

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-Q

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

For the Quarterly Period Ended September 30, 2024

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: 001-40739

DERMATA THERAPEUTICS, INC.

(Exact name of registrant as specified in the charter)

Delaware

(State or other jurisdiction of
incorporation or organization)

86-3218736

(I.R.S. Employer
Identification Number)

3525 Del Mar Heights Rd., #322, San Diego, CA

(Address of principal executive offices)

92130

(Zip Code)

Registrant's telephone number, including area code: 858-800-2543

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

<u>Title of each class</u>	<u>Trading Symbol(s)</u>	<u>Name of each exchange on which registered</u>
Common Stock, par value \$0.0001 per share	DRMA	The Nasdaq Capital Market
Warrants, exercisable for one share of Common Stock	DRMAW	The 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.

Large accelerated filer

Accelerated filer

Non-accelerated Filer

Smaller reporting company

Emerging growth company

If an emerging growth company, indicate by check mark if registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards 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.

There were 2,040,768 shares of Common Stock, par value \$0.0001, of Dermata Therapeutics, Inc. issued and outstanding as of November 12, 2024.

DERMATA THERAPEUTICS, INC.
Form 10-Q
Table of Contents

INDEX

	<u>Page No.</u>
<u>Part I</u> <u>Financial Information</u>	
<u>Item 1:</u> <u>Financial Statements (unaudited)</u>	3
<u>Balance Sheets</u>	3
<u>Statements of Operations</u>	4
<u>Statements of Stockholders' Equity</u>	5
<u>Statements of Cash Flows</u>	7
<u>Notes to Financial Statements</u>	8
<u>Item 2:</u> <u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	20
<u>Item 3:</u> <u>Quantitative and Qualitative Disclosures about Market Risk</u>	29
<u>Item 4:</u> <u>Controls and Procedures</u>	29
<u>Part II</u> <u>Other Information</u>	
<u>Item 1:</u> <u>Legal Proceedings</u>	30
<u>Item 1A:</u> <u>Risk Factors</u>	30
<u>Item 2:</u> <u>Unregistered Sales of Equity Securities and Use of Proceeds</u>	30
<u>Item 3:</u> <u>Defaults Upon Senior Securities</u>	30
<u>Item 4:</u> <u>Mine Safety Disclosures</u>	30
<u>Item 5:</u> <u>Other Information</u>	30
<u>Item 6:</u> <u>Exhibits</u>	31
<u>Signatures</u>	32

PART I**ITEM 1: FINANCIAL STATEMENTS****DERMATA THERAPEUTICS, INC.
Balance Sheets**

	September 30, 2024	December 31, 2023
	(unaudited)	
Assets:		
Cash and cash equivalents	\$ 6,143,752	\$ 7,438,135
Prepaid expenses and other current assets	543,592	540,499
Total assets	<u>\$ 6,687,344</u>	<u>\$ 7,978,634</u>
Liabilities and Stockholders' Equity:		
Liabilities:		
Accounts payable	\$ 863,595	\$ 866,028
Accrued and other current liabilities	1,082,521	757,588
Total liabilities	1,946,116	1,623,616
Commitments and Contingencies (see Note 6)		
Stockholders' Equity:		
Common Stock, par value \$0.0001 per share, 250,000,000 shares authorized; 1,677,768 shares issued and outstanding as of September 30, 2024; 261,998 shares issued and outstanding as of December 31, 2023.	168	26
Additional paid-in capital	67,265,462	59,742,870
Accumulated deficit	(62,524,402)	(53,387,878)
Total stockholders' equity	4,741,228	6,355,018
Total liabilities and stockholders' equity	<u>\$ 6,687,344</u>	<u>\$ 7,978,634</u>

The accompanying notes are an integral part of these financial statements.

DERMATA THERAPEUTICS, INC.
Statements of Operations
(unaudited)

	For the three months ended		For the nine months ended	
	September 30,		September 30,	
	2024	2023	2024	2023
Operating expenses:				
Research and development	\$ 2,401,359	\$ 902,977	\$ 6,011,201	\$ 2,934,541
General and administrative	824,294	909,001	3,301,753	2,887,533
Total operating expenses	<u>3,225,653</u>	<u>1,811,978</u>	<u>9,312,954</u>	<u>5,822,074</u>
Loss from operations	<u>(3,225,653)</u>	<u>(1,811,978)</u>	<u>(9,312,954)</u>	<u>(5,822,074)</u>
Other income and expenses:				
Interest income, net	52,497	92,767	176,431	161,357
Net loss	<u>\$ (3,173,156)</u>	<u>\$ (1,719,211)</u>	<u>\$ (9,136,523)</u>	<u>\$ (5,660,717)</u>
Net loss per share of Common Stock, basic and diluted	<u>\$ (2.04)</u>	<u>\$ (8.09)</u>	<u>\$ (10.22)</u>	<u>\$ (36.91)</u>
Weighted-average basic and diluted Common Stock	1,554,680	212,544	894,168	153,380

The accompanying notes are an integral part of these financial statements.

DERMATA THERAPEUTICS, INC.
Statements of Stockholder's Equity
(unaudited)

	<u>Common Stock</u>		<u>Additional Paid-in Capital</u>	<u>Accumulated Deficit</u>	<u>Total Stockholders' Equity</u>
	<u>Shares</u>	<u>Par Value</u>			
Balance at December 31, 2023	261,998	\$ 26	\$ 59,742,870	\$ (53,387,878)	\$ 6,355,018
Stock-based compensation	-	-	587,234	-	587,234
Issuance of abeyance shares	182,000	18	(18)	-	-
Net loss	-	-	-	(3,134,262)	(3,134,262)
Balance at March 31, 2024	443,998	\$ 44	\$ 60,330,086	\$ (56,522,140)	\$ 3,807,990
Issuance of Common Stock upon exercise of warrants, net of issuance costs	249,336	25	2,320,438	-	2,320,463
Stock-based compensation	-	-	19,608	-	19,608
Settlement of fractional shares paid in cash	(159)	-	(828)	-	(828)
Net loss	-	-	-	(2,829,106)	(2,829,106)
Balance at June 30, 2024	693,175	\$ 69	\$ 62,669,304	\$ (59,351,246)	\$ 3,318,127
Issuance of pre-funded warrants and warrants, net of issuance costs	-	-	3,093,038	-	3,093,038
Issuance of Common Stock upon exercise of pre-funded warrants	167,569	17	151	-	168
Issuance of Common Stock from ATM sales, net of issuance costs	550,024	55	1,482,004	-	1,482,059
Issuance of abeyance shares	267,000	27	(27)	-	-
Stock-based compensation	-	-	20,992	-	20,992
Net loss	-	-	-	(3,173,156)	(3,173,156)
Balance at September 30, 2024	1,677,768	\$ 168	\$ 67,265,462	\$ (62,524,402)	\$ 4,741,228

The accompanying notes are an integral part of these financial statements.

DERMATA THERAPEUTICS, INC.
Statements of Stockholder's Equity
(unaudited)

	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Par Value			
Balance at December 31, 2022	51,338	\$ 5	\$ 51,615,037	\$ (45,593,188)	\$ 6,021,854
Stock-based compensation	-	-	131,260	-	131,260
Issuance of Common Stock and warrants, net of issuance costs	5,666	1	4,174,984	-	4,174,985
Issuance of Common Stock upon exercise of pre-funded warrants	102,208	10	143	-	153
Settlement of fractional shares paid in cash	(59)	-	(40)	-	(40)
Net loss	-	-	-	(2,240,142)	(2,240,142)
Balance at March 31, 2023	159,153	\$ 16	\$ 55,921,384	\$ (47,833,330)	\$ 8,088,070
Stock-based compensation	-	-	131,177	-	131,177
Issuance of Common Stock and warrants, net of issuance costs	30,570	3	1,512,099	-	1,512,102
Issuance of Common Stock upon exercise of pre-funded warrants	22,821	2	32	-	34
Net loss	-	-	-	(1,701,364)	(1,701,364)
Balance at June 30, 2023	212,544	\$ 21	\$ 57,564,692	\$ (49,534,694)	\$ 8,030,019
Stock-based compensation	-	-	131,177	-	131,177
Issuance costs	-	-	(35,419)	-	(35,419)
Net loss	-	-	-	(1,719,211)	(1,719,211)
Balance at September 30, 2023	212,544	\$ 21	\$ 57,660,450	\$ (51,253,905)	\$ 6,406,566

The accompanying notes are an integral part of these financial statements.

DERMATA THERAPEUTICS, INC.
Statements of Cash Flows
(unaudited)

	For the nine months ended	
	September 30,	
	2024	2023
Cash flows from operating activities:		
Net loss	\$ (9,136,523)	\$ (5,660,717)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	627,834	393,614
Increase (decrease) in cash resulting from changes in:		
Prepaid expenses and other current assets	(3,095)	11,294
Accounts payable	(10,324)	(22,244)
Accrued and other current liabilities	272,774	16,427
Total adjustments to reconcile net loss to net cash used in operations	887,189	399,091
Net cash used in operating activities	(8,249,334)	(5,261,626)
Cash flows from financing activities:		
Proceeds from issuance of Common Stock, pre-funded warrants, and warrants, net of issuance costs	6,955,611	5,651,668
Proceeds from exercise of pre-funded warrants	168	187
Payment for fractional shares in reverse stock split	(828)	(40)
Net cash provided by financing activities	6,954,951	5,651,815
Net increase (decrease) in Cash and cash equivalents	(1,294,383)	390,189
Cash and cash equivalents at beginning of period	7,438,135	6,241,294
Cash and cash equivalents at end of period	<u>\$ 6,143,752</u>	<u>\$ 6,631,483</u>
Non-cash financing activities:		
Issuance of abeyance shares	\$ (45)	\$ -
Incremental fair value of May 2024 warrant inducement	\$ 1,526,232	\$ -
Issuance costs in accounts payable or accrued expenses	\$ 60,051	\$ -
Incremental fair value of March 2023 warrant modification	\$ -	\$ 144,765
Supplemental disclosure:		
Cash paid for taxes	\$ 950	\$ 950

The accompanying notes are an integral part of these financial statements.

