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 **March 31, 2025**

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: **000-55347**

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 Global Select 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 May 7, 2025, there were 33,191,622 shares of common stock, $0.001 par value per share, outstanding.

Relmada Therapeutics, Inc.
Index

		Page Number
PART I - FINANCIAL INFORMATION		
Item 1.	Unaudited Condensed Consolidated Financial Statements	1
	Condensed Consolidated Balance Sheets as of March 31, 2025 (unaudited) and December 31, 2024	1

	Unaudited Condensed Consolidated Statements of Operations for the Three Months Ended March 31, 2025 and 2024	2
	Unaudited Condensed Consolidated Statements of Changes in Stockholders' Equity for the Three Months Ended March 31, 2025 and 2024	3
	Unaudited Consolidated Statements of Cash Flows for the Three Months Ended March 31, 2025 and 2024	4
	Notes to Unaudited Condensed Consolidated Financial Statements	5
Item 2.	Management's Discussion and Analysis of Financial Condition and Results of Operations	15
Item 3.	Quantitative and Qualitative Disclosures About Market Risk	23
Item 4.	Controls and Procedures	23
PART II - OTHER INFORMATION		
Item 1.	Legal Proceedings	24
Item 1A.	Risk Factors	24
Item 2.	Unregistered Sales of Equity Securities and Use of Proceeds	24
Item 3.	Defaults Upon Senior Securities	24
Item 4.	Mine Safety Disclosures	24
Item 5.	Other Information	24
Item 6.	Exhibits	25
SIGNATURES		26

PART I - FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

Relmada Therapeutics, Inc.
Condensed Consolidated Balance Sheets

	As of March 31, 2025 (Unaudited)	As of December 31, 2024
Assets		
Current assets:		
Cash and cash equivalents	$ 1,149,706	$ 3,857,026
Short-term investments	25,911,326	41,052,356
Prepaid expenses	596,410	886,461
Total current assets	27,657,442	45,795,843
Other assets	21,975	21,975
Total assets	$ 27,679,417	$ 45,817,818
Commitments and Contingencies (See Note 8)		
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 1,265,010	$ 4,130,563
Accrued expenses	3,966,411	6,160,827
Total current liabilities	5,231,421	10,291,390
Stock appreciation rights	7,505	4,467
Total liabilities	5,238,926	10,295,857
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, 150,000,000 shares authorized, 33,191,622 and 30,174,202 shares issued and outstanding, respectively	33,191	30,174
Additional paid-in capital	680,848,800	676,373,822
Accumulated deficit	(658,441,500)	(640,882,035)
Total stockholders' equity	22,440,491	35,521,961
Total liabilities and stockholders' equity	$ 27,679,417	$ 45,817,818

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 March 31,	
	2025	2024

Operating expenses:		
Research and development	$ 11,951,023	$ 13,305,306
General and administrative	6,267,412	9,682,554
Total operating expenses	18,218,435	22,987,860
Loss from operations	(18,218,435)	(22,987,860)
Other income:		
Interest/investment income, net	440,287	1,055,888
Realized gain on short-term investments	62,952	53,133
Unrealized gain on short-term investments	155,731	50,713
Total other income	658,970	1,159,734
Net loss	$ (17,559,465)	$ (21,828,126)
Loss per common share – basic and diluted	$ (0.58)	$ (0.72)
Weighted average number of common shares outstanding – basic and diluted	30,408,890	30,132,170

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 months ended March 31, 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

	Three months ended March 31, 2024				
	Common Stock		Additional Paid-in	Accumulated	
	Shares	Par Value	Capital	Deficit	Total
Balance - December 31, 2023	30,099,203	$ 30,099	$ 646,229,824	$ (560,902,681)	$ 85,357,242
Stock based compensation	-	-	8,295,468	-	8,295,468
Options exercised for common stock	74,999	75	246,672	-	246,747
ATM Fees	-	-	(25,000)	-	(25,000)
Net loss	-	-	-	(21,828,126)	(21,828,126)
Balance - March 31, 2024	30,174,202	$ 30,174	$ 654,746,964	$ (582,730,807)	$ 72,046,331

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

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

	Three months ended March 31,	
	2025	2024
Cash flows from operating activities		
Net loss	$ (17,559,465)	$ (21,828,126)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	4,477,995	8,295,468
Realized gain on short-term investments	(62,952)	(53,133)
Unrealized gain on short-term investments	(155,731)	(50,713)
Change in operating assets and liabilities:		
Prepaid expenses	290,051	432,723
Accounts payable	(2,865,553)	1,683,092
Accrued expenses	(2,194,416)	(1,516,059)
Stock appreciation rights compensation	3,038	-

