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

FORM 10-Q

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

For the quarterly period ended **March 31, 2024**

or

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

For the transition period from _____ to _____

Commission File Number: **000-55347**

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

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

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

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

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common stock, $0.001 par value per share	**RLMD**	**The NASDAQ Global Select Market**

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. ☒ Yes No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). ☒ Yes No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☒	Smaller reporting company	☒
		Emerging growth company	☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

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

As of May 3, 2024, there were 30,174,202 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 March 31, 2024 (Unaudited)	As of December 31, 2023
Assets		
Current assets:		
Cash and cash equivalents	$ 1,335,018	$ 4,091,568
Short-term investments	82,277,687	92,232,292
Prepaid expenses	752,334	1,185,057
Total current assets	84,365,039	97,508,917
Other assets	43,125	43,125
Total assets	$ 84,408,164	$ 97,552,042
Commitments and Contingencies (See Note 6)		
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 5,189,101	$ 3,506,009
Accrued expenses	7,172,732	8,688,791
Total current liabilities	12,361,833	12,194,800
Total liabilities	12,361,833	12,194,800
Stockholders' Equity:		
Preferred stock, $0.001 par value, 200,000,000 shares authorized, none issued and outstanding	-	-
Class A convertible preferred stock, $0.001 par value, 3,500,000 shares authorized, none issued and outstanding	-	-
Common stock, $0.001 par value, 150,000,000 shares authorized, 30,174,202 and 30,099,203 shares issued and outstanding, respectively	30,174	30,099
Additional paid-in capital	654,746,964	646,229,824
Accumulated deficit	(582,730,807)	(560,902,681)
Total stockholders' equity	72,046,331	85,357,242
Total liabilities and stockholders' equity	$ 84,408,164	$ 97,552,042

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

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

	Three months ended

	March 31,	
	2024	2023
Operating expenses:		
Research and development	$ 13,305,306	$ 15,861,010
General and administrative	9,682,554	12,292,599
Total operating expenses	22,987,860	28,153,609
Loss from operations	(22,987,860)	(28,153,609)
Other income (expenses):		
Interest/investment income, net	1,055,888	1,207,631
Realized gain (loss) on short-term investments	53,133	(666,708)
Unrealized gain on short-term investments	50,713	1,291,110
Total other income (expenses)	1,159,734	1,832,033
Net loss	$ (21,828,126)	$ (26,321,576)
Loss per common share – basic and diluted	$ (0.72)	$ (0.87)
Weighted average number of common shares outstanding – basic and diluted	30,132,170	30,099,203

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

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

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

	Three months ended March 31, 2023				
	Common Stock		Additional Paid-in	Accumulated	
	Shares	Par Value	Capital	Deficit	Total
Balance - December 31, 2022	30,099,203	$ 30,099	$ 602,517,138	$ (462,110,935)	$ 140,436,302
Stock based compensation	-	-	11,354,466	-	11,354,466
Net loss	-	-	-	(26,321,576)	(26,321,576)
Balance - March 31, 2023	30,099,203	$ 30,099	$ 613,871,604	$ (488,432,511)	$ 125,469,192

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

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

	Three months ended March 31,	
	2024	2023
Cash flows from operating activities		
Net loss	$ (21,828,126)	$ (26,321,576)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	8,295,468	11,354,466
Realized (gain) loss on short-term investments	(53,133)	666,708
Unrealized gain on short-term investments	(50,713)	(1,291,110)

Change in operating assets and liabilities:		
Other receivables	-	512,432
Prepaid expenses	432,723	945,606
Accounts payable	1,683,092	(839,971)
Accrued expenses	(1,516,059)	(1,531,649)
Net cash used in operating activities	(13,036,748)	(16,505,094)
Cash flows from investing activities		
Purchase of short-term investments	(7,013,933)	(34,767,287)
Sale of short-term investments	17,072,384	74,770,836
Net cash provided by investing activities	10,058,451	40,003,549
Cash flows from financing activities		
Proceeds from options exercised for common stock	246,747	-
ATM Fees	(25,000)	-
Net cash provided by financing activities	221,747	-
Net (decrease) increase in cash and cash equivalents	(2,756,550)	23,498,455
Cash and cash equivalents at beginning of the period	4,091,568	5,395,905
Cash and cash equivalents at end of the period	$ 1,335,018	$ 28,894,360

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 esmethadone (d-methadone, dextromethadone, REL-1017), an N-methyl-D-aspartate (NMDA) receptor antagonist. Esmethadone is a new chemical entity (NCE) that potentially addresses areas of high unmet medical need in the treatment of central nervous system (CNS) diseases and other disorders. Relmada is also developing a proprietary, modified-release formulation of psilocybin (REL-P11) for metabolic indications.

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

NOTE 2 - 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, 2023 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.

Liquidity

As shown in the accompanying unaudited condensed consolidated financial statements, the Company incurred negative operating cash flows of $13,036,748 for the three months ended March 31, 2024 and has an accumulated deficit of $582,730,807 from inception through March 31, 2024.

