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

FORM 10-Q

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

For the quarterly period ended **September 30, 2022**

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 November 7, 2022, there were 30,099,203 shares of common stock, $0.001 par value per share, outstanding.

Relmada Therapeutics, Inc.
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PART I - FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

Relmada Therapeutics, Inc.
Condensed Consolidated Balance Sheets

	As of September 30, 2022 (Unaudited)	As of December 31, 2021
Assets		
Current assets:		
Cash and cash equivalents	$ 42,524,369	$ 44,443,439
Short-term investments	141,627,805	167,466,167
Lease payments receivable – short term	-	86,377
Prepaid expenses	2,953,739	11,301,535
Total current assets	187,105,913	223,297,518
Other assets	16,095	28,293
Total assets	$ 187,122,008	$ 223,325,811
Commitments and Contingencies (See Note 7)		
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 10,425,841	$ 11,192,502
Accrued expenses	10,351,312	3,868,423
Total current liabilities	20,777,153	15,060,925
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, 28,641,991 and 27,740,147 shares issued and outstanding, respectively	28,642	27,740
Additional paid-in capital	590,482,783	513,304,258
Accumulated deficit	(424,166,570)	(305,067,112)
Total stockholders' equity	166,344,855	208,264,886
Total liabilities and stockholders' equity	$ 187,122,008	$ 223,325,811

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

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

	Three months ended September 30,		Nine months ended September 30,	
	2022	2021	2022	2021
Operating expenses:				
Research and development	$ 30,529,108	$ 33,993,974	$ 86,454,632	$ 65,347,708
General and administrative	8,208,053	8,659,661	36,092,024	26,173,010
Total operating expenses	38,737,161	42,653,635	122,546,656	91,520,718
Loss from operations	(38,737,161)	(42,653,635)	(122,546,656)	(91,520,718)
Other (expenses) income:				
Gain on settlement of fees	-	-	6,351,606	-
Interest/investment income, net	827,614	297,648	1,544,898	1,040,429
Realized loss on short-term investments	(561,648)	(336,949)	(552,171)	(513,328)
Unrealized (loss) gain on short-term investments	(947,512)	86,745	(3,897,135)	(379,699)
Total other (expense) income – net	(681,546)	47,444	3,447,198	147,402
Net loss	$ (39,418,707)	$ (42,606,191)	$ (119,099,458)	$ (91,373,316)
Loss per common share – basic and diluted	$ (1.31)	$ (2.44)	$ (4.04)	$ (5.36)
Weighted average number of common shares outstanding – basic and diluted	30,063,735	17,478,477	29,470,198	17,038,583

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

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

	Nine months ended September 30, 2022				
	Common Stock		Additional Paid-in	Accumulated	
	Shares	Par Value	Capital	Deficit	Total
Balance – December 31, 2021	27,740,147	$ 27,740	$ 513,304,258	$ (305,067,112)	$ 208,264,886
Stock based compensation	-	-	11,930,681	-	11,930,681
ATM offering, net	1,609,343	1,610	29,581,932	-	29,583,542
Warrant exercised for cash	33,334	33	299,973	-	300,006
Options exercised for cash	20,000	20	64,780	-	64,800
Net loss	-	-	-	(39,745,783)	(39,745,783)
Balance – March 31, 2022	29,402,824	29,403	555,181,624	(344,812,895)	210,398,132
Stock based compensation	-	-	12,295,016	-	12,295,016
Warrant exercised for cash	91,058	91	595,259	-	595,350
Options exercised for cash	45,812	46	352,698	-	352,744
ATM offering, net of offering costs	484,900	485	13,144,572	-	13,145,057
Net loss	-	-	-	(39,934,968)	(39,934,968)
Balance – June 30, 2022	30,024,594	30,025	581,569,169	(384,747,863)	196,851,331
Stock based compensation	-	-	8,343,139	-	8,343,139
Warrant exercised for cash	51,527	51	332,865	-	332,916
Options exercised for cash	17,886	18	286,158	-	286,176
Share exchange – Pre-funded warrants, net of fees	(1,452,016)	(1,452)	(48,548)	-	(50,000)
Net loss	-	-	-	(39,418,707)	(39,418,707)
Balance – September 30, 2022	28,641,991	$ 28,642	$ 590,482,783	$ (424,166,570)	$ 166,344,855