Net cash used in operating activities	(18,067,033)	(13,036,748)
Cash flows from investing activities		
Purchase of short-term investments	(487,916)	(7,013,933)
Sale of short-term investments	15,847,629	17,072,384
Net cash provided by investing activities	15,359,713	10,058,451
Cash flows from financing activities		
Proceeds from options exercised for common stock	-	246,747
ATM Fees	-	(25,000)
Net cash provided by financing activities	-	221,747
Net decrease in cash and cash equivalents	(2,707,320)	(2,756,550)
Cash and cash equivalents at beginning of the period	3,857,026	4,091,568
Cash and cash equivalents at end of the period	$ 1,149,706	$ 1,335,018

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, controlled-release intravesical formulation of gemcitabine and docetaxel. NDV-01 is currently in a Phase 2 clinical trial 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, Tourette Syndrome, excessive tremor and other diseases related to excessive GABAergic activity.

The Esmethadone (d-methadone, dextromethadone, REL-1017) program has been paused pending a comprehensive data review of the data generated so far. Esmethadone an N-methyl-D-aspartate (NMDA) receptor antagonist. Esmethadone is a new chemical entity (NCE) that potentially addresses areas of high unmet medical need in the treatment of central nervous system (CNS) diseases and other disorders.

Relmada was also developing a proprietary, modified-release formulation of psilocybin (REL-P11) for metabolic indications. This program was terminated effective May 12, 2025, after a successful P1 study and in light of the adversely changed regulatory environment affecting chronic administration of psylocibin and potentially other psychedelic drugs.

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.

On January 21, 2025, we received a deficiency letter from the Listing Qualifications Department (the "Staff") of The Nasdaq Stock Market advising that, for 30 consecutive business days preceding the notification letter, the Company did not meet the minimum $1.00 per share bid price requirement for continued inclusion on The Nasdaq Global Select Market. The deficiency letter does not result in the immediate delisting of our common stock from the Nasdaq Global Select Market. In accordance with Nasdaq Listing Rule 5810(c)(3)(A) (the "Compliance Period Rule"), we have been provided an initial period of 180 calendar days, or until July 21, 2025 (the "Compliance Date"), to regain compliance with the minimum bid price requirement. If, at any time before the Compliance Date, the bid price for our common stock closes at $1.00 per share or more for a minimum of 10 consecutive business days, as required by the Compliance Period Rule, the Staff will provide written notification to us that we comply with the minimum bid price requirement, unless the Staff exercises its discretion to extend this 10-day period pursuant to Nasdaq Listing Rule 5810(c)(3)(H). While we intend to regain compliance with the minimum bid price requirement, there can be no assurance that we will be able to maintain continued compliance with this rule or the other listing requirements of The Nasdaq Stock Market. If we were unable to meet these requirements, we would receive another delisting notice from the Nasdaq Stock Market for failure to comply with one or more of the continued listing requirements. If our common stock were to be delisted from The Nasdaq Global Select Market, trading of our common stock most likely will be conducted in the over-the-counter market on an electronic bulletin board established for unlisted securities such as the OTC Markets or in the "pink sheets." Such a downgrading in our listing market may limit our ability to make a market in our common stock and which may impact purchases or sales of our securities.

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 is €3,000,000. The Company paid Asarina $2,756,000 on February 5, 2025, which includes 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, we entered into an Exclusive License Agreement with Trigone, an Israeli company. The license agreement is for Trigone's NDV-01 product, which is a novel, sustained-release, intravesical gemcitabine/docetaxel, ready-for-use product candidate for the treatment of NMIBC. 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 sales milestones pending successful commercialization. The Company will also pay a royalty of 3% on any net sales.

NOTE 2 - GOING CONCERN

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 three months ended March 31, 2025, the Company incurred a net loss of $17,559,465 and had negative operating cash flows of $18,067,033. Given the Company's projected operating requirements and its existing cash and cash equivalents and short-term investments, the Company is projecting insufficient liquidity to sustain its operations through one year following the date that the financial statements are issued. These conditions and events raise substantial doubt about the Company's ability to continue as a going concern.

NOTE 2 - GOING CONCERN (continued)

In response to these conditions, management is currently evaluating the size and scope of any subsequent operations and clinical trials that will affect the timing to obtain the required funding of future operations. Financing strategies may include, but are not limited to, the public or private sale of equity or debt securities or from bank or other loans or through strategic collaboration and/or licensing agreements. There can be no assurances that the Company will be able to secure additional financing, or if available, that it will be sufficient to meet its needs or on favorable terms. Because management's plans have not yet been finalized and are not within the Company's control, the implementation of such plans cannot be considered probable. As a result, the Company has concluded that management's plans do not alleviate substantial doubt about the Company's ability to continue as a going concern.

The unaudited condensed consolidated financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts or the amounts and classification of liabilities that might result from the outcome of this uncertainty.

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, 2024 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 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 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 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 $1,149,706 and $3,857,026 at March 31, 2025 and December 31, 2024, respectively, at these institutions exceed the federally insured limits.