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 operations and clinical 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. Further, additional financing does not affect the Company's conclusion that based on the cash on hand and the budgeted cash flow requirements, the Company has sufficient funds to maintain operations for at least 12 months from the issuance of these unaudited condensed consolidated financial statements.

Use of Estimates

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

Cash and Cash Equivalents

The Company considers cash deposits and all highly liquid investments with a maturity of three months or less when purchased to be cash equivalents. The Company's cash deposits are held at two high-credit-quality financial institutions. The Company's cash and cash equivalents balance of $1,335,018 at March 31, 2024 at these institutions exceed the federally insured limits.

NOTE 2 - SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (continued)

Short-term Investments

The Company's investments consist entirely of mutual funds. The securities are measured at fair value based on the net asset value (NAV). Substantially all equity investments in nonconsolidated entities are measured at fair value with recurring changes recognized in earnings, except for those accounted for using equity method accounting. Changes in fair value of the securities are recorded as part of other income on the condensed consolidated statement of operations. Short term investment activity is presented in the investing activities section on the condensed consolidated statement of cash flows.

Short-term investments at March 31, 2024 and December 31, 2023 consisted of mutual funds with a fair value of $82,277,687 and 92,232,292, 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 lease consists of an operating lease for office space. 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 accounts payable. 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 $82,277,687 at March 31, 2024 consist of mutual funds, bank deposits and money market funds and are classified using Level 1 inputs within the fair value hierarchy because the value is based on quoted prices in active markets. Unrealized gains and losses are recorded in the condensed consolidated statement of operations under other income. The Company recorded unrealized gain of $50,713 and an unrealized loss of $1,291,110 included in other income for the three months ended March 31, 2024 and 2023, 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 March 31, 2024 and December 31, 2023, the Company had recognized a valuation allowance to the full extent of the Company's net deferred tax assets since the likelihood of realization of the benefit does not meet the more likely than not threshold.

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

NOTE 2 - SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (continued)

The Company files a U.S. Federal income tax return and various state returns. Uncertain tax positions taken on the Company's tax returns will be accounted for as liabilities for unrecognized tax benefits. The Company will recognize interest and penalties, if any, related to unrecognized tax benefits in general and administrative expenses in the statements of operations. There were no liabilities recorded for uncertain tax positions at March 31, 2024 and December 31, 2023. The open tax years, subject to potential examination by the applicable taxing authority, for the Company are from June 30, 2018 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.

Net Loss per Common Share

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

For the three months ended March 31, 2024 and 2023, the potentially dilutive securities that would be anti-dilutive due to the Company's net loss are not included in the calculation of diluted net loss per share attributable to common stockholders. The anti-dilutive securities are as follows (in common stock equivalent shares):

	Three months ended	
	March 31, 2024	March 31, 2023
Stock options	17,013,135	12,487,917
Common stock warrants	2,235,412	3,027,441
Total	19,248,547	15,515,358

Recent Accounting Pronouncements

In October 2021, the FASB issued ASU 2021-08, "*Business Combinations (Topic 805): Accounting for Contract Assets and Contract Liabilities from Contracts with Customers*". The amendments in this ASU require that an entity (acquirer) recognize, and measure contract assets and contract liabilities acquired in a business combination, including contract assets and contract liabilities arising from revenue contracts with customers, as if it had originated the contracts as of the acquisition date. The amendments in this ASU were effective for annual and interim periods beginning after December 15, 2022. The Company adopted this standard effective January 1, 2023 and the standard did not have a significant impact on our consolidated financial statements.

In November 2023, The FASB issued ASU 2023-07, "*Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures*" which expands annual and interim disclosures for reportable segments, primarily through enhanced disclosures about significant segment expenses. ASU 2023-07 is effective for our annual periods beginning January 1, 2024, and for interim periods beginning January 1, 2025, with early adoption permitted. The Company is currently evaluating the potential effect that the updated standard will have on our financial statement disclosures.

In December 2023, the FASB issued ASU 2023-09, "*Income Taxes (Topic 740): Improvements to Income Tax Disclosures*" to expand the disclosure requirements for income taxes, specifically related to the rate reconciliation and income taxes paid. ASU 2023-09 is effective for our annual periods beginning January 1, 2025, with early adoption permitted. The Company is currently evaluating the potential effect that the updated standard will have on our financial statement disclosures.

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

NOTE 2 - SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (continued)

Subsequent Events

The Company's management reviewed all material events through the date the financial statements were issued for subsequent event disclosure consideration.