	Nine months ended September 30, 2021				
	Common Stock		Additional Paid-in	Accumulated	
	Shares	Par Value	Capital	Deficit	Total
Balance – December 31, 2020	16,332,939	$ 16,333	$ 284,881,716	$ (179,315,303)	$ 105,582,746
Stock based compensation	-	-	5,851,284	-	5,851,284
Warrant exercised for cash	273,491	273	1,460,233	-	1,460,506
Options exercised for cash	141,625	142	467,631	-	467,773
Net loss	-	-	-	(22,215,181)	(22,215,181)
Balance – March 31, 2021	16,748,055	16,748	292,660,864	(201,530,484)	91,147,128
Stock based compensation	-	-	8,268,376	-	8,268,376
Warrant exercised for cash	62,059	62	481,387	-	481,449
Options exercised for cash	7,031	7	49,491	-	49,498
ATM offering, net of offering costs	651,674	652	23,457,398		23,458,050
Net loss	-	-	-	(26,551,944)	(26,551,944)
Balance – June 30, 2021	17,468,819	17,469	324,917,516	(228,082,428)	96,852,557
Warrants issued for license agreement	-	-	10,241,599	-	10,241,599
Stock based compensation	-	-	8,013,970	-	8,013,970
Warrant exercised for cash	20,835	21	174,993	-	175,014
Options exercised for cash	11,900	12	52,144	-	52,156
Equity offering costs	-	-	(42,041)	-	(42,014)
Net loss	-	-	-	(42,606,191)	(42,606,191)
Balance – September 30, 2021	17,501,554	$ 17,502	$ 343,358,208	$ (270,688,619)	$ 72,687,091

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

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

	Nine months ended September 30,	
	2022	2021
Cash flows from operating activities		
Net loss	$ (119,099,458)	$ (91,373,316)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation expense	-	1,258
Warrants issued for license agreement	-	10,241,599
Stock-based compensation	32,568,836	22,133,630
Realized loss on short-term investments	552,171	513,328
Unrealized loss on short-term investments	3,897,135	379,699
Change in operating assets and liabilities:		
Lease payment receivable	86,377	58,967
Prepaid expenses and other assets	8,359,994	(1,812,288)
Accounts payable	(766,661)	4,362,071
Accrued expenses	6,482,889	1,281,821
Net cash used in operating activities	(67,918,717)	(54,213,231)
Cash flows from investing activities		
Purchase of short-term investments	(38,993,173)	(82,476,539)
Sale of short-term investments	60,382,229	119,541,235
Net cash provided by investing activities	21,389,056	37,064,696
Cash flows from financing activities		
Payment of fees for warrants issued for common stock	(50,000)	-
Proceeds from issuance of common stock – net	42,728,599	23,416,036
Proceeds from options exercised for common stock	703,720	569,427
Proceeds from warrants exercised for common stock	1,228,272	2,116,969
Net cash provided by financing activities	44,610,591	26,102,432
Net (decrease) / increase in cash and cash equivalents	(1,919,070)	8,953,897
Cash and cash equivalents at beginning of the period	44,443,439	2,495,397
Cash and cash equivalents at end of the period	$ 42,524,369	11,449,294
Supplemental disclosure of cash flow information:		
Non-cash investing and financing activities:		
Share exchange for Pre-funded warrants	$ 1,452	$ -

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.

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, 2021 and notes thereto contained in the Company's Annual Report on Form 10-K.

Liquidity

As shown in the accompanying unaudited condensed consolidated financial statements, the Company incurred negative operating cash flows of $67,918,717 for the nine months ended September 30, 2022 and has an accumulated deficit of $424,166,570 from inception through September 30, 2022.

Relmada has funded its past operations through equity raises, and most recently in the nine months ended September 30, 2022, the Company raised net proceeds of $42,728,599 from the sale of common stock, through our at-the-market (ATM) equity offering, $703,720 through the exercise of options and $1,228,272 through the exercise of warrants.

On April 8, 2022, we raised net proceeds of $13,145,057 from the sale of common stock through our ATM equity offering. On April 6, 2022, we 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 September 30, 2022, no shares have been issued under this agreement.

NOTE 2 – SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (continued)

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 quarterly 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. Further, additional financing related to subsequent clinical trials 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.

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.

Risks and Uncertainties

The ongoing pandemic may adversely affect our business. Based on the Company's current assessment, the Company does not expect any material impact on its long-term development timeline and its liquidity due to the worldwide spread of the coronavirus (COVID-19). However, the Company is actively monitoring this situation and the possible effects on its financial condition, liquidity, operations, suppliers, industry, and workforce.

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.

NOTE 2 – SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (continued)

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 balance of $42,524,369 at September 30, 2022 at these institutions exceed the federally insured limits.

Short-term Investments

The Company's investments consist entirely of mutual funds. The securities are measured at fair value based on the net asset value (NAV). insubstantially all equity investments are nonconsolidated entities to be 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 unaudited condensed consolidated statement of operations. Short-term investment activity is presented in the investing activities section on the unaudited condensed consolidated statement of cash flows.

Short-term investments at September 30, 2022 consisted of mutual funds with a fair value of $141,627,805.

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.

NOTE 2 – SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (continued)

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 judgement 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 $141,627,805 at September 30, 2022 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 losses of $947,512 and $3,897,135 included in other income for the three and nine months ended September 30, 2022, respectively. The Company recorded an unrealized gain of $86,745 and an unrealized loss of $379,699 included in other income for the three and nine months ended September 30, 2021, respectively.

