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, 2025

☐ **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	**86-3218736**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification Number)
3525 Del Mar Heights Rd., #322, San Diego, CA	**92130**
(Address of principal executive offices)	(Zip Code)

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

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

Title of each class	**Trading Symbol(s)**	**Name of each exchange on which registered**
Common Stock, par value $0.0001 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 1,026,457 shares of Common Stock, par value $0.0001, of Dermata Therapeutics, Inc. issued and outstanding as of November 12, 2025.

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PART I

ITEM 1: FINANCIAL STATEMENTS

DERMATA THERAPEUTICS, INC.
Balance Sheets

	September 30, 2025	December 31, 2024
	(unaudited)	
Assets:		
Cash and cash equivalents	$ 4,664,127	$ 3,161,570
Prepaid expenses and other current assets	407,283	372,318
Total assets	$ 5,071,410	$ 3,533,888
Liabilities and Stockholders' Equity:		
Liabilities:		
Accounts payable (including related party amounts of $185,300 and $0, respectively)	$ 453,427	$ 808,011
Accrued and other current liabilities (including related party amounts of $28,600 and $0, respectively)	657,881	1,164,783
Total liabilities	1,111,308	1,972,794
Commitments and Contingencies (see Note 6)		
Stockholders' Equity:		
Preferred Stock, par value $0.0001 per share, 10,000,000 shares authorized; no shares issued or outstanding as of September 30, 2025 and December 31, 2024	-	-
Common Stock, par value $0.0001 per share, 250,000,000 shares authorized; 844,457 shares issued and outstanding as of September 30, 2025; 251,725 shares issued and outstanding as of December 31, 2024	84	25
Additional paid-in capital	75,332,026	67,236,408
Accumulated deficit	(71,372,008)	(65,675,339)
Total stockholders' equity	3,960,102	1,561,094
Total liabilities and stockholders' equity	$ 5,071,410	$ 3,533,888

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

DERMATA THERAPEUTICS, INC.
Statements of Operations
(unaudited)

	For the three months ended September 30,		For the nine months ended September 30,	
	2025	**2024**	**2025**	**2024**
Operating expenses:				
Research and development	$ 504,387	$ 2,401,359	$ 2,403,363	$ 6,011,201
Selling, general and administrative (including related party amounts of $334,050, $0, $334,050, and $0, respectively)	1,256,284	824,294	3,469,842	3,301,753
Total operating expenses	1,760,671	3,225,653	5,873,205	9,312,954
Loss from operations	(1,760,671)	(3,225,653)	(5,873,205)	(9,312,954)
Other income and expenses:				
Interest income	68,682	52,497	176,536	176,431
Net loss	$ (1,691,989)	$ (3,173,156)	$ (5,696,669)	$ (9,136,523)
Net loss per share of Common Stock, basic and diluted	$ (1.65)	$ (20.41)	$ (6.64)	$ (102.18)
Weighted-average basic and diluted Common Stock	1,026,457	155,465	858,015	89,414

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

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

	Common Stock		Additional Paid-in	Accumulated	Total Stockholders'
	Shares	Par Value	Capital	Deficit	Equity
Balance at December 31, 2024	251,725	$ 25	$ 67,236,408	$ (65,675,339)	$ 1,561,094
Stock-based compensation	-	-	37,189	-	37,189
Issuance of Common Stock and warrants from January 2025 PIPE, net of issuance costs	193,539	19	2,254,702	-	2,254,721
Issuance of Common Stock upon exercise of pre-funded warrants	97,746	10	967	-	977
Issuance of Common Stock and warrants from March 2025 Warrant Inducement, net of issuance costs	60,200	6	5,750,822	-	5,750,828
Net loss	-	-	-	(2,303,587)	(2,303,587)
Balance at March 31, 2025	603,210	$ 60	$ 75,280,088	$ (67,978,926)	$ 7,301,222
Stock-based compensation	-	-	39,234	-	39,234
Issuance of abeyance shares	34,547	4	(4)	-	-
Issuance costs related to the March 2025 Warrant Inducement	-	-	(25,112)	-	(25,112)
Net loss	-	-	-	(1,701,093)	(1,701,093)
Balance at June 30, 2025	637,757	$ 64	$ 75,294,206	$ (69,680,019)	$ 5,614,251
Stock-based compensation	-	-	37,840	-	37,840
Issuance of abeyance shares	206,700	20	(20)	-	-
Net loss	-	-	-	(1,691,989)	(1,691,989)
Balance at September 30, 2025	844,457	$ 84	$ 75,332,026	$ (71,372,008)	$ 3,960,102

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

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

	Common Stock		Additional Paid-in	Accumulated	Total Stockholders'
	Shares	Par Value	Capital	Deficit	Equity
Balance at December 31, 2023	26,150	$ 3	$ 59,742,893	$ (53,387,878)	$ 6,355,018
Stock-based compensation	-	-	587,234	-	587,234
Issuance of abeyance shares	18,200	2	(2)	-	-
Net loss	-	-	-	(3,134,262)	(3,134,262)
Balance at March 31, 2024	44,350	$ 5	$ 60,330,125	$ (56,522,140)	$ 3,807,990
Stock-based compensation	-	-	19,608	-	19,608
Issuance of Common Stock upon exercise of warrants, net of issuance costs	24,933	2	2,320,461	-	2,320,463
Settlement of fractional shares paid in cash	(15)	-	(828)	-	(828)
Net loss	-	-	-	(2,829,106)	(2,829,106)
Balance at June 30, 2024	69,268	$ 7	$ 62,669,366	$ (59,351,246)	$ 3,318,127
Stock-based compensation	-	-	20,992	-	20,992
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	16,756	2	166	-	168
Issuance of Common Stock from ATM sales, net of issuance costs	55,001	5	1,482,054	-	1,482,059
Issuance of abeyance shares	26,700	3	(3)	-	-
Net loss	-	-	-	(3,173,156)	(3,173,156)
Balance at September 30, 2024	167,725	$ 17	$ 67,265,613	$ (62,524,402)	$ 4,741,228

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,	
	2025	**2024**
Cash flows from operating activities:		
Net loss	$ (5,696,669)	$ (9,136,523)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	114,263	627,834
Increase (decrease) in cash resulting from changes in:		
Prepaid expenses and other current assets	(34,965)	(3,095)
Accounts payable	(304,089)	(10,324)
Accrued and other current liabilities	(506,902)	272,774
Total adjustments to reconcile net loss to net cash used in operations	(731,693)	887,189
Net cash used in operating activities	(6,428,362)	(8,249,334)
Cash flows from financing activities:		
Proceeds from issuance of Common Stock and warrants, net of issuance costs	7,980,804	6,955,611
Payment of prior period issuance costs	(50,495)	-
Proceeds from exercise of pre-funded warrants	977	168
Payment for fractional shares in reverse stock split	(367)	(828)
Net cash provided by financing activities	7,930,919	6,954,951
Net increase (decrease) in cash and cash equivalents	1,502,557	(1,294,383)
Cash and cash equivalents at beginning of period	3,161,570	7,438,135
Cash and cash equivalents at end of period	$ 4,664,127	$ 6,143,752
Non-cash financing activities:		
Issuance of abeyance shares	$ (24)	$ (5)
Issuance costs in accounts payable or accrued expenses	-	$ 60,051
Supplemental disclosure:		
Cash paid for taxes	$ 950	$ 950

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

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 development stage biotechnology company focused on the treatment of medical and aesthetic skin conditions and diseases.

Reverse Stock Splits

On July 15, 2025, 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-two 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 August 1, 2025, the Company effected the reverse split of its shares of Common Stock at a ratio of 1-for-10, as approved by the Company's board of directors (the "2025 Reverse Stock Split"). The par value was not adjusted as a result of the 2025 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.

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, 2025, cash and cash equivalents totaled $4.7 million and the Company had an accumulated deficit of $71.4 million. For the nine months ended September 30, 2025, and the year ended December 31, 2024, the Company used cash of $6.4 million and approximately $11.1 million, respectively, in operations. The Company's cash and cash equivalents are expected to fund operations into the second quarter of 2026.

The Company anticipates that it will continue to incur net losses for at least the next twelve months from the date of this filing. While the Company plans to launch its first product candidate in mid-2026, it is uncertain when the Company will generate operating income to sustain operations. 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 use of cash has been for operations, and the Company expects that the principal uses of cash in the future will be for continuing operations, marketing and commercialization activities for current and future product candidates, funding of research and development, conducting preclinical studies and clinical trials, and general working capital requirements. The Company expects that as marketing expenses continue to grow, it will need to raise additional capital to sustain operations.

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, generating product revenue from sales of over the counter ("OTC") products, 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, tariffs, 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, 2024, filed with Securities and Exchange Commission (the "SEC") on March 17, 2025, 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, stock-based compensation, and equity instruments. 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.

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.

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. Additionally, the Company's warrants are equity classified and thereby Level 1 when determining fair value. See further discussion in Note 4 – Equity Securities.

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 selling, general and administrative expenses.