DERMATA THERAPEUTICS, INC.
Notes to Financial Statements
(unaudited)

1. Organization and Basis of Presentation

Dermata Therapeutics, Inc., (the “Company”), was formed in December 2014 as a Delaware limited liability company (“LLC”) under the name Dermata Therapeutics, LLC. On March 24, 2021, the Company converted from an LLC to a Delaware C-corporation and changed its name to Dermata Therapeutics, Inc. The Company is a clinical-stage biotechnology company focused on the treatment of medical and aesthetic skin conditions and diseases.

Reverse Stock Splits

On March 13, 2023, the Company effected a reverse stock split of shares of the Company’s Common Stock at a ratio of 1-for-16 pursuant to an amendment to the Company’s certificate of incorporation approved by the Company’s board of directors and stockholders. The par value was not adjusted as a result of the reverse split. All issued and outstanding shares of Common Stock and per share amounts contained in the financial statements have been retroactively adjusted to reflect this reverse stock split for all periods presented.

On May 7, 2024, the Company held its annual meeting of stockholders at which time the stockholders approved the adoption of an amendment to its Amended and Restated Certificate of Incorporation, as amended, to effect a reverse stock split of its issued and outstanding shares of Common Stock, at a specific ratio, ranging from one-for-five to one-for-thirty, with the exact ratio determined by the Company’s board of directors without further approval or authorization of its stockholders.

On May 16, 2024, the Company effected the reverse split of its shares of Common Stock at a ratio of 1-for-15, as approved by the Company’s board of directors. The par value was not adjusted as a result of the May 2024 reverse stock split. All issued and outstanding shares of Common Stock and per share amounts contained in the financial statements have been retroactively adjusted to reflect this reverse stock split for all periods presented.

Liquidity and Going Concern Uncertainty

Since its inception, the Company has devoted substantially all of its resources to research and development activities and has not generated any revenue or commercialized any product candidates. As of September 30, 2024, cash and cash equivalents totaled \$6.1 million and the Company had an accumulated deficit of \$62.5 million. For the nine months ended September 30, 2024, and the year ended December 31, 2023, the Company used cash of \$8.2 million and \$6.4 million, respectively, in operations. The Company’s cash and cash equivalents are expected to fund operations into the second quarter of 2025. The Company anticipates that it will continue to incur net losses for the foreseeable future. These factors raise substantial doubt about the Company’s ability to continue as a going concern for the one-year period following the date that these financial statements were issued.

Historically, the Company’s principal sources of cash have included proceeds from the issuance of equity securities and debt. The Company’s principal uses of cash have included cash used in operations and payments for license rights. The Company expects that the principal uses of cash in the future will be for continuing operations, funding of research and development, conducting preclinical studies and clinical trials, and general working capital requirements. The Company expects that as research and development expenses continue to grow, it will need to raise additional capital to sustain operations and research and development. The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. The financial statements do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts and classification of liabilities that may result from the possible inability of the Company to continue as a going concern.

Management’s Plan to Continue as a Going Concern

To continue as a going concern, the Company will need, among other things, to raise additional capital resources. Until the Company can generate significant cash from operations, management’s plans to obtain such resources for the Company include proceeds from offerings of the Company’s equity securities or debt, or transactions involving product development, technology licensing or collaboration. Management can provide no assurance that any sources of a sufficient amount of financing or collaboration agreements will be available to the Company on favorable terms, if at all. The Company’s ability to raise additional capital may be adversely impacted by potential worsening of global economic conditions, potential future global pandemics or health crises, and the disruptions to, and volatility in, the credit and financial markets in the United States. Because of historical and expected operating losses and net operating cash flow deficits, there is substantial doubt about the Company’s ability to continue as a going concern for one year from the issuance of the financial statements, which is not alleviated by management’s plans. The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. The financial statements do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts and classification of liabilities that may result from the possible inability of the Company to continue as a going concern.

Basis of Presentation

The accompanying unaudited financial statements have been prepared in accordance with accounting principles generally accepted in the United States (“GAAP”) for interim financial information and in accordance with the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, since they are interim statements, the accompanying financial statements do not include all of the information and notes required by GAAP for complete financial statements. In the opinion of management, the accompanying financial statements reflect all adjustments (consisting of normal recurring adjustments) that are necessary for a fair statement of the financial position, results of operations, cash flows, and stockholders’ equity for the interim periods presented. Interim results are not necessarily indicative of results for a full year. The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the amounts reported in the financial statements and the accompanying notes. Actual results could differ materially from those estimates. The unaudited financial statements included in this Form 10-Q should be read in conjunction with the audited financial statements and notes thereto included in the Company’s Annual Report on Form 10-K for the year ended December 31, 2023, filed with Securities and Exchange Commission (the “SEC”) on March 21, 2024, which includes a broader discussion of the Company’s business and the risks inherent therein.

2. Summary of Significant Accounting Policies

Use of Estimates

The Company’s financial statements are prepared in accordance with GAAP. The preparation of the Company’s financial statements requires management to make estimates and assumptions that impact the reported amounts of assets, liabilities, and expenses and disclosure of contingent assets and liabilities in the financial statements and accompanying notes. On an ongoing basis, management evaluates these estimates and judgments, including those related to accrued research and development expenses. The Company bases its estimates on various assumptions that it believes are reasonable under the circumstances. Actual results may differ from these estimates under different assumptions or conditions.

Segment Information

Operating segments are defined as components of an enterprise about which separate discrete information is available for evaluation by the chief operating decision maker, or decision-making group, in deciding how to allocate resources and in assessing performance. The Company and the Company’s chief operating decision maker view the Company’s operations and manage its business in one operating segment, which is the business of developing and commercializing pharmaceuticals.

Cash and Cash Equivalents

The Company deposits its cash and cash equivalents with accredited financial institutions that are insured by the Federal Deposit Insurance Corporation (“FDIC”), which are held in checking and cash sweep accounts. At times, deposits held may exceed the amount of insurance provided by the FDIC. The Company maintains an insured cash sweep account in which cash from its main operating checking account is invested overnight in highly liquid, short-term investments. The Company considers all highly liquid investments with a maturity date of 90 days or less at the date of purchase to be cash equivalents.

Concentrations of Credit Risk

Financial instruments that potentially subject the Company to a concentration of credit risk consist primarily of cash and cash equivalents. The Company is exposed to credit risk in the event of a default by the financial institutions holding the Company's cash and cash equivalents to the extent of the amounts held in excess of FDIC limits. The Company limits its credit risk by placing its cash and cash equivalents with financial institutions it believes are of high quality. To date, the Company has not experienced any losses on its deposits of cash and cash equivalents.

Deferred Financing Costs

The Company capitalizes certain legal, accounting, and other fees and costs that are directly attributable to in-process equity financings as deferred offering costs until such financings are completed. Upon the completion of an equity financing, these costs are recorded as a reduction of additional paid-in capital of the related financing.

Fair Value Measurement

The Company uses a three-tier fair value hierarchy to prioritize the inputs used in the Company's fair value measurements. These tiers include: Level 1, defined as observable inputs such as quoted prices in active markets for identical assets; Level 2, defined as inputs other than quoted prices in active markets that are either directly or indirectly observable; and Level 3, defined as unobservable inputs in which little or no market data exists, therefore requiring an entity to develop its own assumptions. The Company believes the carrying amount of cash and cash equivalents, accounts payable and accrued expenses approximate their estimated fair values due to the short-term nature of these assets and liabilities.

Interest Income

Interest income consists of interest income earned on cash and cash equivalents from interest bearing demand accounts.

Patent Costs

Patent costs related to obtaining and maintaining patent protection in both the United States and other countries are expensed as incurred. Patents costs are classified as general and administrative expenses.

Research and Development

Research and development costs consist of expenses incurred in connection with the development of the Company's product candidates. Such expenses include expenses incurred under agreements with contract research organizations, manufacturing and supply scale-up expenses and the cost of acquiring and manufacturing preclinical and clinical trial supply, outsourced laboratory services, including materials and supplies used to support the Company's research and development activities, and payments made for license fees and milestones that have not been demonstrated to have commercial value. Such costs are expensed in the periods in which they are incurred. Upfront payments and milestone payments for licensed technology are expensed as research and development as incurred or when the milestone is achieved or is determined to be probable of being achieved. Advanced payments for goods or services to be received in the future for research and development activities are recorded as prepaid expenses and expensed as the related goods are received or services are performed.

Income Taxes

The Company is a C-Corporation and accounts for income taxes under the asset and liability method, which requires the recognition of deferred tax assets and liabilities for the expected future tax consequences of events that have been included in the financial statements. Under this method, deferred tax assets and liabilities are determined on the basis of the differences between the financial statements and tax basis of assets and liabilities using enacted tax rates in effect for the year in which the differences are expected to reverse. The effect of a change in tax rates on deferred tax assets and liabilities is recognized in income in the period that includes the enactment date.

The Company recognizes net deferred tax assets to the extent that the Company believes these assets are more likely than not to be realized. In making such a determination, management considers all available positive and negative evidence, including future reversals of existing taxable temporary differences, projected future taxable income, tax-planning strategies, and results of recent operations. If management determines that the Company would be able to realize its deferred tax assets in the future in excess of their net recorded amount, management would make an adjustment to the deferred tax asset valuation allowance, which would reduce the provision for income taxes.

The Company records uncertain tax positions on the basis of a two-step process whereby (1) management determines whether it is more likely than not that the tax positions will be sustained on the basis of the technical merits of the position and (2) for those tax positions that meet the more-likely-than-not recognition threshold, management recognizes the largest amount of tax benefit that is more than 50 percent likely to be realized upon ultimate settlement with the related tax authority. The Company recognizes interest and penalties related to unrecognized tax benefits within income tax expense. Any accrued interest and penalties are included within the related tax liability.

Stock-Based Compensation

The Company measures and recognizes compensation expense for all stock-based awards made to employees, directors, and non-employees, based on estimated fair values recognized using the straight-line method over the requisite service period. The fair value of options to purchase Common Stock granted to employees is estimated on the grant date using the Black-Scholes valuation model. The calculation of stock-based compensation expense requires that the Company make certain assumptions and judgments about variables used in the Black-Scholes model, including the expected term of the stock-based award, expected volatility of the underlying Common Stock, dividend yield, and the risk-free interest rate. Forfeitures are accounted for in the period they occur. Restricted stock units granted under the Company's 2021 Omnibus Equity Incentive Plan (the "2021 Plan") are measured at the grant date fair value of the Common Stock, with corresponding compensation expense recognized ratably over the requisite service period. Refer to Note 5 - Equity Incentive Plan for further discussion.

