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, 2026**

or

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

For the transition period from _____ to _____

Commission File Number: **001-39082**

RELMADA THERAPEUTICS, INC.
(Exact name of registrant as specified in its charter)

Nevada	**45-5401931**
(State or Other Jurisdiction of Incorporation or Organization)	(I.R.S. Employer Identification No.)
2222 Ponce de Leon, Floor 3 Coral Gables, FL	**33134**
(Address of Principal Executive Offices)	(Zip Code)

(786) 629-1376
(Registrant's Telephone Number, Including Area Code)

N/A
(Former Name, Former Address and Former Fiscal Year, if Changed Since Last Report)

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common stock, $0.001 par value per share	**RLMD**	**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 and posted 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, 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 the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

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

As of November 10, 2026, there were 106,694,846 shares of common stock, $0.001 par value per share, outstanding.

Relmada Therapeutics, Inc.

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PART I - FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

Relmada Therapeutics, Inc.
Condensed Consolidated Balance Sheets

	As of September 30, 2026 (Unaudited)	As of December 31, 2025
Assets		
Current assets:		
Cash and cash equivalents	$ 5,720,325	$ 3,496,540
Short-term investments	196,402,988	89,509,710
Other receivable	10,912	—
Prepaid expenses	2,915,011	977,721
Total current assets	205,049,236	93,983,971
Other assets	247,379	19,500
Total assets	$ 205,296,615	$ 94,003,471
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 2,538,585	$ 1,568,944
Accrued expenses	5,237,116	4,861,583
Total current liabilities	7,775,701	6,430,527
Stock appreciation rights	3,783,853	1,060,931
Total liabilities	11,559,554	7,491,458
Commitments and Contingencies (See Note 8)		
Stockholders' Equity:		
Preferred stock, $0.001 par value, 200,000,000 shares authorized, none issued and outstanding	—	—
Class A convertible preferred stock, $0.001 par value, 3,500,000 shares authorized, none issued and outstanding	—	—
Common stock, $0.001 par value, 200,000,000 and 150,000,000 shares authorized, respectively, 106,694,846 and 73,333,622 shares issued and outstanding, respectively	106,695	73,333
Additional paid-in capital	937,725,893	784,705,878
Accumulated deficit	(744,095,527)	(698,267,198)
Total stockholders' equity	193,737,061	86,512,013
Total liabilities and stockholders' equity	$ 205,296,615	$ 94,003,471

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

Relmada Therapeutics, Inc.
Condensed Consolidated Statements of Operations

(Unaudited)

	Three months ended September 30,		Nine months ended September 30,	
	2026	2025	2026	2025
Operating expenses:				
Research and development	$ 9,217,440	$ 4,036,267	$ 25,699,073	$ 18,806,667
General and administrative	3,878,983	6,291,079	21,870,130	19,960,421
Total operating expenses	13,096,423	10,327,346	47,569,203	38,767,088
Loss from operations	(13,096,423)	(10,327,346)	(47,569,203)	(38,767,088)
Other (expenses) income:				
Interest/investment income, net	2,274,541	247,013	5,535,697	1,008,758
Realized (loss) gain on short-term investments	(435,122)	(81,438)	(482,284)	28,717
Unrealized (loss) gain on short-term investments	(2,605,184)	70,275	(3,312,539)	212,210
Total other (expense) income – net	(765,765)	235,850	1,740,874	1,249,685
Net loss	$ (13,862,188)	$ (10,091,496)	$ (45,828,329)	$ (37,517,403)
Loss per common share – basic and diluted	$ (0.12)	$ (0.30)	$ (0.44)	$ (1.16)
Weighted average number of common shares outstanding – basic and diluted	112,437,710	33,191,622	103,745,599	32,274,238

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

Relmada Therapeutics, Inc.
Condensed Consolidated Statements of Changes in Stockholders' Equity
(Unaudited)

	Three and Nine months ended September 30, 2026				
	Common Stock		Additional Paid-in	Accumulated	
	Shares	Par Value	Capital	Deficit	Total
Balance – December 31, 2025	73,333,622	$ 73,333	$ 784,705,878	$ (698,267,198)	$ 86,512,013
Stock based compensation	—	—	956,186	—	956,186
Proceeds from issuance of common stock, net	29,474,569	29,475	150,352,510	—	150,381,985
ATM Fees	—	—	(65,651)	—	(65,651)
Cashless exercise of pre-funded warrants for common stock	2,082,032	2,082	(2,082)	—	—
Net loss	—	—	—	(19,051,956)	(19,051,956)
Balance – March 31, 2026	104,890,223	104,890	935,946,841	(717,319,154)	218,732,577
Stock based compensation	—	—	902,903	—	902,903
ATM fees	—	—	(66,273)	—	(66,273)
Stock issuance costs	—	—	(199,879)	—	(199,879)
Exercise of pre-funded warrants for common stock	1,682,500	1,683	—	—	1,683
Options exercised	97,123	97	101,400	—	101,497
Net loss	—	—	—	(12,914,185)	(12,914,185)
Balance – June 30, 2026	106,669,846	106,670	936,684,992	(730,233,339)	206,558,323
Stock based compensation	—	—	1,023,176	—	1,023,176
Options exercised	25,000	25	17,725	—	17,750
Net loss	—	—	—	(13,862,188)	(13,862,188)
Balance – September 30, 2026	106,694,846	$ 106,695	$ 937,725,893	$ (744,095,527)	$ 193,737,061

	Three and Nine months ended September 30, 2025				
	Common Stock		Additional Paid-in	Accumulated	
	Shares	Par Value	Capital	Deficit	Total
Balance – December 31, 2024	30,174,202	$ 30,174	$ 676,373,822	$ (640,882,035)	$ 35,521,961
Stock-based compensation	—	—	3,572,769	—	3,572,769
Issuance of Restricted Common Stock	3,017,420	3,017	902,209	—	905,226
Net loss	—	—	—	(17,559,465)	(17,559,465)
Balance – March 31, 2025	33,191,622	33,191	680,848,800	(658,441,500)	22,440,491
Stock-based compensation	—	—	3,448,453	—	3,448,453
ATM Expenses	—	—	(73,021)	—	(73,021)
Net loss	—	—	—	(9,866,442)	(9,866,442)
Balance – June 30, 2025	33,191,622	33,191	684,224,232	(668,307,942)	15,949,481
Stock-based compensation	—	—	3,607,554	—	3,607,554
Net loss	—	—	—	(10,091,496)	(10,091,496)

Balance – September 30, 2025	33,191,622	$ 33,191	$ 687,831,786	$ (678,399,438)	$ 9,465,539

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

Relmada Therapeutics, Inc.
Condensed Consolidated Statements of Cash Flows
(Unaudited)

	Nine months ended September 30,	
	2026	**2025**
Cash flows from operating activities		
Net loss	$ (45,828,329)	$ (37,517,403)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	2,882,265	10,628,776
Stock appreciation rights compensation	3,474,444	216,640
Issuance of restricted common stock	-	905,226
Realized loss (gain) on short-term investments	482,284	(28,717)
Unrealized loss (gain) on short-term investments	3,312,539	(212,210)
Change in operating assets and liabilities:		
Prepaid expenses and other assets	(2,176,081)	(81,285)
Accounts payable	969,641	(2,677,461)
Accrued expenses	375,533	(2,424,331)
Stock appreciation rights	(751,522)	-
Net cash used in operating activities	(37,259,226)	(31,190,765)
Cash flows from investing activities		
Purchase of short-term investments	(199,152,165)	(1,043,307)
Sale of short-term investments	88,464,064	29,834,551
Net cash (used in)/provided by investing activities	(110,688,101)	28,791,244
Cash flows from financing activities		
Proceeds from issuance of common stock	159,999,996	-
Payment of fees for issuance of common stock	(9,817,890)	-
Proceeds from options exercised for common stock	119,247	-
Proceeds from warrants exercised for common stock	1,683	-
ATM expenses	(131,924)	(73,021)
Net cash provided by/(used in) financing activities	150,171,112	(73,021)
Net increase/(decrease) in cash and cash equivalents	2,223,785	(2,472,542)
Cash and cash equivalents at beginning of the period	3,496,540	3,857,026
Cash and cash equivalents at end of the period	$ 5,720,325	$ 1,384,484
Non-cash investing and financing activities:		
Cashless exercise of warrants for common stock	$ (2,082)	$ -

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

Relmada Therapeutics, Inc.
Notes to Unaudited Condensed Consolidated Financial Statements

NOTE 1 - BUSINESS

Relmada Therapeutics, Inc. (Relmada or the Company) (a Nevada corporation), is a clinical-stage, publicly traded biotechnology company focused on the development of NDV-01 and sepranolone.

NDV-01 is a novel, sustained-release formulation of gemcitabine and docetaxel. NDV-01 is currently in a Phase 2 clinical trial in Israel to assess its safety and efficacy in patients with aggressive forms of non-muscle invasive bladder cancer (NMIBC).

Sepranolone is a novel neurosteroid epimer of allopregnanolone. Sepranolone is being developed for the potential treatment of Prader-Willi syndrome, with additional potential indications in Tourette syndrome, essential tremor and other diseases related to excessive GABAergic activity.

The Esmethadone (d-methadone, dextromethadone, REL-1017) program was terminated effective July 7, 2025.