Research and Development Costs

Research and development costs are expensed in the period incurred. Research and development costs primarily consist of salaries and related expenses for personnel, stock-based compensation expense, external research and development costs incurred under agreements with contract research organizations, investigative sites and consultants to conduct clinical studies, costs related to compliance with regulatory requirements, costs related to manufacturing the Company's product candidates for clinical trials, and other allocated expenses.

Payments for research and development activities are based on the terms of the individual agreements, which may differ from the pattern of costs incurred, and payments made in advance of performance are reflected in the accompanying balance sheets as prepaid expenses. The Company records accruals for estimated costs incurred for ongoing research and development activities. When evaluating the adequacy of the accrued liabilities, the Company analyzes progress of the services, including the phase or completion of events, invoices received and contracted costs. The Company uses judgments and estimates to determine the prepaid or accrued balances at the end of any reporting period. Actual results could differ from the Company's estimates.

Selling, General and Administrative Costs

Selling, general and administrative costs are expensed in the period incurred. Selling, general and administrative costs primarily consist of marketing-related expenses, salaries and related expenses for personnel, including stock-based compensation, as well as legal fees incurred relating to corporate and patent matters, professional fees incurred for accounting, auditing, tax, and other consulting services, and insurance costs.

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.

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 ("FASB") 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 and whether the warrants meet all of the requirements for equity classification under ASC 815-40, 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,	
	2025	**2024**
Common Stock options outstanding	20,477	5,227
Common Stock warrants outstanding	1,238,949	506,822
Total potentially dilutive securities	1,259,426	512,049

Recent Accounting Pronouncements

For the nine months ended September 30, 2025, the Company has reviewed recent accounting standards and identified the following as relevant to the Company.

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 adopted ASU 2023-09 as of January 1, 2025; however, there was no impact 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, 2025	December 31, 2024
Prepaid expenses and other current assets:		
Prepaid insurance	$ 356,090	$ 349,824
Prepaid research and development costs	5,367	12,600
Prepaid other and other current assets	45,826	9,894
Total prepaid expenses and other current assets	$ 407,283	$ 372,318
Accrued and other current liabilities:		
Accrued research and development costs	$ 6,420	$ 295,392
Accrued compensation and benefits	594,144	731,632
Accrued other	57,317	137,759
Total accrued and other current liabilities	$ 657,881	$ 1,164,783

4. Equity Securities

A summary of the Company's equity securities as of September 30, 2025, is as follows:

Description	Authorized	Issued	Abeyance	Reserved	Outstanding
Common Stock, par value $0.0001	250,000,000	844,457	182,000	-	844,457
Preferred Stock	10,000,000	-	-	-	-
Warrants	-	1,238,949	-	-	1,238,949
2021 Omnibus Equity Incentive Plan	-	20,568	-	13	20,477
Total equity securities	260,000,000	2,103,974	182,000	13	2,103,883

Common Stock

On March 27, 2025, the Company entered into an inducement offer letter agreement (the "March 2025 Inducement Letter") with a holder (the "Holder") of certain of its existing warrants to purchase an aggregate of 483,447 shares of the Company's Common Stock. Such existing warrants were made up of (i) certain of the May 17, 2024 warrants (the "May 2024 Warrants"), which were issued in two separate series, having an exercise price of $49.10 per share, and (ii) the September 16, 2024 warrants, which were issued in two separate series, having an exercise price of $15.80 per share (the "September 2024 Warrants" and together with the May 2024 Warrants, the "Existing Warrants"). Pursuant to the March 2025 Inducement Letter, the Holder agreed to exercise for cash its Existing Warrants at a reduced exercise price of $12.84 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 Series A Warrants") to purchase up to 498,080 shares of Common Stock (the "New Series A Warrant Shares") and (ii) new Series B common stock purchase warrants (the "New Series B Warrants" and together with the New Series A Warrants, the "New Warrants") to purchase up to 468,813 shares of Common Stock (the "New Series B Warrant Shares" and together with the New Series A Warrant Shares, the "New Warrant Shares"). The New Warrants were exercisable subject to stockholder approval, which the Company received at a stockholder meeting on July 15, 2025. The Company received net proceeds of approximately $5.7 million from the exercise of the Existing Warrants by the Holder, after deducting financial advisor fees and other offering expenses payable by the Company. As of September 30, 2025, the Holder has received 301,447 Common Shares, with the balance of 182,000 shares held in abeyance, to be released to the Holder at the Holder's request.

On January 21, 2025, the Company closed a private placement (the "January 2025 PIPE") priced at the market under Nasdaq rules, in which it sold 193,539 shares of Common Stock, pre-funded warrants to purchase an aggregate of 7,246 shares of Common Stock with an exercise price of $0.01 per share ("January 2025 Pre-Funded Warrants"), and 200,785 warrants (the "January 2025 PIPE Warrants") to purchase up to an aggregate of 200,785 shares of Common Stock. The January 2025 PIPE Warrants have an exercise price of $12.70. Certain Company insiders, including the Company's Chief Executive Officer, Chief Financial Officer and certain members of the Company's board of directors, participated in the January 2025 PIPE. These Company insiders purchased an aggregate of 122,047 shares of Common Stock and January 2025 PIPE Warrants to purchase up to an aggregate of 122,047 shares of Common Stock, for an aggregate purchase price of approximately $1,550,000. The purchase price per share of Common Stock and accompanying January 2025 PIPE Warrant for these Company insiders was the same as paid by other investors in the January 2025 PIPE. The January 2025 Warrants were exercisable subject to stockholder approval, which the Company received at a stockholder meeting on July 15, 2025. In connection with the January 2025 PIPE, the Company entered into a registration rights agreement with the investors, pursuant to which the Company agreed to prepare and file a registration statement with the SEC registering the resale of the shares of Common Stock underlying the securities sold in the January 2025 PIPE financing. The Company filed a Form S-3 on January 30, 2025, which was declared effective by the SEC on February 5, 2025. The Company received net cash proceeds of approximately $2.2 million from the January 2025 PIPE after deducting underwriters' discounts and offering expenses of approximately $0.4 million. During the first quarter of 2025, all of the January 2025 Pre-Funded Warrants were exercised. As of September 30, 2025, no January 2025 Pre-Funded Warrants remained outstanding.

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 191,256 pre-funded warrants to purchase up to an aggregate of 191,256 shares of Common Stock with an exercise price of $0.01 per share (the "September 2024 Pre-Funded Warrants"), and 191,256 series A warrants (the "September 2024 PIPE Series A Common Warrants") to purchase up to an aggregate of 191,256 shares of Common Stock and 191,256 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 191,256 shares of Common Stock. The September 2024 PIPE Warrants have an exercise price of $15.80. 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 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. As of December 31, 2024, 90,500 September 2024 Pre-Funded Warrants remained outstanding, which were exercised during the first quarter of 2025. As of September 30, 2025, no 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 35,580 shares of Common Stock under the ATM Agreement resulting in gross proceeds of $1,157,248 before deducting issuance costs. After issuance of the 35,580 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 19,421 shares of Common Stock under the ATM Agreement resulting in additional gross proceeds of $504,894 before deducting issuance costs. During 2024, the Company issued a total of 55,001 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.

On November 7, 2025, the Company filed a prospectus supplement, pursuant to which the Company may offer and sell, from time to time through Sales Agent, shares of its Common Stock for aggregate proceeds of an additional $1,792,315 (upon the terms and subject to the conditions and limitations set forth in the ATM Agreement). As of the date of this filing, the Company has not sold any additional shares under the ATM Agreement.

On May 21, 2024, the Company closed on inducement agreements (the "May 2024 Inducement") with certain holders (the "May 2024 Holders") of certain of the Company's existing warrants to purchase up to an aggregate of 51,632 shares of the Company's Common Stock, issued to the May 2024 Holders on (i) May 26, 2023 (the "May 2023 Warrants"), having an exercise price of $324.00 per share, and (ii) November 20, 2023, which were issued in two separate series, each having an exercise price of $97.67 per share (together with the May 2023 Warrants, the "May 2024 Existing Warrants"). Pursuant to the May 2024 Inducement, the May 2024 Holders agreed to exercise for cash their May 2024 Existing Warrants at a reduced exercise price of $51.60 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 60,117 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 43,149 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 26,700 abeyance shares related to the May 2024 Warrant Inducement were released to the investor, leaving no further abeyance shares outstanding as of December 31, 2024.

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 issued or outstanding as of September 30, 2025, or December 31, 2024.

Warrants

Summary of Warrants Outstanding

The warrants outstanding as of September 30, 2025, are exercisable into 1,238,949 shares of Common Stock which had a fair value of $5.02 per share, based on the closing trading price on September 30, 2025. The aggregate intrinsic value of warrants outstanding as of September 30, 2025, 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, 2025, was zero.