Income Taxes

The Company accounts for income taxes using the asset and liability method. Accordingly, deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between financial statement carrying amounts of existing assets and liabilities and their respective tax bases. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in the tax rate is recognized in income or expense in the period that the change is effective. Tax benefits are recognized when it is probable that the deduction will be sustained. A valuation allowance is established when it is more likely than not that all or a portion of a deferred tax asset will either expire before the Company is able to realize the benefit, or that future deductibility is uncertain. As of September 30, 2022 and December 31, 2021, the Company had recognized a valuation allowance to the full extent of the Company's net deferred tax assets since the likelihood of realization of the benefit does not meet the more likely than not threshold.

The Company files a U.S. Federal income tax return and various state returns. Uncertain tax positions taken on the Company's tax returns will be accounted for as liabilities for unrecognized tax benefits. The Company will recognize interest and penalties, if any, related to unrecognized tax benefits in general and administrative expenses in the statements of operations. There were no liabilities recorded for uncertain tax positions at September 30, 2022 and December 31, 2021. The open tax years, subject to potential examination by the applicable taxing authority, for the Company are from June 30, 2018 forward.

On August 16, 2022, the Inflation Reduction Act of 2022 (the "IR Act") was signed into federal law. The IR Act provides for, among other things, a new U.S. federal 1% excise tax on certain repurchases of stock by publicly traded U.S. domestic corporations and certain U.S. domestic subsidiaries of publicly traded foreign corporations occurring on or after January 1, 2023. The excise tax is imposed on the repurchasing corporation itself, not its shareholders from which shares are repurchased. The amount of the excise tax is generally 1% of the fair market value of the shares repurchased at the time of the repurchase. However, for purposes of calculating the excise tax, repurchasing corporations are permitted to net the fair market value of certain new stock issuances against the fair market value of stock repurchases during the same taxable year. In addition, certain exceptions apply to the excise tax. The U.S. Department of the Treasury (the "Treasury") has been given authority to provide regulations and other guidance to carry out and prevent the abuse or avoidance of the excise tax.

NOTE 2 – SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (continued)

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 and non-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 loss position.

For the nine months ended September 30, 2022 and 2021, the potentially dilutive securities that would be anti-dilutive due to the Company's net loss are not included in the calculation of diluted net loss per share attributable to common stockholders. The anti-dilutive securities are as follows (in common stock equivalent shares):

	Nine months ended	
	September 30, 2022	September 30, 2021
Stock options	10,719,424	5,043,931
Common stock warrants	4,484,874	3,244,248
Total	15,204,298	8,288,179

NOTE 2 – SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (continued)

Recent Accounting Pronouncements

In November 2021, the FASB issued ASU 2021-10, "*Government Assistance (Topic 832): Disclosures by Business Entities about Government Assistance*". The amendments in this ASU require annual disclosures to increase the transparency of government assistance received by a business entity including information about the nature of the government transactions, related accounting policy, the line items on the balance sheet and income statement that are affected, amounts applicable to each financial statement line item, and significant terms and conditions of the transactions, including commitments and contingencies. The amendments in this ASU are effective for annual periods beginning after December 15, 2021. The Company adopted this standard effective January 1, 2022 and the standard did not have a significant impact on our condensed consolidated financial statements.

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 are effective for annual and interim periods beginning after December 15, 2022. Early adoption is permitted. The Company does not expect this standard to have a material impact on the consolidated financial statements.

In December 2019, the FASB issued ASU 2019-12, *Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes*, which is intended to simplify various aspects related to accounting for income taxes. ASU 2019-12 removes certain exceptions to the general principles in Topic 740 and also clarifies and amends existing guidance to improve consistent application. This guidance is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2020. The Company adopted this standard effective January 1, 2021 and the standard did not have a significant impact on our condensed consolidated financial statements.

In May 2021, the FASB issued ASU No. 2021-04, *Earnings Per Share (Topic 260), Debt—Modifications and Extinguishments (Subtopic 470-50), Compensation—Stock Compensation (Topic 718), and Derivatives and Hedging—Contracts in Entity's Own Equity (Subtopic 815-40)*. ASU 2021-04 outlines how an entity should account for modifications made to equity-classified written call options, including stock options and warrants to purchase the entity's own common stock. The guidance in the ASU requires an entity to treat a modification of an equity-classified written call options that does not cause the option to become liability-classified as an exchange of the original option for a new option. This guidance applies whether the modification is structured as an amendment to the terms and conditions of the equity-classified written call option or as termination of the original option and issuance of a new option. The guidance is effective prospectively for fiscal years beginning after December 15, 2021, including interim periods within those fiscal years. Early adoption is permitted, including in an interim period as of the beginning of the fiscal year that includes that interim period. The Company adopted this standard effective January 1, 2022 and the standard did not have a significant impact on our 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):

	September 30, 2022	December 31, 2021
Insurance	$ 478,500	$ 353,300
Research and Development	2,415,500	10,708,800
Legal	11,000	11,000
Other	48,700	228,400
Total	$ 2,953,700	$ 11,301,500

NOTE 4 – ACCRUED EXPENSES

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

	September 30, 2022	December 31, 2021
Research and development	$ 8,058,900	$ 1,928,000
Professional fees	172,000	168,000
Accrued bonus	1,182,900	1,191,000
Accrued vacation	648,300	450,400
Other	289,200	131,000
Total	$ 10,351,300	$ 3,868,400

NOTE 5 – STOCKHOLDERS' EQUITY

Common Stock

During the nine months ended September 30, 2022, the Company issued 175,919 shares of common stock for cash exercises of warrants for proceeds of $1,228,272.

