemic continues to evolve. As a result of the COVID-19 pandemic, we have faced and may continue to face delays in meeting our anticipated timelines for our ongoing and planned clinical trials.

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 COVID-19 pandemic, the Russian invasion of Ukraine and the unrest in the Middle East. The Company continues to monitor its operating activities in light of these events, and it is possible that these events could result in a variety of risks to the business. 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 drug 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 ("NOLs") as part of the Technology Business Tax Certificate Program (the "NOL Program") sponsored by The New Jersey Economic Development Authority. Under the program, emerging biotechnology companies with unused NOLs and unused research and development credits are allowed to sell these benefits to other New Jersey-based companies. As part of the NOL Program, the Company sold \$1.6 million of its New Jersey NOLs in 2022. The sale of these net operating losses resulted in net proceeds to the Company of approximately \$1.6 million in January 2023. 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 \$1.8 million in net operating losses under this maximum lifetime benefit.

With \$19.5 million in cash and cash equivalents, short-term investments, and interest receivable, coupled with approximately \$1.8 million of future planned sales of the Company's State of New Jersey net operating losses (\$1.5 million in 2023 and \$0.3 million in 2024), the Company believes it has sufficient capital resources to fund its operations for twelve months from the issuance of these financial statements.

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

During 2022 and 2023 through the date of this Quarterly Report filed on Form 10-Q, we issued a total of 3.5 million shares of common stock as discussed below for approximately \$9.5 million in net proceeds.

- 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 by a ratio to be determined by the Board of Directors of the Company (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 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. The Company sold 1,328,274 shares for net proceeds of \$6.2 million

- 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. In 2022, the Company sold 336,075 shares of common stock for net proceeds of \$0.5 million. During the first nine months of 2023, the Company sold 1,878,488 shares of common stock for net proceeds of \$2.8 million.

Significant Accounting Policies

Our significant accounting policies are more fully described in Note 1 to our consolidated financial statements included in our 2022 Annual Report on Form 10-K for the year ended December 31, 2022 filed with the SEC on March 30, 2023. 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, 2023 AND 2022

Results of Operations

For the three months ended September 30, 2023 our net loss was \$3.5 million compared to a net loss of \$6.1 million for the same three-month period of 2022.

With \$19.5 million in cash and cash equivalents, short-term investments, and interest receivable, coupled with approximately \$1.8 million of future planned sales of the Company’s State of New Jersey net operating losses (\$1.5 million in 2023 and \$0.3 million in 2024), the Company believes it has sufficient capital resources to fund its operations for twelve months from the issuance of the financial statements included in this Quarterly Report on Form 10-Q.

	For the Three Months Ended September 30,			
	(In thousands)		Change Increase (Decrease)	
	2023	2022		
Licensing Revenue:	\$ -	\$ 125	\$ (125)	(100.0)%
Operating Expenses:				
Clinical Research				
OVATION	115	412	(297)	(72.1)%
OPTIMA	-	152	(152)	(100.0)%
Other Clinical and regulatory	342	417	(75)	(18.0)%
Subtotal	457	981	(524)	(53.4)%
Non-Clinical R&D and CMC				
OVATION	265	684	(419)	(61.3)%
PlaCCine Vaccine	797	457	339	74.2%
Manufacturing (CMC)	462	287	175	61.0%
Subtotal	1,524	1,428	95	6.7%
Research and development expenses	1,981	2,409	(429)	(17.8)%
General and administrative expenses	1,923	3,891	(1,968)	(50.6)%
Total operating expenses	3,904	6,300	(2,397)	(38.0)%
Loss from operations	\$ (3,904)	\$ (6,175)	\$ (2,272)	(36.8)%

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 the three months ended September 30, 2022. As of December 31, 2022, this contract has been fully amortized and recognized as revenue.

Research and Development Expenses

Research and development (“R&D”) expenses were \$2.0 million in the third quarter of 2023 compared to \$2.4 million in same period of 2022. Costs associated with the OVATION Study were \$0.1 million in the third quarter of 2023 compared to \$0.4 million in the same period of 2022. Costs associated with the OPTIMA Study were insignificant in the third quarter of 2023 compared to \$0.2 million in the same period of 2022. Other clinical and regulatory costs were \$0.3 million in the third quarter of 2023 compared to \$0.4 million in the same period of 2022. R&D costs associated with the development of IMNN-001 to support the OVATION 2 Study were \$0.3 million in the third quarter 2023, a decrease from \$0.7 million in same period of 2022. The development of the PLACCINE DNA vaccine technology platform increased to \$0.8 million in the third quarter of 2023 compared to \$0.5 million in the same period of 2022. CMC costs increased to \$0.5 million in the third quarter of 2023 compared to \$0.3 million in the same period of 2022.