	Quantity of Warrants Outstanding as of			
Description	**September 30, 2025**	**December 31, 2024**	**Exercise Price**	**Expiration Date**
Pre-IPO Series 1a Warrants	19	19	$ 49,200.00	11/15/2026
IPO Warrants	1,230	1,230	16,800.00	8/17/2026
IPO Underwriter Warrants	53	53	19,320.00	8/17/2026
March 2023 Offering Placement Agent Warrants	753	753	579.38	3/16/2028
May 2023 PIPE Placement Agent Warrants	371	371	428.45	5/23/2028
November 2023 Placement Agent Warrants	1,619	1,619	122.09	11/21/2028
May 2024 Series A Common Warrants	2,334	60,117	49.10	11/21/2029
May 2024 Series B Common Warrants	-	43,149	49.10	5/21/2026
May 2024 Placement Agent Warrants	3,613	3,613	64.50	11/21/2029
September 2024 PIPE Series A Common Warrants	-	191,256	15.80	3/18/2030
September 2024 PIPE Series B Common Warrants	-	191,256	15.80	3/17/2026
September 2024 PIPE Placement Agent Warrants	13,386	13,386	22.88	3/18/2030
January 2025 PIPE Warrants	200,785	-	12.70	7/15/2030
January 2025 PIPE Placement Agent Warrants	14,053	-	15.88	7/15/2030
March 2025 Warrant Inducement Series A Warrants	498,080	-	12.84	7/15/2030
March 2025 Warrant Inducement Series B Warrants	468,813	-	12.84	1/15/2027
March 2025 Warrant Inducement Placement Agent Warrants	33,840	-	16.05	7/15/2030
Total warrants outstanding	1,238,949	506,822		

Warrant Inducements

In March 2025, the Company entered into the March 2025 Inducement Letter with a Holder who agreed to exercise 483,447 warrants to purchase Common Stock at a reduced exercise price of $12.84 per share in exchange for 498,080 New Series A Warrants and 468,813 New Series B Warrants with an exercise price of $12.84 per share. The March 2025 Inducement Letter, which resulted in the lowering of the exercise price of the Existing Warrants and the issuance of the New Warrants, is considered a modification of the 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 Existing Warrants to cash exercise their warrants, which raised equity capital and generated net proceeds of approximately $5.7 million. As the Existing Warrants and the 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 $4.9 million as an equity issuance cost.

In May 2024, the Company completed the May 2024 Inducement with the May 2024 Holders who agreed to exercise 51,632 warrants to purchase Common Stock at a reduced exercise price of $51.60 per share in exchange for 60,117 New May 2024 Series A Warrants and 43,149 New May 2024 Series B Warrants with an exercise price of $49.10 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.

Placement Agent Warrants

The Company works with H.C. Wainwright & Co., LLC (the “Placement Agent”) to act as its investment bank for certain financing transactions. Per the terms of the Company’s engagement letter with the Placement Agent, the Placement Agent receives compensation in the form of fees and reimbursed expenses, as well as the issuance to the Placement Agent, or its designees, warrants to purchase Common Stock of the Company equal to 7.0% of aggregate number of Common Stock issued in a related to the financing at an exercise price equal to 125% of the financing price.

5. Equity Incentive Plan

Under the Company’s Omnibus Equity Incentive Plan (the “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 4,193 shares to 7,993 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 five percent evergreen provision resulted in an additional 12,588 shares of Common Stock issuable pursuant to the 2021 Plan as of January 1, 2025.

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, 2025, there remain 13 shares reserved for issuance under the 2021 Plan, as amended.

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, 2024	5,227	$ 58.72	9.3
Options granted	15,250	13.80	-
Options exercised	-	-	-
Options cancelled	-	-	-
Balance at September 30, 2025	20,477	$ 25.27	9.1
Options exercisable at September 30, 2025	6,235	$ 34.97	8.9

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, 674 of the 675 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, 2025, 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, 2025, which was $5.02 per share. The intrinsic value of options outstanding and exercisable as of September 30, 2025, was zero.

As of September 30, 2025, the 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 2.7 years.

Stock-based Compensation Expense

In general, stock-based compensation is allocated to research and development expense or selling, 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,	
	2025	2024	2025	2024
Research and development	$ 7,951	$ 4,677	$ 23,672	$ 246,637
Selling, general and administrative	29,889	16,315	90,591	381,197
Total	$ 37,840	$ 20,992	$ 114,263	$ 627,834

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 Company granted stock options in January 2025 and 2024. There were no stock option grants during the second or third quarters of 2025 or 2024. The following table presents the weighted-average assumptions used for stock options granted during the following periods:

	Nine Months Ended September 30,	
	2025	2024
Grant date fair value	$ 11.59	$ 91.50
Risk-free interest rate	4.65%	4.0%
Dividend yield	0.00%	0.00%
Expected life in years	5.9	5.9
Expected volatility	110%	110%

6. Commitments and Contingencies

Clinical Trials

In March 2025, the Company announced positive topline results for its XYNGARI™ Phase 3 STAR-1 clinical trial. The total contract amount with the clinical research organization was approximately $7.2 million, which extended from the fourth quarter of 2023 into the second quarter of 2025. During the nine months ended September 30, 2025, the Company recognized $0.7 million in research and development expense for the STAR-1 clinical trial. During the three and nine months ended September 30, 2024, the Company recognized $1.8 million and $4.2 million, respectively, in research and development expense for the STAR-1 clinical trial. The STAR-1 clinical trial was completed in the second quarter of 2025, and no further expenses are expected to be incurred.

Supplier Agreement

As a result of Russia's invasion of Ukraine, the United States has 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 product candidates. 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 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. Depending on the extent and breadth of new sanctions, export controls, or tariffs 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 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. ("Villani") 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 pharmaceutical 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 has agreed 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 agreed 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, 2025, 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, 2025. On November 10, 2025, the Company received a notice of material breach and demand for cure (the "Notice") from Villani alleging that the Company breached the License Agreement as a result of the Company's recent strategic shift to focus on over-the-counter pharmaceutical products. The Notice alleges that the Company (i) failed to use Commercially Reasonable Efforts (as defined in the License Agreement) to pursue a prescription product business, (ii) failed to provide Villani with advance notice of certain submissions to regulatory authorities, (iii) used Licensed Know-How (as defined in the License Agreement) outside of the Field (as defined in the License Agreement) and (iv) the Company's anticipated OTC kits do not qualify as Licensed Products (as defined in the License Agreement). On November 11, 2025, Villani delivered an additional notice to the Company (the "Additional Notice") whereby Villani requested (i) the reversion and assignment of all assets regarding *Spongilla*-based products back to Villani, (ii) that the Company preserve all *Spongilla* inventory, and (iii) the Company preserve all documents, data, and tangible materials related to *Spongilla*. The Company disputes the allegations contained in the Notice and the Additional Notice and is engaged in discussions with Villani to resolve such disputes. If the parties are unable to reach a resolution, then either party, pursuant to the License Agreement, may file for arbitration or termination of the License Agreement. To date, the License Agreement has not been terminated and continues in full force. At this point in time, the Company is unable to predict the final outcome of this dispute.

Collaboration Agreement

On January 17, 2025, the Company entered into a Clinical Trial Collaboration Agreement (the "Clinical Trial Agreement") with Revance Therapeutics, Inc. ("Revance"), pursuant to which the Company and Revance intend to conduct a multi-center clinical trial (the "Trial") to evaluate the topical application of XYNGARI™, the Company's topical Spongilla powder (formerly referred to as DMT310), with DAXXIFY® (daxibotulinumtoxinA-lanm), Revance's botulinum toxin type A. Pursuant to the terms of the Clinical Trial Agreement, Revance has granted the Company a non-exclusive, worldwide, non-transferable, royalty-free license, with a right to sublicense (subject to limitations), to use certain Revance intellectual property, solely as necessary or useful for the Company to conduct the trial under the Clinical Trial Agreement. The Company has granted Revance a similar license to use XYNGARI™ and other compound(s) under the Clinical Trial Agreement. The Clinical Trial Agreement will terminate upon completion of the Trial, the delivery of the data resulting from the Trial and the completion of any statistical analyses of the data resulting from the Trial. Either party may terminate the Clinical Trial Agreement upon a material breach by the other party that remains uncured following 30 days after the date of written notice of such breach. In addition, either party may terminate the Clinical Trial Agreement immediately upon written notice if such party reasonably deems it necessary in order to protect the safety, health or welfare of subjects enrolled in the Trial. The Company has agreed to sponsor, conduct, and fund the Phase 2a clinical trial; however, no activities have been initiated by either party. As of September 30, 2025, the Company has not incurred any expenses related to the Revance Clinical Trial Agreement.

Registration Rights Agreement

In connection with the January 2025 PIPE (see Note 4), the Company entered into a Registration Rights Agreement with the purchasers, dated as of January 21, 2025 (the "Registration Rights Agreement"). The Registration Rights Agreement provides that the Company shall file a registration statement covering the resale of all the registrable securities (as defined in the Registration Rights Agreement) with the SEC. The registration statement on Form S-3 required under the Registration Rights Agreement was filed with the SEC on January 30, 2025, and became effective on February 5, 2025.