Relmada was also developing a proprietary, modified-release formulation of psilocybin (REL-P11) for metabolic indications. This program was terminated effective May 12, 2025.

On February 3, 2025, the Company entered into an Asset Purchase Agreement (the Purchase Agreement) with Asarina Pharma AB (Asarina), a Swedish corporation, pursuant to which the Company has agreed, subject to the terms and conditions set forth therein, to purchase from Asarina all right, title, and interest in sepranolone, a Phase 2b ready neurosteroid being developed for the potential treatment of Prader-Willi syndrome, Tourette syndrome, essential tremor and other diseases related to excessive GABAergic activity. The total purchase price for sepranolone was €3,000,000. The Company paid Asarina $2,756,000 on February 5, 2025, which included a credit of $250,000 for a previous payment made by the Company to Asarina pursuant to an exclusivity agreement dated October 25, 2024.

On March 24, 2025, the Company entered into an Exclusive License Agreement with Trigone, a privately held Israeli company. The license agreement was for Trigone's NDV-01 product candidate, which is a novel, sustained-release, formulation of gemcitabine and docetaxel, with the potential to be a best-in-class intravesical treatment across the NMIBC disease spectrum. Under the terms of the agreement, the Company made a $3,500,000 upfront payment on March 25, 2025, and issued 3,017,420 shares of common stock, which represented 10% of the Company's outstanding shares on such date, for exclusive worldwide rights to NDV-01, excluding Israel, India and South Africa.

In addition, the Company will pay up to approximately $200 million in development, regulatory and commercial milestones. The Company will also pay a royalty of 3% on worldwide net sales. As of December 31, 2025, a milestone had been achieved with a $2 million payment. The milestone payment was accrued for as of December 31, 2025 and paid to Trigone in January 2026. As of September 30, 2026, no additional milestones were achieved.

In addition to the normal risks associated with a new business venture, there can be no assurance that the Company's research and development will be successfully completed or that any product will be approved or commercially viable. The Company is subject to risks common to companies in the biotechnology industry including, but not limited to, dependence on collaborative arrangements, development by the Company or its competitors of new technological innovations, dependence on key personnel, protection of proprietary technology, and compliance with the Food and Drug Administration (FDA) and other governmental regulations and approval requirements.

NOTE 2 – LIQUIDITY

These unaudited condensed consolidated financial statements have been prepared in accordance with generally accepted accounting principles applicable to a going concern, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business.

As shown in the accompanying unaudited condensed consolidated financial statements, the Company has incurred losses and negative cash flows from operations since inception and expects to incur additional losses until such time that it can generate significant revenue from the commercialization of its product candidates. During the nine months ended September 30, 2026, the Company incurred a net loss of $45,828,329 and had negative operating cash flows of $37,259,226.

On November 5, 2025, the Company announced the closing of its underwritten offering of 40,142,000 shares of its common stock and, in lieu of common stock to certain investors, pre-funded warrants to purchase up to 5,315,000 shares of common stock. The shares of common stock were sold at an offering price of $2.20 per share, and the pre-funded warrants were sold at an offering price of $2.199 per pre-funded warrant, which represents the per share offering price for the common stock less the $0.001 per share exercise price for each such pre-funded warrant. The net proceeds to the Company from the offering, before deducting other expenses payable by the Company, and excluding the exercise of any pre-funded warrants, were approximately $94 million.

On March 9, 2026, the Company entered into a Securities Purchase Agreement for a private placement with certain institutional and accredited investors (collectively, the Purchasers). The Purchasers purchased 29,474,569 shares of the Company's common stock, par value $0.001 per share and pre-funded warrants up to 4,210,527 shares of common stock. The closing of the Private Placement occurred on March 11, 2026. The shares of common stock were sold at an offering price of $4.75 per share, and the pre-funded warrants were sold at an offering price of $4.749 per pre-funded warrant, which represents the per share purchase price for the common stock less the $0.001 per share exercise price for each such pre-funded warrant. The net proceeds from the Purchase Agreement, after deducting fees, other expenses payable by the Company, and excluding the exercise of any pre-funded warrants, were approximately $150 million.

As of the date of this report, Management believes that the Company's existing cash and cash equivalents and short-term investments will enable it to fund operating expenses and capital expenditure requirements for at least 12 months from the issuance of these unaudited condensed consolidated financial statements. Beyond that point management will evaluate the size and scope of any subsequent trials that will affect the timing of additional financing through public or private sales of equity or debt securities or from bank or other loans or through strategic collaboration and/or licensing agreements. Any such expenditures related to any subsequent clinical trials will not be incurred until such additional financing is raised. As a result, the Company concluded the Company has sufficient funds to maintain operations for at least 12 months from the issuance of these unaudited condensed consolidated financial statements.

NOTE 3 - SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Basis of Presentation

The accompanying unaudited condensed consolidated financial statements and related notes have been prepared in accordance with accounting principles generally accepted in the United States of America (U.S. GAAP) for interim unaudited condensed consolidated financial information. Accordingly, they do not include all of the information and footnotes required by U.S. GAAP for complete consolidated financial statements. The unaudited condensed consolidated financial statements reflect all adjustments (consisting of normal recurring adjustments) which are, in the opinion of management, necessary for a fair statement of the results for the interim periods presented. Interim results are not necessarily indicative of the results for the full year. These unaudited condensed consolidated financial statements should be read in conjunction with the audited consolidated financial statements of the Company for the year ended December 31, 2025 and notes thereto contained in the Company's Annual Report on Form 10-K.

Principles of Consolidation

The unaudited condensed consolidated financial statements include the Company's accounts and those of the Company's wholly-owned subsidiary. All significant intercompany accounts and transactions have been eliminated in consolidation.

Use of Estimates

The preparation of unaudited condensed consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the unaudited condensed consolidated financial statements and the reported amounts of revenues and expenses for the reporting period. Actual results could differ from those estimates. The significant estimates are stock-based compensation expenses, stock appreciation rights expense and recorded amounts related to income taxes.

Cash and Cash Equivalents

The Company considers cash deposits and all highly liquid investments with a maturity of three months or less when purchased to be cash and cash equivalents. The Company's cash deposits are held at two high-credit-quality financial institutions. The Company's cash and cash equivalents are carried at cost, which approximates their fair value. The Company's cash and cash equivalents balance of $5,720,325 and $3,496,540 at September 30, 2026 and December 31, 2025, respectively, at these institutions exceed the federally insured limits.

NOTE 3 - SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (continued)

Short-term Investments

The Company's investments consist entirely of mutual fund and corporate debt securities. Mutual fund securities are measured at fair value based on the net asset value "NAV". Corporate debt securities are measured at fair value using observable inputs. Changes in fair value of the securities are recorded as part of other income on the unaudited condensed consolidated statement of operations. Short-term investment activity is presented in the investing activities section on the condensed consolidated statements of cash flows.

Short-term investments at September 30, 2026 and December 31, 2025 consisted of mutual funds and corporate debt securities with an aggregate fair value of $196,402,988 and $89,509,710, respectively.

Patents

Costs related to filing and pursuing patent applications are recorded as general and administrative expense and expensed as incurred since recoverability of such expenditures is uncertain.

Leases

The Company recognizes its leases with a term of greater than a year on the balance sheet by recording right-of-use assets and lease liabilities. Leases can be classified as either operating leases or finance leases. Operating leases will result in straight-line lease expense, while finance leases will result in front-loaded expense. The Company's leases consist of operating leases for office space for terms of 12 months or less. The Company does not recognize a lease liability or right-of-use asset on the balance sheet for short-term leases. Instead, the Company recognizes short-term lease payments as an expense on a straight-line basis over the lease term. A short-term lease is defined as a lease that, at the commencement date, has a lease term of 12 months or less and does not include an option to purchase the underlying asset that the lessee is reasonably certain to exercise.

Fair Value of Financial Instruments

The Company's financial instruments primarily include cash, short-term investments, and stock appreciation rights. Due to the short-term nature of cash and accounts payable the carrying amounts of these assets and liabilities approximate their fair value.

Fair value is defined as the price that would be received to sell an asset or paid to transfer a liability (an exit price) in an orderly transaction between market participants at the reporting date. A fair value hierarchy has been established for valuation inputs that gives the highest priority to quoted prices in active markets for identical assets or liabilities and the lowest priority to unobservable inputs. The fair value hierarchy is as follows:

> Level 1 Inputs - Unadjusted quoted prices in active markets for identical assets or liabilities that the reporting entity has the ability to access at the measurement date.
>
> Level 2 Inputs - Inputs other than quoted prices included in Level 1 that are observable for the asset or liability, either directly or indirectly. These might include quoted prices for similar assets or liabilities in active markets, quoted prices for identical or similar assets or liabilities in markets that are not active, inputs other than quoted prices that are observable for the asset or liability (such as interest rates, volatilities, prepayment speeds, credit risks, etc.) or inputs that are derived principally from or corroborated by market data by correlation or other means.
>
> Level 3 Inputs - Prices or valuation techniques that require inputs that are both significant to the fair value measurement and unobservable (supported by little or no market activity).

As required by Accounting Standard Codification (ASC) Topic No. 820 - 10 *Fair Value Measurement*, financial assets and liabilities are classified based on the lowest level of input that is significant to the fair value measurement. The Company's assessment of the significance of a particular input to the fair value measurement requires judgment and may affect the valuation of the fair value of assets and liabilities and their placement within the fair value hierarchy levels.