Warrants

The Company performs an assessment of warrants upon issuance to determine their proper classification in the financial statements based upon the warrant's specific terms, in accordance with the authoritative guidance provided in Financial Accounting Standards Board Accounting Standards Codification ("ASC") 480, *Distinguishing Liabilities from Equity* ("ASC 480"), and ASC 815-40, *Derivatives and Hedging – Contracts in Entity's Own Equity* ("ASC 815-40"). The assessment considers whether the warrants are freestanding financial instruments pursuant to ASC 480-40 and whether the warrants meet all of the requirements for equity classification under ASC 815, including whether the warrants are indexed in the Company's own Common Stock and whether the warrant holders could potentially require cash settlement of the warrants.

For issued or modified warrants that meet all the criteria for equity classification, the warrants are required to be recorded as a component of additional paid-in capital. For issued or modified warrants that do not meet all the criteria for equity classification, the warrants are required to be liability-classified and recorded at their initial fair value on the date of issuance and remeasured at fair value at each balance sheet date thereafter. The Company has performed an assessment of all warrants issued and modified and determined that the Company's warrants are equity-classified.

Comprehensive Loss

Comprehensive loss includes net loss and other comprehensive income (loss) for the periods presented. The Company did not have other comprehensive income (loss) items such as unrealized gains and losses and so for the periods presented, comprehensive loss was equal to the net loss.

Net Loss Per Share of Common Stock

Basic net loss per share is calculated by dividing net loss attributable to common shareholders by the weighted-average number of shares outstanding during the period. The weighted-average number of shares of Common Stock outstanding includes (i) pre-funded warrants because their exercise requires only nominal consideration for the delivery of shares, and (ii) shares held in abeyance because there is no consideration required for delivery of the shares, (collectively, “basic shares”), without consideration of common stock equivalents. Diluted net loss per share is calculated by adjusting basic shares outstanding for the dilutive effect of common stock equivalents outstanding for the period. For purposes of the diluted net loss per share calculation, stock options and warrants are considered to be common stock equivalents but are excluded from the calculation of diluted net loss per common stock if their effect would be anti-dilutive.

The common share equivalents that are not included in the calculation of diluted net loss per share of Common Stock but could potentially dilute basic earnings per share in the future are as follows:

	As of September 30,	
	2024	2023
Common Stock options	52,341	6,763
Common Stock warrants	5,068,723	309,549
Total potentially dilutive securities	5,121,064	316,312

Recent Accounting Pronouncements

For the nine months ended September 30, 2024, the Company has reviewed recent accounting standards and identified the following as relevant to the Company.

In November 2023, the Financial Accounting Standards Board (“FASB”) issued Accounting Standards Update (“ASU”) No. 2023-07, *Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures (“ASU 2023-07”)*, which requires public entities to disclose information about their reportable segments’ significant expenses and other segment items on an interim and annual basis. Public entities with a single reportable segment are required to apply the disclosure requirements in ASU 2023-07, as well as all existing segment disclosures and reconciliation requirements in ASC 280 on an interim and annual basis. ASU No 2023-07 is effective for annual reporting periods beginning after December 15, 2023, and for interim reporting periods beginning January 1, 2025, with early adoption permitted. The Company is currently evaluating the impact of this guidance on its financial statement disclosures.

In December 2023, the FASB issued ASU No. 2023-09, *Income Taxes (Topic 740): Improvements to Income Tax Disclosures (“ASU 2023-09”)*. ASU 2023-09 requires disaggregated information about a reporting entity’s effective tax rate reconciliation as well as information on income taxes paid. ASU 2023-09 is effective for public entities with annual periods beginning after December 15, 2024, with early adoption permitted. The Company is currently evaluating the impact of this guidance on its financial statements and income tax footnote.

In November 2024, the FASB issued ASU No. 2024-03, *Disaggregation of Income Statement Expenses (“ASU 2024-03”)*. ASU 2024-03 requires additional disclosures and disaggregation of certain costs and expenses presented on the face of the income statement. ASU 2024-03 is effective for annual reporting periods beginning after December 15, 2026, and interim reporting periods beginning after December 15, 2027, with early adoption permitted. The Company is currently evaluating the impact of this guidance on its financial statements.

3. Balance Sheet Details

The following provides certain balance sheet details:

	September 30, 2024	December 31, 2023
Prepaid expenses and other current assets:		
Prepaid insurance	\$ 488,562	\$ 426,413
Prepaid research and development costs	18,000	91,232
Prepaid other and other current assets	37,030	22,854
Total prepaid expenses and other current assets	\$ 543,592	\$ 540,499
Accrued and other current liabilities:		
Accrued research and development costs	\$ 655,989	\$ 40,596
Accrued compensation and benefits	327,235	716,490
Accrued other	99,297	502
Total accrued and other current liabilities	\$ 1,082,521	\$ 757,588

4. Equity Securities

A summary of the Company's equity securities as of September 30, 2024, is as follows:

Description	Authorized	Issued	Pre-funded Warrants	Reserved	Outstanding
Common Stock, par value \$0.0001	250,000,000	1,677,768	1,745,000	-	1,677,768
Preferred Stock	10,000,000	-	-	-	-
Warrants (excluding pre-funded warrants)	-	5,068,723	-	-	5,068,723
2021 Omnibus Equity Incentive Plan	-	53,255	-	26,675	52,341
Total equity securities	260,000,000	6,799,746	1,745,000	26,675	6,798,832

Common Stock

On September 17, 2024, the Company closed a private placement (the "September 2024 PIPE") priced at the market under Nasdaq rules, in which it sold 1,912,569 pre-funded warrants to purchase up to an aggregate of 1,912,569 shares of Common Stock with an exercise price of \$0.001 per share (the "September 2024 Pre-Funded Warrants"), and 1,912,569 series A warrants (the "September 2024 PIPE Series A Common Warrants") to purchase up to an aggregate of 1,912,569 shares of Common Stock and 1,912,569 series B warrants (the "September 2024 PIPE Series B Common Warrants" and together with the September 2024 PIPE Series A Warrants, the "September 2024 PIPE Warrants") to purchase up to an aggregate of 1,912,569 shares of Common Stock. The September 2024 PIPE Warrants have an exercise price of \$1.58. In connection with the September 2024 PIPE, the Company entered into a registration rights agreement with the investor, pursuant to which the Company agreed to prepare and file a registration statement with the Securities and Exchange Commission (the "SEC") registering the resale of the shares of Common Stock underlying the securities sold in the September 2024 PIPE financing. The Company filed a Form S-3 on September 19, 2024, which was declared effective by the SEC on September 24, 2024. The Company received net cash proceeds of approximately 3.1 million from the September 2024 PIPE after deducting underwriters' discounts and offering expenses of approximately \$0.4 million. During the third quarter of 2024, 167,569 of the 1,912,569 September 2024 Pre-Funded Warrants were exercised by the investor. As of September 30, 2024, 1,745,000 September 2024 Pre-Funded Warrants remained outstanding.

In June 2024, the Company entered into an At The Market Offering Agreement (the "ATM Agreement") with a sales agent (the "Sales Agent"), providing for the sale of up to \$1,157,761 of its shares of Common Stock as set forth in the ATM Agreement. The Sales Agent will be entitled to compensation at a fixed commission rate of 3.0% of the gross sales price of the shares of Common Stock sold pursuant to the ATM Agreement, as well as other transactional fees. During July 2024, the Company issued 355,806 shares of Common Stock under the ATM Agreement resulting in gross proceeds of \$ 1,157,248 before deducting issuance costs. After issuance of the 355,806 shares during July 2024, \$513 remained registered under the ATM Agreement. On August 2, 2024, the Company increased the maximum aggregate offering amount of Common Stock issuable under the ATM Agreement by \$ 505,000, from \$1,157,761 to \$1,662,761. During September 2024, the Company issued 194,218 shares of Common Stock under the ATM Agreement resulting in additional gross proceeds of \$504,894 before deducting issuance costs. During the quarter ended September 30, 2024, the Company issued a total of 550,024 shares from its ATM resulting in net proceeds of \$1.5 million after deducting issuer costs and other expenses related to setting up and issuing shares from the Company's ATM. As of September 30, 2024, the Company does not have any remaining capacity under its ATM Agreement.

On May 21, 2024, the Company closed on inducement agreements (the “May 2024 Inducement”) with certain holders (the “Holders”) of certain of the Company’s existing warrants to purchase up to an aggregate of 516,336 shares of the Company’s Common Stock, issued to the Holders on (i) May 26, 2023 (the “May 2023 Warrants”), having an exercise price of \$32.40 per share, and (ii) November 2023 New Warrants (as defined below), which were issued in two separate series, each having an exercise price of \$9.7665 per share (together with the May 2023 Warrants, the “May 2024 Existing Warrants”). Pursuant to the May 2024 Inducement, the Holders agreed to exercise for cash their May 2024 Existing Warrants at a reduced exercise price of \$5.16 per share in consideration for the Company’s agreement to issue in a private placement (i) new Series A Common Stock purchase warrants (the “New May 2024 Series A Warrants”) to purchase up to 601,174 shares of Common Stock, and (ii) new Series B Common Stock purchase warrants (the “New May 2024 Series B Warrants”) and together with the New May 2024 Series A Warrants, the “New May 2024 Warrants”) to purchase up to 431,498 shares of Common Stock. The Company received net proceeds of approximately \$2.3 million from the exercise of the May 2024 Existing Warrants by the Holders, after deducting placement agent fees and other offering expenses payable by the Company.

Related to the May 2024 Inducement, during July 2024, the balance of 267,000 of abeyance shares related to the May 2024 Warrant Inducement were released to the investor. Accordingly, shares outstanding increased by 267,000 during the third quarter of 2024 related to the issuance of the 267,000 abeyance shares from the May 2024 Warrant Inducement, leaving no further abeyance shares outstanding as of September 30, 2024.