During the nine months ended September 30, 2022, the Company issued 83,698 shares of common stock for the exercise of options for proceeds of $703,720.

On May 15, 2020, the Company entered into an Open Market Sale Agreement with Jefferies LLC, as sales agent ("Jefferies"), pursuant to which the Company could offer and sell, from time to time, through Jefferies, shares of the Company's common stock, having an aggregate offering price of up to $75,000,000. The Company was not obligated to sell any shares under the agreement. During the nine months ended September 30, 2022, the Company issued 2,094,243 shares of common stock for net cash proceeds of $42,728,599 under the agreement.

On April 6, 2022, we 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 September 30, 2022, no shares have been issued under this agreement.

Options and Warrants

In December 2014, the Company's Board of Directors adopted, and shareholders approved Relmada's 2014 Stock Option and Equity Incentive Plan, as amended, 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 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.

Stock options are exercisable generally for a period of 10 years from the date of grant and generally vest over four years. The shareholders will vote at their annual meeting in 2023 on a management proposal to increase the shares available to be issued under the 2021 Plan. There can be no assurance such amendment will be approved. As of September 30, 2022, options for 166,482 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 September 30, 2022, no stock appreciation rights have been issued.

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 routinely reviews its calculation of volatility changes in future volatility, the Company's life cycle, its peer group, and other factors.

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.

On January 1, 2022, 50,000 options were issued to a consultant with an exercise price of $22.53 and a 10-year term, vesting over a 1-year period. The options granted include performance vesting based on the Company's achievement of performance metrics. The options have an aggregate fair value of $847,583, calculated using the Black-Scholes option-pricing model. Variables used in the Black-Scholes option-pricing model include: (1) discount rate of 1.53% (2) expected life of 5.5 years, (3) expected volatility of 96%, and (4) zero expected dividends.

From January 1, 2022 through March 14, 2022, 110,000 options were issued to various consultants with an exercise price ranging from $18.00 to $21.46 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 $1.6 million, calculated using the Black-Scholes option-pricing model. Variables used in the Black-Scholes option-pricing model include: (1) discount rate of 1.53 – 2.00% (2) expected life of 6.25 years, (3) expected volatility of 98%, and (4) zero expected dividends.

NOTE 5 – STOCKHOLDERS' EQUITY (continued)

On March 28, 2022, the Company awarded a total of 15,000 options to an employee with an exercise price of $25.76 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 $307,845 calculated using the Black Scholes option-pricing model. Variables used in the Black-Scholes option-pricing model include: (1) discount rate of 2.55% (2) expected life of 6.25 years, (3) expected volatility of 98%, and (4) zero expected dividends.

From April 25, 2022 through May 5, 2022, 260,000 options were issued to various consultants with an exercise price ranging from $22.40 to $25.52 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 $4.6 million, calculated using the Black-Scholes option-pricing model. Variables used in the Black-Scholes option-pricing model include: (1) discount rate of 2.85 – 3.04% (2) expected life of 6.25 years, (3) expected volatility of 95%, and (4) zero expected dividends.

From July 1, 2022 through September 29, 2022, 260,000 options were issued to various consultants with an exercise price ranging from $18.30 to $36.19 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 $5.0 million calculated using the Black-Scholes option-pricing model. Variables used in the Black-Scholes option-pricing model include: (1) discount rate of 2.9 – 3.94% (2) expected life of 6.25 years, (3) expected volatility of 93-94%, and (4) zero expected dividends.

On March 30, 2021, 50,000 options were issued to a consultant with an exercise price of $34.93 and a 10-year term, vesting over a 10-year period. The options granted include performance vesting based on the Company's achievement of performance metrics. The options have an aggregate fair value of $1.6 million, calculated using the Black-Scholes option-pricing model. Variables used in the Black-Scholes option-pricing model include: (1) discount rate of 1.73% (2) expected life of 10 years, (3) expected volatility of 102%, and (4) zero expected dividends.

At September 30, 2022, the Company has unrecognized stock-based compensation expense of approximately $121.7 million related to unvested stock options over the weighted average remaining service period of 2.43 years.

Options

A summary of the changes in options during the nine months ended September 30, 2022 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, 2021	10,330,622	$ 22.52	9.00	$ 46,088,534
Granted	745,000	$ 23.61	9.55	$ -
Exercised	(83,698)	$ 8.41	-	$ -
Forfeited	(272,500)	$ 29.28	-	$ -
Outstanding at September 30, 2022	10,719,424	$ 22.53	8.40	$ 163,311,188
Options exercisable at September 30, 2022	3,706,254	$ 21.64	7.27	$ 62,486,845

Warrants

A summary of the changes in outstanding warrants during the nine months ended September 30, 2022 is as follows:

	Number of Shares	Weighted Average Exercise Price Per Share
Outstanding and vested at December 31, 2021	3,208,777	$ 16.45
Granted	1,452,016	$ 0.001
Exercised	(175,919)	$ 6.98
Outstanding at September 30, 2022	4,484,874	$ 11.50
Warrants Vested at September 30, 2022	4,190,999	$ 10.04

NOTE 5 – STOCKHOLDERS' EQUITY (continued)

On September 20, 2022, the Company entered into an agreement with an investor to exchange 1,452,016 shares of outstanding common stock for 1,452,016 prefunded warrants. The 1,452,016 shares of common stock were returned to treasury. These warrants have an exercise price of $0.001 and a 9.99% beneficial ownership limitation.