The Company's short-term investment instruments of $196,402,988 at September 30, 2026 consist of mutual funds and corporate debt securities.

Mutual fund securities are classified using Level 1 inputs within the fair value hierarchy because they are valued using NAV per share in an active market and are readily redeemable at that value on a daily basis without restriction. As of September 30, 2026, the mutual fund securities balance was $145,944,809.

Corporate debt securities are classified using Level 2 inputs within the fair value hierarchy because they are measured using observable inputs such as benchmark yields, credit spreads, and quoted prices for similar securities in active or inactive markets. As of September 30, 2026, the corporate securities balance was $50,458,179.

NOTE 3 - SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (continued)

Unrealized gains and losses are recorded in the condensed consolidated statement of operations as unrealized gain on short-term investments. The Company recorded unrealized losses of $2,605,184 and $3,312,539 included in other income for the three and nine months ended September 30, 2026, respectively. The Company recorded unrealized gains of $70,275 and $212,210 included in other income for the three and nine months ended September 30, 2025, respectively.

The Company's stock appreciation rights liability is a mark-to-market liability and classified within Level 3 of the fair value hierarchy as the Company is using a Black-Scholes option pricing model. Significant unobservable inputs included expected term and volatility. The expected term was calculated using the simplified method. The volatility is calculated based on the Company's historical stock price over a period of time.

As of September 30, 2026, the stock appreciation rights liability had a fair value of $3,783,853. Significant inputs for Level 3 stock appreciation rights liability fair value measurement at September 30, 2026 are disclosed in Footnote 6.

There have been no transfers in and out of Level 3 during the three and nine months ended September 30, 2026 and 2025, respectively.

Income Taxes

The Company accounts for income taxes using the asset and liability method. Accordingly, deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between financial statement carrying amounts of existing assets and liabilities and their respective tax bases. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in the tax rate is recognized in income or expense in the period that the change is effective. Tax benefits are recognized when it is probable that the deduction will be sustained. A valuation allowance is established when it is more likely than not that all or a portion of a deferred tax asset will either expire before the Company is able to realize the benefit, or that future deductibility is uncertain. As of September 30, 2026, and December 31, 2025, the Company had recorded a valuation allowance to the full extent of the Company's net deferred tax assets since the likelihood of realization of the benefit does not meet the more likely than not threshold.

The Company files a U.S. Federal income tax return and various state returns. Uncertain tax positions taken on the Company's tax returns will be accounted for as liabilities for unrecognized tax benefits. The Company will recognize interest and penalties, if any, related to unrecognized tax benefits in general and administrative expenses in the statements of operations. There were no liabilities recorded for uncertain tax positions at September 30, 2026 and December 31, 2025. The open tax years, subject to potential examination by the applicable taxing authority, for the Company are from December 31, 2021 forward.

Research and Development

Research and development costs primarily consist of research contracts for the advancement of product development, salaries and benefits, stock-based compensation, and consultants. The Company expenses all research and development costs in the period incurred. The Company makes an estimate of costs in relation to clinical study contracts. The Company analyzes the progress of studies, including the progress of clinical studies and phases, invoices received and contracted costs when evaluating the adequacy of the amount expensed and the related prepaid asset and accrued liability.

Stock-Based Compensation

The Company measures the cost of employee services received in exchange for an award of equity instruments based on the grant-date fair value of the award. That cost is recognized over the period during which an employee is required to provide service in exchange for the award - the requisite service period. The grant-date fair value of employee share options is estimated using the Black-Scholes option pricing model adjusted for the unique characteristics of those instruments.

Stock Appreciation Rights

Pursuant to the terms of the Company's 2021 Equity Incentive Plan, the Company may grant cash-settled Stock Appreciation Rights ("SARs") that are classified as liabilities under ASC 718 (*Compensation—Stock Compensation*). These SARs allow employees to receive cash payments based on the appreciation of the Company's stock price over a specified period.

The initial fair value of SARs is determined on the grant date using the Black-Scholes option pricing model. SARs are remeasured at fair value at each reporting date using the Black-Scholes pricing model until they are exercised or expire. Changes in fair value are recognized in the income statement as a compensation expense. Compensation expense is recognized over the service period, which is the period during which employees are required to provide service in exchange for the award.

Upon exercise, the Company will settle SARs in cash based on the difference between the fair value of the underlying shares at the exercise date and the exercise price.

NOTE 3 - SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (continued)

Pre-Funded Warrants

The Company may issue pre-funded equity classified warrants that are exercisable for shares of common stock at a nominal exercise price. As the exercise price of the pre-funded warrants is nominal, the underlying shares are included in basic earnings per share from the issuance date.

Reclassification

Certain amounts in the prior period's unaudited condensed consolidated financial statements have been reclassified to conform to the current period presentation. These reclassifications had no impact on previously reported net loss, total assets, total liabilities, or stockholders' equity.

Net Loss per Common Share

Basic loss per common share attributable to common stockholders is calculated by dividing the net loss attributable to common stockholders by the weighted-average number of common shares outstanding for the period, without consideration for common stock equivalents. Diluted loss per common share attributable to common stockholders is computed by dividing the net loss attributable to common stockholders by the weighted-average number of common share equivalents outstanding for the period determined using the treasury-stock method. Dilutive common stock equivalents are comprised of options and warrants to purchase common stock. For all periods presented, there is no difference in the number of shares used to calculate basic and diluted shares outstanding due to the Company's net losses in each period.

For the nine months ended September 30, 2026 and 2025, the potentially dilutive securities that would be anti-dilutive due to the Company's net loss are not included in the calculation of diluted net loss per share attributable to common stockholders. The anti-dilutive securities are as follows (in common stock equivalent shares):

	Nine months ended	
	September 30, 2026	September 30, 2025
Stock options	15,513,355	14,149,986
Common stock warrants	565,085	750,908
Total	16,078,440	14,900,894

Recent Accounting Standards

In November 2024, the FASB issued ASU 2024-03, *Income Statement - Reporting Comprehensive Income - Expense Disaggregation Disclosures (Subtopic 220-40)*. ASU 2024-03 requires specified information about certain costs and expenses be disclosed in the notes to the financial statements, including the expense caption on the face of the income statement in which they are disclosed, in addition to a qualitative description of remaining amounts not separately disaggregated. Entities will also be required to disclose their definition of "selling expenses" and the total amount in each annual period. The standard is effective for the Company for annual periods beginning January 1, 2027 and for interim periods beginning January 1, 2028, with updates applied either prospectively or retrospectively. Early adoption is permitted. The Company is currently evaluating the impact of this guidance on its disclosures.

In May 2025, the FASB issued ASU 2025-03, *Business Combinations (Topic 805) and Consolidation (Topic 810)* . This ASU provides clarifications related to step acquisitions and simplifies certain consolidation assessments involving variable interest entities. The standard is effective for the Company for annual and interim periods beginning January 1, 2027, with updates applied prospectively. Early adoption is permitted. The Company is currently evaluating the impact of this guidance on its consolidated financial statements.

In May 2025, the FASB issued ASU 2025-04, *Compensation – Stock Compensation (Topic 718) and Revenue from Contracts with Customers (Topic 606)*. This ASU clarifies when awards fall under stock compensation guidance. This standard is effective for the Company for annual, and interim periods beginning January 1, 2027, with updates applied retrospectively or modified retrospectively. Early adoption is permitted. The Company is currently evaluating the impact of this guidance on its consolidated financial statements.

In April 2026, the FASB issued ASU 2026-01, *Equity—Initial Measurement of Paid-in-Kind Dividends on Equity-Classified Preferred Stock (Topic 505)*. This ASU clarifies the initial measurement and recognition of paid-in-kind (PIK) dividends on equity-classified preferred stock, including the timing and classification of such dividends within equity. The guidance is intended to reduce diversity in practice and improve comparability in the accounting for preferred stock instruments with PIK features. The standard is effective for the Company for annual and interim periods beginning January 1, 2027, with early adoption permitted. The guidance is to be applied either prospectively or on a modified retrospectively basis. The Company is currently evaluating the impact of this guidance on its consolidated financial statements and related disclosures.

NOTE 4 - PREPAID EXPENSES

Prepaid expenses consisted of the following (rounded to nearest $100):

	September 30, 2026	December 31, 2025
Insurance	$ 740,000	$ 411,900
Research and Development	1,873,800	496,500
Legal	140,600	—
Other	160,600	69,300
Total	$ 2,915,000	$ 977,700

NOTE 5 - ACCRUED EXPENSES

Accrued expenses consisted of the following (rounded to nearest $100):

	September 30, 2026	December 31, 2025
Research and development	$ 2,414,000	$ 3,971,700
Professional fees	311,100	220,000
Accrued bonus	1,555,700	—
Accrued vacation	588,500	535,500
Other	367,800	134,400
Total	$ 5,237,100	$ 4,861,600

NOTE 6 - STOCK APPRECIATION RIGHTS

During the nine months ended September 30, 2026, 275,000 cash-settled stock appreciation rights have been issued to employees and consultants with an exercise price of $4.11 to $7.42 with a 10-year term and vesting over a 4-year period. Variables used in the Black-Scholes option-pricing model include: (1) discount rate of 3.81% - 4.21%, (2) expected life of 6.25 years, (3) expected volatility of 129.5% - 134.7%, and (4) zero expected dividends.