NOTE 3 - PREPAID EXPENSES

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

	March 31, 2024	December 31, 2023
Insurance	$ 135,000	$ 365,100
Research and Development	477,900	695,000
Other	139,400	125,000
Total	$ 752,300	$ 1,185,100

NOTE 4 - ACCRUED EXPENSES

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

	March 31, 2024	December 31, 2023
Research and development	$ 6,133,700	$ 5,394,700
Professional fees	256,200	174,000
Accrued bonus	305,800	2,632,400
Accrued vacation	371,500	372,200
Other	105,500	115,500
Total	$ 7,172,700	$ 8,688,800

NOTE 5 - STOCKHOLDERS' EQUITY

Common Stock

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

On April 6, 2022, the Company entered into a new Open Market Sale Agreement with Jefferies, as sales agent, pursuant to which we may offer and sell, from time to time, through Jefferies, shares of our common stock, having an aggregate offering price of up to $100,000,000. We are not obligated to sell any shares under the agreement. As of March 31, 2024, no shares have been issued under this agreement.

Options and Warrants

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

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

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

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

These combined plans allowed for the granting of up to 13,052,942 options or other stock awards.

Stock options are exercisable generally for a period of 10 years from the date of grant and generally vest over four years. As of March 31, 2024, no shares were available for future grants under the 2014 or 2021 Plan. The shareholders will vote at their annual meeting in 2024 on a management proposal to increase the shares available to be issued under the 2021 Plan by 4.5 million shares. There can be no assurance such amendment will be approved. As of March 31, 2024, options for 3,960,193 shares of common stock had been issued subject to approval by the shareholders of this amendment. If the amendment is not approved, such options will be forfeited.

As of March 31, 2024, no stock appreciation rights have been issued.

NOTE 5 - STOCKHOLDERS' EQUITY (continued)

The Company utilizes the Black-Scholes option pricing model to estimate the fair value of stock options and warrants. The risk-free interest rate assumptions were based upon the observed interest rates appropriate for the expected term of the equity instruments. The expected dividend yield was assumed to be zero as the Company has not paid any dividends since its inception and does not anticipate paying dividends in the foreseeable future. The expected volatility was based on historical volatility.

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

From January 1, 2024 through March 31, 2024, 50,000 options were issued to a consultant with an exercise price of $3.44 and a 10-year term, vesting over a 4 year period. The options granted include time-based vesting grants. The options have an aggregate fair value of approximately $148,000 calculated using the Black-Scholes option-pricing model. Variables used in the Black-Scholes option-pricing model include: (1) discount rate of 4.1% (2) expected life of 6.25 years, (3) expected volatility of 113.5 %, and (4) zero expected dividends.

At March 31, 2024, the Company has unrecognized stock-based compensation expense of approximately $54.0 million related to unvested stock options which will be recognized over the weighted average remaining service period of 2.30 years.

Options

A summary of the changes in options during the three months ended March 31, 2024 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, 2023	17,416,192	$ 12.99	8.3	$ 11,183,370
Granted	50,000	$ 3.44	9.81	$ 60,500
Exercised	(74,999)	$ -	-	$ -
Forfeited	(18,057)	$ -	-	$ -
Cancelled	(360,001)	$ -	-	$ -
Outstanding at March 31, 2024	17,013,135	$ 13.20	8.02	$ 15,146,066
Options exercisable at March 31, 2024	7,947,879	$ 19.39	6.94	$ 2,491,510

Warrants

A summary of the changes in outstanding warrants during the three months ended March 31, 2024 is as follows:

	Number of Shares	Weighted Average Exercise Price Per Share
Outstanding Warrants at December 31, 2023	2,381,366	$ 20.02
Forfeited	(145,954)	-
Outstanding at March 31, 2024	2,235,412	$ 20.81
Warrants Vested at March 31, 2024	2,117,037	$ 20.17

At March 31, 2024, the Company had approximately $2.4 million of unrecognized compensation expense related to outstanding warrants.

At March 31, 2024, the aggregate intrinsic value of warrants vested and outstanding was $39,119.

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 months ended March 31, 2024 and 2023 (rounded to nearest $00):

	Three Months Ended March 31, 2024	Three Months Ended March 31, 2023
Research and development	$ 1,699,300	$ 1,994,200
General and administrative	6,596,200	9,360,300
Total	$ 8,295,500	$ 11,354,500

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

NOTE 6 - COMMITMENTS AND CONTINGENCIES

License Agreements

Wonpung

On August 20, 2007, the Company entered into a License Development and Commercialization Agreement with Wonpung Mulsan Co, a shareholder of the Company. Wonpung has exclusive territorial rights in countries it selects in Asia to market up to two drugs the Company was developing at the time of the signing of the agreement and a right of first refusal (ROFR) for up to an additional five drugs that the Company may develop in the future as defined in more detail in the license agreement. If the parties cannot agree to terms of a license agreement then the Company shall be able to engage in discussions with other potential licensors. As of March 31, 2024, no discussions are active between the Company and Wonpung.

The Company received an upfront license fee of $1,500,000 and will earn royalties of up to 12% of net sales for up to two licensed products it is currently developing. The licensing terms for the ROFR products are subject to future negotiations and binding arbitration. The terms of each licensing agreement will expire on the earlier of any time from 15 years to 20 years after licensing or on the date of commercial availability of a generic product to such licensed product in the licensed territory.