At September 30, 2022, the Company had approximately $6.7 million of unrecognized compensation expense related to outstanding warrants.

At September 30, 2022, the aggregate intrinsic value of warrants vested and outstanding was approximately $113.1 million and $113.1 million, respectively.

Stock-based compensation by class of expense

The following summarizes the components of stock-based compensation expense which includes stock options and warrants in the unaudited consolidated statements of operations for the nine months ended September 30, 2022 and 2021 (rounded to nearest $00):

	Nine Months Ended September 30, 2022	Nine Months Ended September 30, 2021
Research and development	$ 5,674,600	$ 14,341,700
General and administrative	26,894,200	18,033,500
Total	$ 32,568,800	$ 32,375,200

NOTE 6 – RELATED PARTY TRANSACTIONS

Effective March 6, 2020, Dr. Ottavio Vitolo, the Company's Chief Medical Officer and Head of Research and Development, entered into a Separation and Severance Agreement with the Company. Pursuant to the terms of the agreement, the Company agreed to pay Dr. Vitolo severance of $200,000 in accordance with his employment contract. In addition, Dr. Vitolo's options granted under the Company's 2014 Stock Option and Equity Incentive Plan continued to vest until September 6, 2020. Dr. Vitolo had until March 6, 2021 to exercise his vested options and he was allowed to use a cashless exercise provision to exercise his vested options. Dr. Vitolo exercised 126,562 options during 2020 and the remaining options expired on March 6, 2021. The agreement also contains customary confidentiality, release, and non-disparagement provisions, and the Company paid accrued and unpaid salary, vacation time and attorney's fees totaling approximately $45,000.

Effective December 31, 2020, Dr. Thomas Wessel, the Company's Executive Vice President, Head of Research and Development, entered into a Separation and Severance Agreement with the Company. Pursuant to the terms of the agreement, the Company agreed to pay Dr. Wessel severance of $237,500 in accordance with his employment contract. In addition, Dr. Wessel's options granted under the Company's 2014 Stock Option and Equity Incentive Plan continue to vest until June 30, 2021. Dr. Wessel had until December 31, 2021 to exercise his vested options and he shall be allowed to use a cashless exercise provision to exercise his vested options. All of Dr. Wessel's options expired on December 31, 2021. The agreement also contains customary confidentiality, release, and non-disparagement provisions, and the Company paid accrued vacation time totaling approximately $28,940.

NOTE 7 – 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 September 30, 2022, 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 was developing at the time of the signing of the agreement. 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.

NOTE 7 – COMMITMENTS AND CONTINGENCIES (continued)

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 or $2 million, for the first commercial sale of product in the field that has a single active pharmaceutical ingredient, and for the first commercial sale of product in the field of product that has more than one active pharmaceutical ingredient, respectively. As of September 30, 2022, 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 September 30, 2022, 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 Acting Chief Medical Officer, are among the scientists affiliated with Arbormentis, LLC.

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 – 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 a 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 year 2022 with monthly rent of approximately $9,000. The Company's previous lease at 880 Third Avenue, 12th Floor, New York, NY 10022 was terminated as of July 31, 2021. In accordance with ASC 842, *Leases*, the Company has elected the practical expedient and recognizes rent expense evenly over the 12 months. For the nine months ended September 30, 2022 and 2021, the Company recognized lease expense of approximately $75,700 and $87,100, respectively.

On June 8, 2017, the Company entered into an Amended and Restated License Agreement with Actinium Pharmaceuticals, Inc. Pursuant to the terms of the agreement, Actinium licensed the furniture, fixtures, equipment and tenant improvements located in its office (FFE) for a license fee of $7,529 per month until December 8, 2022. Actinium had at any time during the term of this agreement the right to purchase the FFE for $496,914, less any previously paid license fees. On July 7, 2022, Actinium exercised its right to purchase the FFE for $52,698. The license of FFE qualified as a sales-type lease. At inception, the Company derecognized the underlying assets of $493,452, recognized discounted lease payments receivable of $397,049 using the discount rate of 8.38% and recognized loss on sales-type lease of fixed assets of $96,403. For the nine months ended September 30, 2022 and 2021, the Company recognized lease income of approximately $2,500 and $8,800, respectively. As of September 30, 2022, there were no future payments to be received as a result of the exercised right to purchase.

NOTE 8 – 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 $87,900 and $101,100 for the nine months ended September 30, 2022 and 2021, respectively.