General and Administrative Expenses

General and administrative expenses were \$1.9 million in the third quarter of 2023 compared to \$3.9 million in the same period of 2022. The \$2.0 million decrease is due to lower non-cash stock compensation expenses of \$0.3 million, employee related costs of \$1.0 million, legal expenses of \$0.6 million, and insurance costs of \$0.1 million.

Other non-operating expense was \$0.4 million in the third quarter of 2023 compared to other non-operating expense of \$26,276 in the comparable prior year period. The Company incurred debt extinguishment expense on its loan facility with Silicon Valley Bank in the second quarter of 2023 of \$0.3 million. Investment income from the Company’s short-term investments increased by \$0.4 million for the third quarter of 2023 compared with the prior year period in 2022 due to higher returns on these investments.

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. As of December 31, 2022, the Company wrote off the \$13.4 million carrying value of this asset, thereby recognizing a non-cash charge of \$13.4 million in the fourth quarter of 2022. The Company fair value of the IPR&D is zero at September 30, 2023.

Change in Earn-out Milestone Liability

As of September 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. At December 31, 2022, the Company wrote off the earn-out milestone liability as a result of the requirements not being achieved.

FINANCIAL REVIEW FOR THE NINE MONTHS ENDED SEPTEMBER 30, 2023 AND 2022

Results of Operations

For the nine months ended September 30, 2023, our net loss was \$14.6 million compared to a net loss of \$22.7 million for the same nine-month period of 2022.

With \$19.5 million in cash and cash equivalents, short-term investments, and interest receivable, coupled with approximately \$1.8 million of future planned sales of the Company's State of New Jersey net operating losses (\$1.5 million in 2023 and \$0.3 million in 2024), the Company believes it has sufficient capital resources to fund its operations for twelve months from the issuance of the financial statements included in this Quarterly Report on Form 10-Q.

	For the Nine Months Ended September 30,			
	(In thousands)		Change Increase (Decrease)	
	2023	2022		
Licensing Revenue:	\$ -	\$ 375	\$ (375)	(100.0)%
Operating Expenses:				
Clinical Research				
OVATION	707	1,195	(488)	(40.8)%
OPTIMA	-	950	(950)	(100.0)%
Other Clinical and regulatory	1,088	1,662	(574)	(34.5)%
Subtotal	1,795	3,807	(2,012)	(52.9)%
Non-Clinical R&D and CMC				
OVATION	1,026	2,444	(1,418)	(58.0)%
PlaCCine Vaccine	3,077	1,629	1,448	88.9%
Manufacturing (CMC)	1,836	850	986	116.1%
Subtotal	5,939	4,923	1,016	20.6%
Research and development expenses	7,734	8,730	(996)	(11.4)%
General and administrative expenses	7,328	9,640	(2,312)	(24.0)%
Total operating expenses	15,062	18,370	(3,308)	(18.0)%
Loss from operations	\$ (15,062)	\$ (17,995)	\$ (2,933)	(16.3)%

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 nine months ended September 30, 2022. As of December 31, 2022, this contract has been fully amortized and recognized as revenue.

Research and Development Expenses

Research and development ("R&D") expenses were \$7.7 million in the first nine months of 2023 compared to \$8.7 million in same period of 2022. Costs associated with the OVATION 2 Study were \$0.7 million in the first nine months of 2023 compared to \$1.2 million in the same period of 2022. Costs associated with the OPTIMA Study were insignificant in the first nine months of 2023 compared to \$1.0 million in the same period of 2022. Other clinical and regulatory costs were \$1.1 million in the first nine months of 2023 compared to \$1.7 million in the same period of 2022. R&D costs associated with the development of IMNN-001 to support the OVATION 2 Study were \$1.0 million in the first nine months of 2023, a decrease from \$2.4 million in same period of 2022. The development of the PLACCINE DNA vaccine technology platform increased to \$3.1 million in the first nine months of 2023 compared to \$1.6 million in the same period of 2022. CMC costs increased to \$1.8 million in the first nine months of 2023 compared to \$0.9 million in the same period of 2022.