At September 30, 2026, the Company revalued the cash-settled stock appreciation rights using a stock price of $3.77 and an exercise price of $0.45- $7.42. Variables used in the Black-Scholes option-pricing model include: (1) discount rate of 5.05% - 5.14%, (2) expected life of 4 – 6 years, (3) expected volatility of 129% - 152% and (4) zero expected dividends.

As of September 30, 2026, the total liability related to cash-settled SARs is $3,783,853, reflecting the fair value as of the reporting date. During the three months ended September 30, 2026, the Company recorded a reduction in compensation related to the cash-settled SARs in the amount of $1,296,228, included $367,742 and $928,486 of research and development and general and administrative expense, respectively, in the accompanying unaudited condensed consolidated statements of operations. During the nine months ended September 30, 2026, the Company recorded compensation related to the cash-settled SARs in the amount of $3,474,444, included $796,344 and $2,678,100 in research and development and general and administrative expenses, respectively in the accompanying unaudited condensed consolidated statements of operations. During the nine months ended September 30, 2026, the Company paid out $751,522 for the exercise of cash settled SARs.

A summary of the changes in SARs during the nine months ended September 30, 2026 is as follows:

	Number of Cash-Settled SARS	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term	Aggregate Intrinsic Value
Outstanding at December 31, 2025	5,434,125	$ 3.55	9.83	$ 6,915,214
Granted	275,000	$ 5.35	9.56	-
Exercised	(129,812)	-	-	-
Cancelled	(434,250)	-	-	-
Forfeited	(3,125)	-	-	-
Outstanding at September 30, 2026	5,141,938	$ 3.67	9.11	$ 2,127,470
SARs vested at September 30, 2026	1,020,873	$ 3.54	9.06	$ 230,859

At September 30, 2026, the Company has unrecognized compensation expense of approximately $13.7 million related to unvested stock appreciation rights which will be recognized over the weighted average remaining service period of 3.11 years.

NOTE 7 - STOCKHOLDERS' EQUITY

Common Stock

During the nine months ended September 30, 2026, the Company issued 122,123 shares of common stock for the exercise of 122,123 options for cash proceeds of $119,247.

During the nine months ended September 30, 2026, the Company issued 1,682,500 shares of common stock for the exercise of 1,682,500 pre-funded warrants for cash proceeds of $1,683.

During the nine months ended September 30, 2026, holders exercised pre-funded warrants to purchase 2,082,500 shares of common stock on a cashless basis. The Company issued 2,082,032 shares of common stock upon exercise and received no cash proceeds.

As of September 30, 2026, pre-funded warrants to purchase 5,760,527 shares of common stock remained outstanding. The prefunded warrants are exercisable at $0.001 per share, are subject to beneficial ownership limitations, and are classified as equity.

During the nine months ended September 30, 2025, the Company issued 3,017,420 shares of restricted common stock in accordance with the license agreement with Trigone Pharma. The Company recognized $905,226 of research and development compensation expense related to the restricted common stock issued as part of the transaction.

On April 6, 2022, the Company entered into a new Open Market Sale Agreement with Jefferies, as sales agent, pursuant to which we may offer and sell, from time to time, through Jefferies, shares of our common stock, having an aggregate offering price of up to $100 million. We are not obligated to sell any shares under the agreement. As of September 30, 2026, no shares have been issued under this agreement.

On March 9, 2026, the Company entered into a Securities Purchase Agreement for a private placement with certain institutional and accredited investors (collectively, the Purchasers). The Purchasers purchased 29,474,569 shares of the Company's common stock, par value $0.001 per share and pre-funded warrants up to 4,210,527 shares of common stock. The closing of the Private Placement occurred on March 11, 2026. The shares of common stock were sold at an offering price of $4.75 per share, and the pre-funded warrants were sold at an offering price of $4.749 per pre-funded warrant, which represents the per share purchase price for the common stock less the $0.001 per share exercise price for each such pre-funded warrant. The net proceeds from the Purchase Agreement, after deducting fees payable by the Company, and excluding the exercise of any pre-funded warrants, were approximately $150 million.

Options and Warrants

In December 2014, the Board of Directors adopted, and the Company's shareholders approved Relmada's 2014 Stock Option and Equity Incentive Plan, as amended (the "Plan"), which allows for the granting of 5,152,942 common stock awards, stock appreciation rights, and incentive and nonqualified stock options to purchase shares of the Company's common stock to designated employees, non-employee directors, and consultants and advisors.

In May 2021, the Company's Board of Directors adopted, and shareholders approved Relmada's 2021 Equity Incentive Plan (the "2021 Plan") which allows for the granting of 1,500,000 options or other stock awards. In subsequent years the Company's Board of Directors adopted, and shareholders approved amendments to the

2021 plan to increase the shares of the Company's common stock available to be issued under the plan to 12,900,000 shares.

These combined plans allowed for the granting of up to 18,052,942 options or other stock awards.

Stock options are exercisable generally for a period of 10 years from the date of grant and generally vest over four years.

The Company uses the simplified method for share-based compensation to estimate the expected term for employee option awards for share-based compensation in its option-pricing model.

NOTE 7 - STOCKHOLDERS' EQUITY (continued)

Options

A summary of the changes in options during the nine months ended September 30, 2026 is as follows:

	Number of Options	Weighted Average Exercise Price Per Share	Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value
Outstanding and expected to vest at December 31, 2025	15,020,604	$ 12.51	6.69	$ 20,007,758
Granted	915,000	$ 4.78	—	$ —
Exercised	(122,123)	$ 0.98	—	$ —
Cancelled	(125)	$ 6.20	—	$ —
Forfeited	(300,001)	$ 0.71	—	$ —
Outstanding at September 30, 2026	15,513,355	$ 12.37	6.10	$ 10,359,539
Options exercisable at September 30, 2026	11,564,581	$ 15.75	5.15	$ 4,235,723

At September 30, 2026, the Company has unrecognized stock-based compensation expense of approximately $8.4 million related to unvested stock options which will be recognized over the weighted average remaining service period of 2.76 years.

During nine months ended September 30, 2026, there were 915,000 options granted with the weighted average exercise price of approximately $4.78 per share.

For the year ended December 31, 2025, the weighted average fair value of options granted was approximately $1.38 per share.

The weighted average fair value per share was calculated using the Black-Scholes model with the following specific assumptions:

	Nine Months Ended September 30, 2026	Year Ended December 31, 2025
Risk free interest rate	4.18 to 5.11%	3.85 to 4.16%
Dividend yield	0%	0%
Volatility	129%	126.4 - 134.4%
Expected term (in years)	6.25	6.25

NOTE 7 - STOCKHOLDERS' EQUITY (continued)

Warrants

A summary of the changes in outstanding equity-warrants during the nine months ended September 30, 2026 is as follows:

	Number of Shares	Weighted Average Exercise Price Per Share
Outstanding Warrants at December 31, 2025	5,880,085	$ 2.86
Granted	4,210,527	0.001
Exercised	(3,765,000)	—
Outstanding at September 30, 2026	6,325,612	$ 2.66

Warrants Vested at September 30, 2026	6,325,612	$ 2.66

The warrants granted during the nine months ended September 30, 2026 consist of 4,210,527 pre-funded warrants issued to investors in connection with the Company's March 2026 private placement. The pre-funded warrants have an exercise price of $0.001 per share and are classified as equity.

At September 30, 2026, the Company had $0 of unrecognized compensation expense related to outstanding warrants.

At September 30, 2026, the aggregate intrinsic value of warrants exercisable was $21,717,201.

Stock-based compensation by class of expense

The following table summarizes the components of stock-based compensation expense which includes stock options and warrants in the unaudited consolidated statements of operations for the nine months ended September 30, 2026 and 2025 (rounded to nearest $100):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
Research and development	$ 330,700	$ 183,300	$ 786,200	$ 514,300
General and administrative	692,500	3,424,300	2,096,000	10,114,500
Total	$ 1,023,200	$ 3,607,600	$ 2,882,200	$ 10,628,800

Relmada Therapeutics, Inc.
Notes to Unaudited Condensed Consolidated Financial Statements

NOTE 8 - COMMITMENTS AND CONTINGENCIES

License Agreements

Third Party Licensor

Based upon a prior acquisition, the Company assumed an obligation to pay a third party (Dr. Charles E. Inturrisi and Dr. Paolo Manfredi – see below): (A) royalty payments up to 2% on net sales of licensed products that are not sold by sublicensee and (B) on each and every sublicense earned royalty payment received by licensee from its sublicensee on sales of license product by sublicensee, the higher of (i) 20% of the royalties received by licensee; or (ii) up to 2% of net sales of sublicensee. The Company will also make milestone payments of up to $4 or $2 million, for the first commercial sale of product in the field that has a single active pharmaceutical ingredient, and for the first commercial sale of product in the field of product that has more than one active pharmaceutical ingredient, respectively. As of September 30, 2026, the Company has not generated any revenue related to this license agreement.