NOTE 9 – SUBSEQUENT EVENTS

On October 19, 2022, a cashless exercise of the 1,452,016 prefunded warrants was transacted with 1,451,795 shares of common shares issued and the remaining 221 warrants being cancelled.

Subsequent to September 30, 2022, 5,417 outstanding warrants were exercised for total cash proceeds of $36,252.

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 or 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 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. This was a double-blind, placebo-controlled Phase 2 clinical trial evaluating the safety, tolerability and efficacy of two oral doses of REL-1017, 25 mg once a day and 50 mg once a day, as an adjunctive treatment in patients with major depressive disorder (MDD), who experienced an inadequate response to 1 to 3 treatments with an antidepressant medication.

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.

Key findings:

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.

MADRS: Analysis of Change from Baseline to Day 7 and to Day 14 ITT Population

	Day 2			Day 4			Day 7			Day 14		
	LS Means Difference	P-value	d	LS Means Difference	P-value	d	LS Means Difference	P-value	d	LS Means Difference	P-value	d
REL-1017 25mg vs Placebo	-1.9	0.4340	0.3	-7.9	0.0087	0.9	-8.7	0.0122	0.8	-9.4	0.0103	0.9
REL-1017 50mg vs Placebo	-0.3	0.9092	0.0	-7.6	0.0096	0.8	-7.2	0.0308	0.7	-10.4	0.0039	1.0

LS = Least Squares; d = Cohen's effect size

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 in 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.

Following discussions with the Food and Drug Administration (FDA), Relmada's adjunctive MDD Phase 3 program includes the following key attributes:

- The Phase 3 program consists of two sister, two-arm, placebo-controlled clinical trials. Each trial is being conducted in 55 clinical sites in the United States. Patients will add either a 25 mg oral dose of REL-1017 once per day or placebo to their ongoing antidepressant treatment.

- The primary endpoint to be evaluated will be the change from baseline on the MADRS score at day-28 for REL-1017 compared to placebo. Success on this endpoint with the collection of sufficient safety data could support the use of REL-1017 for chronic treatment, if approved.

- The change from baseline and the 7-day MADRS score will serve as a key secondary endpoint and will provide information on the time to treatment effect.

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 MDD.

On October 4, 2021, Relmada announced RELIANCE III, the monotherapy trial for the Company's lead product candidate, 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 Major Depressive Disorder (MDD), did not achieve its primary endpoint, which was a statistically significant improvement in depression symptoms compared to placebo as measured by the Montgomery-Asberg Depression Rating Scale (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.

Patients who complete the RELIANCE trials are eligible to rollover into the long-term, open-label study, which also is expected to include subjects who had not previously participated in a REL-1017 clinical trial.

In addition, in order to support potential regulatory submissions seeking approval for REL-1017 as an adjunctive treatment, the FDA confirmed that, based on what is known at this time, Relmada will not be required to conduct a two-year carcinogenicity study of REL-1017, as sufficient clinical data have been generated to date. The FDA also confirmed that Relmada does not need to conduct a thorough QT analysis (TQT) cardiac study in humans to support cardiac safety in potential regulatory submissions for REL-1017, as the data provided so far and the data generated by the Phase 3 program will be adequate to evaluate the cardiac safety profile of REL-1017.

Human Abuse Potential (HAP) Study top-line results - Oxycodone:

On July 27, 2021, we 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 maximum tolerated dose, 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 on REL-1017.

Human Abuse Potential (HAP) Study top-line results - Ketamine:

On February 23, 2022, we 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, 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 were seen for the secondary endpoints.

Key Upcoming Anticipated Milestones

We expect multiple key milestones over the next 12-18 months. These include:

- Results of RELIANCE I adjunctive MDD trial by year-end 2022.
- Results of RELIANCE II adjunctive MDD trial during 2023.
- Results of RELIANCE – OLS (Long-term, Open-label) study in MDD in the first half of 2023.

Our Development Program

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

Background

In 2014, the National Institute of Mental Health (NIMH) estimated that 15.7 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, only about half of Americans diagnosed with major depression in a given year receive treatment. 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 Auvelityä), 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

In addition to developing esmethadone as an adjunctive treatment of MDD, we are evaluating other indications that Relmada may explore in the future, including restless leg syndrome and other glutamatergic system activation related diseases.

Recent Development

On September 20, 2022, we entered into an agreement with an investor to exchange 1,452,016 shares of outstanding common stock for 1,452,016 prefunded warrants. The 1,452,016 shares of common stock were returned to treasury. These warrants had an exercise price of $0.001 and a 9.99% beneficial ownership limitation. On October 19, 2022, the investor net exercised all 1,452,016 prefunded warrants, with 1,451,795 shares of common stock issued and the remaining 221 warrants being cancelled.

Our Corporate History and Background

We are a clinical-stage, publicly traded biotechnology company developing NCEs and novel verions of drug products that potentially address areas of high unmet medical need in the treatment of depression and other CNS diseases.

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 net loss of $119,099,458 for the nine months ended September 30, 2022. At September 30, 2022, we have an accumulated deficit of $424,166,570.

