**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 **June 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: **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 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 August 4, 2026, there were 106,669,846 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 June 30, 2026 (Unaudited) | As of December 31, 2025 |
|---|---|---|
| **Assets** | | |
| Current assets: | | |
| Cash and cash equivalents | $ 11,334,370 | $ 3,496,540 |
| Short-term investments | 206,396,805 | 89,509,710 |
| Other receivable | 10,912 | - |
| Prepaid expenses | 1,297,590 | 977,721 |
| Total current assets | 219,039,677 | 93,983,971 |
| Other assets | 19,500 | 19,500 |
| Total assets | $ 219,059,177 | $ 94,003,471 |
| **Liabilities and Stockholders' Equity** | | |
| Current liabilities: | | |
| Accounts payable | $ 2,409,190 | $ 1,568,944 |
| Accrued expenses | 5,011,583 | 4,861,583 |
| Total current liabilities | 7,420,773 | 6,430,527 |
| Stock appreciation rights | 5,080,081 | 1,060,931 |
| Total liabilities | 12,500,854 | 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 shares authorized, 106,669,846 and 73,333,622 shares issued and outstanding, respectively | 106,670 | 73,333 |
| Additional paid-in capital | 936,684,992 | 784,705,878 |
| Accumulated deficit | (730,233,339) | (698,267,198) |
| Total stockholders' equity | 206,558,323 | 86,512,013 |
| Total liabilities and stockholders' equity | $ 219,059,177 | $ 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 June 30, | | Six months ended June 30, | |
|---|---|---|---|---|
| | 2026 | 2025 | 2026 | 2025 |
| Operating expenses: | | | | |
| Research and development | $ 8,393,789 | $ 2,819,377 | $ 16,481,634 | $ 14,770,400 |
| General and administrative | 6,617,238 | 7,401,929 | 17,991,147 | 13,669,342 |
| Total operating expenses | 15,011,027 | 10,221,306 | 34,472,781 | 28,439,742 |
| Loss from operations | (15,011,027) | (10,221,306) | (34,472,781) | (28,439,742) |
| Other (expenses) income: | | | | |
| Interest/investment income, net | 2,301,394 | 321,458 | 3,261,156 | 761,745 |
| Realized (loss) gain on short-term investments | (37,294) | 47,203 | (47,162) | 110,156 |
| Unrealized (loss) gain on short-term investments | (167,258) | (13,797) | (707,354) | 141,934 |
| Total other income | 2,096,842 | 354,864 | 2,506,640 | 1,013,835 |
| Net loss | $ (12,914,185) | $ (9,866,442) | $ (31,966,141) | $ (27,425,907) |
| Loss per common share – basic and diluted | $ (0.11) | $ (0.30) | $ (0.32) | $ (0.86) |
| Weighted average number of common shares outstanding – basic and diluted | 112,375,941 | 33,191,622 | 99,327,509 | 31,807,943 |

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 Six months ended June 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 |

| | Three and Six months ended June 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 |

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



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

| | Six months ended June 30, | |
|---|---|---|
| | 2026 | 2025 |
| **Cash flows from operating activities** | | |
| Net loss | $ (31,966,141) | $ (27,425,907) |
| Adjustments to reconcile net loss to net cash used in operating activities: | | |
| Stock-based compensation | 1,859,089 | 7,021,222 |
| Stock appreciation rights compensation | 4,019,150 | 27,649 |
| Issuance of restricted common stock | - | 905,226 |
| Realized loss/(gain) on short-term investments | 47,162 | (110,156) |
| Unrealized loss/(gain) on short-term investments | 707,354 | (141,934) |
| Change in operating assets and liabilities: | | |
| Prepaid expenses and other assets | (319,869) | 411,834 |
| Accounts payable | 840,246 | (2,768,652) |
| Accrued expenses | 150,000 | (2,388,191) |
| Other receivable | (10,912) | - |
| Net cash used in operating activities | (24,673,921) | (24,468,909) |
| | | |
| **Cash flows from investing activities** | | |
| Purchase of short-term investments | (174,270,466) | (809,375) |
| Sale of short-term investments | 56,628,855 | 22,847,630 |
| Net cash (used in)/provided by investing activities | (117,641,611) | 22,038,255 |
| | | |
| **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 | 101,497 | - |
| Proceeds from warrants exercised for common stock | 1,683 | - |
| ATM fees | (131,924) | (73,021) |
| **Net cash provided/(used in) by financing activities** | 150,153,362 | (73,021) |
| Net increase/(decrease) in cash and cash equivalents | 7,837,830 | (2,503,675) |
| **Cash and cash equivalents at beginning of the period** | 3,496,540 | 3,857,026 |
| | | |
| **Cash and cash equivalents at end of the period** | $ 11,334,370 | $ 1,353,351 |
| **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, excessive 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.