Upon the occurrence of any Event (as defined in the Registration Rights Agreement), which, among others, prohibits the purchasers from reselling the securities for more than ten consecutive calendar days or more than an aggregate of fifteen calendar days during any 12-month period, and should the registration statement cease to remain continuously effective, the Company would be obligated to pay to each purchaser, on each monthly anniversary of each such Event, an amount in cash, as partial liquidated damages and not as a penalty, equal to the product of 2.0% multiplied by the aggregate subscription amount paid by such purchaser in the Private Placement, up to a maximum of 12% of the aggregate subscription amount. As of September 30, 2025, the Company determined that the likelihood of the Company incurring liquidated damages pursuant to the Registration Rights Agreement is remote, and as such, no accrual of these payments is required as of September 30, 2025.

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. 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 ("CODM"), 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 identifying, developing, and commercializing pharmaceutical products for the treatment of medical and aesthetic skin conditions and diseases.

The CODM, who is the Chief Executive Officer ("CEO"), President, and Chairman of the Board, manages and allocates resources to the operations of the Company on an entity-wide basis. The Company's measure of segment profit or loss is net loss. Managing and allocating resources on an entity-wide basis enables the CEO to assess the overall level of resources available and how to best deploy these resources across functions and research and development projects that are in line with the Company's long-term company-wide strategic goals. Consistent with this decision-making process, the CEO uses financial information for purposes of evaluating performance, forecasting future period financial results, allocating resources, and setting incentive targets. Operating expenses are used to monitor budget versus actual results. The CODM does not review assets in evaluating the results of the Company, and therefore, such information is not presented.

Given the Company's September 2025 strategic pivot to prioritize the development and distribution of OTC products, the segment information disclosure has been recast for all periods presented to reflect this change. The following table summarizes the segment's financial information including the Company's significant segment expenses:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2025	2024	2025	2024
Research and development				
Clinical	$ -	$ 1,920,092	$ 705,645	$ 4,359,819
Chemistry, manufacturing and controls	36,274	127,781	320,104	346,273
Personnel related	468,113	353,486	1,377,614	1,305,109
Total research and development	504,387	2,401,359	2,403,363	6,011,201
Selling, general and administrative				
Public company compliance	475,503	562,777	1,991,676	2,147,927
Marketing	472,940	-	472,940	-
Personnel related	307,841	261,517	1,005,226	1,153,826
Total selling, general and administrative	1,256,284	824,294	3,469,842	3,301,753
Interest income	68,682	52,497	176,536	176,431
Net loss	$ (1,691,989)	$ (3,173,156)	$ (5,696,669)	$ (9,136,523)

8. Related Party Transactions

In September 2025, the Company entered into a Master Services Agreement (the "MSA") with Wilder & Partners, LLC ("Wilder"), an agency that assists the Company in branding, marketing, and product design for the Company's first product launch, expected in mid-2026. The founding partner of Wilder is the CEO's son-in-law and as such, falls in accordance with the Company's Policy and Procedures for Related Party Transactions. Accordingly, the Board of Directors, inclusive of the Audit Committee, considered, reviewed, and unanimously approved the retention of Wilder as the branding agency, authorizing management to negotiate and execute an agreement on terms substantially consistent with the proposal reviewed. For the three and nine months ended September 30, 2025, the Company incurred approximately $0.5 million of marketing expenses related to Wilder, of which approximately $0.2 million was outstanding and included in accounts payable and other accrued expenses as of September 30, 2025.

In connection with the January 2025 PIPE financing, certain Company insiders, including the Company's CEO, Chief Financial Officer and certain members of the Company's board of directors, participated in the offering. These Company insiders purchased an aggregate of 122,047 shares of Common Stock and Warrants to purchase up to an aggregate of 122,047 shares of Common Stock, for an aggregate purchase price of $1.55 million. The purchase price per share and accompanying Warrant for these Company insiders was the same as paid by other investors in the January 2025 PIPE.

9. Subsequent Event

Subsequent to September 30, 2025, at the Holder's request, the Company delivered the remaining balance of 182,000 shares of Common Stock which were held in abeyance related to the March 2025 Warrant Inducement. Accordingly, no further shares are held in abeyance.

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;
- the expectation that any planned OTC formulation, dosage, combination, or indications fall inside the scope of an applicable OTC monograph, will not require a new drug application, and are otherwise not challenged by FDA, state boards, or other regulators, any of which could delay or prevent launch or require reformulation, relabeling, additional testing, or other corrective actions;
- the possibility that positive clinical data generated in the Rx setting are not predictive of consumer experience or commercial performance in the OTC context, and the limits such data may impose on the scope of permissible OTC claims;
- our ability to timely secure and scale manufacturing, packaging, and quality systems suitable for OTC commercialization, including meeting lot release, stability, shelf life, and container-closure requirements, and to manage product returns, recalls, or withdrawals if quality issues arise;
- our ability to successfully execute our strategic pivot from Rx to OTC, including our capacity to design, formulate, manufacture, package and distribute products that comply with applicable federal, state and international OTC requirements and standards, including FDA OTC monographs, current good manufacturing practices applicable to OTC products, labeling and Drug Facts requirements, and other enforcement policies;
- our ability to establish and maintain distribution and sales channels, including direct-to-consumer e-commerce, professional/clinic channels, and any retail partners, and to manage channel economics, chargebacks, returns, and working capital needs;

- 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 not yet available for commercial sale;
- our ability to acquire sufficient quantities of raw material needed to manufacture our product candidates;
- our, or that of our third-party manufacturers, ability to manufacture cGMP quantities of our product candidates as required for clinical trials and, subsequently, our ability to manufacture commercial quantities of our product candidates for commercial sale;
- our lack of a sales and marketing organization and our ability to effectively commercialize our product candidates, including in connection with our recent pivot to the OTC market;
- our dependence on third parties to manufacture our product candidates;
- 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;
- impacts of increased trade tariffs, import quotas or other trade restrictions or measures taken by the United States and other countries, including the recent and potential changes in U.S. trade policies that have been and may be made by the Trump presidential administration;
- acceptance of our business model by investors;
- the accuracy of our estimates regarding expenses and capital requirements;
- the accuracy of our estimate forecast for future commercial sales of our product candidates;
- 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 scientific leader in dermatology dedicated to the development and commercialization of products that address common and underserved skin conditions. In March 2025, we announced that we achieved statistically significant results from our Phase 3 STAR-1 clinical trial of XYNGARI™, formerly our lead prescription ("Rx") candidate incorporating our *Spongilla* technology for moderate-to-severe acne. XYNGARI™ demonstrated statistically significant results across all three co-primary endpoints at weeks 4, 8, and 12 when compared with placebo. Following the successful completion of the STAR-1 trial, we conducted a full assessment of the Rx landscape and the continued Rx development pathway for XYNGARI™. In September 2025, after an extensive review of current trends in dermatology, changing patient preferences, and go-to market costs, management, with support from the our board of directors, determined that a strategic shift to developing and distributing OTC pharmaceutical dermatology products that are backed by science would be a better path to commercialization with potentially greater financial upside. We believe we can leverage the data generated with our *Spongilla* technology to create OTC pharmaceutical products that are effective and that patients want to use. This repositioning should accelerate our path to commercialization, reduce our regulatory burden, and decrease company expenses, all while being able to address broader consumer segments in the dermatology space.

We believe the dermatology market, from both an OTC and Rx perspective, has seen a substantial shift over the last few years, with an increasing trend of consumers first relying on OTC treatments for common dermatological diseases and conditions such as acne vulgaris (or "acne"), psoriasis vulgaris (or "psoriasis"), and acne rosacea (or "rosacea"), among others. Common dermatology issues, like acne with over 50 million patients in the U.S., are well known by patients with extensive publicly available information and thus patients are more willing to treat these diseases with OTC offerings prior to seeing a dermatologist. Over 70% of patients with acne first choose to try OTC products and wait at least one year before scheduling a visit with a dermatologist. Additionally, due to the lower price point for OTC products, a desire for self-administration, difficulty getting appointments with dermatologists, and enhanced convenience, many consumers are first relying on OTC products to fill their treatment needs. We believe that we can apply the clinical knowledge we've gained over the last ten years to design products that incorporate OTC pharmaceutical ingredients with our *Spongilla* technology to offer patients easy access to affordable and effective OTC treatments for acne, psoriasis, seborrheic dermatitis and other skin diseases and conditions. While this is a major shift in strategy for our company, we believe it is the best path forward to meet our mission of providing patients with efficacious and safe treatment options.

We are currently working with a branding agency to build a new brand identity for our OTC treatments, that represents our core values of providing patients skin care products that are natural but scientifically proven to work. We believe this new brand identity will bridge the gap between Rx therapies and OTC pharmaceutical products, allowing patients to take control of their skin care needs and feel confident about the treatment outcomes of the products we plan to offer. As part of this new brand identity, we will be developing visual and verbal identities that bring to life the core essence of the new brand, which incorporates scientifically backed technology that targets the underlying causes of skin diseases with a consumer-friendly approach. We want customers to experience the efficacy and safety we saw in our previous clinical studies and to feel proud of their skin after using our products. We plan to develop and distribute a variety of OTC products that are backed by science but are easily accessible by patients who are more comfortable treating their skin problems independently with readily available OTC therapies. Our core values will remain unchanged during this strategic shift as we strive to provide patients with affordable, safe, and effective treatment options, but now they can directly order our products rather than having to see a physician to be prescribed treatment. We believe patients are seeking greater flexibility and freedom in treating their skin as a majority of patients first turn to OTC products before seeing a dermatologist. With the continued regulatory oversight of the OTC marketplace, patients should maintain confidence in the OTC therapies they can purchase without a prescription.