Inturrisi / Manfredi

In January 2018, we entered into an Intellectual Property Assignment Agreement (the Assignment Agreement) and License Agreement (the License Agreement and together with the Assignment Agreement, the Agreements) with Dr. Charles E. Inturrisi and Dr. Paolo Manfredi (collectively, the Licensor). Pursuant to the Agreements, Relmada assigned its existing rights, including patents and patent applications, to esmethadone in the context of psychiatric use (the Existing Invention) to Licensor. Licensor then granted Relmada under the License Agreement a perpetual, worldwide, and exclusive license to commercialize the Existing Invention and certain further inventions regarding esmethadone in the context of other indications such as those contemplated above. In consideration of the rights granted to Relmada under the License Agreement, Relmada paid the Licensor an upfront, non-refundable license fee of $180,000. Additionally, Relmada was to pay Licensor $45,000 every three months until the earliest to occur of the following events: (i) the first commercial sale of a licensed product anywhere in the world, (ii) the expiration or invalidation of the last to expire or be invalidated of the patent rights anywhere in the world, or (iii) the termination of the License Agreement. Relmada was to also pay Licensor tiered royalties with a maximum rate of 2%, decreasing to 1.75%, and 1.5% in certain circumstances, on net sales of licensed products covered under the License Agreement. Relmada was to also pay Licensor tiered payments up to a maximum of 20%, and decreasing to 17.5%, and 15% in certain circumstances, of all consideration received by Relmada for sublicenses granted under the License Agreement.

On July 7, 2025, the Company delivered to the Licensor formal notice of termination of the License Agreement, ending the Company's participation in the previously announced esmethadone development program. As a result of the notice of termination, all material obligations under the license agreement with the Licensor ceased as of October 5, 2025, which was 90 days after the date of the notice. There were no fees or costs associated with the termination of the License Agreement.

Arbormentis, LLC

On July 16, 2021, the Company entered into a License Agreement with Arbormentis, LLC, a privately held Delaware limited liability company, by which the Company acquired development and commercial rights to a novel psilocybin and derivate program from Arbormentis, LLC, worldwide excluding the countries of Asia. The Company collaborated with Arbormentis, LLC on the development of new therapies targeting neurological and psychiatric disorders, leveraging its understanding of neuroplasticity, and focusing on this emerging new class of drugs targeting the neuroplastogen mechanism of action. Under the terms of the License Agreement, the Company paid Arbormentis, LLC an upfront fee of $12.7 million, consisting of a mix of cash and warrants to purchase the Company's common stock, in addition to potential milestone payments totaling up to approximately $160 million related to pre-specified development and commercialization milestones. Arbormentis, LLC was also eligible to receive a low single digit royalty on net sales of any commercialized therapy resulting from this agreement.

The licensed program stems from an international collaboration among U.S., European and Swiss scientists that has focused on the discovery and development of compounds that may promote neural plasticity. Dr. Paolo Manfredi, co-inventor of REL-1017, and Dr. Marco Pappagallo, are among the scientists affiliated with Arbormentis, LLC.

On May 12, 2025, the Company delivered to Arbormentis LLC a formal notice of termination of the License Agreement, ending the Company's participation in the previously announced psilocybin development program. As a result of the cancellation, all obligations under the license agreement with Arbormentis ceased as of August 10, 2025, which was 90 days after the date of notice. There were no fees or costs associated with the termination of the License Agreement.

NOTE 8 - COMMITMENTS AND CONTINGENCIES (continued)

Trigone

On March 24, 2025, the Company entered into an Exclusive License Agreement with Trigone, a privately held Israeli company. The license agreement was for Trigone's NDV-01 product candidate, which is a novel, sustained-release, formulation of gemcitabine/docetaxel, with the potential to be a best-in-class intravesical treatment of the NMIBC disease spectrum. Under the terms of the agreement, the Company made a $3,500,000 upfront payment on March 25, 2025, and issued 3,017,420 shares of common stock, which represent 10% of the Company's outstanding shares, for exclusive worldwide rights to NDV-01, excluding Israel, India and South Africa.

In addition, the Company will pay up to $200 million in development, regulatory and commercial milestones. The Company will also pay a royalty of 3% on worldwide net sales. As of December 31, 2025, a milestone had been achieved with a $2 million payment. The milestone payment was accrued for as of December 31, 2025 and paid to Trigone in January 2026. As of September 30, 2026, no additional milestones were achieved.

Leases and Subleases

On August 1, 2021, the Company relocated its corporate headquarters to 2222 Ponce de Leon, Floor 3, Coral Gables, FL 33134, pursuant to a lease agreement with monthly rent of approximately $11,000. The lease period was for five months. The lease agreement expired on December 31, 2021 and was renewed for each subsequent year with monthly rent for the years ended December 31, 2026 and 2025 of approximately $4,600, and $4,500, respectively.

Beginning on May 29, 2024, we leased office space at 12 E 49th Street, New York, NY 10022 with monthly rent of approximately $10,500; that lease expired on May 30, 2025 with the Company continuing to lease the space under a month-to-month option. On September 28, 2026, the Company executed a lease for a new office space at 12 E 49th Street, New York, NY 10022 with monthly rent of approximately $26,833. The new lease will commence once work have been substantially completed and the month-to-month lease will then be terminated.

In accordance with ASC 842, *Leases*, the Company has elected the practical expedient and recognizes rent expense evenly over the 12 months.

For the three months ended September 30, 2026 and 2025, the Company recognized lease expense of approximately $45,400 and $43,000, respectively. For the nine months ended September 30, 2026 and 2025, the Company recognized lease expense of approximately $138,600 and $141,600, respectively.

Legal

From time to time, the Company may become involved in lawsuits and other legal proceedings that arise in the course of business. Litigation is subject to inherent uncertainties, and it is not possible to predict the outcome of litigation with total confidence. The Company is currently not aware of any legal proceedings or potential claims against it whose outcome would be likely, individually or in the aggregate, to have a material adverse effect on the Company's business, financial condition, operating results, or cash flows.

NOTE 9 - OTHER POST-RETIREMENT BENEFIT PLAN

Relmada participates in a multiemployer 401(k) plan that permits eligible employees to contribute funds on a pretax basis subject to maximum allowed under federal tax provisions. The Company matches 100% of the first 3% of employee contributions, plus 50% of employee contributions that exceed 3% but do not exceed 5%.

The employees choose an amount from various investment options for both their contributions and the Company's matching contribution. The Company's contribution expense was $156,700 and $151,200 for the nine months ended September 30, 2026 and 2025, respectively.

NOTE 10 - SEGMENT REPORTING

The Company determined its reporting units in accordance with ASC 280, *Segment Reporting*. Reportable operating segments are determined based on the management approach, as defined by ASC 280, and is based on the way that the chief operating decision-maker (CODM) organizes segments within the Company for making operating decisions, assessing performance, and allocating resources. Reportable segments are based on products and services, geography, legal structure, management structure, or any other manner in which management disaggregates the Company.

The Company operates as a single reportable segment focused on clinical stage drug development. The Company's CODM is its chief executive officer and chief financial officer, who act jointly.

The CODM assesses performance and makes operating decisions about allocating resources based on the research and development operating expenses on the Condensed Consolidated Statements of Operations and is the Company's measure of segment loss. The CODM compares actual research and development expenses to budget and forecast to monitor spending and evaluate progress toward development milestones.

The measure of segment assets is total cash and cash equivalents and short-term investments, which is regularly provided to the CODM in the Company's forecasts and is reported on the Company's Condensed Consolidated Balance Sheet. The Company's cash and cash equivalents and short-term investments balance of $202,123,313 and $93,006,250 at September 30, 2026 and December 31, 2025, respectively.

The following table provides the operating expenses of our clinical stage drug development segment for the three and nine months ended September 30, 2026 and 2025 (rounded to the nearest $100):

	Three months ended September 30,		Nine months ended September 30,	
	2026	2025	2026	2025
Clinical Study Expense	$ 2,710,800	$ 1,083,100	$ 7,664,800	$ 9,823,300
Other Research Expense	761,800	852,800	2,722,400	3,386,000
Manufacturing and Drug Storage Expense	4,215,300	752,000	9,652,000	989,200
Compensation Expense	1,566,500	990,400	4,077,300	2,986,500
Stock-based Compensation Expense	(37,000)	358,000	1,582,600	1,621,700
Total Research and Development Expense	$ 9,217,400	$ 4,036,300	$ 25,699,100	$ 18,806,700

NOTE 11 - SUBSEQUENT EVENTS

On October 9, 2026, the Company entered into a service agreement with Scinai Biopharma Services Ltd. ("Scinai") for manufacturing and related services supporting the Company's NDV-01 clinical development program. In addition to service fees and reimbursements, the agreement provides for contingent success-based consideration payable to Scinai in shares of the Company's common stock having an aggregate reference value of $1.0 million, which becomes earned if the Company submits the initial NDV-01 IND to the FDA on or before December 31, 2026, and the IND becomes effective without a clinical hold. If issuance of the shares is prevented, reduced or not completed by the outside payment date, the Company must pay the corresponding earned consideration in cash. See Part II, Item 2 of this Report.

ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATION

FORWARD-LOOKING STATEMENT NOTICE

This Quarterly Report on Form 10-Q (this Report) contains forward looking statements that involve risks and uncertainties, principally in the sections entitled "Risk Factors," and "Management's Discussion and Analysis of Financial Condition and Results of Operations." All statements other than statements of historical fact contained in this Quarterly Report, including statements regarding future events, our future financial performance, business strategy and plans and objectives of management for future operations, are forward-looking statements. We have attempted to identify forward-looking statements by terminology including "anticipates," "believes," "can," "continue," "could," "estimates," "expects," "intends," "may," "plans," "potential," "predicts," "should," or "will" or the negative of these terms or other comparable terminology. Although we do not make forward-looking statements unless we believe we have a reasonable basis for doing so, we cannot guarantee their accuracy. These statements are only predictions and involve known and unknown risks, uncertainties and other factors, including the risks outlined under "Risk Factors" or elsewhere in this Quarterly Report, which may cause our or our industry's actual results, levels of activity, performance or achievements expressed or implied by these forward-looking statements. Moreover, we operate in a very competitive and rapidly changing environment. New risks emerge from time to time and it is not possible for us to predict all risk factors, nor can we address the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause our actual results to differ materially from those contained in any forward-looking statements. All forward-looking statements included in this document are based on information available to us on the date hereof, and we assume no obligation to update any such forward-looking statements.

You should not place undue reliance on any forward-looking statement, each of which applies only as of the date of this Quarterly Report on Form-10-Q. Before you invest in our securities, you should be aware that the occurrence of the events described in the section entitled "Risk Factors" and elsewhere in this Quarterly Report could negatively affect our business, operating results, financial condition and stock price. Except as required by law, we undertake no obligation to update or revise publicly any of the forward-looking statements after the date of this Quarterly Report on Form-10-Q to conform our statements to actual results or changed expectations.

Business Overview

Relmada Therapeutics, Inc. (Relmada, the Company, we or us) (a Nevada corporation), is a publicly traded, clinical-stage biotechnology company. We substantially redesigned our development programs following a comprehensive strategic review in late 2024 and early 2025. We concluded in our review that the most promising path to create shareholder value was to lever our extensive drug development expertise and clinical operations capabilities by acquiring new development candidates, while terminating further work on esmethadone (d-methadone, dextromethadone or REL-1017). Hence we accelerated ongoing efforts to augment our development pipeline while diversifying its risk, which culminated in the licensing of NDV-01, a novel, sustained-release, delivery formulation of a chemotherapy regimen widely used to treat non muscle-invasive bladder cancer (NMIBC) that is currently in Phase 2, and the acquisition of sepranolone, a Phase 2b-ready neurosteroid with potential applications in Prader-Willi syndrome (PWS), Tourette syndrome (TS), essential tremor and other diseases related to excessive GABAergic activity.

Following the 2024 REL-1017 setback and subsequent post hoc analyses, the program was terminated effective July 7, 2025.

We also had been developing REL-P11, a modified-release formulation of psilocybin, as an investigational agent for the treatment of metabolic disease. Effective May 12, 2025, this program was terminated.

Currently, our lead product candidate, NDV-01, is a novel, sustained-release formulation of gemcitabine and docetaxel, with the potential to be a best-in-class intravesical treatment across the NMIBC disease spectrum. NDV-01 is currently in a Phase 2 clinical trial in Israel to assess its safety and efficacy in patients with aggressive forms of NMIBC. We intend to develop NDV-01 for two separate indications: (1) the treatment of high-risk, 2nd line Bacillus Calmette-Guérin (BCG)-unresponsive NMIBC and (2) the treatment of intermediate risk NMIBC patients in the adjuvant setting. We expect to file a United States Investigational New Drug (IND) application with the U.S. Food and Drug Administration (FDA) by year-end 2026. Subsequently, upon IND clearance, we anticipate initiation of Phase 3 programs for each indication.

Our second product, sepranolone is a novel neurosteroid epimer of allopregnanolone. Sepranolone is being developed for the potential treatment of PWS, with additional potential indications in TS, essential tremor and other diseases related to excessive GABAergic activity. We expect to file an IND application with the FDA by year-end 2026. Upon IND clearance, we anticipate initiation of a Phase 2b study in PWS.

Progress in Strategic Execution

On February 6, 2025, Relmada announced the acquisition from Asarina Pharma AB (Asarina) of sepranolone, a Phase 2b ready neurosteroid being developed for the potential treatment of PWS, with additional potential indications in TS, essential tremor and other diseases related to the excessive GABAergic activity.

On March 25, 2025, Relmada announced the in-license agreement from Trigone Pharma Ltd. (Trigone) of NDV-01, a novel, sustained-release, delivery formulation of a widely used chemotherapeutic regimen used to treat NMIBC.

Key Upcoming Anticipated Milestones

We expect several key milestones over the next upcoming months. These include:

- NDV-01 United States IND filing with the FDA by year-end 2026
- NDV-01 High-risk, 2nd line BCG-unresponsive NMIBC Phase 3 Trial Initiation – Upon IND clearance
- NDV-01 Intermediate Risk NMIBC in the Adjuvant Setting Phase 3 Trial Initiation – Upon IND clearance
- Sepranolone – United States IND filing with FDA by year-end 2026
- Sepranolone - Initiation of a Phase 2b clinical trial in PWS – Upon IND clearance

Our Development Programs

NDV-01 Program

NDV-01, our lead program, was in-licensed on March 24, 2025. NDV-01 is a novel, intravesical delivery technology designed for the long-acting, sustained release of gemcitabine and docetaxel. This combination therapy has gained significant interest as an alternative to BCG for treating NMIBC, especially given the global BCG shortage since 2019, and for patients who do not respond adequately to BCG. Clinical studies have shown that gemcitabine and docetaxel achieve response rates and Recurrence-Free Survival comparable to or better than BCG. However, conventional administration is cumbersome, requiring sequential drug delivery over three to four hours, with limited tumor exposure time.

NDV-01 potentially addresses these limitations by enabling a single administration in less than 5 minutes, delivering sustained, localized chemotherapy for up to 10 days. This extended exposure enhances the therapeutic effect while improving patient convenience.

NDV-01 is formulated as a sustained-release intravesical therapy containing gemcitabine and docetaxel. By maintaining continuous drug exposure within the bladder, NDV-01 may optimize local efficacy while minimizing systemic absorption and associated side effects. Unlike conventional intravesical instillations, which result in fluctuating drug levels, NDV-01 provides a continuous release of both agents over 10 days. This sustained delivery may improve cancer cell eradication and reduce recurrence risk while lowering the frequency of administration.

The Company previously announced the successful completion and receipt of written feedback from a Type B pre-IND submissions with the FDA regarding the planned Phase 3 program for NDV-01 in NMIBC patients. Relmada secured FDA alignment on certain key elements of the planned Phase 3 pivotal program for NDV-01, expected to begin upon IND clearance, and incorporating two studies for two separate indications:

- A single-arm, open-label clinical trial in 2nd line high-risk, BCG-unresponsive with Carcinoma in situ (CIS) NMIBC population
- A single registrational study in intermediate risk NMIBC in the adjuvant setting, which will follow an open-label, randomized-to-observation design

Also, importantly, the FDA agreed with our proposal to rely on FDA's prior findings of safety for Gemzar and Taxotere and published literature for the non-clinical safety assessment of NDV-01 because this is a proposed 505(b)(2) approval.

About the Planned High-Risk Registrational Study

The planned pivotal Phase 3 study in 2nd-line, high risk, BCG-unresponsive NMIBC with CIS will be an open-label, single-arm trial evaluating:

- **Primary endpoint:** Complete Response (CR) rate at any time
- **Key secondary endpoint:** Duration of Response (DOR)
- **Assessments:** Cystoscopy, cytology, and biopsy per protocol

The design reflects FDA's written guidance on the study population, endpoint selection, and evaluation methodology and is consistent with prior FDA precedents for single-arm registrational trials in NMIBC.

About the Planned Intermediate-Risk Registrational Study

The planned pivotal Phase 3 study in intermediate-risk NMIBC in the adjuvant setting will be an open label randomized-to-observation study:

- **Primary endpoint:** Disease Free Survival (DFS)
- **Key secondary endpoint:** Duration of Response (DOR)
- **Assessments:** Cystoscopy, cytology, and biopsy per protocol

The design reflects FDA's written guidance on the study population, endpoint selection, and evaluation methodology.

Relmada expects to file a United States IND application for NDV-01 with the FDA by year-end 2026.

Sepranolone Program

The GABAergic system is the primary inhibitory neurotransmitter pathway. It consists of two types of receptors, $GABA_A$ and $GABA_B$. $GABA_A$ receptors are a major target for neuropsychiatric drugs, including benzodiazepines, barbiturates and anesthetic agents. The GABAergic system regulates a host of physiological and neurological functions and their related moods and behaviors. The principal positive physiologic modulators of the GABAergic system are the neurotransmitter GABA (γ-aminobutyric acid) and the positive allosteric modulator allopregnanolone. GABA generally inhibits nervous system excitability and thereby produces a calming effect that reduces anxiety and compulsive behavior, among other manifestations. While allopregnanolone typically enhances GABA's calming effects, in some individuals it paradoxically exacerbates anxiety and compulsive behavior.

Sepranolone is a synthetic version of isoallopregnanolone, a naturally occurring neurosteroid that counteracts the effects of allopregnanolone. Sepranolone is designed to normalize $GABA_A$ receptor activity by targeting two specific receptor subtypes (alpha-2 and alpha-4) without directly interfering with GABA signaling, making it a novel and selective treatment approach for diseases such as PWS and TS and other disorders that feature compulsive behavior.

Relmada expects to file a United States IND application for sepranolone with the FDA by year-end 2026.