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 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, the Company entered into an Exclusive License Agreement with Trigone, a privately held Israeli company. The license agreement is 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 June 30, 2026, no additional milestones were achieved.





**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 six months ended June 30, 2026, the Company incurred a net loss of $31,966,141 and had negative operating cash flows of $24,673,921.

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, before 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 of $11,334,370 and $3,496,540 at June 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 June 30, 2026 and December 31, 2025 consisted of mutual funds and corporate debt securities with an aggregate fair value of $206,396,805 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 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.

**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 $206,396,805 at June 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 June 30, 2026, the mutual fund securities balance was $152,475,069.

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 June 30, 2026, the corporate securities balance was $53,921,736.





**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 $167,258 and $707,354 included in other income for the three and six months ended June 30, 2026, respectively. The Company recorded an unrealized loss of $13,797 and an unrealized gain of $141,934 included in other income for the three and six months ended June 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 June 30, 2026, the stock appreciation rights liability had a fair value of $5,080,081. Significant inputs for Level 3 stock appreciation rights liability fair value measurement at June 30, 2026 are disclosed in Footnote 6.

There have been no transfers in and out of level 3 during the three and six months ended June 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 June 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 June 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.

As of June 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):

| | June 30, 2026 | June 30, 2025 |
|---|---|---|
| Stock options | 14,948,356 | 14,158,927 |
| Common stock warrants | 565,085 | 750,908 |
| Total | 15,513,441 | 14,909,835 |

**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 on a prospectively or modified retrospectively. 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 $00):

| | June 30, 2026 | December 31, 2025 |
|---|---|---|
| Insurance | $ 87,300 | $ 411,900 |
| Research and Development | 971,800 | 496,500 |
| Legal | 140,300 | - |
| Other | 98,200 | 69,300 |
| Total | $ 1,297,600 | $ 977,700 |

**NOTE 5 - ACCRUED EXPENSES**

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

| | June 30, 2026 | December 31, 2025 |
|---|---|---|
| Research and development | $ 3,157,800 | $ 3,971,700 |
| Professional fees | 194,800 | 220,000 |
| Accrued bonus | 1,001,300 | - |
| Accrued vacation | 584,800 | 535,500 |
| Other | 72,900 | 134,400 |
| Total | $ 5,011,600 | $ 4,861,600 |

**NOTE 6 - STOCK APPRECIATION RIGHTS**

During the six months ended June 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 130% - 135% and (4) zero expected dividends.

At June 30, 2026, the Company revalued the cash-settled stock appreciation rights using a stock price of $6.92 and an exercise price of $0.45 - $7.42. Variables used in the Black-Scholes option-pricing model include: (1) discount rate of 4.19% - 4.25%, (2) expected life of 4.25 – 6.25 years, (3) expected volatility of 130% - 152% and (4) zero expected dividends.

As of June 30, 2026, the total liability related to cash-settled SARs is $5,080,081, reflecting the fair value as of the reporting date. During the three months ended June 30, 2026, the Company recorded compensation related to the cash-settled SARs in the amount of $2,093,020, included $361,496 and $1,731,524 in research and development and general and administrative expenses, respectively in the accompanying unaudited condensed consolidated statements of operations. During the six months ended June 30, 2026, the Company recorded compensation related to the cash-settled SARs in the amount of $4,770,672, included $1,164,086 and $3,606,586 in research and development and general and administrative expenses, respectively in the accompanying unaudited condensed consolidated statements of operations.