Short-term Investments

The Company's investments consist entirely of mutual funds. The securities are measured at fair value based on the net asset value "NAV". Substantially all equity investments in nonconsolidated entities are measured at fair value with recurring changes recognized in earnings, except for those accounted for using equity accounting methods. 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 statement of cash flows.

Short-term investments at March 31, 2025 and December 31, 2024 consisted of mutual funds with a fair value of $25,911,326 and $41,052,356, 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 consists 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.

NOTE 3 - SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (continued)

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 $25,911,326 at March 31, 2025 consist of mutual funds and are classified using Level 1 inputs within the fair value hierarchy because they are valued using NAV. Unrealized gains and losses are recorded in the condensed consolidated statement of operations as unrealized gain on short-term investment. The Company recorded unrealized gains of $155,731 and $50,713 included in other income (expense) for the three months ended March 31, 2025 and 2024, 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 March 31, 2025, the stock appreciation rights liability had a fair value of $7,505. Significant inputs for Level 3 stock appreciation rights liability fair value measurement at March 31, 2025 are (1) discount rate of 3.96% - 4.03%, (2) expected life of 5.50 – 6.00 years, (3) expected volatility of 128% - 131%, (4) zero expected dividends, (5) stock price of $0.27 and (6) exercise price of $0.45 - $3.84.

There have been no transfers in and out of level 3 during the three-months ended March 31, 2025.

NOTE 3 - SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (continued)

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 March 31, 2025 and December 31, 2024, the Company had recognized 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 March 31, 2025 and December 31, 2024. The open tax years, subject to potential examination by the applicable taxing authority, for the Company are from December 31, 2020 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)

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 three months ended March 31, 2025 and 2024, 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):

	Three months ended	
	March 31, 2025	March 31, 2024
Stock options	11,258,927	17,013,135
Common stock warrants	872,908	2,235,412
Total	12,131,835	19,248,547

Adoption of Recent Accounting Standards

In November 2023, The FASB issued ASU 2023-07, "*Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures*" which expands annual and interim disclosures for reportable segments, primarily through enhanced disclosures about significant segment expenses. ASU 2023-07 is effective for our annual periods beginning January 1, 2024, and for interim periods beginning January 1, 2025, with early adoption permitted. The Company adopted this standard effective January 1, 2024 and the standard did not have significant impact on our consolidated financial statements.

In December 2023, the FASB issued ASU 2023-09, "*Income Taxes (Topic 740): Improvements to Income Tax Disclosures*" to expand the disclosure requirements for income taxes, specifically related to the rate reconciliation and income taxes paid. ASU 2023-09 was effective for our annual periods beginning January 1, 2025. The Company adopted this standard effective January 1, 2025 and the updated standard did not have a significant impact on our consolidated financial statement disclosures.

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.

NOTE 4 - PREPAID EXPENSES

Prepaid expenses consisted of the following (rounded to nearest $00):

	March 31, 2025	December 31, 2024
Insurance	$ 195,000	$ 403,100
Research and Development	265,900	391,200
Other	135,500	92,200
Total	$ 596,400	$ 886,500

NOTE 5 - ACCRUED EXPENSES

Accrued expenses consisted of the following (rounded to nearest $00):

	March 31, 2025	December 31, 2024
Research and development	$ 2,566,400	$ 4,514,800
Professional fees	313,200	362,600
Accrued bonus	457,300	732,300
Accrued vacation	561,900	421,700
Other	67,600	129,400
Total	$ 3,966,400	$ 6,160,800

NOTE 6 - STOCK APPRECIATION RIGHTS

During the three months ended March 31, 2025, 300,000 cash-settled stock appreciation rights have been issued to consultants with an exercise price of $0.45 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 4.43%, (2) expected life of 6.25 years, (3) expected volatility of 135%, and (4) zero expected dividends.

At March 31, 2025, the Company revalued the cash-settled stock appreciation rights using a stock price of $0.27 and an exercise price of $0.45 - $3.84. Variables used in the Black-Scholes option-pricing model include: (1) discount rate of 3.96% - 4.03%, (2) expected life of 5.50 – 6.00 years, (3) expected volatility of 128% - 131% and (4) zero expected dividends.

As of March 31, 2025, the total liability related to cash-settled SARs is $7,505, reflecting the fair value as of the reporting date. During the quarter ended March 31, 2025, the Company recorded compensation related to the cash-settled SARs in the amount of $3,038, included in research and development expenses in the accompanying unaudited condensed consolidated statements of operations.