On November 20, 2023, the Company closed on an inducement agreement (the “November 2023 Inducement”) with a holder (the “Holder”) of certain of its existing warrants to purchase up to 231,473 shares of the Company’s Common Stock, issued to the Holder on (i) April 25, 2022 (as amended on March 20, 2023, the “April 2022 Warrants”) and (ii) March 20, 2023 (the “March 2023 Warrants”) together with the April 2022 Warrants, the “November 2023 Existing Warrants”). The November 2023 Existing Warrants had an exercise price of \$42.30. Pursuant to the November 2023 Inducement, the Holder agreed to exercise for cash its November 2023 Existing Warrants at a reduced exercise price of \$9.7665 per share in consideration for the Company’s agreement to issue in a private placement (i) new series A Common Stock purchase warrants (the “November 2023 Series A Common Warrants”) to purchase 247,196 shares of Common Stock and (ii) new series B Common Stock purchase warrants (the “November 2023 Series B Common Warrants”) and together with the November 2023 Series A Common Warrants, the “November 2023 New Warrants”) to purchase 215,749 shares of Common Stock. The November 2023 New Warrants were exercisable subject to stockholder approval, which the Company received at a stockholder meeting on January 12, 2024. The Company received net cash proceeds of approximately \$2.0 million from the November 2023 Inducement after deducting underwriters’ discounts and offering expenses of approximately \$0.3 million.

Related to the November 2023 Inducement, as of December 31, 2023, the Holder left 182,000 shares in abeyance at the Company’s transfer agent to be delivered to the Holder at their request, which were then delivered to the Holder on January 8, 2024. Accordingly, as of December 31, 2023, 182,000 shares were held in abeyance, which were not issued and not outstanding. Since all the abeyance shares from the November 2023 Inducement were pulled by the Holder in January 2024, there were no remaining November 2023 Inducement shares held in abeyance as of September 30, 2024.

On May 26, 2023, the Company closed a private placement (the “May 2023 PIPE”) priced at the market under Nasdaq rules, in which it sold 80,570 shares of its Common Stock together with 22,821 pre-funded warrants to purchase up to an aggregate of 53,391 shares of Common Stock with an exercise price of \$0.0001 per share (the “May 2023 Pre-Funded Warrants”), and 53,391 warrants to purchase up to an aggregate of 53,391 shares of Common Stock with an exercise price of \$32.40 per share (the “May 2023 PIPE Common Warrants”) at a combined offering price of \$34.275. The May 2023 PIPE Common Warrants were set to expire on November 27, 2028. The Company received net cash proceeds of approximately \$1.5 million from the May 2023 PIPE after deducting underwriters’ discounts and offering expenses of approximately \$0.3 million. The May 2023 Pre-Funded Warrants were exercised fully during the second quarter of 2023. The May 2023 PIPE Common Warrants were exercised as part of the May 2024 Inducement.

On March 20, 2023, the Company closed a public offering (the “March 2023 Offering”) priced at the market under Nasdaq rules, in which it sold an aggregate of (i) 5,666 shares of Common Stock, (ii) pre-funded warrants (the “March 2023 Pre-Funded Warrants”) to purchase up to an aggregate of 102,208 shares of Common Stock with an exercise price of \$0.0001 per share, (iii) Series A warrants (the “March 2023 Series A Common Warrants”) to purchase up to an aggregate of 107,874 shares of Common Stock, and (iv) Series B warrants (the “March 2023 Series B Common Warrants”) and collectively with the March 2023 Series A Common Warrants, the “March 2023 Offering Warrants”) to purchase up to an aggregate of 107,874 shares of Common Stock. The March 2023 Offering Warrants had an exercise price of \$42.30 per share. The Company received net cash proceeds of approximately \$4.2 million after deducting the underwriter’s discounts and offering expenses of approximately \$0.8 million. The March 2023 Pre-Funded Warrants were fully exercised during the first quarter of 2023, and the March 2023 Offering Warrants were exercised as part of the November 2023 Inducement.

Preferred Stock

While the Company has 10,000,000 shares of preferred stock authorized with a par value of \$0.0001, no shares of preferred stock are outstanding as of September 30, 2024, or December 31, 2023, respectively.

Warrants

Summary of Warrants Outstanding

The table below lists outstanding warrants for the dates presented, excluding 1,745,000 pre-funded warrants with an exercise price of \$0.001. The warrants outstanding as of September 30, 2024, are exercisable into 5,068,723 shares of Common Stock which had a fair value of \$1.64 per share, based on the closing trading price on September 30, 2024, the last trading day prior to September 30, 2024. The aggregate intrinsic value of warrants outstanding as of September 30, 2024, is calculated as the difference between the exercise price of the warrants and the closing market price of the Company's Common Stock on that date. The intrinsic value of warrants outstanding as of September 30, 2024, was \$0.2 million.

Description	Quantity of Warrants Outstanding as of		Exercise Price	Expiration Date
	September 30, 2024	December 31, 2023		
	Pre-IPO Series 1a Warrants	279		
Pre-IPO Class B Common Warrants	268	268	1,377.60	12/31/2024
IPO Warrants	12,320	12,320	1,680.00	8/17/2026
IPO Underwriter Warrants	535	535	1,932.00	8/17/2026
March 2023 Offering Series A Common Warrants	-	107,874	42.30	3/20/2028
March 2023 Offering Series B Common Warrants	-	107,874	42.30	7/20/2025
March 2023 Offering Placement Agent Warrants	7,549	7,549	57.94	3/16/2028
May 2023 PIPE Common Warrants	-	53,391	32.40	11/27/2028
May 2023 PIPE Placement Agent Warrants	3,736	3,736	42.84	5/23/2028
November 2023 Series A Common Warrants	-	247,196	9.7665	11/20/2028
November 2023 Series B Common Warrants	-	215,749	9.7665	3/20/2026
November 2023 Placement Agent Warrants	16,202	16,202	12.21	11/20/2028
May 2024 Series A Common Warrants	601,174	-	4.91	11/21/2029
May 2024 Series B Common Warrants	431,498	-	4.91	5/21/2026
May 2024 Placement Agent Warrants	36,144	-	6.45	11/21/2029
September 2024 PIPE Series A Common Warrants	1,912,569	-	1.58	3/18/2030
September 2024 PIPE Series B Common Warrants	1,912,569	-	1.58	3/17/2026
September 2024 PIPE Placement Agent Warrants	133,880	-	2.29	3/18/2030
Total warrants outstanding	5,068,723	772,973		

Warrant Inducements

In May 2024, the Company completed the May 2024 Inducement with the Holders who agreed to exercise 516,336 warrants to purchase Common Stock at a reduced exercise price of \$5.16 per share in exchange for 601,174 New May 2024 Series A Warrants and 431,498 New May 2024 Series B Warrants with an exercise price of \$4.91 per share. The May 2024 Inducement, which resulted in the lowering of the exercise price of the May 2024 Existing Warrants and the issuance of the May 2024 New Warrants, is considered a modification of the May 2024 Existing Warrants under the guidance ASC 815-40. The modification is consistent with the equity issuance classification under that guidance as the reason for the modification was to induce the holders of the May 2024 Existing Warrants to cash exercise their warrants, which raised equity capital and generated net proceeds of approximately \$2.3 million. As the May 2024 Existing Warrants and the May 2024 New Warrants were classified as equity instruments before and after the exchange, and as the exchange is directly attributable to an equity offering, the Company recognized the effect of the modification of approximately \$1.5 million as an equity issuance cost.

In November 2023, the Company completed the November 2023 Inducement, in which a Holder agreed to exercise 231,472 common warrants to purchase Common Stock at a reduced exercise price of \$5.16 per share in exchange for 247,196 November 2023 Series A Warrants and 215,749 November 2023 Series B Warrants with an exercise price of \$9.7655 per share. The November 2023 New Warrants were exercisable subject to stockholder approval, which the Company received at a stockholder meeting on January 12, 2024. The November 2023 Inducement, which resulted in the lowering of the exercise price of the November 2023 Existing Warrants and the issuance of the November 2023 New Warrants, is considered a modification of the November 2023 Existing Warrants under the guidance of ASC 815-40. The modification is consistent with the equity issuance classification under that guidance as the reason for the modification was to induce the holder of the November 2023 Existing Warrants to cash exercise their warrants, which raised equity capital and generated net proceeds for the Company of approximately \$2.0 million. As the November 2023 Existing Warrants and the November 2023 New Warrants were classified as equity instruments before and after the exchange, and as the exchange is directly attributable to an equity offering, the Company recognized the effect of the modification of approximately \$3.0 million as an equity issuance cost.

Warrant Modification

In connection with the March 2023 Offering, the Company agreed to amend the terms of the April 2022 PIPE Common Warrants, which were held by the purchaser in the March 2023 Offering. The exercise price of the April 2022 PIPE Common Warrants was reduced from \$318.00 to \$42.30 per share upon closing of the March 2023 Offering. The original expiration date of the April 2022 PIPE Common Warrants was May 12, 2027, which was extended to five years after the closing of the March 2023 Offering, or March 20, 2028. The modification of the April 2022 PIPE Common Warrants was accounted for as a modification of equity-linked instruments. In accordance with ASU 2021-04, as the warrants were classified as equity instruments before and after the modification, and as the modification was directly attributable to an equity offering, the Company recognized the effect of the modification of approximately \$0.1 million as an equity issuance cost. The April 2022 PIPE Warrants were exercised as part of the November 2023 Inducement.

5. Equity Incentive Plan

Under the Company's 2021 Plan as amended, the Company may grant options to purchase shares of Common Stock, restricted stock awards, performance stock awards, incentive bonus awards, other cash-based awards or directly issue shares of Common Stock to employees, directors, and consultants of the Company. At the Company's 2024 Annual Meeting of Stockholders held on May 7, 2024, the Company's stockholders approved an amendment to the Company's 2021 Plan to increase the number of shares of Common Stock authorized for issuance thereunder from 41,937 shares to 79,930 shares. Further at the Company's 2024 Annual Meeting of Stockholders, the Company's stockholders approved an amendment to the Company's 2021 Plan, to increase the evergreen provision from one percent to five percent of the total number of the Company's Common Stock outstanding starting on January 1, 2025. The one percent evergreen provision resulted in an additional 2,620 and 513 shares of Common Stock issuable pursuant to the 2021 Plan as of January 1, 2024, and 2023, respectively.

Stock awards may be granted at an exercise price per share of not less than 100% of the fair market value at the date of grant. Stock awards granted are exercisable over a maximum term of 10 years from the date of grant and generally vest over a period of four years for employees and one year for directors of the Company's Board and consultants.

As of September 30, 2024, there remain 26,675 shares reserved for issuance under the 2021 Plan, as amended.