We view this shift in consumer preferences as a significant benefit for the research we have completed to date. Over the past several years we have gained substantial knowledge of various dermatology diseases and what seems to work in treating these diseases. We plan to leverage this knowledge in creating a whole product line of skin care treatments that patients can access directly. We plan to launch our first product in the middle of 2026 which will consist of a once-weekly, topical acne kit that can be used by patients with mild, moderate, or severe acne. We have gained tremendous understanding of our *Spongilla* technology over the past 8 years and deeply understand the benefits of it being combined with OTC monograph active ingredients 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 fine, purified powder and mixed with a fluidizing agent immediately prior to application by the patient. *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 our *Spongilla* technology 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 an ingredient that optimizes the mechanical components as well as the organic components, while eliminating any harmful bacteria that could be found in a freshwater sponge. We believe these unique components used in tandem with an OTC monograph active ingredient could produce a superior OTC product candidate unlike anything currently on the market. We plan for our product candidates to have multiple mechanisms of action for the treatment of skin diseases and conditions.

Prior to our strategic switch to develop and distribute OTC pharmaceutical products, our U.S. Food and Drug Administration ("FDA") investigational new drug applicant, XYNGARI™, was intended to utilize our *Spongilla* technology as a stand-alone product for the once weekly treatment of a variety of skin diseases, with our initial focus being the treatment of moderate to severe acne. In March 2025, we announced that our XYNGARI™ Phase 3 **S**pongilla **T**reatment of **A**cne **R**esearch ("STAR-1") trial topline data met all co-primary endpoints at week 12. XYNGARI™ demonstrated highly statistically significant difference compared with placebo for all primary endpoints after 12 weeks of once weekly treatments. XYNGARI™ patients saw a rapid and sustained therapeutics treatment effect in absolute reduction in inflammatory lesion counts with a -11.4 lesion reduction at week four, -14.7 lesion reduction at week 8, and -16.8 lesion reduction at week 12 compared to -8.6, -10.9, and -13.1 lesion reduction for placebo at weeks 4, 8, and 12, respectively. XYNGARI™ patients also saw a rapid and sustained therapeutics treatment effect in absolute reduction in noninflammatory lesion counts with a -12.4 lesion reduction at week four, -15 lesions reduction at week 8, and -17.3 lesion reduction at week 12 compared to -8.8, -10.4, and -12.4 lesion reduction for placebo at weeks 4, 8, and 12, respectively. Lastly, we observed a sustained therapeutics treatment effect as measured in the investigator's global assessment (IGA) of acne scale. IGA is measured on a 5-point scale (0-4), with 4 being severe, 3 being moderate, 2 being mild, 1 being almost clear and 0 being clear. To be considered a responder, patients had to achieve a score of 0 (clear) or 1 (almost clear). There were 11.9% of XYNGARI™ patients that were considered a responder at week four, 21.6% of XYNGARI™ patients being considered a responder at week 8, and 29.4% of XYNGARI™ patients being considered a responder at week 12 compared to 6.2%, 8.0%, and 15.2% of placebo patients being considered a responder at weeks 4, 8, and 12, respectively. In fact, approximately 80% of the XYNGARI™ patients had at least a 1-grade change in their acne at the end of the study. The Phase 3 STAR-1 trial was double-blind, randomized, placebo controlled, and enrolled 520 patients with moderate-to-severe acne, age 9 years or older across sites in the United States and Latin America. The co-primary endpoints included absolute reduction in inflammatory and noninflammatory lesion counts and the improvement in investigators global assessment ("IGA") of acne. Patients were treated once a week for 12 weeks with either XYNGARI™ or placebo and were evaluated monthly. While we saw positive results from the STAR-1 study, after evaluating the prescription dermatology market and regulatory hurdles for approval, we made the strategic decision to withdraw our investigational new drug application ("IND") for XYNGARI™ for the treatment of acne. We believe this strategic decision will provide us greater flexibility to leverage the many novel features and benefits of our *Spongilla* technology in a variety of skin care products for the OTC marketplace.

We are currently finalizing the components and container closure for our initial acne kit, as well as completing the brand identity, with an expected launch in the middle of 2026. The acne kit will be a topical product applied once weekly by patients at home or in a dermatology or esthetician's office. The product will utilize one active ingredient from FDA's OTC acne monograph, which consist of OTC drugs that are generally recognized by FDA as safe and effective, in predefined doses, for specific therapeutic categories. These OTC active ingredients can be used alone or in combination with other ingredients and marketed as a treatment for various skin diseases or conditions, like acne. For our initial acne kit we plan on incorporating salicylic acid as the active ingredient in combination with our unique *Spongilla* technology to distribute a novel acne treatment kit we believe is unlike anything currently on the market. Based on years of testing we have learned that our Spongilla technology has a unique combination of mechanical components and chemical components, that provide unique benefits against various skin conditions. 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* are the bacteria that cause inflammatory lesions in acne patients). The spicules also cause turnover of the top layer of dead skin, thereby increasing collagen production resulting in skin rejuvenation. Additionally, we believe the newly created microchannels provide a conduit for *Spongilla* powder's naturally occurring chemical compounds to be delivered to the dermis and pilosebaceous glands, helping to kill the *C. acnes* and reduce inflammation. In addition to anti-microbial compounds, the *Spongilla* powder also appears to have anti-inflammatory chemical compounds, as demonstrated during *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 *Spongilla* powder'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. We believe the combination of an FDA approved OTC active ingredient with the multiple biological and mechanical effects of our *Spongilla* technology could be important factors in treating multiple inflammatory skin diseases.

On January 17, 2025, we entered into a Clinical Trial Collaboration Agreement (the "Collaboration Agreement") with Revance Therapeutics, Inc. ("Revance") where we intended to conduct a Phase 2a clinical trial to evaluate the topical application of XYNGARI™ followed by the topical application of DAXXIFY® for the treatment of primary axillary hyperhidrosis. In light of our recent strategic shift to develop and distribute OTC pharmaceutical products, we plan to continue to discuss future opportunities for this collaboration with Revance. At this time, the initiation of the Phase 2a clinical trial has been placed on hold. We still believe there is a potential to utilize our *Spongilla* technology for the topical delivery of botulinum toxin, but with our strategic decision to withdraw the XYNGARI™ IND, we are currently evaluating the regulatory and commercial opportunities for this program.

While the initiation of the Phase 2a clinical study is on hold, we continue to evaluate alternative ways to leverage our *Spongilla* technology as a novel platform to enhance the topical delivery of large-molecules, like botulinum toxin, as a needle-free alternative to conventional intradermal injection of large molecules for medical and aesthetic skin conditions. Typically, for facial aesthetics, botulinum toxins are injected into facial muscles to reduce forehead, lateral canthal, and glabella deep lines. While currently only approved for the treatment of axillary hyperhidrosis, intradermal injections of botulinum toxin primarily affect neuromodulatory at the level of cutaneous nerves, sweat glands, and superficial muscle fibers, not via deep muscular paralysis as with intramuscular injections. However, there have been many studies conducted with intradermal injections of botulinum toxin for various aesthetic and medical skin conditions, showing its broad potential application. This is because the mechanism of action of botulinum toxin in the dermis acts to block acetylcholine release from the presynaptic nerve terminals. The primary effects are 1) reduced cholinergic activity (eccrine glands reduce sweating, sebaceous glands reduce sebum production, arrector pili and superficial muscle fibers reduce fine wrinkling resulting in smoother skin), 2) modulation of sensory nerves leading to a reduction in neurogenic inflammation, itching, and erythema (redness), and 3) indirect skin-tightening due to mild reduction of superficial muscle tone and possible microvascular effects. Intradermal injections of botulinum toxin have also shown cosmetic effects, including skin smoothing through reducing pore size, reducing fine lines, and a mild lifting effect from dermal tightening and reducing oil and sweat reduction. However, due to the difficulty, pain, and time-consuming nature of intradermal injections, there still remains few approved or widely practiced treatment options.

We believe our *Spongilla* technology can increase the number of intradermal uses for botulinum toxin by leveraging the unique microstructure of our *Spongilla* technology, to create microchannels into the dermis, enabling improved dermal penetration of botulinum toxins (i.e. Botox®). Using our microstructures to create microchannels into the dermis avoids the need to give multiple intradermal injections, which can be painful for patients and very time consuming for the dermatologist or esthetician. Additionally, our technology can allow for broad coverage of larger surface areas of the skin, which we believe will provide a better field effect of the botulinum toxin

We plan to leverage this platform for broad applicability across dermatologic and aesthetic skin conditions, potentially allowing dermatologists and estheticians to increase uses for the intradermal delivery of botulinum toxin. We believe this non-invasive approach could meaningfully expand the therapeutic and aesthetic utility of botulinum toxin for conditions such as axillary, palmar and plantar hyperhidrosis, acne, acne scars, rosacea, and improved skin aesthetics (including improvements in skin luminosity and brightness, reducing pore size and number of pores, reducing fine lines, and reducing skin oiliness by decreasing sebum production). Our initial clinical proof-of-concept studies using our *Spongilla* technology have demonstrated the ability to deliver botulinum toxin into the dermis for improvement in facial aesthetics and reduction in sweat production in patients with primary axillary hyperhidrosis. We plan to continue to explore additional uses for this platform and look forward to getting our technology in the hands of estheticians and dermatologists so they may better serve their patients.