A summary of the changes in SARs during the three months ended March 31, 2025 is as follows:

	Number of Cash-Settled SARS	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term	Aggregate Intrinsic Value
Outstanding at December 31, 2024	110,000	$ 0.99	9.58	$ -
Granted	300,000	$ 0.33	9.76	$ -
Outstanding at March 31, 2025	410,000	$ 1.32	9.65	$ -
SARs vested at March 31, 2025	-	$ -	-	$ -

At March 31, 2025, the Company has unrecognized compensation expense of approximately $82,300 related to unvested stock appreciation rights which will be recognized over the weighted average remaining service period of 3.65 years.

NOTE 7 - STOCKHOLDERS' EQUITY

Common Stock

During the year ended December 31, 2024, the Company issued 74,999 shares of common stock for the exercise of options for proceeds of $246,747.

During the three months ended March 31, 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 $100,000,000. We are not obligated to sell any shares under the agreement. As of March 31, 2025, no shares have been issued under this agreement.

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 May 2022, the Company's Board of Directors adopted, and shareholders approved an amendment to the 2021 Plan to increase the shares of the Company's common stock available for issuance thereunder by 3,900,000 shares.

In May 2023, the Company's Board of Directors adopted and shareholders approved an amendment to the 2021 Plan to increase the shares of the Company's common stock available for issuance thereunder by 2,500,000 shares.

These combined plans allowed for the granting of up to 13,052,942 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.

From January 1, 2025 through March 31, 2025, 203,567 options were issued with an exercise price of $0.30 and a 10-year term, vesting over a 4 year period. The options granted include time-based vesting grants. The options have an aggregate fair value of approximately $54,963 calculated using the Black-Scholes option-pricing model. Variables used in the Black-Scholes option-pricing model include: (1) discount rate of 4.05% - 4.16% (2) expected life of 6.25 years, (3) expected volatility of 126%, and (4) zero expected dividends.

NOTE 7 - STOCKHOLDERS' EQUITY (continued)

Options

A summary of the changes in options during the three months ended March 31, 2025 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, 2024	12,263,017	$ 16.61	6.01	$ -
Granted	203,567	$ 0.30	-	$
Cancelled	(1,207,657)	$ 17.34	-	$ -
Outstanding at March 31, 2025	11,258,927	$ 16.24	6.46	$ -
Options exercisable at March 31, 2025	8,748,097	$ 19.02	6.02	$ -

At March 31, 2025, the Company has unrecognized stock-based compensation expense of approximately $12.8 million related to unvested stock options which will be recognized over the weighted average remaining service period of 1.99 years.

Warrants

A summary of the changes in outstanding warrants during the three months ended March 31, 2025 is as follows:

	Number of Shares	Weighted Average Exercise Price Per Share
Outstanding Warrants at December 31, 2024	1,382,613	$ 17.02
Expired	(509,705)	-
Outstanding at March 31, 2025	872,908	$ 29.25
Warrants Vested at March 31, 2025	865,033	$ 29.28

At March 31, 2025, the Company had approximately $112,300 of unrecognized compensation expense related to outstanding warrants.

At March 31, 2025, the aggregate intrinsic value of warrants vested and outstanding was $0.

Stock-based compensation by class of expense

The following table summarizes the components of stock-based compensation expense which includes restricted stock, stock options, and warrants in the unaudited consolidated statements of operations for the three months ended March 31, 2025 and 2024 (rounded to nearest $00):

	Three Months Ended March 31, 2025	Three Months Ended March 31, 2024
Research and development	$ 1,067,300	$ 1,699,300
General and administrative	3,410,700	6,596,200
Total	$ 4,478,000	$ 8,295,500

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 March 31, 2025, 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 will 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 will 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 will 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. As of March 31, 2025, no events have occurred, and the Company continues to pay Licensor $45,000 every three months.

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 will collaborate 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 is also eligible to receive a low single digit royalty on net sales of any commercialized therapy resulting from this agreement. The license agreement is terminable by the Company but is perpetual and not terminable by the licensor absent material breach of its terms by the Company.

The new 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 will cease as of the effective termination date, which is 90 days after the date of notice.

Trigone

On March 24, 2025, we entered into an Exclusive License Agreement with Trigone, an Israeli company. The license agreement is for Trigone's NDV-01 product, which is a novel, sustained-release, intravesical gemcitabine/docetaxel, ready-for-use product candidate for the treatment of NMIBC. 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 sales milestones pending successful commercialization. The Company will also pay a royalty of 3% on any net sales.

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

NOTE 8 - COMMITMENTS AND CONTINGENCIES (continued)

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 end December 31, 2025 and 2024 of approximately $4,100, and $7,000, respectively.

Beginning on December 1, 2023, we leased office space at 12 E 49th Street, New York, NY 10022 with monthly rent of approximately $12,000; that lease was terminated on May 31, 2024.

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 expires on May 30,

2025.

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 March 31, 2025 and 2024, the Company recognized lease expense of approximately $44,800 and $62,400, 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 POSTRETIREMENT 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 $47,700 and $35,000 for the three months ended March 31, 2025 and 2024, 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, 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.