General and Administrative Expenses

General and administrative expenses were \$7.3 million in the first nine months of 2023 compared to \$9.6 million in the same period of 2022. The \$2.3 million decrease was primarily attributable to lower non-cash stock compensation expenses of \$0.8 million, employee related costs of \$0.6 million, legal expenses of \$0.6 million, insurance costs of \$0.4 million, public company expenses of \$0.2 million offset by higher consulting fees of \$0.2 million and salary expense of \$0.1 million.

Other non-operating income was \$0.4 million in the first nine months of 2023 compared to other non-operating expenses of \$4.7 million in the comparable prior year period. In the first quarter of 2022, the Company incurred a one-time payment of \$4.5 million in interest and offering expenses resulting from the sale and subsequent redemption of \$30.0 million of convertible redeemable preferred stock. The Company incurred higher interest expense on its loan facility with Silicon Valley Bank in the first quarter of 2023 due to raising interest rates. Investment income from the Company's short-term investments increased by \$0.8 million for the first nine months of 2023 compared with the prior year period in 2022 due to higher returns on these investments.

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. As of December 31, 2022, the Company wrote off the \$13.4 million carrying value of this asset, thereby recognizing a non-cash charge of \$13.4 million in the fourth quarter of 2022. The company fair value of the IPR&D is zero at September 30, 2023.

Change in Earn-out Milestone Liability

As of September 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 first nine months of 2022. At December 31, 2022, the Company wrote off the earn-out milestone liability as a result of the requirements not being achieved.

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, the sale of the Company's NOLs, amounts received under our product licensing agreement with Yakult and our technology development agreement with Hisun. The process of developing IMNN-001 and other drug 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 \$383 million at September 30, 2023.

At September 30, 2023, we had total current assets of \$21.7 million and current liabilities of \$5.3 million, resulting in net working capital of \$16.4 million. At September 30, 2023, we had cash and cash equivalents, short-term investments, interest receivable on short-term investments, net proceeds on the sale of net operating losses and money market investments of \$19.5 million. At December 31, 2022, we had total current assets of \$36.8 million and current liabilities of \$10.0 million, resulting in net working capital of \$26.8 million. We have substantial future capital requirements to continue our research and development activities and advance our drug 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 2023 was \$15.2 million. Net cash provided by investing activities was \$14.3 million during the first nine months of 2023. Cash used by financing activities during the first nine months of 2023 totaled \$3.7 million due to the early repayment of the SVB loan (see Note 10). At September 30, 2023, we had cash and cash equivalents, short-term investments, interest receivable on short term investments, net proceeds on the sale of net operating losses and money market investments of \$19.5 million. The Company believes it has sufficient capital resources to fund its operations for twelve months from the issuance of the financial statements included in this Quarterly Report on Form 10-Q. See Financing Overview.

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

Not required for smaller reporting companies.

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, 2023, 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 errors 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. 1:20-cv-15228 (the “Spar Action”). The plaintiff alleged that the Company and Individual Defendants made false and misleading statements regarding one of the Company’s drug 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. 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. On February 6, 2023, the U.S. District Court granted a Motion to Dismiss filed by the Company and Spar Individual Defendants and granted Plaintiff leave to file an amended complaint within 30 days. Plaintiff did not file an amended complaint within the 30-day deadline. In September 2023, the U.S. District Court issued an Order for Dismissal without prejudice.

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.

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 2022 Annual Report on Form 10-K. The risks and uncertainties described in our 2022 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, Use of Proceeds and Issuer Purchases of Equity Securities.

None.

Item 3. Defaults Upon Senior Securities.

None.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

None.

Item 6. Exhibits.

- 31.1+ [Certification of Chief Executive Officer pursuant to Rule 13a-14\(a\)/15d-14\(a\), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.](#)
- 31.2+ [Certification of Chief Financial Officer pursuant to Rule 13a-14\(a\)/15d-14\(a\), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.](#)
- 32.1* [Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.](#)
- 101** The following materials from the Company’s Quarterly Report on Form 10-Q for the quarter ended September 30, 2023 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, 2023

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

**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, 2023

By: /s/ Corinne Le Goff

Corinne Le Goff

President and Chief Executive Officer

**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, 2023

By: /s/ Jeffrey W. Church

Jeffrey W. Church

Executive Vice President and Chief Financial Officer

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, 2023 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, 2023

By: /s/ Corinne Le Goff

Corinne Le Goff
President and Chief Executive Officer

November 14, 2023

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.