Third Party Licensor

Based upon a prior acquisition, the Company assumed an obligation to pay third parties (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 million or $2 million, for the first commercial sale of product in the field that has a single active pharmaceutical ingredient, and for the first commercial sale of product in the field of product that has more than one active pharmaceutical ingredient, respectively. As of March 31, 2024, the Company has not generated any revenue related to this license agreement.

Inturrisi / Manfredi

In January 2018, we entered into an Intellectual Property Assignment Agreement (the Assignment Agreement) and License Agreement (the License Agreement and together with the Assignment Agreement, the Agreements) with Dr. Charles E. Inturrisi and Dr. Paolo Manfredi (collectively, the Licensor). Pursuant to the Agreements, Relmada assigned its existing rights, including patents and patent applications, to esmethadone in the context of psychiatric use (the Existing Invention) to Licensor. Licensor then granted Relmada under the License Agreement a perpetual, worldwide, and exclusive license to commercialize the Existing Invention and certain further inventions regarding esmethadone in the context of other indications such as those contemplated above. In consideration of the rights granted to Relmada under the License Agreement, Relmada paid the Licensor an upfront, non-refundable license fee of $180,000. Additionally, Relmada will pay Licensor $45,000 every three months until the earliest to occur of the following events: (i) the first commercial sale of a licensed product anywhere in the world, (ii) the expiration or invalidation of the last to expire or be invalidated of the patent rights anywhere in the world, or (iii) the termination of the License Agreement. Relmada will also pay Licensor tiered royalties with a maximum rate of 2%, decreasing to 1.75%, and 1.5% in certain circumstances, on net sales of licensed products covered under the License Agreement. Relmada will also pay Licensor tiered payments up to a maximum of 20%, and decreasing to 17.5%, and 15% in certain circumstances, of all consideration received by Relmada for sublicenses granted under the License Agreement. As of March 31, 2024, no events have occurred, and the Company continues to pay Licensor $45,000 every three months.

Arbormentis, LLC

On July 16, 2021, the Company entered into a License Agreement with Arbormentis, LLC, a privately held Delaware limited liability company, by which the Company acquired development and commercial rights to a novel psilocybin and derivate program from Arbormentis, LLC, worldwide excluding the countries of Asia. The Company will collaborate with Arbormentis, LLC on the development of new therapies targeting neurological and psychiatric disorders, leveraging its understanding of neuroplasticity, and focusing on this emerging new class of drugs targeting the neuroplastogen mechanism of action. Under the terms of the License Agreement, the Company paid Arbormentis, LLC an upfront fee of $12.7 million, consisting of a mix of cash and warrants to purchase the Company's common stock, in addition to potential milestone payments totaling up to approximately $160 million related to pre-specified development and commercialization milestones. Arbormentis, LLC is also eligible to receive a low single digit royalty on net sales of any commercialized therapy resulting from this agreement. The license agreement is terminable by the Company but is perpetual and not terminable by the licensor absent material breach of its terms by the Company.

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

NOTE 6 - COMMITMENTS AND CONTINGENCIES (continued)

Leases and Sublease

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 the calendar years 2022, 2023, and 2024, with monthly rent of approximately $9,000, $7,000, and $7,000, respectively.

Beginning on January 1, 2023, we also leased office space at 880 Third Avenue, 12th Floor, New York, NY 10022 with monthly rent of approximately $14,500: that lease was terminated on November 30, 2023.

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

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

For the three months ended March 31, 2024 and 2023, the Company recognized lease expense of approximately $62,400 and $51,700, 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 7 - OTHER POST-RETIREMENT BENEFIT PLAN

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

The employees choose an amount from various investment options for both their contributions and the Company's matching contribution. The Company's contribution expense was approximately $35,000 and $40,400 for the three months ended March 31, 2024 and 2023, respectively.

NOTE 8 - SUBSEQUENT EVENTS

None.

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 clinical-stage biotechnology company focused on the development of esmethadone (d-methadone, dextromethadone, REL-1017), an N-methyl-D-aspartate (NMDA) receptor antagonist. Esmethadone, an isomer of methadone, is a new chemical entity (NCE) that potentially addresses areas of high unmet medical need in the treatment of central nervous system (CNS) diseases and other disorders.

Our lead product candidate, esmethadone, is being developed as a rapidly acting, oral agent for the treatment of depression and other potential indications. On October 15, 2019 we reported top-line data from study REL-1017-202. During late 2022, we announced RELIANCE I and III, both Phase 3 trials, did not achieve their primary endpoints. Relmada has completed its long term, open label study and plans to complete two additional ongoing adjunctive Phase 3 trials (RELIANCE II and RELIGHT).

Relmada also intends, in 2024, to enter human studies of its proprietary, modified-release formulation of psilocybin (REL-P11) in doses that we believe are lower than those associated with psychedelic effects for metabolic indications.