Management determined the Company's operations constitute a single reportable segment in accordance with ASC 280: clinical stage drug development. The Company derives all of its losses from the development of clinical stage drugs expenses. The Company's CODM is its chief executive officer and chief financial officer. The CODM assesses performance and makes operating decisions about allocating resources based on the research and development operating expenses on the Consolidated Statements of Operations. The CODM does not review assets in evaluating the results of the clinical stage development, and therefore, such information is not presented.

The following table provides the operating expenses of our clinical stage drug development segment (rounded to the nearest $00):

	March 31, 2025	March 31, 2024
Clinical Study Expense	$ 7,960,600	$ 3,172,600
Other Research Expense	1,831,000	7,066,900
Manufacturing and Drug Storage Expense	155,600	292,500
Pre-clinical Expense	-	33,700
Compensation Expense	933,500	1,040,300
Stock-based Compensation Expense	1,070,300	1,699,300
Total Research and Development Expense	$ 11,951,000	$ 13,305,300

NOTE 11 - SUBSEQUENT EVENTS

On May 12, 2025, the Company delivered to Arbormentis LLC a formal notice of termination of the Company's License Agreement with Arbormentis LLC, ending the Company's participation in the previously announced psilocybin development program. This decision was made following a strategic review of the Company's research and development priorities. As a result of the cancellation, all obligations under the license agreement with Arbormentis will cease as of the effective termination date, which is 90 days after the date of notice. The Company does not expect any material financial impact resulting from this termination.

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 occasioned by disappointing interim analysis results in December 2024 indicating that our then lead development candidate, esmethadone (d-methadone, dextromethadone, or REL-1017) for the adjunctive treatment of Major Depressive Disorder (MDD), was unlikely to succeed in its pivotal trial. 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 pausing further work on REL-1017. Hence we accelerated ongoing efforts to augment our development pipeline while diversifying its risk, which culminated in the recently announced licensing of NDV-01, a novel delivery formulation of a chemotheraphy 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.

We also had been developing REL-P11, a modified-release formulation of psilocybin, as an investigational agent for the treatment of metabolic disease. The REL-P11 program has successfully completed a Phase 1 safety study. However, in light of an ongoing strategic review of this business opportunity, the changing regulatory landscape for the chronic use of psychedelics, its early stage of development and the acquisition of new, more advanced product candidates, effective May 12, 2025, this program has been terminated.

REL-1017 Program Updates

Since 2013, we had been developing esmethadone as our lead product candidate as an oral agent for the treatment of depression and other potential indications. In December 2024, we reported that the pre-planned interim analysis, conducted by the Independent Data Monitoring Committee (DMC), of Reliance II, our Phase 3 study of esmethadone as a potential adjunctive treatment for MDD, indicated that the study was futile and unlikely to meet the primary efficacy endpoint with statistical significance, and that we would pause the Reliance II and Relight Phase 3 studies of esmethadone.

Following this 2024 REL-1017 setback, which we believe mostly likely resulted from an overwhelming placebo response—a trend that has become more common than exceptional in central nervous system (CNS) clinical trials—the program has been paused pending a comprehensive data review, after which we will make a decision regarding the future of this program.

Strategic Business Review and New Approach

Following a comprehensive evaluation of the Company's business strategy and growth opportunities, management and the Board of Directors have implemented on an enhanced approach aimed at maximizing shareholder value.

This refined strategy remains focus on:

- Innovation – Advancing novel and differentiated therapeutic solutions
- Addressing Unmet Medical Needs – Targeting areas with significant gaps in treatment
- Large Market Opportunities – Prioritizing programs with substantial commercial potential
- Intellectual Property Protection – Strengthen and extending patent coverage to safeguard long-term value

Key Strategic Priorities

Under this updated approach, we will continue to emphasize:

- Leveraging Development Expertise – Focusing on high-value therapeutic areas while rigorously assessing development risks, market viability, and success probabilities
- Pipeline Diversification – Expanding and balancing our portfolio to mitigate risk and enhance growth potential
- Prioritizing Mid- to Late-Stage Programs – Concentrating resources on assets with clear path to commercialization
- Accelerating Market Entry – Streamline development timelines to bring therapies to patients faster
- Pursuing Cost-Effective Development Paths – Optimizing resource allocation and strategic partnerships
- Targeted Commercialization Strategy – Focusing on opportunities that require minimal sales and marketing infrastructure

This strategic framework positions the Company for long-term growth while maintaining execution and financial prudence.

Progress in Strategic Execution

We commenced a strategic review in December 2024 of our then existing development pipeline and the opportunities open to us given our core strengths in every aspect of drug development, with particular expertise in CNS. That process recently resulted in a series of transactions that have considerably expanded and strengthened Relmada's potential to create shareholder value. Since January 1, 2025, we have successfully closed two important transactions, NDV-01 in-licensing and Sepranolone acquisition, which align with our new strategy.