Fair Value Measurement

The Company uses the Black-Scholes option valuation model, which requires the use of highly subjective assumptions, to determine the fair value of stock-based awards. The fair value of each employee stock option is estimated on the grant date under the fair value method using the Black-Scholes model. The estimated fair value of each stock option is then expensed over the requisite service period, which is generally the vesting period. The assumptions and estimates that the Company uses in the Black-Scholes model are as follows:

- *Fair Value of Common Stock.* The fair value of Common Stock is measured as the Company’s closing price of Common Stock on the date of grant.
- *Risk-Free Interest Rate.* The Company bases the risk-free interest rate used in the Black-Scholes valuation model on the implied yield available on U.S. Treasury zero-coupon issues with a term equivalent to that of the expected term of the options.
- *Expected Term.* The expected term represents the period that the Company’s stock-based awards are expected to be outstanding, which is calculated using the simplified method for stock-based awards granted to employees, as the Company has insufficient historical information to provide a basis for an estimate. The simplified method calculates the expected term as the average of the vesting term plus the contractual life of the options. As permitted under ASC 718, the Company has elected to use the contractual term as the expected term for certain non-employee awards, on an award-by-award basis.
- *Volatility.* The Company determines the price volatility based on the historical volatilities of industry peers as it has limited trading history for its Common Stock price. Industry peers consist of several public companies in the biotechnology industry with comparable characteristics, including clinical trials progress and therapeutic indications.
- *Dividend Yield.* The expected dividend assumption is based on the Company’s current expectations about its anticipated dividend policy. To date, the Company has not declared any dividends to common shareholders and, therefore, the Company has used an expected dividend yield of zero.

The following table presents the weighted-average assumptions used for stock options granted during the following periods:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Grant date fair value	\$ 1.60	\$ 63.45	\$ 4.78	\$ 63.45
Risk-free interest rate	3.7%	3.9%	3.9%	3.9%
Dividend yield	0.00%	0.00%	0.00%	0.00%
Expected life in years	10.0	6.1	7.9	6.1
Expected volatility	102.8%	112%	106.7%	112%

Stock-based Compensation Expense

In general, stock-based compensation is allocated to research and development expense or general and administrative expense according to the classification of cash compensation paid to the employee, director, or consultant to whom the stock award was granted.

The following table summarizes the total stock-based compensation expense related to stock options included in the Company's statements of operations:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Research and development	\$ 4,677	\$ 48,425	\$ 246,637	\$ 145,275
General and administrative	16,315	82,752	381,197	248,339
Total	\$ 20,992	\$ 131,177	\$ 627,834	\$ 393,614

Stock Option Award Activity

A summary of the Company's 2021 Plan stock option activity is as follows:

	Number of Options Outstanding	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (in Years)
Balance at December 31, 2023	6,763	\$ 609.81	7.8
Options granted	52,325	5.61	-
Options exercised	-	-	-
Options cancelled	(6,747)	607.99	-
Balance at September 30, 2024	52,341	\$ 6.03	9.6
Options exercisable at September 30, 2024	3,124	\$ 16.16	9.2

In January 2024, the Board unanimously approved to provide employees and directors of the Company the opportunity to cancel outstanding, out-of-the-money, stock options without consideration, in accordance with an option cancellation agreement. Accordingly, 6,747 of the 6,763 stock options outstanding as of December 31, 2023, were cancelled in February 2024.

In accordance with accounting guidance provided in ASC 718, since the stock option cancellations were not accompanied by a concurrent grant, or offer to grant, a replacement award, any unrecognized compensation cost was recognized at the cancellation date. Accordingly, the Company recognized stock-based compensation expense of \$568,372 resulting from the stock option cancellation during the first quarter of 2024.

The aggregate intrinsic value of options outstanding and exercisable as of September 30, 2024, is calculated as the difference between the exercise price of the underlying options and the closing market price of the Company's Common Stock on September 30, 2024, the last trading day prior to September 30, 2024, which was \$ 1.64 per share. The intrinsic value of options outstanding and exercisable as of September 30, 2024, was zero.

As of September 30, 2024, total unrecognized compensation cost related to stock options was approximately \$0.2 million and the weighted average period over which this cost is expected to be recognized is 2.6 years.

6. Commitments and Contingencies

Clinical Trials

During the fourth quarter of 2023, the Company initiated a Phase 3 clinical trial, STAR-1, which is expected to report top-line data in 2025. The total contract amount with the clinical research organization is approximately \$7.0 million, which will extend from the fourth quarter of 2023 to the first half of 2025, and which has a 30-day termination notice period. As of September 30, 2024, the Company has recognized \$4.7 million in expense for the STAR-1 trial.

Supplier Agreement

As a result of Russia's invasion of Ukraine, the United States, the United Kingdom, and the European Union governments, among others, have developed coordinated sanctions and export-control measure packages against Russian individuals and entities. The Company is currently a party to an exclusive supply agreement for the supply of the *Spongilla* raw material used in DMT310 and DMT410. The counterparty to this supply agreement is a Russian entity. The imposition of enhanced export controls and economic sanctions on transactions with Russia and Russian entities by the United States, the United Kingdom, and/or the European Union could prevent the Company from performing under this existing contract or any future contract it may enter or may prevent the Company from remitting payment for raw material purchased from the Company's supplier. The Company has received multiple shipments of raw material from its supplier subsequent to the implementation of export controls and sanctions, containing additional quantities of *Spongilla* raw material, which will provide the Company with sufficient quantities of *Spongilla* to initiate and complete two Phase 3 studies in moderate-to-severe acne and support filing a new drug application for DMT310 in acne upon the successful completion of two Phase 3 studies. Depending on the extent and breadth of new sanctions or export controls that may be imposed against Russia, otherwise or as a result of the impact of the war in Ukraine, it is possible that the Company's ability to obtain additional supply of the *Spongilla* raw material used in DMT310 and DMT410 could be negatively impacted, which could adversely affect its business, results of operations, and financial condition.

License Agreements

On March 31, 2017, the Company entered into a license agreement, as amended (the "License Agreement") with Villani, Inc. whereby Villani has granted the Company an exclusive, sub-licensable, royalty-bearing license (the "License") under the Licensed Patents (as defined in the License Agreement), to formulate, develop, seek regulatory approval for, make or sell products that contain *Spongilla lacustris* (alone or in combination with other active or inactive ingredients) for the treatment of diseases, disorders and conditions of the skin, including but not limited to acne, rosacea, psoriasis, atopic dermatitis, seborrheic dermatitis, actinic keratosis and eczema that were developed using certain licensed know-how ("Licensed Products"). The Company is responsible for the development (including manufacturing, packaging, non-clinical studies, clinical trials and obtaining regulatory approval and commercialization (including marketing, promotion, distribution, etc.)) for all Licensed Products. The original License Agreement was amended in 2019, and pursuant to the amended License Agreement, the Company was required to make future milestone payments to Villani in an aggregate amount of up to \$20.25 million upon the achievement of specified development and sales milestones, payable in cash or in equity, at the option of Villani, as well as single-digit royalty payments on net sales. On July 30, 2021, the Company further amended the License Agreement in the Second Amendment to the License and Settlement Agreement (the "Second Amendment"). Pursuant to the Second Amendment, the Company is required to make future milestone payments to Villani in an aggregate amount of up to \$40.5 million upon the achievement of specified development and sales milestones, payable in cash or in equity, at the option of Villani, as well as single-digit royalty payments on net sales. The Second Amendment includes customary terms relating to, among others, indemnification, intellectual property protection, confidentiality, remedies, and warranties. As of September 30, 2024, the Company evaluated the likelihood of the Company achieving the specified milestones and determined that the likelihood is not yet probable and as such no accrual of these payments is required as of September 30, 2024.

Legal Proceedings

In the normal course of business, the Company may be involved in legal proceedings or threatened legal proceedings. The Company is not a party to any legal proceedings or aware of any threatened legal proceedings which are expected to have a material adverse effect on its financial condition, results of operations or liquidity.

7. Subsequent Events

Subsequent to September 30, 2024, the Company has issued 363,000 shares of Common Stock related to the exercise of the September 2024 Pre-Funded Warrants, leaving 1,382,000 of the September 2024 Pre-Funded Warrants outstanding.

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 should be read together with our financial statements and the related notes and the other financial information included elsewhere in this Quarterly Report. This discussion contains forward-looking statements that involve risks and uncertainties. Our actual results could differ materially from those anticipated in these forward-looking statements as a result of various factors, including those discussed below and elsewhere in this Quarterly Report, particularly those under "Risk Factors."

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report contains forward-looking statements made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995 under Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. Forward-looking statements include statements with respect to our beliefs, plans, objectives, goals, expectations, anticipations, assumptions, estimates, intentions, and future performance, and involve known and unknown risks, uncertainties, and other factors, which may be beyond our control, and which may cause our actual results, performance, or achievements to be materially different from future results, performance or achievements expressed or implied by such forward-looking statements. All statements other than statements of historical fact are statements that could be forward-looking statements. You can identify these forward-looking statements through our use of words such as "may," "can," "anticipate," "assume," "should," "indicate," "would," "believe," "contemplate," "expect," "seek," "estimate," "continue," "plan," "point to," "project," "predict," "could," "intend," "target," "potential" and other similar words and expressions of the future.

There are a number of important factors that could cause the actual results to differ materially from those expressed in any forward-looking statement made by us. These factors include, but are not limited to:

- our lack of operating history;
- the expectation that we will incur significant operating losses for the foreseeable future and will need significant additional capital;
- our current and future capital requirements to support our development and commercialization efforts for our product candidates and our ability to satisfy our capital needs;
- our dependence on our product candidates, which are still in various stages of clinical development;
- our ability to acquire sufficient quantities of raw material needed to manufacture our drug product;
- our, or that of our third-party manufacturers, ability to manufacture cGMP quantities of our product candidates as required for pre-clinical and clinical trials and, subsequently, our ability to manufacture commercial quantities of our product candidates;
- our ability to complete required clinical trials for our product candidates and obtain approval from the FDA or other regulatory agencies in different jurisdictions;
- our lack of a sales and marketing organization and our ability to commercialize our product candidates if we obtain regulatory approval;
- our dependence on third parties to manufacture our product candidates;
- our reliance on third-party CROs to conduct our clinical trials;

- our ability to maintain or protect the validity of our intellectual property;
- our ability to internally develop new inventions and intellectual property;
- interpretations of current laws and the passages of future laws;
- acceptance of our business model by investors;
- the accuracy of our estimates regarding expenses and capital requirements;
- our ability to adequately support organizational and business growth; and
- other factors discussed in our most recent Annual Report on Form 10-K.