Our Corporate History and Background

We are a clinical-stage, publicly traded biotechnology company developing new chemical entities (NCE) and novel versions of drug products that potentially address areas of high unmet medical need in the treatment of cancer, neurological disorders, and other diseases.

Currently, none of our product candidates has been approved for sale in the United States or elsewhere. We have no commercial products nor do we have a sales or marketing infrastructure. In order to market and sell our products we must conduct clinical trials on patients and obtain regulatory approvals from appropriate regulatory agencies, like the FDA in the United States, and similar organizations elsewhere in the world.

We have not generated revenues and do not anticipate generating revenues for the foreseeable future. We had a net loss of approximately $45,828,300 for the nine months ended September 30, 2026. At September 30, 2026, we had an accumulated deficit of approximately $744,095,500.

Business Strategy

Our strategy is to leverage our considerable industry experience, understanding of pharmaceutical markets and development expertise to identify, develop and commercialize product candidates with significant market potential that can fulfill unmet medical needs. We have assembled a management team along with both scientific advisors, and business advisors with significant industry and regulatory experience to lead and execute the development and commercialization of our product candidates.

Intellectual Property Portfolio and Market Exclusivity

We have more than 40 issued patents and pending patent applications related to sepranolone for multiple uses, including diseases and disorders exhibiting compulsive behaviors such as, TS, obsessive-compulsive disorder, and gambling disorder, potentially providing coverage beyond 2038.

We have more than 10 issued patents and pending patent applications related to NDV-01 for multiple uses, including formulations and methods for sustained-release of therapeutics for treatment of diseases such as bladder cancer, potentially providing coverage beyond 2038.

In April 2026, the Company filed a provisional patent application with the United States Patent and Trademark Office directed to pharmaceutical formulations and methods of treatment related to NDV-01. The provisional filing has the potential to form the basis for broad world-wide patent filings for the NDV-01 program. If issued, patents claiming priority to the provisional filing will be expected to have a term until April 2047.

Available Information

Reports we file with the Securities and Exchange Commission (SEC) pursuant to the Exchange Act of 1934, as amended (the Exchange Act), including annual and quarterly reports, and other reports we file are available on the SEC's website at sec.gov.

Results of Operations

For the Three Months Ended September 30, 2026 versus September 30, 2025:

	Three Months Ended September 30, 2026	Three Months Ended September 30, 2025	Increase (Decrease)
Operating Expenses			
Research and development	$ 9,217,440	$ 4,036,267	$ 5,181,173
General and administrative	3,878,983	6,291,079	(2,412,096)
Total	$ 13,096,423	$ 10,327,346	$ 2,769,077

Research and Development Expense

Research and development expense for the three months ended September 30, 2026 was approximately $9,217,400 compared to $4,036,300 for the three months ended September 30, 2025, an increase of approximately $5,181,100. The change was primarily driven by:

- Increase in manufacturing and drug storage costs of $3,463,300
- Increase in study costs of $1,627,700 associated with the ramp-up of NDV-01 and sepranolone studies;
- Increase in compensation expense of $576,100 due to an increase in research and development employees and their related bonus;
- Decrease in stock-based compensation expense of $367,700;
- Decrease in other research expenses of $91,000 primarily associated with the winding down of the REL-1017 302 and 304 studies in 2025; and
- Decrease in stock appreciation rights expense of $27,300.

General and Administrative Expense

General and administrative expense for the three months ended September 30, 2026 was approximately $3,879,000 compared to $6,291,100 for the three months ended September 30, 2025, a decrease of approximately $2,412,100. The change was primarily due to:

- Decrease in stock-based compensation expense of $2,746,000;
- Decrease in stock appreciation rights expense of $928,500;
- Increase in compensation expense of $1,007,500 due to an increase of general and administrative employees and their related bonuses; and
- Increase in other general and administrative expenses of $254,900 primarily due to an increase in consulting services.

Other Income

Interest/investment income was approximately $2,274,500 and $247,000 for the three months ended September 30, 2026 and 2025, respectively. The increase was due to higher average investment balance. Realized loss on short-term investments was approximately $435,100 and $81,400 for the three months ended September 30, 2026 and 2025. Unrealized loss on short-term investments was approximately $2,605,200 for the three months ended September 30, 2026 compared to an unrealized gain of $70,300 for the three months ended September 30, 2025.

Net Loss

The net loss for the Company for the three months ended September 30, 2026 and 2025 was approximately $13,862,200 and $10,091,500, respectively. The Company had loss per share basic and diluted of $0.12 and $0.30 for the three months ended September 30, 2026 and 2025, respectively.

Income Taxes

The Company did not provide for income taxes for the three months ended September 30, 2026 and 2025, since there was a loss and a full valuation allowance against all deferred tax assets.

Results of Operations

For the Nine Months Ended September 30, 2026 versus September 30, 2025:

	Nine Months Ended September 30, 2026	Nine Months Ended September 30, 2025	Increase (Decrease)
Operating Expenses			
Research and development	$ 25,699,073	$ 18,806,667	$ 6,892,406
General and administrative	21,870,130	19,960,421	1,909,709
Total	$ 47,569,203	$ 38,767,088	$ 8,802,115

Research and Development Expense

Research and development expense for the nine months ended September 30, 2026 was approximately $25,699,100 compared to $18,806,700 for the nine months ended September 30, 2025, an increase of approximately $6,892,400. The increase was primarily due to:

- Increase in manufacturing and drug storage costs of $8,662,800;
- Increase in compensation expense of $1,090,800 due to an increase in research and development employees and their related bonuses.
- Increase in stock appreciation rights expense of $796,400;
- Decrease in study costs of $2,158,500 associated with a decrease of 302 and 304 study expenses due to the wind-down of these studies;
- Decrease in stock-based compensation expense of $835,500; and
- Decrease in other research expenses of $663,600 primarily associated with the wind-down of the 302 and 304 studies in 2025.

General and Administrative Expense

General and administrative expense for the nine months ended September 30, 2026 was approximately $21,870,100 compared to $19,960,400 for the nine months ended September 30, 2025, an increase of approximately $1,909,700. The increase was primarily due to:

- Increase in compensation expense of $5,768,000 primarily related an increase of general and administrative employees and their related bonuses;
- Increase in stock appreciation rights expense of $2,678,100;
- Increase in other general and administrative expenses of $1,496,500 primarily due to an increase in consulting services; and
- Decrease in stock-based compensation expense of $8,032,900 related to option grants to employees and key consultants that reached the end of their vesting at the end of 2025.

Other Income

Interest / investment income was approximately $5,535,700 and $1,008,800 for the nine months ended September 30, 2026 and 2025, respectively. The increase was due to higher interest rates and investment yields and a higher average balance. Realized loss on short-term investments was approximately $482,300 for the nine months ended September 30, 2026 compared to a realized gain of $28,700 for the nine months ended September 30, 2025. Unrealized loss on short-term investments was approximately $3,312,500 for the nine months ended September 30, 2026 compared to an unrealized gain of $212,200 for the nine months ended September 30, 2025.

Net Loss

The net loss for the Company for the nine months ended September 30, 2026 and 2025 was approximately $45,828,300 and $37,517,400 respectively. The Company had loss per share, basic and diluted of $0.44 and $1.16 for the nine months ended September 30, 2026 and 2025, respectively.

Income Taxes

The Company did not provide for income taxes for the nine months ended September 30, 2026 and 2025, since there was a loss and a full valuation allowance against all deferred tax assets.

Liquidity

As shown in the accompanying unaudited condensed consolidated financial statements, the Company has incurred losses and negative cash flows from operations since inception and expects to incur additional losses until such time that it can generate significant revenue from the commercialization of its product candidates. During the nine months ended September 30, 2026, the Company incurred a net loss of $45,828,329 and had negative operating cash flows of $37,259,226.

On November 5, 2025, the Company announced the closing of its underwritten offering of 40,142,000 shares of its common stock and, in lieu of common stock to certain investors, pre-funded warrants to purchase up to 5,315,000 shares of common stock. The shares of common stock were sold at an offering price of $2.20 per share, and the pre-funded warrants were sold at an offering price of $2.199 per pre-funded warrant, which represents the per share offering price for the common stock less the $0.001 per share exercise price for each such pre-funded warrant. The net proceeds to the Company from the offering, after deducting other expenses payable by the Company, and excluding the exercise of any pre-funded warrants, were approximately $94 million.

On March 9, 2026, the Company entered into a Securities Purchase Agreement for a private placement with certain institutional and accredited investors (collectively, the Purchasers). The Purchasers purchased 29,474,569 shares of the Company's common stock, par value $0.001 per share and pre-funded warrants up to 4,210,527 shares of common stock. The closing of the Private Placement occurred on March 11, 2026. The shares of common stock were sold at an offering price of $4.75 per share, and the pre-funded warrants were sold at an offering price of $4.749 per pre-funded warrant, which represents the per share purchase price for the common stock less the $0.001 per share exercise price for each such pre-funded warrant. The net proceeds from the Purchase Agreement, after deducting fees payable by the Company, and excluding the exercise of any pre-funded warrants, were approximately $150 million.