We have a limited operating history. Since our inception, our operations have focused on developing XYNGARI™ and DMT410, our topical botulinum toxin program, 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 $77.5 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 $5.7 million and $9.1 million for the nine months ended September 30, 2025, and 2024, respectively. As of September 30, 2025, we had an accumulated deficit of $71.4 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 future activities, as we:

- develop OTC pharmaceutical kits for the treatment of acne;
- prepare for commercial launch of OTC pharmaceutical kits for the treatment of acne, including hiring additional marketing personnel;
- continue development of DMT410 for the treatment of aesthetic and medical skin conditions, including proof of concept clinical trials;
- manufacture our product candidates for 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.

OTC Pharmaceutical Requirements

We plan to develop and distribute OTC pharmaceutical products, such as topical acne products, that are subject to FDA and foreign regulation. Under the U.S. OTC monograph system, OTC pharmaceutical products that meet established conditions are generally recognized as safe and effective and do not require the submission and approval of a new drug application. The FDA OTC monographs include well-known ingredients and specify requirements for permitted indications, required warnings and precautions, allowable combinations of ingredients and dosage levels. Pharmaceutical products marketed under the OTC monograph system must conform to specific quality, formula, and labeling requirements. Following the passage of the CARES Act, FDA is updating and working to finalize current monographs.

All facilities where OTC pharmaceutical products are manufactured, tested, packaged, stored or distributed must comply with current Good Manufacturing Practices ("cGMP") regulations and/or regulations promulgated by competent authorities in the countries where the facilities are located. All of our pharmaceutical products are manufactured, tested, packaged, stored and distributed according to cGMP regulations. The FDA performs periodic audits to ensure that our facilities remain in compliance with all appropriate regulations. The failure of a facility to be in compliance may lead to a breach of representations made to customers or to regulatory action against us related to the products made in that facility, such as seizure, injunction or recall. Serious product quality concerns could also result in governmental actions against us that, among other things, could result in the suspension of production or distribution of our products, product seizures, loss of certain licenses or other governmental penalties, and could have a material adverse effect on our financial condition or operating results. We are required to report serious adverse events associated with the use of our OTC pharmaceutical products marketed in the U.S. and other countries where such products are sold.

We cannot predict whether new legislation regulating our activities will be enacted or what effect any legislation would have on our business.

OTC Pharmaceutical Pre- and Post-market Regulation

Before and after an OTC pharmaceutical product is commercialized, numerous regulatory requirements apply, including:

- international quality system regulations, including those of the FDA and other regulatory authorities, impose cGMP requirements governing the methods used in, and the facilities and controls used for, the design, manufacture, packaging, servicing, labeling, storage, installation, and distribution of all finished OTC pharmaceuticals intended for human use;

- global standards and regulations affecting product design and development, including requirements to keep existing products current to the "state of the art," and doing an ongoing assessment of the risk acceptability, adopting risk control measures where appropriate, and re-assessing the clinical benefit;

- labeling regulations, including a prohibition on product promotion for unapproved or "off label" uses;

- the drug reporting regulation requiring a manufacturer to report to the regulatory authorities if its drug may have caused or contributed to a death or serious injury in a way that would likely cause or contribute to a death or serious injury if it were to recur and ongoing post-market surveillance of the product and like-products to continuously evaluate the benefit/risk over the life of the product; and

- regulations on corrections and removals which require a manufacturer to report recalls and field actions to the regulatory authorities if initiated to reduce a risk to health posed by the device or to remedy a violation of the applicable laws.

Recent Developments

On July 15, 2025, we held our annual meeting of stockholders at which time our stockholders approved the adoption of an amendment to our 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-two to one-for-thirty, with the exact ratio determined by our board of directors without further approval or authorization of its stockholders. On August 1, 2025, we effected the reverse split of our shares of Common Stock at a ratio of 1-for-10, as approved by our board of directors, with no adjustment to par value. All issued and outstanding shares of Common Stock and per share amounts contained in our financial statements have been retroactively adjusted to reflect this reverse stock split for all periods presented.

On September 10, 2025, we announced a strategic pivot to shift our focus to developing and distributing OTC pharmaceutical products for the dermatology market. We plan to focus on developing and launching multiple products that can be sold directly to consumers to treat their various skin diseases and conditions. We believe this strategic shift, through leveraging the FDA's OTC monograph pathway, could accelerate our ability to launch a commercial dermatology product, reduce our regulatory burden, and give us access to a broader consumer market. We are currently working with a branding agency to develop the commercial launch strategy while also beginning the manufacturing process for our initial product launch, which we expect to occur in the middle of 2026.

ATM Agreement

In June 2024, we entered into the ATM Agreement with H.C. Wainwright & Co., LLC , as Sales Agent, pursuant to which we may offer and sell, from time to time through Sales Agent, 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 2024, we sold 55,001 shares of Common Stock under the ATM Agreement, for net proceeds of $1.4 million after deducting $0.2 million of compensation to Sales Agent and other administration fees. During the nine months ended September 30, 2025, we sold no shares of Common Stock under the ATM Agreement.

On November 7, 2025, we filed a prospectus supplement, pursuant to which we may offer and sell, from time to time through Sales Agent, shares of our Common Stock for aggregate proceeds of an additional $1,792,315 (upon the terms and subject to the conditions and limitations set forth in the ATM Agreement). As of the date of this filing, we have not sold any additional shares under the ATM Agreement.

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 GAAP. 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

To date, our research and development expenses have been related to the clinical development and manufacturing costs of our product candidates. Research and development expenses include salaries and related expenses for personnel, including stock-based compensation, as well as external party costs for clinical, nonclinical, and manufacturing of our product candidates. Research and development expenses are recognized as incurred and payments made prior to the receipt of goods or services to be used in research and development are capitalized until the goods or services are received. Research and development estimates will be subject to change as additional information becomes available.

In March 2025, we announced topline results from our Phase 3 STAR-1 clinical trial and we completed the trial in the second quarter of 2025. We expect that research and development costs will decrease in fiscal year 2026 as we will no longer conduct FDA-regulated clinical trials under IND for NDA, and the cost of manufacturing OTC products is significantly less than manufacturing FDA-regulated products.

Selling, General and Administrative Costs

Selling, general and administrative expenses consist primarily of salaries, benefits, stock-based compensation for personnel in executive, finance, business development, marketing and other corporate administrative functions. Selling, general and administrative expenses also include pre-commercial launch activities prior to product launch, including marketing expenses, legal fees incurred relating to corporate and patent matters, professional fees incurred for accounting, auditing, tax and administrative consulting services, and insurance costs.

We expect our selling, general and administrative expenses to increase in 2026. The increase in expenses is due to our planned launch of our first product candidate in mid-2026, including the development and commencement of our marketing campaigns and initiatives, the hiring of marketing personnel and engagement of consultants to support full commercialization activities, and the addition of programs to support commercialization activities.

We expect to continue to incur audit, legal, regulatory and tax-related services associated with maintaining compliance with exchange listing and SEC requirements, director and officer insurance premiums, board of director fees, investor relations costs associated with operating as a public company, patent costs and defense, and general and administrative personnel.

Warrants

We perform 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 ("FASB") 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 and whether the warrants meet all of the requirements for equity classification under ASC 815-40, including whether the warrants are indexed in our 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. We have performed an assessment of all warrants issued and modified and determined that our warrants are equity classified.

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 and commercialization 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, 2025, and 2024

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

	Three Months Ended September 30,		
	2025	**2024**	**Difference**
Operating expenses:			
Research and development	$ 504,387	$ 2,401,359	$ (1,896,972)
Selling, general and administrative	1,256,284	824,294	431,990
Total operating expenses	1,760,671	3,225,653	(1,464,982)
Losses from operations	(1,760,671)	(3,225,653)	1,464,982
Other income and expenses:			
Interest income, net	68,682	52,497	16,185
Net loss	$ (1,691,989)	$ (3,173,156)	$ 1,481,167

Research and Development Expenses

Research and development expenses decreased by $1.9 million from $2.4 million for the three months ended September 30, 2024, to $0.5 million for the three months ended September 30, 2025. The decrease in research and development expenses resulted from $1.9 million of decreased clinical expenses from the XYNGARI™ STAR-1 acne study, which completed enrollment during the fourth quarter of 2024 and completed expenses during the second quarter of 2025.

Selling, General and Administrative Expenses

Selling, general and administrative expenses increased by $0.4 million from $0.8 million for the three months ended September 30, 2024, to $1.3 million for the three months ended September 30, 2025. The increase in selling, general and administrative expense was the result of $0.5 million of increased marketing expenses, as we are preparing for our first product launch in mid-2026, partially offset by $0.1 million of decreased audit fees.