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, 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 delivery formulation of a widely used chemotherapeutic regimen used to treat NMIBC.

Key Upcoming Anticipated Milestones

We expect multiple key milestones over the next 12 months. These include:

- NDV-01 Six-month data from ongoing Phase 2 NMBIC Study – Mid 2025

- NDV-01 Nine-month data from ongoing Phase 2 NMBIC Study – 3rd Quarter 2025
- NDV-01 Twelve-month data from ongoing Phase 2 NMBIC Study – Year end 2025
- NDV-01 United States Investigative New Drug clearance – 1st Half 2026
- Sepranolone - Initiation of clinical trial in PWS – 1st Half 2026

Our Development Programs

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.

Data from an open-label Phase 2a randomized study demonstrated that Sepranolone has the potential to improve TS symptoms versus standard of care alone, as measured by changes in the YGTSS scoring system (the world-standard Yale Global Tic Severity Scale) compared to baseline. In the 12-week, dual-center, parallel-group study, 26 subjects were treated with Sepranolone (10 mg, administered by subcutaneous injection twice weekly in addition to standard of care (SOC) versus standard of care alone.

The Phase 2a results showed competitive tic reduction and improved quality of life while displaying no CNS off-target effects. Sepranolone not only reduced tic severity in its primary clinical endpoint as measured by YGTSS by 28% (p=0.051) – but also achieved positive results in four key secondary endpoints compared with standard of care:

- 69% greater increase of Quality of Life (using the Gilles de la Tourette Syndrome Quality of Life total score (GTS-QOL)
- 50% greater reduction in impairment (YGTSS)
- 44% greater reduction of the premonitory urge to tic (PUTS – the Premonitory Urge to Tic scale)

Importantly, no off-target CNS effects or systemic side effects were observed in this study. Further, Sepranolone has been evaluated in multiple clinical neuro/hormonal studies involving over 335 participants and has demonstrated a favorable safety profile.

Relmada is currently evaluating the nonclinical and clinical strategy for the development of Sepranolone.

NDV-01 Program

The second program we recently in-licensed, NDV-01, is a novel intravesicular delivery technology designed for the long-acting, controlled release of gemcitabine and docetaxel. This combination therapy has gained significant interest as an alternative to Bacillus Calmette-Guérin (BCG) for treating NMIBC, especially given the global BCG shortage since 2019. 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 10 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 controlled-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.

NDV-01 is currently in a Phase 2 clinical trial evaluating its safety and efficacy in patients with aggressive NMIBC. The Phase 2 study is a single-arm, single-center study evaluating the safety and efficacy of NDV-01 in patients with High Grade-NMIBC. Patients are treated with NDV-01 in a biweekly induction phase, follow by monthly maintenance for up to one year, with regular assessments via cystoscopy, cytology, and biopsy, as indicated. The primary efficacy endpoints are safety and complete response rate (Complete Response Rate at 12 months), and secondary efficacy endpoints are duration of response (DOR) and event free survival (EFS).

On April 28, 2025, the Company announced positive initial data from the Phase 2 study. As of the latest cut-off, a total of 26 patients had been enrolled: 20 patients had reached the 3-month assessment with 7 reaching the 6-month assessment.

Highlights of the initial Phase 2 data:

3-month Assessment:

- 85% Overall Response Rate (ORR)

- 83.3% High-Grade Recurrence-Free Survival (HGRFS) in papillary disease
- 100% Complete Response in CIS patients

At any time point:

- 90% ORR
- 88.8% HGRFS in papillary disease
- 100% Complete Response in CIS patients

Disease status at 6-month Assessment:

- 100% of evaluable patients achieved disease free status.

Safety:

- No treatment related adverse events greater than Grade 1.
- The most common treatment emergent adverse events (TEAEs) were urinary urgency, flank pain, and dysuria, all of which were mild and transient, resolving in 24-28 hours.
- No patients discontinued treatment due to adverse events.

Esmethadone (d-Methadone, dextromethadone, REL-1017) as a treatment for MDD

Esmethadone's mechanism of action, as a low affinity, non-competitive NMDA channel blocker or antagonist, is fundamentally differentiated from most currently FDA-approved antidepressants, as well as all atypical antipsychotics used adjunctively with standard, FDA-approved antidepressants. Working through the same brain mechanisms as ketamine and esketamine but potentially lacking their adverse side effects, esmethadone is being developed as a rapidly acting, oral agent for the treatment of depression and potentially other CNS conditions.

Relmada has paused this program pending a comprehensive data review, after which a decision regarding the future of this program will be made.