A summary of the changes in SARs during the six months ended June 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 | 9.62 | $ 200,250 |
| Exercised/Cancelled/Forfeited | (232,937) | - | - | - |

| | | | | |
|---|---|---|---|---|
| Outstanding at June 30, 2026 | 5,476,188 | $ 3.69 | 9.37 | $ 17,712,146 |
| SARs vested at June 30, 2026 | 697,500 | $ 3.52 | 9.30 | $ 2,372,208 |

At June 30, 2026, the Company has unrecognized compensation expense of approximately $30,240,904 related to unvested stock appreciation rights which will be recognized over the weighted average remaining service period of 3.36 years.





**NOTE 7 - STOCKHOLDERS' EQUITY**

**Common Stock**

During the six months ended June 30, 2026, the Company issued 97,123 shares of common stock for the exercise of 97,123 options for cash proceeds of $101,497.

During the six months ended June 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 six months ended June 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 June 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 six months ended June 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 June 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.

Options

A summary of the changes in options during the six months ended June 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 | 25,000 | $ 6.69 | - | $ - |
| Exercised | (97,123) | $ 1.05 | - | $ - |
| Cancelled | (125) | $ 6.20 | - | $ - |
| Outstanding at June 30, 2026 | 14,948,356 | $ 12.58 | 6.18 | $ 37,022,991 |
| Options exercisable at June 30, 2026 | 11,157,446 | $ 16.24 | 5.31 | $ 17,604,100 |

**NOTE 7 - STOCKHOLDERS' EQUITY (continued)**

At June 30, 2026, the Company has unrecognized stock-based compensation expense of approximately $5.8 million related to unvested stock options which will be recognized over the weighted average remaining service period of 2.62 years.

During six months ended June 30, 2026, there were 25,000 options granted with the weighted average fair value of approximately $6.06 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:

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

Warrants

A summary of the changes in outstanding equity-warrants during the six months ended June 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) | 0.001 |
| Outstanding at June 30, 2026 | 6,325,612 | $ 2.66 |
| Warrants Vested at June 30, 2026 | 6,325,612 | $ 2.66 |

The warrants granted during the six months ended June 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 June 30, 2026, the Company had $0 of unrecognized compensation expense related to outstanding warrants.

At June 30, 2026, the aggregate intrinsic value of warrants exercisable was $39,914,036.

**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 three and six months ended June 30, 2026 and 2025 (rounded to nearest $00):

| | Three Months Ended June 30, | | Six Months Ended June 30, | |
|---|---|---|---|---|
| | 2026 | 2025 | 2026 | 2025 |
| Research and development | $ 218,500 | $ 168,900 | $ 455,500 | $ 331,000 |
| General and administrative | 684,400 | 3,279,500 | 1,403,600 | 6,690,200 |
| Total | $ 902,900 | $ 3,448,400 | $ 1,859,100 | $ 7,021,200 |





**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 June 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 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 was also eligible to receive a low single digit royalty on net sales of any commercialized therapy resulting from this agreement.

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 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.

Trigone

On March 24, 2025, the Company entered into an Exclusive License Agreement with Trigone, a privately held Israeli company. The license agreement is 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 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 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 any worldwide 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 June 30, 2026, no additional milestones were achieved.





**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 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 49$^{th}$ 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.

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 June 30, 2026 and 2025, the Company recognized lease expense of approximately $47,500 and $53,700, respectively. For the six months ended June 30, 2026 and 2025, the Company recognized lease expense of approximately $93,200 and $98,500, 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 $109,500 and $100,700 for the six months ended June 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.

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 for the three and six months ended June 30, 2026 and 2025 (rounded to the nearest $00):

| | Three months ended June 30, | | Six months ended June 30, | |
|---|---|---|---|---|
| | 2026 | 2025 | 2026 | 2025 |
| Clinical Study Expense | $ 3,482,900 | $ 779,600 | $ 4,954,000 | $ 8,740,200 |
| Other Research Expense | 842,100 | 702,200 | 1,960,500 | 2,533,200 |
| Manufacturing and Drug Storage Expense | 2,652,500 | 81,600 | 5,436,700 | 237,200 |
| Compensation Expense | 836,300 | 1,062,700 | 2,510,800 | 1,996,100 |
| Stock-based Compensation Expense | 580,000 | 193,300 | 1,619,600 | 1,263,700 |
| Total Research and Development Expense | $ 8,393,800 | $ 2,819,400 | $ 16,481,600 | $ 14,770,400 |

**NOTE 11 - SUBSEQUENT EVENTS**

On July 27, 2026, 500,000 options were granted to an employees with an exercise price of $5.20



**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 an 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 the FDA by year-end 2026
- Sepranolone - Initiation of a Phase 2 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 that 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.