Nine Months Ended September 30, 2025, and 2024

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

	Nine Months Ended September 30,		
	2025	**2024**	**Difference**
Operating expenses:			
Research and development	$ 2,403,363	$ 6,011,201	$ (3,607,838)
Selling, general and administrative	3,469,842	3,301,753	168,089
Total operating expenses	5,873,205	9,312,954	(3,439,749)
Loss from operations	(5,873,205)	(9,312,954)	3,439,749
Other income and expenses:			
Interest expense, net	176,536	176,431	105
Net loss	$ (5,696,669)	$ (9,136,523)	$ 3,439,854

Research and Development Expenses

Research and development expenses decreased by $3.6 million from $6.0 million for the nine months ended September 30, 2024, to $2.4 million for the nine months ended September 30, 2025. The decrease in research and development expenses resulted from approximately $3.6 million of decreased clinical expenses from the XYNGARI™ STAR-1 acne study, which completed enrollment during the fourth quarter of 2024.

Selling, General and Administrative Expenses

Selling, general and administrative expenses increased by approximately $0.2 million from $3.3 million for the nine months ended September 30, 2024, to approximately $3.5 million for the nine months ended September 30, 2025. The increase in selling, general and administrative expense was the result of $0.5 million of increased marketing expenses partially offset by $0.3 million of decreased audit fees. We expect marketing expenses to increase as we are preparing for our first product launch in mid-2026.

Cash Flows

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

	Nine Months Ended September 30,	
	2025	**2024**
Statements of cash flows data:		
Total net cash provided by (used in):		
Operating activities	$ (6,428,362)	$ (8,249,334)
Financing activities	$ 7,930,919	$ 6,954,951
Increase (decrease) in cash and cash equivalents	$ 1,502,557	$ (1,294,383)

Operating activities

Cash used in operations of $6.4 million for the nine months ended September 30, 2025, was the result of the net loss of $5.7 million and decreases in accounts payable and accrued expenses and other current liabilities of $0.8 million, partially offset by non-cash stock-based compensation of $0.1 million.

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.

Financing activities

Cash provided by financing activities of $7.9 million for the nine months ended September 30, 2025, was primarily the result of the January 2025 PIPE financing which raised net proceeds of approximately $2.2 million, and the March 2025 Inducement financing which raised net proceeds of $5.7 million.

Cash provided by financing activities of approximately $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 $1.4 million during the third quarter of 2024, and the May 2024 warrant inducement financing which raised net proceeds of $2.3 million.

Liquidity and Capital Resources

Since our inception, we have incurred net losses and have not generated any revenue. As of September 30, 2025, our cash and cash equivalents totaled $4.7 million, and we had an accumulated deficit of $71.4 million. For the nine months ended September 30, 2025, and the year ended December 31, 2024, we used cash of $6.4 million and approximately $11.1 million, respectively, in operations. We expect our cash resources to fund operations into the second quarter of 2026. We anticipate that we will continue to incur net losses for the foreseeable future, or until product candidate revenues exceed operating expenses, which timing is uncertain at this time.

Historically, our principal sources of cash have included proceeds from the issuance of equity and proceeds from the issuance of debt. Our principal use of cash has been cash used in operations. Our projected principal uses of cash for the next 12 months are the following expected activities related to our OTC product launch, which is expected in mid-2026:

- product formulation optimization, bench testing, and small-scale manufacturing runs;
- packaging development, consumer product testing, brand development, and marketing activities in preparation for commercial launch;
- ongoing research and development related to additional OTC product launches; and
- general working capital requirements.

We expect that selling, general and administrative expenses, including marketing, will continue to grow, and therefore, we will need to raise additional capital to sustain operations until we can generate operating income.

Funding Requirements

We are focused on preparing for the launch of our first commercial OTC product, a monthly kit containing four weekly acne treatments, which is planned for mid-2026, based on our current operating plan and anticipated expenditures associated with formulation and pre-commercial activities. We anticipate we will incur net losses for the next several years until we can generate sufficient operating income from our OTC products. Our primary uses of capital are, and we expect will continue to be, compensation and related expenses, marketing, external manufacturing, legal and other regulatory expenses, and administrative and overhead costs. Our future funding requirements will be heavily determined by the potential income generated from revenues related to our OTC product candidates. In addition, we may seek opportunities to identify, acquire or in license and develop additional drug candidates, potentially build commercial capabilities, and expand our corporate infrastructure.

We believe that our existing cash and cash equivalents will be sufficient to fund our operating expenses into the second quarter of 2026. We have based this estimate of cash runway on assumptions that may prove to be wrong, and we could deplete 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.

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.

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.

Our future funding requirements will depend on many factors, including:

- the number and characteristics of the product candidates we pursue;
- the scope, progress, results, and costs of researching and developing our product candidates, and conducting any clinical trials;
- the timing of, and the costs involved in, obtaining regulatory approvals for our product candidates;
- the cost of manufacturing our product candidates and any candidates 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;
- the timing, receipt and amount of sales of, or milestone payments related to or royalties on, our current or future drug candidates, if any;
- revenues derived from the sale of our OTC products, if any;
- pace and cost of product formulation and validation of our OTC acne product;
- timing and scale of commercial launch activities, including digital and retail distribution partnerships;
- cost of manufacturing scale-up and establishing compliant supply chains; and
- extent of marketing and consumer acquisition spending required to gain initial market traction.

To continue to grow our business over the longer term, we plan to commit substantial resources to marketing our first OTC product. Additionally, 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 research studies and stability testing, contract manufacturing organizations for manufacturing and other services, agencies for branding, marketing, and product design for our first product launch, expected in mid-2026, and others 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, 2025. 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, 2025, 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, 2024, filed with the SEC on March 17, 2025. No material changes to such risk factors have occurred during the nine months ended September 30, 2025, except as described below.

Risk Related to Our Transition from the Prescription ("Rx") Regulatory Framework to OTC Pathways

Our shift from an Rx regulatory framework to OTC monograph pathways could introduce significant regulatory risks that could delay or prevent product launches, require reformulation or relabeling, restrict indications or target populations, and materially increase costs.

Unlike prescription drugs, OTC products must be shown to be safe and effective for consumer self-selection and self-use without a healthcare professional's supervision. For products marketed under the OTC monograph system (implemented through FDA administrative orders), our products must meet all applicable conditions for "generally recognized as safe and effective" ("GRASE"), including specific active ingredients, indications, strengths, dosage forms, dosing intervals, age ranges, warnings, and Drug Facts Labeling. If any aspect of our product(s)—such as an active ingredient, indication, combination of actives, strength, dosage form, route of administration, dosing directions, or age range—falls outside the applicable monograph conditions, we may be required to reformulate, relabel, narrow the intended population or indications, or submit a request for an amended administrative order supported by additional data. FDA may decline to modify the relevant administrative order, require more data than we anticipate, or take longer than expected to act on a request, any of which could delay launches or prevent us from marketing the product as designed. Evolving FDA orders or compliance sweeps, including changes to impurity limits (such as nitrosamines), new contraindications or age restrictions, or additional warnings, can also emerge late in development and force unplanned reformulation, relabeling, or withdrawal—resulting in write-offs of packaging or finished goods, extensions of stability programs, and missed commercialization timelines.

While we were pursuing XYNGARI as a prospective candidate for approval under the FDA New Drug Application process, we have since withdrawn the investigational new drug application for XYNGARI and no longer consider it an investigational product. While we believe that our prospective OTC acne kit is distinct from XYNGARI and will comply with the applicable OTC monograph, a form of our Spongilla technology and H_2O_2 will be included as inactive ingredients in our OTC acne kit with no therapeutic claims. If the FDA determines that either or both substances are active ingredients in our OTC acne kit, our OTC acne kit will not fit within the OTC monograph and we could have to reformulate the kit or could be subject to enforcement action for marketing an unapproved new drug, which could result in consequences, including, but not limited to, a warning letter, product seizure, and/or civil or criminal penalties.

For products that do not fit within an OTC monograph or for which we seek novel claims, actives, or conditions of use, we may pursue an OTC NDA. OTC NDAs generally require consumer behavior evidence that differs from Rx approvals, including label comprehension, self selection, and, in many cases, actual use studies, as well as human factors and packaging usability validation. If study participants misinterpret labeling, fail to self select appropriately, make dosing errors, or misuse the product, we may need multiple iterative cycles of label revisions, packaging or device redesign, and retesting. FDA may also require additional clinical or post marketing safety data to support broader, unsupervised consumer use; impose narrower indications, higher minimum ages, or dosing restrictions; or convene advisory committee review—all of which can delay approval or materially diminish the commercial viability of the product.

Any of these regulatory dynamics—alone or in combination—could delay or prevent product launches, require us to reformulate, relabel, restrict indications or target populations, write off inventory and packaging, expand study programs, or incur greater user fees and manufacturing costs. If we are unable to timely secure applicable administrative orders or if chosen, OTC NDA approvals, on commercially acceptable terms, or if we must significantly alter our products, labeling, or packaging to meet OTC requirements, our development timelines, revenue prospects, operating margins, inventory levels, and relationships with customers and channel partners could be materially adversely affected.