Esmethadone (d-methadone, dextromethadone, REL-1017) in other indications

While our strategy was to focus on the development of esmethadone as an adjunctive treatment for MDD, we are also evaluating other indications that Relmada may explore in the future, including restless leg syndrome and other glutamatergic system activation related diseases.

Psilocybin Program

Relmada acquired the development and commercial rights to a novel psilocybin and derivative program from Arbormentis LLC in July of 2021. The original focus of the program was limited to neurodegenerative diseases. Psilocybin has neuroplastogen™ effects that have the potential to ameliorate the consequences of multiple neurodegenerative conditions. The pleiotropic metabolic effects of low-dose psilocybin were discovered while studying its neuroplastogen™ potential in a rodent model deficient in neurogenesis – obese rodents maintained on a high fructose, high fat diet (HFHFD). Specifically, in a rodent model of metabolic dysfunction-associated steatotic liver disease (MASLD), beneficial effects of psilocybin were observed on multiple metabolic parameters, including reduced hepatic steatosis, reduced body weight gain, and fasting blood glucose levels.

Effective May 12, 2025, Relmada has terminated this program in light of an ongoing strategic review of this business opportunity, the changing regulatory landscape for psychedelics, its early stage of development and the acquisition of new, more advanced product candidates.

Our Corporate History and Background

We are a clinical-stage, publicly traded biotechnology company developing NCEs and novel versions of drug products that potentially address areas of high unmet medical need in the treatment of cancer, neurological disorders, depression 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 $17,559,500 for the three months ended March 31, 2025. At March 31, 2025, we had an accumulated deficit of approximately $658,441,500.

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 PWS, TS, obsessive-compulsive disorder, and gambling disorder, potentially providing coverage beyond 2030.

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

We have more than 50 issued patents and pending patent applications related to REL-1017 for multiple uses, including psychological and neurological conditions, potentially providing coverage beyond 2033. We have also secured an Orphan Drug Designation from the FDA for d-methadone for "the treatment of postherpetic neuralgia" (postherpetic neuralgia is lasting pain in areas of skin affected by previous outbreaks of shingles, caused by the varicella zoster, or herpes zoster, virus) which, upon potential NDA approval, carries 7-year FDA Orphan Drug marketing exclusivity. In the European Union, some of our prospective products may be eligible up to 10 years of market exclusivity, which includes 8 years data exclusivity and 2 years market exclusivity. In addition to any granted patents, REL-1017 will be eligible for market exclusivity to run concurrently with the term of the patent for 5 years in the U.S. (Hatch Waxman Act) and may be eligible for an additional 6 months of pediatric exclusivity and up to 10 years of exclusivity in the European Union. We believe an extensive intellectual property estate of US and foreign patents and applications, once approved, will protect our technology and products.

Key Strengths

We believe that the key elements for our market success include:

- Compelling lead product opportunities in NDV-01 and Sepranolone.
- Experienced management team with considerable drug development expertise;
- Multiple potential bladder cancer related indications for NDV-01.
- Extensive safety database for Sepranolone as well as promising signal of efficacy in Tourette Syndrome
- Substantial and growing IP portfolio for both Sepranolone and NDV-01
- Scientific support of leading experts: Our scientific advisors include clinicians and scientists who are affiliated with a number of highly regarded medical institutions.

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, can be inspected and copied at the public reference facilities maintained by the SEC at 100 F Street NE, Washington, D.C. 20549.

Results of Operations

For the Three Months Ended March 31, 2025 versus March 31, 2024

	Three Months Ended March 31, 2025	Three Months Ended March 31, 2024	Increase (Decrease)
Operating Expenses			
Research and development	$ 11,951,023	$ 13,305,306	$ (1,354,283)
General and administrative	6,267,412	9,682,554	(3,415,142)
Total	$ 18,218,435	$ 22,987,860	$ (4,769,425)

Research and Development Expense

Research and development expense for the three months ended March 31, 2025 was approximately $11,951,000 compared to $13,305,300 for the three months ended March 31, 2024, a decrease of approximately $1,354,300. The change was primarily driven by:

- Decrease in other research expenses of $5,269,600 primarily associated with the winding down of the REL-1017 302 and 304 studies in 2025;
- Decrease in stock-based compensation expense of $629,000;
- Decrease in manufacturing and drug storage costs of $136,900;
- Decrease in compensation expense of $106,800 due to a decrease in research and development employees and their related bonus; and
- Increase in study costs of $4,788,000 associated with the acquisition of Sepranolone and NDV-01.

General and Administrative Expense

General and administrative expense for the three months ended March 31, 2025 was approximately $6,267,400 compared to $9,682,600 for the three months ended March 31, 2024, a decrease of approximately $3,415,200. The change was primarily due to:

- Decrease in stock-based compensation expense of $3,185,500;
- Decrease in other general and administrative expenses of $287,400 primarily due to an decrease in consulting services; and
- Increase in compensation expense of $57,700 due to an increase of general and administrative employees and their related bonuses.