The foregoing does not represent an exhaustive list of matters that may be covered by the forward-looking statements contained herein or risk factors that we are faced with that may cause our actual results to differ from those anticipated in our forward-looking statements. Please see “Risk Factors” for additional risks which could adversely impact our business and financial performance.

All forward-looking statements are expressly qualified in their entirety by this cautionary notice. You are cautioned not to place undue reliance on any forward-looking statements, which speak only as of the date of this report, or the date of the document incorporated by reference into this report. We have no obligation, and expressly disclaim any obligation, to update, revise or correct any of the forward-looking statements, whether as a result of new information, future events or otherwise. We have expressed our expectations, beliefs and projections in good faith, and we believe they have a reasonable basis. However, we cannot assure you that our expectations, beliefs, or projections will result or be achieved or accomplished.

Overview

We are a late-stage medical dermatology company focused on identifying, developing, and commercializing innovative pharmaceutical product candidates for the treatment of medical and aesthetic skin conditions and diseases we believe represent significant market opportunities.

Dermatological diseases such as acne vulgaris (or acne), psoriasis vulgaris (or psoriasis), hyperhidrosis, and various aesthetic indications, affect millions of people worldwide each year which may negatively impact their quality of life and emotional well-being. While there are multiple current treatment options for these indications on the market, we believe that most have significant drawbacks, including underwhelming efficacy, cumbersome application regimens and varying negative side effects, all of which we believe lead to decreased patient compliance. A majority of these indications are first treated with topical therapy; however, many patients frequently switch treatments or discontinue treatment altogether due to patient dissatisfaction. This is primarily due to slow and modest response rates, early onset of negative side effects, daily application schedules and long duration of therapy. Given the limitations with current topical therapies, we believe there is a significant opportunity to address the needs of frustrated patients searching for topical products that satisfy their dermatological and lifestyle needs.

Our two product candidates, DMT310 and DMT410, both incorporate our proprietary, multifaceted, *Spongilla* technology to topically treat a variety of dermatological conditions. Our *Spongilla* technology is derived from a naturally grown freshwater sponge, *Spongilla lacustris* or *Spongilla*, which is processed into a powder that is mixed with a fluidizing agent immediately prior to application to form an easily applicable paste. *Spongilla* is a unique freshwater sponge that only grows in commercial quantities in select regions of the world and under specific environmental conditions, all of which give it its distinctive anti-microbial, anti-inflammatory, and mechanical properties. The combination of these environmental conditions, the proprietary harvesting protocols developed with our exclusive supplier, and our post-harvest processing procedures produce a pharmaceutical product candidate that optimizes the mechanical components as well as the chemical components of the sponge to create a product candidate with multiple mechanisms of action for the treatment of medical and aesthetic skin diseases and conditions.

We believe our *Spongilla* technology platform will enable us to develop and formulate singular and combination products that are able to target the topical delivery of chemical compounds into the dermis for a variety of dermatology indications. We believe the combination of *Spongilla*'s mechanical and chemical components (which we believe have demonstrated, *in-vitro*, anti-microbial and anti-inflammatory properties), add to the versatility of our *Spongilla* technology platform's effectiveness as a singular product, in the treatment of a wide variety of medical skin diseases like acne and psoriasis. We also believe the mechanical properties of our *Spongilla* technology allows for the intradermal delivery of a variety of large molecules, like botulinum toxins, monoclonal antibodies, or dermal fillers, to target treatment sites, through topical application without the need for needles.

Our lead product candidate, DMT310, is intended to utilize our *Spongilla* technology for the once weekly treatment of a variety of skin diseases, with our initial focus being the treatment of acne vulgaris, which has a U.S. market size of approximately 30 million diagnosed patients. We recently initiated a Phase 3 program of DMT310 in moderate-to-severe acne. Both studies will be double-blinded, randomized, placebo-controlled, and enroll up to 550 patients, age 9 years or older across sites in the United States and Latin America. The primary endpoints include absolute reduction in inflammatory and noninflammatory lesions and the improvement in investigators global assessment ("IGA") of acne, which are the same endpoints used in our Phase 2b study of DMT310 for moderate-to-severe acne. Patients will be treated once a week for 12 weeks with either DMT310 or placebo and will be evaluated monthly. The second Phase 3 study will be followed by a long-term extension study. We recently announced enrollment of 50% of the total expected patients in the STAR-1 study and we expect to have top-line results from the first Phase 3 study in the first quarter of 2025. Previously, DMT310 has shown its ability to treat the multiple causes of acne in a Phase 2b study where we initially saw a 45% reduction in inflammatory lesions after four treatments, with DMT310 achieving statistically significant improvements at all time points for all three primary endpoints throughout the study (reduction in inflammatory lesions, reduction in non-inflammatory lesions, and improvement in IGA). In addition, based on the multiple mechanisms of action and anti-inflammatory effect seen with the DMT310 acne trial, we completed a Phase 1b proof of concept, or POC, trial in psoriasis where we saw encouraging results warranting further investigation.

DMT310 consists of two grams of powder processed from the naturally grown freshwater sponge, *Spongilla lacustris*. The patient mixes the powder with a fluidizing agent (3% hydrogen peroxide) immediately prior to application by the patient to form an easy-to-apply paste. The paste is applied like a mud mask and is left on the skin for approximately ten to fifteen minutes, after which time it is washed off with water. Due to the unique combination of DMT310's mechanical components and chemical components, and based on our Phase 2 acne data, we believe patients will only need to apply DMT310 once weekly to produce the desired treatment effect. The mechanical components of the *Spongilla* powder consist of many microscopic siliceous, needle-like spicules that, when massaged into the skin, penetrate the stratum corneum (the skin's outermost protective layer) and create microchannels into the dermis where pro-inflammatory cytokines and bacteria reside. We believe that the penetration of the spicules also leads to the opening of microchannels, which allow oxygen to enter pilosebaceous glands, helping to kill *C. acnes*, which grow in an anaerobic (without oxygen) environment (*C. acnes* is the bacteria that cause inflammatory lesions in acne patients). The spicules also cause rejuvenation of the top layer of dead skin, thereby increasing collagen production. Additionally, we believe the newly created microchannels provide a conduit for DMT310's naturally occurring chemical compounds to be delivered to the dermis and pilosebaceous glands, helping to kill the *C. acnes* and fight inflammation. In addition to these anti-microbial compounds, DMT310 also appears to have anti-inflammatory chemical compounds, as demonstrated in *in vitro* experiments, that inhibit inflammation through the reduction of *C. acnes* stimulated IL-8 production and by inhibiting IL-17A and IL-17F expression in human cell lines. Also, during *in vitro* studies of DMT310's organic compounds, we observed the inhibition of the lipogenesis of sebocytes, which may translate to a reduction in sebum (an oily and waxy substance produced by the human body's sebaceous glands) production and the oiliness of the skin in patients, which was observed by a number of clinical investigators in our Phase 2 acne studies. We believe the combination of these biological and mechanical effects could be important factors in treating multiple inflammatory skin diseases, as seen in our clinical trials.

Our second product candidate utilizing our *Spongilla* technology is DMT410, our combination treatment. DMT410 is intended to consist of one treatment of our proprietary sponge powder followed by one topical application of botulinum toxin for delivery into the dermis. Currently, BOTOX®, is the only approved botulinum toxin to be delivered to the dermis by intradermal injections, which can be painful for the patient and time-consuming for the physician. However, we believe DMT410's ability to topically deliver a botulinum toxin into the dermis could have similar levels of efficacy to intradermal injections of botulinum toxin, with fewer tolerability issues, and a quicker application time, possibly replacing the need for intradermal injections. We first tested DMT410 with BOTOX® in a Phase 1 POC trial of axillary hyperhidrosis patients, which saw 80% of patients achieve a reduction in gravimetric sweat production greater than 50% four weeks after a single treatment. With almost 40% of the hyperhidrosis market currently being treated with intradermal injections of BOTOX®, we believe there could be significant opportunity for DMT410 to break into this market and replace intradermal injections of botulinum toxin with a topical delivery option. Based on DMT410's ability to effectively deliver botulinum toxin to the dermis as observed in the Phase 1 axillary hyperhidrosis trial, we also conducted a Phase 1 POC trial of DMT410 with BOTOX® for the treatment of multiple aesthetic skin conditions, including reduction of pore size, sebum production, and fine lines, among others. In November 2021, we announced top-line results from this trial, where we saw promising data that we believe warrants further investigation of DMT410. Given that BOTOX® is a Type A toxin, and acts through a similar pathway as other Type A botulinum toxins, we are discussing partnering opportunities with multiple companies that have a botulinum toxin type A to move our DMT410 program into additional clinical studies.

We have a limited operating history. Since our inception, our operations have focused on developing DMT310 and DMT410, organizing and staffing our company, raising capital, establishing our supply chain and manufacturing processes, further characterizing the multiple mechanisms of action of our *Spongilla* technology, building an intellectual property portfolio, and conducting non-clinical and clinical trials. We do not have any product candidates approved for marketing and have not generated any revenue from product sales. We have funded our operations primarily through the sale of our equity securities and debt securities. Since inception, we have raised an aggregate of approximately \$68.8 million of gross proceeds from the sale of our debt and equity securities.

We have not generated any revenue to date and have incurred significant operating losses. Our net losses were \$3.2 million and \$1.7 million for the three months ended September 30, 2024, and 2023, respectively, and our net losses were \$9.1 million and \$5.7 million for the nine months ended September 30, 2024, and 2023, respectively. As of September 30, 2024, we had an accumulated deficit of \$62.5 million. We expect to continue to incur significant expenses and operating losses for the foreseeable future. We anticipate that our expenses will increase significantly in connection with our ongoing activities, as we:

- complete development of DMT310 for the treatment of acne, including non-clinical studies and Phase 3 clinical trials;
- prepare and file for regulatory approval of DMT310 for the treatment of moderate-to-severe acne;
- identify a botulinum toxin partner for DMT410 for the treatment of medical and aesthetic skin conditions and diseases;
- continue development of DMT410 for the treatment of treatment of aesthetic and medical skin conditions, including Phase 1 and Phase 2 clinical trials;
- prepare for commercialization of DMT310, if approved, including the hiring of sales and marketing personnel;
- manufacture our product candidates for additional Phase 2 and Phase 3 trials and commercial sale;
- hire additional research and development and selling, general and administrative personnel;
- maintain, expand, and protect our intellectual property portfolio; and
- incur additional costs associated with operating as a public company.