As of the date of this report, Management believes that the Company's existing cash and cash equivalents and short-term investments will enable it to fund operating expenses and capital expenditure requirements for at least 12 months from the issuance of these unaudited condensed consolidated financial statements. Beyond that point management will evaluate the size and scope of any subsequent trials that will affect the timing of additional financings through public or private sales of equity or debt securities or from bank or other loans or through strategic collaboration and/or licensing agreements. Any such expenditures related to any subsequent clinical trials will not be incurred until such additional financing is raised. As a result, the Company concluded the Company has sufficient funds to maintain operations for at least 12 months from the issuance of these unaudited condensed consolidated financial statements.

The following table sets forth selected cash flow information for the periods indicated below:

	Nine Months Ended September 30, 2026	Nine Months Ended September 30, 2025
Cash used in operating activities	$ (37,259,226)	$ (31,190,765)
Cash (used in)/provided by investing activities	(110,688,101)	28,791,244
Cash provided by/(used in) financing activities	150,171,112	(73,021)
Net increase/(decrease) in cash and cash equivalents	$ 2,223,785	(2,472,542)

For the nine months ended September 30, 2026, cash used in operating activities was $37,259,226 primarily due to the net loss of $45,828,329 offset by non-cash stock-based compensation charges of $2,882,265 and stock appreciation rights compensation of $2,722,922. There were realized losses and unrealized losses on short-term investments of $482,284 and $3,312,539, respectively. In addition, there was a decrease in operating assets and liabilities of $830,907.

For the nine months ended September 30, 2025, cash used in operating activities was $31,190,765 primarily due to the net loss of $37,517,403 offset by non-cash stock-based compensation charges of $10,628,776, stock appreciation rights compensation of $216,640 and proceeds from the issuance of restricted common stock of $905,226. There were realized gains and unrealized gains on short-term investments of $28,717 and $212,210, respectively. In addition, there was a decrease in

operating assets and liabilities of $5,183,077.

For the nine months ended September 30, 2026, cash used in investing activities was $110,688,101, due to $199,152,165 of purchases of short-term investments offset by $88,464,064 of sales of short-term investments.

For the nine months ended September 30, 2025, cash provided by investing activities was $28,791,244, due to $1,043,307 of purchases of short-term investments offset by $29,834,551 of sales of short-term investments.

Net cash provided by financing activities for the nine months ended September 30, 2026, was $150,171,112 due to proceeds from the issuance of common stock for $159,999,996, proceeds from options exercised for common stock of $119,247, and proceeds from warrants exercised for common stock of $1,683 offset by fees for issuance of common stock of $9,817,890 and ATM expenses of $131,924.

Net cash used in financing activities for the nine months ended September 30, 2025 was $73,021 related to ATM expenses.

Effects of Inflation

Our assets are primarily monetary, consisting of cash and cash equivalents and short-term investments. Because of their liquidity, these assets are not directly affected by inflation. However, the rate of inflation affects our expenses, such as those for employee compensation and contract services, which could increase our level of expenses and the rate at which we use our resources.

Commitments and Contingencies

Please refer to Note 10 in our Annual Report on Form 10-K for the year ended December 31, 2025 under the heading Commitments and Contingencies. To our knowledge there have been no material changes to the risk factors that were previously disclosed in the Company's Annual Report on Form 10-K for the year ended December 31, 2025. Additional risks and uncertainties not currently known to us or that we currently deem to be immaterial also may materially adversely affect our business, financial condition and/or operating results.

Critical Accounting Policies and Estimates

A critical accounting policy is one that is both important to the portrayal of a company's financial condition and results of operations and requires management's most difficult, subjective or complex judgments, often as a result of the need to make estimates about the effect of matters that are inherently uncertain.

Our unaudited condensed consolidated financial statements are presented in accordance with U.S. GAAP, and all applicable U.S. GAAP accounting standards effective as of September 30, 2026 have been taken into consideration in preparing the unaudited consolidated financial statements. The preparation of unaudited condensed consolidated financial statements requires management to make estimates and assumptions that affect the reported amounts of assets, liabilities, and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses for the reporting period. Management bases its estimates on historical experience and on various assumptions that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. On a continual basis, management reviews its estimates utilizing currently available information, changes in facts and circumstances, historical experience, and reasonable assumptions. After such reviews, and if deemed appropriate, management's estimates are adjusted accordingly. Actual results could differ from those estimates and assumptions under different and/or future circumstances. Management considers an accounting estimate to be critical if:

- it requires assumptions to be made that were uncertain at the time the estimate was made; and
- changes in the estimate, or the use of different estimating methods that could have been selected, could have a material impact on results of operations or financial condition.

We evaluate our estimates and assumptions on an ongoing basis and none of the Company's estimates and assumptions used within the unaudited condensed consolidated financial statements involve a high level of estimation uncertainty. For additional discussion regarding the application of the significant accounting policies, see Note 3 to the Company's unaudited condensed consolidated financial statements included in this report.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK.

There have been no material changes to our exposures to market risks as disclosed under the heading "Quantitative and Qualitative Disclosures About Market Risks" in the annual Management's Discussion and Analysis of Financial Condition and Results of Operations contained in our Form 10-K for the year ended December 31, 2025.

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

We carried out an evaluation, under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, of the effectiveness of the design and operation of our disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the Exchange Act). Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by an issuer in the reports that it files or submits under the Exchange Act is accumulated and communicated to the issuer's management, including its principal executive and principal financial officers, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure. Based upon our evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures are effective as of September 30, 2026, in ensuring that material information that we are required to disclose in reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission rules and forms.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting, as such term is defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act, during the three months ended September 30, 2026 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

From time to time, the Company may become involved in lawsuits and other legal proceedings that arise in the course of business. Litigation is subject to inherent uncertainties, and it is not possible to predict the outcome of litigation with total confidence. The Company is currently not aware of any legal proceedings or potential claims against it whose outcome would be likely, individually or in the aggregate, to have a material adverse effect on the Company's business, financial condition, operating results, or cash flows.

ITEM 1A. RISK FACTORS

There have been no material changes to the risk factors under Part I, Item 1A of our Form 10-K for the year ended December 31, 2025.

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

On October 9, 2026, the Company entered into a service agreement with Scinai Biopharma Services Ltd. ("Scinai") for manufacturing and related services supporting the Company's NDV-01 clinical development program. In addition to service fees and reimbursements, the agreement provides for contingent success-based consideration payable to Scinai in shares of the Company's common stock, par value $0.001 per share, having an aggregate reference value of $1.0 million.

The consideration becomes earned if the Company submits the initial NDV-01 investigational new drug application ("IND") to the U.S. Food and Drug Administration ("FDA") on or before December 31, 2026, and the IND becomes effective for the proposed clinical study upon expiration of the FDA's initial 30-calendar-day review period, or earlier if affirmatively permitted by the FDA, without imposition of a clinical hold. The milestone applies solely to the initial NDV-01 IND arising from the project and does not extend to a later resubmission or a different IND unless otherwise agreed in writing.

The number of shares issuable will be determined by dividing $1.0 million by the average closing sale price of the Company's common stock for the five trading days immediately preceding, but excluding, the IND submission date. Issuance is subject to applicable securities laws, required corporate approvals, Nasdaq requirements and contractual ownership and issuance limitations. Earned consideration is generally payable within 10 business days, as defined in the agreement, after satisfaction of the milestone, with a limited extension to no later than 30 such business days. If issuance is prevented, reduced or not completed by that outside payment date, the Company must pay the corresponding earned consideration in cash.

Any shares issued under the agreement are intended to be issued in reliance on the exemption from registration provided by Section 4(a)(2) of the Securities Act of 1933, as amended. Scinai represented that it is an accredited investor, is acquiring the securities for investment purposes and has had access to information concerning the Company. The shares will be subject to applicable transfer restrictions, and the agreement contemplates a 12-month contractual lock-up commencing upon issuance. The Company will receive no cash proceeds from any such issuance; the shares will constitute additional consideration for Scinai's services.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES.

None.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

ITEM 5. OTHER INFORMATION

Director and Officer Trading Arrangements

No directors or executive officers of the Company adopted, modified or terminated a Rule 10b5-1 trading arrangement or a non-Rule 10b5-1 trading arrangement (as defined in Item 408(c) of Regulation S-K) during the quarterly period covered by this Report.

ITEM 6. EXHIBITS

Copies of the following documents are included as exhibits to this report pursuant to Item 601 of Regulation S-K

Exhibit No.	Title of Document	Location
31.1	Certification of the Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002	Filed herewith
31.2	Certification of the Principal Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002	Filed herewith
32.1	Certification of the Chief Executive Officer pursuant to 18 U.S.C. Section 1350 as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002*	Furnished herewith
32.2	Certification of the Principal Financial Officer pursuant to 18 U.S.C. Section 1350 as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002*	Furnished herewith

101.INS	Inline XBRL Instance Document.	Filed herewith
101.SCH	Inline XBRL Taxonomy Extension Schema Document.	Filed herewith
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document.	Filed herewith
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document.	Filed herewith
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document.	Filed herewith
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document.	Filed herewith
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101).	Filed herewith

* The Exhibit attached to this Form 10-Q shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934 (the "Exchange Act") or otherwise subject to liability under that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such filing.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

Date: November 12, 2026

By: /s/ Sergio Traversa
Sergio Traversa
Chief Executive Officer
(Duly Authorized Officer and
Principal Executive Officer)

/s/ Maged Shenouda
Maged Shenouda
Chief Financial Officer
(Duly Authorized Officer and
Principal Financial and Accounting Officer)