Esmethadone (d-Methadone, dextromethadone, REL-1017)

Phase 2 Clinical Trial

In the REL-1017-202 study, 62 subjects, with an average age of 49.2 years, with an average Hamilton Depression Rating Scale score of 25.3 and an average Montgomery-Asberg Depression Rating Scale (MADRS) score of 34.0 (severe depression), were randomized. Other demographic characteristics were balanced across all arms. After an initial screening period, subjects were randomized to one of three arms: placebo, REL-1017 25 mg or REL-1017 50 mg, in addition to stable background antidepressant therapy. Subjects in the REL-1017 treatment arms received one loading dose of either 75 mg (25 mg arm) or 100 mg (50 mg arm) of REL-1017. Subjects were treated inpatient for 7 days and discharged home at Day 9. They returned for follow-up visits at Day 14 and Day 21. Efficacy was measured on Days 2, 4 and 7 in the dosing period and on Day 14, one week after treatment discontinuation. 61 subjects received all treatment doses and were included in the per-protocol population (PPP) treatment analysis; 57 subjects completed all visits. All 62 randomized subjects were part of the intention-to-treat (ITT) analysis. No differences were observed between the ITT and PPP analyses and results.

We observed that subjects in both the REL-1017 25 mg and 50 mg treatment groups experienced statistically significant improvement on all efficacy measures tested as compared to subjects in the placebo group, including: MADRS; the Clinical Global Impression – Severity (CGI-S) scale; the Clinical Global Impression – Improvement (CGI-I) scale; and the Symptoms of Depression Questionnaire (SDQ).

Improvements on the MADRS endpoint appeared on Day 4 in both REL-1017 dose groups and continued through Day 7 and Day 14, seven days after treatment discontinuation, with P values< 0.03 and large effect sizes (a measure of quantifying the difference between two groups), ranging from 0.7 to 1.0. Similar findings emerged from the CGI-S and CGI-I scales.

The study also confirmed the tolerability profile of REL-1017, which was observed in the Phase 1 studies. Subjects experienced only mild and moderate adverse events (AEs), and no serious adverse events, without significant differences between placebo and treatment groups. The AEs observed in the Phase 2a clinical study were of the same nature as those observed in the Phase 1 clinical studies of d-Methadone, and there was no evidence of either treatment induced psychotomimetic and dissociative AEs or withdrawal signs and symptoms upon treatment discontinuation.

Phase 3 Program

On December 20, 2020, Relmada announced that the first patient had been enrolled in the first Phase 3 clinical trial (RELIANCE I) for the Company's lead product candidate, REL-1017, as an adjunctive treatment for MDD.

On April 1, 2021, Relmada announced the initiation of RELIANCE II, the second of two sister pivotal Phase 3 clinical trials (RELIANCE I and RELIANCE II) for the Company's lead product candidate, REL-1017, as an adjunctive treatment for Major Depressive Disorder (MDD).

On October 4, 2021, Relmada announced the initiation of RELIANCE III study, a monotherapy trial for the Company's lead product candidate, REL-1017.

In addition, on October 4, 2021, Relmada announced that in order to support potential regulatory submissions seeking approval for REL-1017 as adjunctive and

monotherapy treatment, the Food and Drug Administration (FDA) confirmed that, based on what was known at the time, Relmada would not be required to conduct a two-year carcinogenicity study of REL-1017, as sufficient clinical data had been generated to date. The FDA also confirmed that Relmada would not need to conduct a TQT cardiac study in humans to support cardiac safety in potential regulatory submissions for REL-1017, as the data already provided and the data to be generated by the Phase 3 program would be adequate to evaluate the cardiac safety profile of REL-1017.

On August 9, 2022, Relmada announced that the FDA granted Fast Track designation to REL-1017 as a monotherapy for the treatment of MDD.

On October 13, 2022, Relmada announced that its RELIANCE III study, evaluating REL-1017 in the monotherapy setting for MDD, did not achieve its primary endpoint, which was a statistically significant improvement in depression symptoms compared to placebo as measured by MADRS on Day 28. In the study, the REL-1017 treatment arm showed a MADRS reduction of 14.8 points at Day 28 versus 13.9 points for the placebo arm, a higher than expected placebo response.

On December 7, 2022, Relmada announced that its RELIANCE I study, evaluating REL-1017 as an adjunctive treatment for MDD, did not achieve its primary endpoint, which was a statistically significant improvement in depression symptoms compared to placebo as measured by MADRS on Day 28. In the study, the REL-1017 treatment arm (n= 113) showed a MADRS reduction of 15.1 points at Day 28 versus 12.9 points for the placebo arm (n=114), which is a clinically meaningful difference of 2.3 points on the MADRS. The study also showed a nominally statistically significant difference in the response rate, with a response rate of 39.8% in the REL-1017 arm vs 27.2% in the placebo arm ($p<0.05$). Additionally, in a prespecified per protocol population analysis, the REL-1017 treatment arm (n=101) showed a MADRS reduction of 15.6 points at Day 28 versus 12.5 points for the placebo arm (n=97), a difference of 3.1 points, with nominal p=0.051.

Patients who completed the RELIANCE trials were eligible to rollover into the long-term, open-label study, Study 310, which also included subjects who had not previously participated in a REL-1017 clinical trial. This rollover study completed subject visits on July 11, 2023.