We will need additional financing to support our operations. We may seek to fund our operations through public or private equity or debt financings or other sources. Adequate additional financing may not be available to us on acceptable terms, or at all. Our failure to raise capital when needed or on favorable terms would have a negative impact on our financial condition and our ability to pursue our business strategy. We will need to generate significant revenues to achieve profitability, and we may never do so.

Recent Developments

In July 2024, we reached the 50% patient enrollment milestone in the first of two Phase 3 clinical trials of DMT310 in moderate-to-severe acne. We expect to receive top-line results from the first Phase 3 trial, referred to as STAR-1, in the first quarter of 2025. Both Phase 3 studies will be double-blinded, randomized, placebo-controlled, and enroll up to 550 patients, age 9 years or older across sites in the United States and Latin America. The primary endpoints include absolute reduction in inflammatory and noninflammatory lesions and the improvement in investigators global assessment (IGA) of acne. Patients will be treated once a week for 12 weeks with either DMT310 or placebo and will be evaluated monthly.

ATM Agreement

In June 2024, we entered into an At The Market Offering Agreement (the “ATM Agreement”) with H.C. Wainwright & Co., LLC (“HCW”), as sales agent, pursuant to which we may offer and sell, from time to time through HCW, shares of our common stock for aggregate proceeds of up to \$1,662,761 (upon the terms and subject to the conditions and limitations set forth in the ATM Agreement). In the nine months ended September 30, 2024, we sold 550,024 shares of common stock under the ATM Agreement, for net proceeds of \$1.5 million, after deducting \$0.1 million of compensation to HCW and other administration fees.

Critical Accounting Policies and Use of Estimates

We have based our management’s discussion and analysis of financial condition and results of operations on our financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of these financial statements requires us to make estimates that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements as well as expenses during the reporting periods. On an ongoing basis, we evaluate our estimates and judgments, including those related to clinical development expenses. We base our estimates on historical experience and on various other factors that we believe to be appropriate under the circumstances. Actual results may differ from these estimates under different assumptions or conditions.

While our significant accounting policies are more fully discussed in Note 2 - Summary of Significant Accounting Policies to our unaudited financial statements contained within this Form 10-Q, we believe that the following accounting policies are critical to the process of making significant judgments and estimates in the preparation of our financial statements.

Research and Development Expenses

We rely on third parties to conduct our clinical studies and to provide services, including data management, statistical analysis, and electronic compilation. Once our clinical trials begin, at the end of each reporting period, we will compare the payments made to each service provider to the estimated progress towards completion of the related project. Factors that we will consider in preparing these estimates include the number of patients enrolled in studies, milestones achieved, and other criteria related to the efforts of our vendors. These estimates will be subject to change as additional information becomes available. Depending on the timing of payments to vendors and estimated services provided, we will record net prepaid or accrued expenses related to these costs.

Fluctuations in Operating Results

Our results of operations have fluctuated significantly from period to period in the past and are likely to continue to do so in the future. We anticipate that our quarterly and annual results of operations will be impacted for the foreseeable future by several factors, including the progress and timing of expenditures related to the development of our product candidates. Due to these fluctuations, we believe that the period-to-period comparisons of our operating results are not a good indication of our future performance.

Results of Operations**Three Months Ended September 30, 2024, and 2023**

The following table summarizes our results of operations for the periods presented:

	Three Months Ended September 30,		
	2024	2023	Difference
Operating expenses:			
Research and development	\$ 2,401,359	\$ 902,977	\$ 1,498,382
General and administrative	824,294	909,001	(84,707)
Total operating expenses	<u>3,225,653</u>	<u>1,811,978</u>	<u>1,413,675</u>
Losses from operations	(3,225,653)	(1,811,978)	(1,413,675)
Other income and expenses:			
Interest income, net	52,497	92,767	40,270
Net loss	<u>\$ (3,173,156)</u>	<u>\$ (1,719,211)</u>	<u>\$ (1,453,945)</u>

Research and Development Expenses

Research and development expenses increased by \$1.5 million from \$0.9 million for the three months ended September 30, 2023, to \$2.4 million for the three months ended September 30, 2024. The increase in research and development expenses in the third quarter of 2024 as compared to the same period in 2023 resulted from \$1.8 million of increased clinical expenses from the DMT310 STAR-1 acne study initiated in late 2023, offset by \$0.3 million of decreased chemistry, manufacturing, and controls, or CMC, expenses.

General and Administrative Expenses

General and administrative expenses decreased by \$0.1 million from \$0.9 million for the three months ended September 30, 2023, to \$0.8 million for the three months ended September 30, 2024. The decrease in general and administrative expenses in the third quarter of 2024 as compared to the same period of 2023 resulted from \$0.1 million in decreased insurance costs.

Other Income and Expenses

Other income and expenses decreased by \$40,270 from \$92,767 for the three months ended September 30, 2023, to \$52,497 for the three months ended September 30, 2024. The decrease in interest income resulted from less cash and cash equivalents available for earning interest income.

Nine Months Ended September 30, 2024, and 2023

The following table summarizes our results of operations for the periods presented:

	Nine Months Ended September 30,		
	2024	2023	Difference
Operating expenses:			
Research and development	\$ 6,011,201	\$ 2,934,541	\$ 3,076,660
General and administrative	3,301,753	2,887,533	414,220
Total operating expenses	<u>9,312,954</u>	<u>5,822,074</u>	<u>3,490,880</u>
Loss from operations	(9,312,954)	(5,822,074)	(3,490,880)
Other income and expenses:			
Interest expense, net	176,431	161,357	15,074
Net loss	<u>\$ (9,136,523)</u>	<u>\$ (5,660,717)</u>	<u>\$ (3,475,806)</u>

[Table of Contents](#)

Research and Development Expenses

Research and development expenses increased by \$3.1 million from \$2.9 million for the nine months ended September 30, 2023, to \$6.0 million for the nine months ended September 30, 2024. The increase in research and development expenses resulted from \$4.0 million of increased clinical expenses from the DMT310 STAR-1 acne study initiated in late 2023, offset by \$0.7 million of decreased chemistry, manufacturing, and controls, or CMC, expenses and \$0.2 million of decreased non-clinical expenses.

General and Administrative Expenses

General and administrative expenses increased by \$0.4 million from \$2.9 million for the nine months ended September 30, 2023, to \$3.3 million for the nine months ended September 30, 2024. This increase resulted from \$0.5 million of increased audit fees as well as \$0.1 million of increased stock-based compensation, offset by \$0.2 million of decreased insurance costs.

Other Income and Expenses

Other income and expenses increased by \$15,074 from \$161,357 for the nine months ended September 30, 2023, to \$176,431 for the nine months ended September 30, 2024. The increase in interest income resulted from interest rate increases.

Cash Flows

The following table summarizes our cash flows from operating and financing activities:

	Nine Months Ended September 30,	
	2024	2023
Statements of cash flows data:		
Total net cash provided by (used in):		
Operating activities	\$ (8,249,332)	\$ (5,261,626)
Financing activities	\$ 6,954,949	\$ 5,651,815
Increase (decrease) in cash and cash equivalents	\$ (1,294,383)	\$ 390,189

Operating activities

Cash used in operations of \$8.2 million for the nine months ended September 30, 2024, was the result of the net loss of \$9.1 million, offset by increases in non-cash stock-based compensation of \$0.6 million and increases in accrued expenses of \$0.3 million.

Cash used in operations of \$5.3 million for the nine months ended September 30, 2023, was the result of the net loss of \$5.7 million, offset by non-cash stock-based compensation of \$0.4 million.

Financing activities

Cash provided by financing activities of \$7.0 million for the nine months ended September 30, 2024, was the result of the September 2024 PIPE financing which raised net proceeds of \$3.1 million, sales of the Company's shares through the ATM Agreement which raised net proceeds of \$1.5 million during the third quarter of 2024, and the May 2024 warrant inducement financing which raised net proceeds of \$2.3 million.

Cash provided by financing activities of \$5.7 million for the nine months ended September 30, 2023, was the result of \$4.2 million of net proceeds received from the issuance of Common Stock and warrants issued in the March 2023 Offering, as well as \$1.5 million of net proceeds received from the May 2023 Offering.

Liquidity and Capital Resources

Since our inception, we have not generated any revenue or commercialized any products. As of September 30, 2024, our cash and cash equivalents totaled \$6.1 million, and we had an accumulated deficit of \$62.5 million. For the nine months ended September 30, 2024, and the year ended December 31, 2023, we used cash of \$8.2 million and \$6.4 million, respectively, in operations. We expect our cash resources to fund operations into the second quarter of 2025. We anticipate that we will continue to incur net losses for the foreseeable future.

Historically, our principal sources of cash have included proceeds from the issuance of common and preferred equity and proceeds from the issuance of debt. Our principal uses of cash have included cash used in operations (including clinical development of our product candidates and general and administrative expenses) and payments for license rights. We expect that the principal uses of cash in the future will be for continuing operations, funding of research and development, and general working capital requirements. We expect that as research and development expenses continue to grow, we will need to raise additional capital to sustain operations and research and development activities.

Funding Requirements

We plan to focus in the near term on the development, regulatory approval, and potential commercialization of DMT310 for the treatment of acne. We anticipate we will incur net losses for the next several years as we complete clinical development of DMT310 for the treatment of acne and psoriasis and continue research and development of DMT410 for the treatment of aesthetic and medical skin conditions. In addition, we plan to seek opportunities to identify, acquire or in license and develop additional drug candidates, potentially build commercial capabilities, and expand our corporate infrastructure. We may not be able to complete the development and initiate commercialization of these programs if, among other things, our clinical trials are not successful or if the FDA does not approve our drug candidate arising out of our current clinical trials when we expect, or at all.

Our primary uses of capital are, and we expect will continue to be, compensation and related expenses, clinical costs, external research and development services, legal and other regulatory expenses, and administrative and overhead costs. Our future funding requirements will be heavily determined by the resources needed to support the development of our drug candidates.