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 Risk-NMIBC. Patients are treated with NDV-01 in a biweekly induction phase, followed 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).

*Twelve-Month Safety and Efficacy Data*

We obtained twelve-month safety and efficacy data for our Phase 2 study of NDV-01 in high-risk NMIBC. Among 48 enrolled patients who received at least one dose, no new safety signals were observed with respect to the type, frequency or severity of adverse events. No patients experienced Grade ≥3 treatment-related adverse events, and no patients discontinued treatment due to adverse events. Of the 48 patients, 30 (63%) experienced a treatment-related adverse event. Among treatment-related adverse events, 54% were transient uncomfortable urination (dysuria), 8% were asymptomatic positive urine culture and 8% were hematuria.
Efficacy and Tolerability

| **Efficacy Evaluable Patients (Complete Response (CR))** | **(n/N)** | **%** |
|---|---|---|
| Anytime | 36/38 | 95% |
| 3 month | 33/38 | 87% |
| 6 month | 25/29 | 76% |
| 9 month | 22/26 | 85% |
| 12 month | 19/25 | 76% |
| 12 month KM analysis | - | 83% |

N= 48 patients in overall population; KM: Kaplan-Meier analysis; 10 patients awaiting 3 month response assessment

| **BCG-UR Subpopulation* CR** | **(n/N)** | **%** |
|---|---|---|

| | | |
|---|---|---|
| Anytime | 16 /17 | 94% |
| 3 month | 14 /17 | 82% |
| 6 month | 12 /14 | 86% |
| 9 month | 10 /11 | 91% |
| 12 month | 8 /10 | 80% |
| 12 month KM analysis | - | 84% |

N= 20 patients dosed in BCG-UR subpopulation; * BCG-UR defined by FDA definition; BCG-UR: Bacillus Calmette-Guérin (BCG)- Unresponsive; KM: Kaplan-Meier analysis; 3 patients awaiting 3 month assessment

- No patient had progression to muscle-invasive disease
- No patient underwent radical cystectomy



The Company also 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 by year-end 2026, 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.

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)
- 35% greater clinical improvement and ~75% fewer patients worsening on the Tourette Syndrome-Clinical Global Impression (TS-CGI) 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.

Sepranolone was well tolerated with no serious treatment emergent adverse events reported. The most common adverse events were of mild or moderate intensity related to injection sites, with pain, erythema and pruritus being the most common.

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 $31,966,100 for the six months ended June 30, 2026. At June 30, 2026, we had an accumulated deficit of approximately $730,233,300.



**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, 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 June 30, 2026 versus June 30, 2025

| | Three Months Ended June 30, 2026 | Three Months Ended June 30, 2025 | Increase (Decrease) |
|---|---|---|---|
| **Operating Expenses** | | | |
| Research and development | $ 8,393,789 | $ 2,819,377 | $ 5,574,412 |
| General and administrative | 6,617,238 | 7,401,929 | (784,691) |
| **Total** | $ 15,011,027 | $ 10,221,306 | $ 4,789,721 |

**Research and Development Expense**

Research and development expense for the three months ended June 30, 2026 was approximately 8,393,800 compared to $2,819,400 for the three months ended June

30, 2025, an increase of approximately $5,574,400. The change was primarily driven by:

- Increase in study costs of $2,703,300 associated with the ramp-up of NDV-01 and sepranolone studies;
- Increase in manufacturing and drug storage costs of $2,570,900;
- Increase in stock appreciation rights expense of $337,100;
- Increase in other research expenses of $139,900 primarily associated with the ramp-up of NDV-01 and sepranolone studies in 2026;
- Increase in stock-based compensation expense of $49,600; and
- Decrease in compensation expense of $226,400 due to a decrease in research and development employees and their related bonus.