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), Zulresso® (Sage), Spravato® (Johnson & Johnson) and Auvelityä (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", which, upon NDA approval, carries 7-year FDA Orphan Drug marketing exclusivity. In the European Union, some of our actual and 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) plus 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 Phase 3 trials for the adjunctive treatment of MDD.

- Robust and highly statistically significant, efficacy seen with esmethadone in a randomized Phase 2 trial, with the primary endpoint at 7 days, and onset of action seen at 4 days, with 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.

- 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.

- Substantial IP portfolio and market protection with approved and filed patent applications provide coverage beyond 2033.

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 September 30, 2022 versus September 30, 2021

	Three Months Ended September 30, 2022	Three Months Ended September 30, 2021	Increase (Decrease)
Operating Expenses			
Research and development	$ 30,529,108	$ 33,993,974	$ (3,464,866)
General and administrative	8,208,053	8,659,661	(451,608)
Total	$ 38,737,161	$ 42,653,635	$ (3,916,474)

Research and Development Expense

Research and development expense for the three months ended September 30, 2022 was approximately $30,529,100 compared to $33,994,000 for the three months ended September 30, 2021, a decrease of approximately $3,464,900. The decrease was primarily driven by:

- Decrease in stock-based compensation expense of $8,655,200 primarily related to warrants issued for a license agreement to Arbormentis, LLC in 2021 for $10,241,600;

- Increase in other research expenses of $5,825,500 primarily associated with the addition of consultants contracted to assist in the execution of our Phase 3 trials;

- Decrease in study costs of $516,700 associated with the execution of four Phase 3 trials;

- Decrease in manufacturing and drug storage costs of $332,800; and

- Increase in compensation expense of $214,300 due to higher employee-related salaries and benefits.

General and Administrative Expense

General and administrative expense for the three months ended September 30, 2022 was approximately $8,208,100 compared to $8,659,700 for the three months ended September 30, 2021, a decrease of approximately $451,600. The decrease was primarily due to:

- Decrease in stock-based compensation expense of $1,257,200 primarily related to options granted to employees;

- Increase in other general and administrative expenses of $608,600 primarily due to an increase in consulting services; and

- Increase in compensation expense of $197,000 due to higher employee-related salaries and benefits.

Other Income (Expense)

Interest / investment income was approximately $827,600 and $297,600 for the three months ended September 30, 2022 and 2021, respectively. Realized loss on short-term investments was approximately $561,600 and $336,900 for the three months ended September 30, 2022 and 2021, respectively. Unrealized loss on short-term investments was approximately $947,500 for the three months ended September 30, 2022 compared to an unrealized gain of $86,700 for the three months ended September 30, 2021.

Income Taxes

The Company did not provide for income taxes for the three months ended September 30, 2022 and 2021, since there was a loss and a full valuation allowance against all deferred tax assets.

Net Loss

The net loss for the Company for the three months ended September 30, 2022 and 2021 was approximately $39,418,700 and $42,606,200 respectively. The Company had loss per share, basic and diluted of $1.31 and $2.44 for the three months ended September 30, 2022 and 2021, respectively.

For the Nine Months Ended September 30, 2022 versus September 30, 2021

	Nine Months Ended September 30, 2022	Nine Months Ended September 30, 2021	Increase (Decrease)
Operating Expenses			
Research and development	$ 86,454,632	$ 65,347,708	$ 21,106,924
General and administrative	36,092,024	26,173,010	9,919,014
Total	$ 122,546,656	$ 91,520,718	$ 31,025,938

Research and Development Expense

Research and development expense for the nine months ended September 30, 2022 was approximately $86,454,600 compared to $65,347,700 for the nine months ended September 30, 2021, an increase of approximately $21,106,900. The increase was primarily driven by:

- Increase in other research expenses of $16,849,800 primarily associated with the addition of consultants contracted to assist in the execution of our Phase 3 trials;
- Increase in study costs of $13,918,200 associated with the execution of four Phase 3 trials;
- Decrease in stock-based compensation expense of $8,667,100 primarily related to warrants issued for license agreement to Arbormentis, LLC in 2021 for $10,241,600;
- Decrease in manufacturing and drug storage costs of $812,800; and
- Decrease in compensation expense of $181,200 due to lower employee-related salaries and benefits.

General and Administrative Expense

General and administrative expense for the nine months ended September 30, 2022 was approximately $36,092,000 compared to $26,173,000 for the nine months ended September 30, 2021, an increase of approximately $9,919,000. The increase was primarily due to:

- Increase in stock-based compensation expense of $8,860,800 primarily related to options granted to employees, as well as the hiring of two additional employees;
- Increase in other general and administrative expenses of $1,128,400 primarily due to an increase in consulting services; and
- Decrease in compensation expense of $70,200 due to lower employee-related costs.

Other Income (Expense)

Interest / investment income was approximately $1,544,900 and $1,040,400 for the nine months ended September 30, 2022 and 2021, respectively. Realized loss on short-term investments was approximately $552,200 and $513,300 for the nine months ended September 30, 2022 and 2021, respectively. Unrealized loss on short-term investments was approximately $3,897,100 and $379,700 for the nine months ended September 30, 2022 and 2021, respectively. Gain on settlement fees was $6,351,600 for the nine months ended September 30, 2022.