On September 20, 2023, Relmada announced efficacy results for the de novo (or new to treatment) patients (204 patients) and safety results for all subjects (627 patients) from Study 310 of REL-1017 in patients with MDD. Patients treated daily with REL-1017 for up to one year experienced rapid, clinically meaningful, and sustained improvements in depressive symptoms and associated functional impairment. REL-1017 was well-tolerated with long-term dosing, showing low rates of adverse events and discontinuations due to adverse events. The most commonly reported adverse events deemed to be treatment-related all occurred included headache, nausea and dizziness. No new safety signals were detected.

On August 23, 2023, Relmada announced the dosing of the first patient in RELIGHT, a Phase 3 clinical trial for REL-1017, as an adjunctive treatment for MDD.

Human Abuse Potential (HAP) Studies

Top-line Results - Oxycodone:

On July 27, 2021, Relmada announced top-line results that showed that all three doses of REL-1017 (25 mg, 75 mg and 150 mg, the therapeutic, supratherapeutic and maximum tolerated doses (MTD), respectively) tested in recreational opioid users, demonstrated a highly statistically significant difference vs. the active control drug, oxycodone 40 mg. The study's primary endpoint was a measure of "likability" with the subjects rating the maximum effect (or Emax) for Drug Liking "at the moment", using a 1=100 bipolar rating scale (known as a visual analog scale or VAS), with 100 as the highest likability, 50 as neutral (placebo-like), and 0 the highest dislike. In summary, all tested doses of REL-1017, including the 150 mg MTD, showed a highly statistically significant difference in abuse potential versus oxycodone with p-values less than 0.05. Consistent results were seen for the secondary endpoints. Additionally, all REL-1017 doses including 150 mg (6 times the therapeutic dose and MTD) were statistically equivalent to placebo ($p<0.05$). These results support the lack of opioid effects of REL-1017.

Top-line Results - Ketamine:

On February 23, 2022, Relmada announced top-line results that showed that all three doses of REL-1017 (25 mg, 75 mg, and 150 mg, the therapeutic, supratherapeutic and MTD, respectively) tested in recreational drug users, demonstrated a substantial (30+ points) and statistically significant difference vs. the active control drug, intravenous ketamine 0.5 mg/kg over 40 minutes, and, importantly, were statistically equivalent to placebo. The study's primary endpoint was a measure of "likability" with the subjects rating the maximum effect (or Emax) for Drug Liking "at this moment", using a 1-100 bipolar rating scale (known as a visual analog scale or VAS), with 100 as the highest likability, 50 as neutral (placebo-like), and 0 the highest dislike. Consistent results are seen for the secondary endpoints.

Psilocybin Program (REL-P11):

On October 11, 2023, Relmada announced that it intends to enter human studies of its proprietary, modified-release formulation of psilocybin (REL-P11) for metabolic indications in doses that we believe are lower than those associates with psychedelic effects. The Company plans to commence a single-ascending dose Phase 1 trial in obese patients in the first half of 2024 to define the pharmacokinetic, safety and tolerability profile of Relmada's modified-release psilocybin formulation (REL-P11) in this population, followed by a Phase 2a trial to establish clinical proof-of-concept.

Pre-clinical data in a rodent model of metabolic dysfunction-associated steatotic liver disease (MASLD) demonstrated beneficial effects of psilocybin on multiple metabolic parameters, including reduced hepatic steatosis, reduced body weight gain, and fasting blood glucose levels.

Key Upcoming Anticipated Milestones

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

- Complete enrollment in the ongoing RELIANCE II study, which is planned to enroll approximately 300 patients, with top-line data in the second half of 2024.
- Initiate Phase 1 trial in obese patients with the modified-release formulation of psilocybin (REL-P11) in the first half of 2024.

Our Development Program

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

Background

In 2021, the National Institute of Mental Health (NIMH) estimated that 21.0 million adults aged 18 or older in the United States had at least one major depressive episode in the past year. According to data from nationally representative surveys supported by NIMH, about 61% of adult Americans diagnosed with major depression received treatment in 2021. Of those receiving treatment with as many as four different standard antidepressants, 33% of drug-treated depression patients do not achieve adequate therapeutic benefits according to the Sequenced Treatment Alternatives to Relieve Depression (STAR*D) trial published in the American Journal of Psychiatry.

In addition to the high failure rate, only two of the marketed products for depression, esketamine (marketed by Johnson and Johnson as Spravato®), an in-clinic nasal spray treatment, and dextromethorphan-bupropion (marketed by Axsome as Auvelity™), can demonstrate rapid antidepressant effects, while the other currently approved products can take two to eight weeks to show activity. The urgent need for improved, faster acting antidepressant treatments is underscored by the fact that severe depression can be life-threatening, due to heightened risk of suicide.