**General and Administrative Expense**

General and administrative expense for the three months ended June 30, 2026 was approximately $6,617,200 compared to $7,401,900 for the three months ended June 30, 2025, a decrease of approximately $784,700. The change was primarily due to:

- Decrease in stock-based compensation expense of $2,595,100;
- Decrease in compensation expense of $578,800 due to a decrease of general and administrative employees and their related bonuses;
- Increase in stock appreciation rights expense of $1,731,300; and
- Increase in other general and administrative expenses of $657,900 primarily due to an increase in consulting services.

**Other Income**

Interest/investment income was approximately $2,301,400 and $321,500 for the three months ended June 30, 2026 and 2025, respectively. The increase was due to higher average investment balance. Realized loss on short-term investments was approximately $37,300 for the three months ended June 30, 2026 compared to a realized gain of $47,200 for the three months ended June 30, 2025. Unrealized loss on short-term investments was approximately $167,300 and $13,800 for the three months ended June 30, 2026 and 2025.

**Net Loss**

The net loss for the Company for the three months ended June 30, 2026 and 2025 was approximately $12,914,200 and $9,866,400, respectively. The Company had loss per share basic and diluted of $0.11 and $0.30 for the three months ended June 30, 2026 and 2025, respectively.

**Income Taxes**

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



**Results of Operations**

For the Six Months Ended June 30, 2026 versus June 30, 2025

| | Six Months Ended June 30, 2026 | Six Months Ended June 30, 2025 | Increase (Decrease) |
|---|---|---|---|
| **Operating Expenses** | | | |
| Research and development | $ 16,481,634 | $ 14,770,400 | $ 1,711,234 |
| General and administrative | 17,991,147 | 13,669,342 | 4,321,805 |
| **Total** | $ 34,472,781 | $ 28,439,742 | $ 6,033,039 |

**Research and Development Expense**

Research and development expense for the six months ended June 30, 2026 was approximately $16,481,600 compared to $14,770,400 for the six months ended June 30, 2025, an increase of approximately $1,711,200. The increase was primarily due to:

- Increase in manufacturing and drug storage costs of $5,199,500;
- Increase in stock appreciation rights expense of $1,136,600;
- Increase in compensation expense of $514,700 due to an increase in research and development employees and their related bonuses;
- Decrease in study costs of $3,786,200 associated with the acquisitions of sepranolone and NDV-01 in the first quarter of 2025 offset with a decrease of 302 and 304 study expenses due to the wind-down of these studies;
- Decrease in stock-based compensation expense of $780,700; and
- Decrease in other research expenses of $572,700 primarily associated with the wind-down of the 302 and 304 studies.

**General and Administrative Expense**

General and administrative expense for the six months ended June 30, 2026 was approximately $17,991,100 compared to $13,669,300 for the six months ended June 30, 2025, an increase of approximately $4,321,800. The increase was primarily due to:

- Increase in compensation expense of $4,760,600 primarily related an increase of general and administrative employees and their related bonuses;
- Increase in stock appreciation rights expense of $3,606,400;
- Increase in other general and administrative expenses of $1,241,400 primarily due to an increase in consulting services; and
- Decrease in stock-based compensation expense of $5,286,600 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 $3,261,200 and $761,700 for the six months ended June 30, 2026 and 2025, respectively. The increase was due to higher average investment balance. Realized loss on short-term investments was approximately $47,200 for the six months ended June 30, 2026 compared to a realized gain of approximately $110,200 for the six months ended June 30, 2025. Unrealized loss on short-term investments was approximately $707,400 for the six months ended June 30, 2026 compared to an unrealized gain of $141,900 for the six months ended June 30, 2025.

**Net Loss**

The net loss for the Company for the six months ended June 30, 2026 and 2025 was approximately $31,966,100 and $27,425,900 respectively. The Company had loss per share, basic and diluted of $0.32 and $0.86 for the six months ended June 30, 2026 and 2025, respectively.

**Income Taxes**

The Company did not provide for income taxes for the six months ended June 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 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 six months ended June 30, 2026, the Company incurred a net loss of $31,966,141 and had negative operating cash flows of $24,673,921.