Counterfeit, intellectual-property-infringing, or other unauthorized versions ("Counterfeit Copies") of our products, particularly in our OTC business, could harm consumers and adversely affect us.

Our industry has been and continues to be challenged by illegal counterfeiting. Third parties have illegally distributed and sold, and may in the future illegally distribute and sell, counterfeit versions of OTC medicines or other products, which do not meet the rigorous manufacturing and testing standards applicable to the authentic producer of those OTC medicines or products. Such counterfeit versions may contain harmful substances, the wrong dose of an active pharmaceutical ingredient ("API") or no API at all, depriving consumers of the therapeutic benefit of these products. However, to distributors and consumers, counterfeit copies may be visually indistinguishable from the authentic versions and, as a result, the counterfeit copies may be sold by retailers or purchased by consumers in error. In particular, we may be unable to prevent sales of counterfeit copies online, particularly if our sales on various e-commerce platforms grow. Counterfeit copies pose a risk to consumer health and safety because of the conditions under which they are manufactured, which are often in unregulated, unlicensed, uninspected, and unsanitary sites, as well as the lack of regulation of and information about their contents. Counterfeit copies could adversely affect our business, results of operations, or financial condition by being mistakenly attributed to, or impacting consumer confidence in, our authentic products, potentially resulting in lost sales, damage to our reputation or our brands, product recalls, and an increased threat of legal or regulatory proceedings.

Disruptions to our distribution operations could adversely affect our ability to deliver our products to consumers and customers.

Our ability to receive inventory and deliver products to distributors, customers, and consumers on a timely basis depends on the proper functioning of our manufacturing, supplier, and distribution operations, and interruptions or delays in these operations could adversely affect our business, results of operations, or financial condition. Distribution disruptions can occur for many reasons, including manufacturing or supplier disruptions, labor disputes or shortages, concentration or insolvency of distributors or logistics providers, site-specific incidents, natural disasters, political unrest, terrorist attacks, cybersecurity incidents, epidemics, pandemics, other unfavorable economic or market conditions, trade embargoes, customs and tax requirements and similar factors, increases in transportation or shipping costs, issues with overseas shipments, reductions in the transportation capacity of carriers, disruptions to transportation infrastructure, and other unexpected delivery interruptions or delays. We are also subject to risks of damage to, or loss of, our products while they are stored in our warehousing facilities or being delivered by our shipping vendors. Distributors, customers, and consumers rely on timely receipt of our products and any repeated, intermittent or long-term disruption to, or failure of, the operations of our warehousing and distribution facilities could lead to lower sales and profitability, excess inventory, reputational damage or loss of loyalty to our brands. In addition, as we continue to grow our business, we may need to continue to update or expand our warehousing and distribution facilities, which may require significant amounts of capital, or engage additional third-party distributors and shipping vendors, which may increase the risks to our business associated with reliance on third parties.

We face intense competition from consumer products companies, both in the U.S. and in international markets.

We anticipate that our OTC products will compete with other widely advertised, promoted and merchandised brands within each product category and from retailers, including supermarkets, mass merchandisers, wholesale clubs, drugstores, convenience stores, home stores, dollar and other discount stores, other specialty stores and websites and other e-commerce channels, which are increasingly offering private label and retailer-branded brands and generic non-branded products in certain categories, which typically are sold at lower prices, and consumers are increasingly seeking lower cost "private label" products.

Shifting consumer behavior, including continuing shifts to online shopping, may also increase competition, as larger legacy competitors and newer digitally native brands have increasingly moved into consumer products and staples. We expect many of our competitors to be large companies, including, among others, Procter & Gamble, L'Oréal, Unilever, The Estée Lauder Companies, and Colgate-Palmolive Company. Many of these companies have greater financial resources than we do, and these competitors, as well as new market entrants, may therefore, have the capacity to outspend us on advertising and promotional activities and introduce competing products or adopt new technologies, such as artificial intelligence and machine learning, more quickly, successfully and effectively, and respond more effectively to changing business and economic conditions than we can. We expect our products to generally compete on the basis of performance, brand recognition, price, value or other benefits to consumers. Significant price competition may require us to reduce the prices for our products to price levels that do not offset manufacturing cost increases, to respond to competitive and customer pressures and to maintain market share. Increases to our prices, as a result of inflationary pressures or otherwise, could cause declining sales of products whose prices we have increased. Ongoing periods of high inflation or increased costs resulting from higher tariffs imposed by the U.S. or other countries could lead to price increases on our products, potentially adversely impacting demand for our products. Advertising, promotion, merchandising and packaging also have a significant impact on retail customer decisions regarding the brands and product lines they sell and on consumer purchasing decisions. A newly introduced consumer product (whether improved or newly developed) usually encounters intense competition requiring substantial expenditures for advertising, sales promotion and trade merchandising. If a product gains consumer acceptance, it normally requires continued advertising, promotional support and product improvements to maintain its relative market position. If our advertising, marketing and promotional programs, including the use of digital and social media to reach consumers, are not effective, our sales growth may decline.

Risks Related to Our License Agreement

If we are found to have breached our obligations under our license agreement, we could lose rights that may be important to our business.

We are a party to certain license agreements that impose various diligence, milestone, royalty, insurance and other obligations on us. If we fail to comply with these obligations, the respective licensors may have the right to terminate the license, in which event we may not be able to develop or market the affected product candidate. The loss of such rights could materially adversely affect our business, financial condition, operating results and prospects. For example, on November 10, 2025, we received a notice of material breach and demand for cure (the "Notice") from the licensor pursuant to our License Agreement, dated March 31, 2017 (the "License Agreement"), with Villani, Inc. ("Villani"), alleging that we breached the License Agreement as a result of our recent strategic shift to focus on over-the-counter pharmaceutical products. The Notice alleges that we (i) failed to use Commercially Reasonable Efforts (as defined in the License Agreement) to pursue a prescription product business, (ii) failed to provide Villani with advance notice of certain submissions to regulatory authorities, (iii) used Licensed Know-How (as defined in the License Agreement) outside of the Field (as defined in the License Agreement) and (iv) our anticipated OTC kits do not qualify as Licensed Products (as defined in the License Agreement). On November 11, 2025, Villani delivered an additional notice (the "Additional Notice") whereby Villani requested (i) the reversion and assignment of all assets regarding *Spongilla*-based products back to Villani, (ii) that we preserve all *Spongilla* inventory, and (iii) we preserve all documents, data, and tangible materials related to *Spongilla*. We dispute the allegations contained in the Notice and Additional Notice and are engaged in discussions with Villani to resolve such disputes. If the parties are unable to reach a resolution, then the either party, pursuant to the License Agreement, may file for arbitration or termination of the License Agreement. To date, the License Agreement has not been terminated and continues in full force. At this point in time, we are unable to predict the final outcome of this dispute.

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

Rule 10b5-1 Trading Plans

During the fiscal quarter ended September 30, 2025, 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.

License Agreement

On November 10, 2025, we received the Notice from Villani alleging that we breached the License Agreement as a result of our recent strategic shift to focus on over-the-counter pharmaceutical products. The Notice alleges that we (i) failed to use Commercially Reasonable Efforts (as defined in the License Agreement) to pursue a prescription product business, (ii) failed to provide Villani with advance notice of certain submissions to regulatory authorities, (iii) used Licensed Know-How (as defined in the License Agreement) outside of the Field (as defined in the License Agreement), and (iv) our anticipated OTC kits do not qualify as Licensed Products (as defined in the License Agreement). On November 11, 2025, Villani delivered the Additional Notice whereby Villani requested (i) the reversion and assignment of all assets regarding *Spongilla*-based products back to Villani, (ii) that we preserve all *Spongilla* inventory, and (iii) we preserve all documents, data, and tangible materials related to *Spongilla*. We dispute the allegations contained in the Notice and Additional Notice and are engaged in discussions with Villani to resolve such disputes. If the parties are unable to reach a resolution, then the either party, pursuant to the License Agreement, may file for arbitration or termination of the License Agreement. To date, the License Agreement has not been terminated and continues in full force. At this point in time, we are unable to predict the final outcome of this dispute.

ITEM 6: EXHIBITS

Exhibit No.	Description
3.1	Certificate of Amendment to the Amended and Restated Certificate of Incorporation of Dermata Therapeutics, Inc., dated July 30, 2025 (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed with the SEC on July 30, 2025).

31.1*	Certification of the Principal Executive Officer pursuant to Rule 13a-14(a) or Rule 15d-14(a).
31.2*	Certification of the Principal 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

* Filed herewith.
** Furnished, not filed.

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.

Dermata Therapeutics, Inc.

Date: November 14, 2025

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)

EXHIBIT 31.1

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, 2025, 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 14, 2025

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

EXHIBIT 31.2

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, 2025, 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 14, 2025

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

EXHIBIT 32.1

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, 2025 (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 14, 2025

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

Dated: November 14, 2025

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.