Esmethadone Overview and Mechanism of Action

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

In chemistry an enantiomer, also known as an optical isomer, is one of two stereoisomers that are mirror images of each other that are non-superimposable (not identical), much as one's left and right hands are the same except for being reversed along one axis. A racemic compound, or racemate, is one that has equal amounts of left- and right-handed enantiomers of a chiral molecule. For racemic drugs, often only one of a drug's enantiomers is responsible for the desired physiologic effects, while the other enantiomer is less active or inactive.

As a single isomer of racemic methadone, esmethadone has been shown to possess NMDA antagonist properties with virtually no traditional opioid or ketamine-like adverse events at the expected therapeutic doses. In contrast, racemic methadone is associated with common opioid side effects that include anxiety, nervousness, restlessness, sleep problems (insomnia), nausea, vomiting, constipation, diarrhea, drowsiness, and others. It has been shown that the left (levo) isomer, l-methadone, is largely responsible for methadone's opioid activity, while the right (dextro) isomer, esmethadone, at the currently therapeutic doses used in development is virtually inactive as an opioid while maintaining affinity for the NMDA receptor.

NMDA receptors are present in many parts of the CNS and play important roles in regulating neuronal activity and promoting synaptic plasticity in brain areas important for cognitive functions such as executive function, learning and memory. Based on these premises, esmethadone could show benefits in several different CNS indications.

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

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

Psilocybin Program

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

Our Corporate History and Background

We are a clinical-stage, publicly traded biotechnology company developing NCEs and novel versions of drug products that potentially address areas of high unmet medical need in the treatment of depression and other CNS diseases. We are also developing a novel modified release formulation of psilocybin for the treatment of metabolic indications.

Currently, none of our product candidates have 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 $21,828,126 for the three months ended March 31, 2024. At March 31, 2024, we had an accumulated deficit of $582,730,807.

Business Strategy

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

We plan to further develop esmethadone as our priority program. As the drug esmethadone is an NCE, the regulatory pathway required to support a new drug application (NDA) submission involves a full clinical development program. We plan to continue to generate intellectual property (IP) that will further protect our products from competition. We will also continue to prioritize our product development activities after taking into account the resources we have available, market dynamics and potential for adding value.

Market Opportunity

We believe that the market for addressing areas of high unmet medical need in the treatment of CNS diseases will continue to be large for the foreseeable future and that it will represent a sizable revenue opportunity for us. For example, the World Health Organization (WHO) has estimated that CNS diseases affect nearly 2 billion people globally, making up approximately 40% of total disease burden (based on disability adjusted life years), compared with 13% for cancer and 12% for cardiovascular disease.

The depression treatment market is segmented on the basis of antidepressants drugs, devices, and therapies. Antidepressants are the largest and most popular market segment. The antidepressants segment consists of large pharmaceutical and generic companies, such as Eli Lilly, Pfizer, GlaxoSmithKline, Allergan, Sage Therapeutics and Johnson & Johnson. Some of the notable drugs produced by these companies are Cymbalta® (Eli Lilly), Effexor® (Pfizer), Pristiq® (Pfizer), ZURZUVANE™ (Sage), Spravato® (Johnson & Johnson) and (Auvelity™ (Axsome).

Intellectual Property Portfolio and Market Exclusivity

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

Key Strengths

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

- Compelling lead product opportunity, REL-1017 currently in two Phase 3 trials for the adjunctive treatment of MDD (RELIANCE II and RELIGHT) that build on the knowledge obtained from RELIANCE I, which did not meet its primary endpoint.
- Robust and highly statistically significant, efficacy seen with esmethadone in a randomized Phase 2 trial with the primary endpoint at 7 days, with onset of action seen at 4 days, and the effect carrying through to 14 days (7 days post-treatment).
- Successful Phase 1 safety studies of esmethadone and strong clinical activity signal in depression established in three independent animal models in preclinical studies.
- Potential in additional multiple indications in underserved markets with large patient population in other affective disorders, and cognitive disorders.
- Substantial esmethadone IP portfolio and market protection: approved and filed patent applications provide coverage beyond 2033.
- Portfolio diversification with the development of a novel psilocybin (REL-P11) for the treatment of metabolic indications. This program is expected to enter human studies, to define its pharmacokinetic, safety and tolerability profile, in first half of 2024.
- Scientific support of leading experts: Our scientific advisors include clinicians and scientists who are affiliated with a number of highly regarded medical institutions such as Harvard, Cornell, Yale, and University of Pennsylvania.

Available Information

Reports we file with the Securities and Exchange Commission (SEC) pursuant to the Exchange Act of 1934, as amended (the Exchange Act), including annual and quarterly reports, and other reports we file, can be inspected and copied at the public reference facilities maintained by the SEC at 100 F Street NE, Washington, D.C. 20549.