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:

| | Six Months Ended June 30, 2026 | Six Months Ended June 30, 2025 |
|---|---|---|
| Cash used in operating activities | $ (24,673,921) | $ (24,468,909) |
| Cash (used in)/provided by investing activities | (117,641,611) | 22,038,255 |
| Cash (used in)/provided by financing activities | 150,153,362 | (73,021) |
| Net increase/(decrease) in cash and cash equivalents | $ 7,837,830 | (2,503,675) |

For the six months ended June 30, 2026, cash used in operating activities was $24,673,921 primarily due to the net loss of $31,966,141 offset by non-cash stock-based compensation charges of $1,859,089 and stock appreciation rights compensation of $4,019,150. There were realized and unrealized losses on short-term investments of $47,162 and $707,354, respectively. In addition, there was an increase in operating assets and liabilities of $659,465.

For the six months ended June 30, 2025, cash used in operating activities was $24,468,909 primarily due to the net loss of $27,425,907 offset by non-cash stock-based compensation charges of $7,,021,222 and stock appreciation rights compensation of $27,649 and proceeds from the issuance of restricted common stock of $905,226. There were realized gains and unrealized gains on short-term investments of $110,156 and $141,934, respectively. In addition, there was an increase in operating assets and liabilities of $4,745,009.

For the six months ended June 30, 2026, cash used in investing activities was $117,641,611, due to $174,270,466 of purchases of short-term investments offset by $56,628,855 of sales of short-term investments.

For the six months ended June 30, 2025, cash provided by investing activities was $22,038,255, due to $809,375 of purchases of short-term investments offset by $22,847,630 of sales of short-term investments.

Net cash provided by financing activities for the six months ended June 30, 2026 was $150,153,362 due to proceeds from the issuance of common stock for $159,999,996, proceeds from options exercised for common stock of $101,497, 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 fees of $131,924.

Net cash used in financing activities for the six months ended June 30, 2025 was $73,021 related to ATM fees.



**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 June 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 June 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 June 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 March 11, 2026, we issued and sold in a private placement to certain institutional and accredited investors (i) 29,474,569 shares of our common stock, at a price of $4.75 per share, and (ii) pre-funded warrants to purchase up to 4,210,527 shares of common stock at a price of $4.749 per pre-funded warrant, with an exercise price of $0.001 per share. Each of the pre-funded warrants is immediately exercisable and may be exercised at any time, subject to customary 9.99% (or, at the election of the purchaser, 4.99%) beneficial ownership limitations. We engaged Jefferies LLC, Leerink Partners LLC, Piper Sandler & Co. and Mizuho Securities USA LLC as placement agents for the private placement and agreed to pay customary placement fees and reimburse certain expenses of the placement agents. These securities were issued without registration under the Securities Act of 1933, as amended, in reliance upon the exemption afforded by Section 4(a)(2) thereof, as not involving any public offering. For additional information about the private placement, see Item 1.01 of the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on March 9, 2026.

### ITEM 3. DEFAULTS UPON SENIOR SECURITIES.

None.

### ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

### ITEM 5. OTHER INFORMATION

*Director and Officer Trading Arrangements*

On May 18, 2026, Charles Ence, the Company's Chief Accounting and Compliance Officer, adopted an individual trading plan intended to satisfy the affirmative defense conditions of Rule 10b5-1 under the Exchange Act, which has a term of eight months beginning September 17, 2026 to sell up to 268,361 shares of our common stock issuable upon exercise of stock options, subject to certain conditions. Unless otherwise terminated pursuant to its terms, the plan will terminate on April 16, 2027, or when all of the shares under the plan are sold.

On May 19, 2026, Charles Casamento, the Company's Chairman of the Board of Directors, adopted an individual trading plan intended to satisfy the affirmative defense conditions of Rule 10b5-1 under the Exchange Act, which has a term of twelve months beginning September 1, 2026 to sell up to 134,579 shares of our common stock issuable upon exercise of stock options, subject to certain conditions. Unless otherwise terminated pursuant to its terms, the plan will terminate on September 1, 2027, or when all of the shares under the plan are sold.

No other 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 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: August 6, 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)