As a publicly traded company, we will incur significant legal, accounting, and other expenses that we were not required to incur as a private company. In addition, the Sarbanes-Oxley Act of 2002, as well as rules adopted by the Securities and Exchange Commission (the "SEC"), and Nasdaq, requires public companies to implement specified corporate governance practices that were not applicable to us as a private company. We expect these rules and regulations will increase our legal and financial compliance costs and will make some activities more time-consuming and costly.

We believe that our existing cash and cash equivalents will be sufficient to fund our operating expenses and capital expenditure requirements into the second quarter of 2025. We have based this estimate of cash runway on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we expect. We anticipate that we will continue to incur net losses for the foreseeable future. These factors raise substantial doubt about our ability to continue as a going concern for the one-year period following the date that these financial statements were issued. We will require additional capital to complete the Phase 3 studies for DMT310 for the treatment of acne, continue development of DMT310, and to pursue in-licenses or acquisitions of other drug candidates. Therefore, based on our recurring losses from operations incurred since inception, expectation of continuing operating losses for the foreseeable future, and the need to raise additional capital to finance future operations, we are developing plans to mitigate this risk, which may consist of raising additional capital through some combination of equity or debt financings, and/or potentially new collaborations, business transactions, and reducing cash expenditures. If we are not able to secure adequate additional funding, we may be forced to make significant reductions in our operations and the pursuit of our growth strategy. In that event, we may have to delay, scale back, or eliminate some or all of our research and development programs and activities which could adversely affect our business prospects, or we may be unable to continue operations.

Table of Contents

We may raise additional capital through the sale of equity or convertible debt securities. In such an event, the terms of these securities may include liquidation or other preferences that adversely affect the rights of the holders of our Common Stock.

Because of the numerous risks and uncertainties associated with research, development, and commercialization of pharmaceutical drugs, we are unable to estimate the exact amount of our working capital requirements. Our future funding requirements will depend on many factors, including:

- the number and characteristics of the drug candidates we pursue;
- the scope, progress, results, and costs of researching and developing our drug candidates, and conducting preclinical studies and clinical trials;
- the timing of, and the costs involved in, obtaining regulatory approvals for our drug candidates;
- the cost of manufacturing our drug candidates and any drugs we successfully commercialize;
- our ability to establish and maintain strategic collaborations, licensing or other arrangements and the financial terms of such agreements;
- the costs involved in preparing, filing, prosecuting, maintaining, defending, and enforcing patent claims, including litigation costs and the outcome of such litigation; and
- the timing, receipt and amount of sales of, or milestone payments related to or royalties on, our current or future drug candidates, if any.

To continue to grow our business over the longer term, we plan to commit substantial resources to research and development, clinical trials of our product candidates, and other operations and potential product acquisitions and in licensing. We have evaluated and expect to continue to evaluate a wide array of strategic transactions as part of our plan to acquire or in license and develop additional products and product candidates to augment our internal development pipeline. Strategic transaction opportunities that we may pursue could materially affect our liquidity and capital resources and may require us to incur additional indebtedness, seek equity capital or both. In addition, we may pursue development, acquisition or in licensing of approved or development products in new or existing therapeutic areas or continue the expansion of our existing operations. Accordingly, we expect to continue to opportunistically seek access to additional capital to license or acquire additional products, product candidates or companies to expand our operations, or for general corporate purposes. Strategic transactions may require us to raise additional capital through one or more public or private debt or equity financings or could be structured as a collaboration or partnering arrangement. We have no arrangements, agreements, or understandings in place at the present time to enter into any acquisition, in licensing or similar strategic business transaction.

Contractual Obligations and Commitments

We do not currently own or lease any office space.

We enter into contracts in the normal course of business with contract research organizations for clinical trials, preclinical research studies and testing, manufacturing and other services and products for operating purposes. These contracts generally provide for termination upon notice, and therefore we believe that our non-cancelable obligations under these agreements are not material.

JOBS Act Accounting Election

We are an emerging growth company, as defined in the Jumpstart Our Business Startups Act of 2012 (the “JOBS Act”). Under the JOBS Act, emerging growth companies can delay adopting new or revised accounting standards issued subsequent to the enactment of the JOBS Act until such time as those standards apply to private companies. We have irrevocably elected not to avail ourselves of this exemption from new or revised accounting standards and, therefore, will be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies.

Recent Accounting Pronouncements

See Item 1 of Part I, “Notes to Financial Statements — Note 2 — Summary of Significant Accounting Policies” for a discussion of recent accounting pronouncements.

ITEM 3: QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Not applicable.

ITEM 4: CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures as of September 30, 2024. The term “disclosure controls and procedures,” as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized, and reported, within the time periods specified in the SEC’s rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company’s management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

Based on the evaluation of our disclosure controls and procedures as of September 30, 2024, our Chief Executive Officer and Chief Financial Officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

Evaluation of Changes in Internal Control over Financial Reporting

There was no change in our internal control over financial reporting (as defined in Rule 13a-15(f) of the Exchange Act) that occurred during the period to which this report relates that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting. Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risks that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate. From time to time, we make changes to our internal control over financial reporting that are intended to enhance its effectiveness and which do not have a material effect on our overall internal control over financial reporting.

PART II – OTHER INFORMATION

ITEM 1: LEGAL PROCEEDINGS

None.

ITEM 1A: RISK FACTORS

Our operations and financial results are subject to various risks and uncertainties, including those described in Part I, Item 1A, “Risk Factors” in our Annual Report on Form 10-K for the year ended December 31, 2023, filed with the SEC on March 21, 2024. No material changes to such risk factors have occurred during the quarter ended September 30, 2024.

ITEM 2: UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS

None.

ITEM 3: DEFAULTS UPON SENIOR SECURITIES

None.

ITEM 4: MINE SAFETY DISCLOSURES

Not applicable.

ITEM 5: OTHER INFORMATION

(a) None.

(b) None.

(c) During the fiscal quarter ended September 30, 2024, no director or “officer” (as defined in Rule 16a-1(f) under the Exchange Act) of the Company adopted or terminated any “Rule 10b5-1 trading arrangement” or “non-Rule 10b5-1 trading arrangement,” as each term is defined in Item 408(c) of Regulation S-K.

ITEM 6: EXHIBITS

Exhibit No.	Description
4.1	Form of September 2024 PIPE Pre-Funded Warrant (incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed with the SEC on September 17, 2024).
4.2	Form of September 2024 PIPE Series A/Series B Warrant (incorporated by reference to Exhibit 4.2 to the Company's Current Report on Form 8-K filed with the SEC on September 17, 2024).
4.3	Form of September 2024 PIPE Placement Agent Warrant (incorporated by reference to Exhibit 4.3 to the Company's Current Report on Form 8-K filed with the SEC on September 17, 2024).
10.1	Form of September 2024 PIPE Securities Purchase Agreement (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the SEC on September 17, 2024).
10.2	Form of Registration Rights Agreement (incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed with the SEC on September 17, 2024).
31.1*	Certification of the Principal Executive Officer pursuant to Rule 13a-14(a) or Rule 15d-14(a).
31.2*	Certification of the Chief Financial Officer pursuant to Rule 13a-14(a) or Rule 15d-14(a).
32.1**	Certification of Principal Executive Officer and Principal Financial Officer pursuant to Rule 13a-14(b) or Rule 15d-14(b).
101.INS*	XBRL Instance Document - the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document
101.SCH*	Inline XBRL Taxonomy Extension Schema Document
101.CAL*	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF*	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB*	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE*	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibits 101)

* Filed herewith.

** Furnished, not filed.

† Indicates a management contract or compensation plan, contract or arrangement.

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.

Date: November 13, 2024

Dermata Therapeutics, Inc.

By: /s/ Gerald T. Proehl
Gerald T. Proehl
President and Chief Executive Officer
(Principal Executive Officer)

By: /s/ Kyri K. Van Hoose
Kyri K. Van Hoose
Senior Vice President, Chief Financial Officer
(Principal Financial Officer and Principal Accounting Officer)

**CERTIFICATION OF CHIEF EXECUTIVE OFFICER PURSUANT
TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, Gerald T. Proehl, certify that:

1. I have reviewed this quarterly report on Form 10-Q for the period ended September 30, 2024, of Dermata Therapeutics, 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 the 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 (the registrant's fourth fiscal quarter in the case of an annual report) 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(s) 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.

Date: November 13, 2024

/s/ Gerald T. Proehl
Gerald T. Proehl
Chief Executive Officer
(Principal Executive Officer)

**CERTIFICATION OF CHIEF FINANCIAL OFFICER PURSUANT
TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, Kyri K. Van Hoose, certify that:

1. I have reviewed this quarterly report on Form 10-Q for the quarter ended September 30, 2024, of Dermata Therapeutics, 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 the 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 (the registrant's fourth fiscal quarter in the case of an annual report) 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.

Date: November 13, 2024

/s/ Kyri K. Van Hoose
Kyri K. Van Hoose
Chief Financial Officer
(Principal Financial Officer)

**CERTIFICATION OF CHIEF EXECUTIVE OFFICER AND
CHIEF FINANCIAL OFFICER PURSUANT TO
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

This Certification is being filed pursuant to 18 U.S.C. Section 1350, as adopted by Section 906 of the Sarbanes-Oxley Act of 2002. This Certification is included solely for the purpose of complying with the provisions of Section 906 of the Sarbanes-Oxley Act and is not intended to be used for any other purpose. In connection with the accompanying Periodic Report on Form 10-Q of Dermata Therapeutics, Inc. (the "Company") for the quarter ended September 30, 2024 (the "Quarterly Report"), each of Gerald T. Proehl, as Chief Executive Officer, and Kyri K. Van Hoose, as Chief Financial Officer, certifies in his or her capacity as such officer of the Company, that to such officer's knowledge:

- 1) The Quarterly Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- 2) The information contained in the Quarterly Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: November 13, 2024

By: /s/ Gerald T. Proehl
Gerald T. Proehl
Chief Executive Officer
(Principal Executive Officer)

Dated: November 13, 2024

By: /s/ Kyri K. Van Hoose
Kyri K. Van Hoose
Chief Financial Officer
(Principal Financial Officer)

This certification shall not be deemed "filed" for any purpose, nor shall it be deemed to be incorporated by reference into any filing under the Securities Act of 1933 or the Exchange Act.