Other Income

Interest/investment income was approximately $440,300 and $1,055,900 for the three months ended March 31, 2025 and 2024, respectively. The decrease was due to lower average investment balance. Realized gain on short-term investments was approximately $63,000 and $53,100 for the three months ended March 31, 2025 and

2024, respectively. Unrealized gain on short-term investments for the three months ended March 31, 2025 and 2024 was approximately $155,700 and $50,700, respectively.

Income Taxes

The Company did not provide for income taxes for the three months ended March 31, 2025 and 2024, since there was a loss and a full valuation allowance against all deferred tax assets.

Net Loss

The net loss for the Company for the three months ended March 31, 2025 and 2024 was approximately $17,559,500 and $21,828,100 respectively. The Company had loss per share, basic and diluted of $0.58 and $0.72 for the three months ended March 31, 2025 and 2024, respectively.

Liquidity

As shown in the accompanying audited 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 three months ended March 31, 2025, the Company incurred a net loss of $17,559,465 and had negative operating cash flows of $18,067,033. Given the Company's projected operating requirements and its existing cash and cash equivalents and short-term investments, the Company is projecting insufficient liquidity to sustain its operations through one year following the date that the financial statements are issued. These conditions and events raise substantial doubt about the Company's ability to continue as a going concern.

In response to these conditions, management is currently evaluating the size and scope of any subsequent operations and clinical trials that will affect the timing to obtain the required funding of future operations. Financing strategies may include, but are not limited to the public or private sale of equity or debt securities or from bank or other loans or through strategic collaboration and/or licensing agreements. There can be no assurances that the Company will be able to secure additional financing, or if available, that it will be sufficient to meet its needs or on favorable terms. Because management's plans have not yet been finalized and are not within the Company's control the implementation of such plans cannot be considered probably. As a result, the Company concluded that management's plans do not alleviate substantial doubt about the Company's ability to continue as a going concern.

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

	Three Months Ended March 31, 2025	Three Months Ended March 31, 2024
Cash used in operating activities	$ (18,067,033)	$ (13,036,748)
Cash provided by investing activities	15,359,713	10,058,451
Cash provided by financing activities	-	221,747
Net decrease in cash and cash equivalents	$ (2,707,320)	(2,756,550)

For the three months ended March 31, 2025, cash used in operating activities was $18,067,033 primarily due to the net loss of $17,559,465 offset by non-cash stock-based compensation charges of $4,477,995. There were realized gains and unrealized gains on short-term investments of $62,952 and $155,731, respectively. In addition, there was an increase in operating assets and liabilities of $4,766,880.

For the three months ended March 31, 2024, cash used in operating activities was $13,036,748 primarily due to the net loss of $21,828,126 offset by non-cash stock-based compensation charges of $8,295,468. There were realized gains and unrealized gains on short-term investments of $53,133 and $50,713, respectively. In addition, there was a decrease in operating assets and liabilities of $599,756.

For the three months ended March 31, 2025, cash provided by investing activities was $15,359,713 due to $487,916 of purchases of short-term investments offset by $15,847,629 of sales of short-term investments.

For the three months ended March 31, 2024, cash provided by investing activities was $10,058,451 due to $7,013,933 of purchases of short-term investments offset by $17,072,384 of sales of short-term investments.

Net cash provided by financing activities for the three months ended March 31, 2025 was $0.

Net cash provided by financing activities for the three months ended March 31, 2024 was $221,747 due to proceeds from options exercised for common stock of $246,747 offset by ATM fees of $25,000.

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, 2024 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, 2024. 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 March 31, 2025 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, 2024.

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 March 31, 2025, 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 March 31, 2025 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, 2024.

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

On March 24, 2025, pursuant to the Exclusive License Agreement with Trigone, we issued to Trigone 3,017,420 shares of our common stock. The issuance of these shares was exempt from registration under the Securities Act of 1933, as amended, pursuant to Section 4(a)(2) thereof as not involving any public offering.

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.

Termination of Psilocybin License

On May 12, 2025, the Company delivered to Arbormentis LLC a formal notice of termination of the Company's License Agreement with Arbormentis LLC, 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 will cease as of the effective termination date, which is 90 days after the date of notice.

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
10.1	Asset Purchase Agreement between Relmada Therapeutics, Inc. and Asarina Pharma AB, dated February 3, 2025	Incorporated by reference to Exhibit 10.1 to Current Report on Form 8-K filed on February 6, 2025
10.2	Exclusive License Agreement between Trigone Pharma, Ltd., and Relmada Therapeutics, Inc., dated March 24, 2025†	Filed herewith
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 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 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.

† Certain portions of this Exhibit have been redacted pursuant to Item 601(b)(10)(iv) of Regulation S-K.

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: May 12, 2025

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)