Results of Operations

For the Three Months Ended March 31, 2024 versus March 31, 2023

	Three Months Ended March 31, 2024	Three Months Ended March 31, 2023	Increase (Decrease)
Operating Expenses			
Research and development	$ 13,305,306	$ 15,861,010	$ (2,555,704)
General and administrative	9,682,554	12,292,599	(2,610,045)
Total	$ 22,987,860	$ 28,153,609	$ (5,165,749)

Research and Development Expense

Research and development expense for the three months ended March 31, 2024 was approximately $13,305,300 compared to $15,861,000 for the three months ended March 31, 2023, a decrease of approximately $2,555,700. The change was primarily driven by:

- Decrease in study costs of $3,658,900 associated with the completion of the long-term, open-label study, Study 310 in 3rd Quarter 2023, as well as RELIANCE I and III in late 2022;
- Decrease in stock-based compensation expense of $294,800;
- Increase in other research expenses of $1,330,800 primarily associated with the ramp-up of the 302 and 304 studies in 2024;

- Increase in compensation expense of $61,300 due to an increase in research and development employees and their related bonus; and
- Increase in manufacturing and drug storage costs of $5,900.

General and Administrative Expense

General and administrative expense for the three months ended March 31, 2024 was approximately $9,682,600 compared to $12,292,600 for the three months ended March 31, 2023, a decrease of approximately $2,610,000. The change was primarily due to:

- Decrease in stock-based compensation expense of $2,764,100;
- Increase in other general and administrative expenses of $92,100 primarily due to an increase in consulting services; and
- Increase in compensation expense of $62,000 related to an increase of general and administrative employees and their related bonuses.

Other Income (Expense)

Interest/investment income was approximately $1,055,900 and $1,207,600 for the three months ended March 31, 2024 and 2023, respectively. The decrease was due to higher interest rates and investment yields. Realized gain on short-term investments was approximately $53,100 and realized loss was $666,700 for the three months ended March 31, 2024 and 2023, respectively. Unrealized gain on short-term investments for the three months ended March 31, 2024 was approximately $50,700 compared to approximately $1,291,100 for the three months ended March 31, 2023.

Net Loss

The net loss for the Company for the three months ended March 31, 2024 and 2023 was approximately $21,828,100 and $26,351,600 respectively. The Company had loss per share, basic and diluted of $0.72 and $0.87 for the three months ended March 31, 2024 and 2023, respectively.

Income Taxes

The Company did not provide for income taxes for the three months ended March 31, 2024 and 2023, since there was a loss and a full valuation allowance against all deferred tax assets.

Liquidity

As shown in the accompanying financial statements, the Company incurred negative operating cash flows of $13,036,748 for the three months ended March 31, 2024 and has an accumulated deficit of $582,730,807 from inception through March 31, 2024. At March 31, 2024 the Company had cash and cash equivalents, and short-term investments of $83,612,705.

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 operations and clinical 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. Further, additional financing does not affect the Company's conclusion that based on the cash on hand and the budgeted cash flow requirements, 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:

	Three Months Ended March 31, 2024	Three Months Ended March 31, 2023
Cash used in operating activities	$ (13,036,748)	$ (16,505,094)
Cash provided by investing activities	10,058,451	40,003,549
Cash provided by financing activities	221,747	-
Net increase/(decrease) in cash and cash equivalents	$ (2,756,550)	23,498,455)

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

For the three months ended March 31, 2023, cash used in operating activities was $16,505,094 primarily due to the net loss of $26,321,576 offset by non-cash stock-based compensation charges of $11,354,466. There were realized losses and unrealized gains on short-term investments of $666,708 and $1,291,110, respectively. In addition, there was a decrease in operating assets and liabilities of $913,582.

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

For the three months ended March 31, 2023, cash provided by investing activities was $40,003,549 related to the purchase of $34,767,288 and the sale of $74,770,836

short-term investments.

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

There was no cash provided by financing activities for the three months ended March 31, 2023.

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 7 in our Annual Report on Form 10-K for the year ended December 31, 2023 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, 2023. Additional risks and uncertainties not currently known to us or that we currently deem to be immaterial also may materially adversely affect our business, financial condition and/or operating results.

Critical Accounting Policies and Estimates

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

Our unaudited condensed consolidated financial statements are presented in accordance with U.S. GAAP, and all applicable U.S. GAAP accounting standards effective as of March 31, 2024 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 2 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, 2023.

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

We carried out an evaluation, under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, of the effectiveness of the design and operation of our disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the Exchange Act). Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by an issuer in the reports that it files or submits under the Exchange Act is accumulated and communicated to the issuer's management, including its principal executive and principal financial officers, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure. Based upon our evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures are effective as of March 31, 2024, in ensuring that material information that we are required to disclose in reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission rules and forms.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting, as such term is defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act, during the three months ended March 31, 2024 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, 2023.

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

None.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES.

None.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

ITEM 5. OTHER INFORMATION

None.

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 herewithin
31.2	Certification of the Principal Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002	Filed herewithin
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*	Filed herewithin
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*	Filed herewithin
101.INS	Inline XBRL Instance Document.	Filed herewithin
101.SCH	Inline XBRL Taxonomy Extension Schema Document.	Filed herewithin
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document.	Filed herewithin
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document.	Filed herewithin
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document.	Filed herewithin
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document.	Filed herewithin
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101).	Filed herewithin

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

SIGNATURES

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

Date: May 8, 2024

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)