Income Taxes

The Company did not provide for income taxes for the nine months ended September 30, 2022 and 2021, since there was a loss and a full valuation allowance against all deferred tax assets.

Net Loss

The net loss for the Company for the nine months ended September 30, 2022 and 2021 was approximately $119,099,500 and $91,373,300 respectively. The Company had loss per share, basic and diluted of $4.04 and $5.36 for the nine months ended September 30, 2022 and 2021, respectively.

Liquidity

As shown in the accompanying financial statements, the Company incurred negative operating cash flows of $67,918,717 for the nine months ended September 30, 2022 and has an accumulated deficit of $424,166,570 from inception through September 30, 2022. At September 30, 2022 the Company had cash and cash equivalents, and short-term investments of $184,152,174.

Relmada has funded its past operations through equity raises and in the nine months ended September 30, 2022, the Company raised net proceeds of $42,728,599 from the sale of common stock through our ATM equity offering, and $703,720 through the exercise of options and $1,228,272 through the exercise of warrants.

On April 8, 2022, we raised net proceeds of $13,145,057 from the sale of common stock through our ATM equity offering. On April 6, 2022, we 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 September 30, 2022, no shares have been issued under this agreement.

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. Further, additional financing related to subsequent clinical trials does not affect the Company's conclusion that the Company has sufficient funds to maintain operations for at least 12 months from the filing of this report.

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

	Nine Months Ended September 30, 2022	Nine Months Ended September 30, 2021
Cash used in operating activities	$ (67,918,717)	$ (54,213,231)
Cash provided by investing activities	21,389,056	37,064,696
Cash provided by financing activities	44,610,591	26,102,432
Net (decrease) / increase in cash and cash equivalents	$ (1,919,070)	8,953,897

For the nine months ended September 30, 2022, cash used in operating activities was $67,918,717 primarily due to the net loss of $119,099,458, decrease in accounts payable of $766,661, offset by non-cash stock compensation charges of $32,568,836, decrease in prepaid expenses and other assets of $8,359,994, increase in accrued expenses of $6,482,889, decrease in lease payment receivable of $86,377, unrealized loss of $3,897,135, and realized loss of $552,171.

For the nine months ended September 30, 2021, cash used in operating activities was $54,213,231 primarily due to the net loss of $91,373,316, increase in prepaid expense of $1,812,288, offset by non-cash stock compensation charges of $32,375,229, increase in accounts payable of 4,362,071, increase in accrued expenses of 1,281,821, decrease in lease payment receivable of $58,967, unrealized loss of $379,699, and realized loss of $513,328.

For the nine months ended September 30, 2022, cash provided by investing activities was $21,389,056 related to the net purchase of short-term investments.

For the nine months ended September 30, 2021, cash provided by investing activities was $37,064,696 related to the net purchase of short-term investments.

Net cash provided by financing activities for the nine months ended September 30, 2022 was $44,610,591 due to sales of common stock of $42,728,599, proceeds from warrants exercised for common stock of $1,228,272, and proceeds from options exercised for common stock of $703,720.

Net cash provided by financing activities for the nine months ended September 30, 2021 was $26,102,432 due to sales of common stock of $23,416,036, proceeds from warrants exercised for common stock of $2,116,969, and proceeds from options exercised for common stock of $569,427.

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 9 in our Annual Report on Form 10-K for the year ended December 31, 2021 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, 2021. Additional risks and uncertainties not currently known to us or that we currently deem to be immaterial also may materially adversely affect our business, financial condition and/or operating results.

Critical Accounting Policies and Estimates

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

Our unaudited condensed consolidated financial statements are presented in accordance with U.S. GAAP, and all applicable U.S. GAAP accounting standards effective as of September 30, 2022 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 judgements 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 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 the 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 MD&A contained in our Form 10-K for the year ended December 31, 2021.

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

We carried out an evaluation, under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, of the effectiveness of the design and operation of our disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the Exchange Act). Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by an issuer in the reports that it files or submits under the Exchange Act is accumulated and communicated to the issuer's management, including its principal executive and principal financial officers, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure. Based upon our evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures are effective as of September 30, 2022, 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 nine months ended September 30, 2022 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

Effects of COVID-19

The pandemic caused by an outbreak of COVID-19 has resulted, and is likely to continue to result, in significant national and global economic disruption and may adversely affect our business. Based on the Company's current assessment, the Company does not expect any material impact on its long-term development timeline and its liquidity due to the worldwide spread of the COVID-19 virus. However, the Company is actively monitoring this situation and the possible effects on its financial condition, liquidity, operations, suppliers, industry, and workforce.

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, 2021, which include more detailed risk factors related to COVID-19.

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

On September 20, 2022, we entered into an agreement with an investor to exchange 1,452,016 shares of outstanding common stock for 1,452,016 prefunded warrants. The 1,452,016 shares of common stock were returned to treasury. These warrants had an exercise price of $0.001 and a 9.99% beneficial ownership limitation. On October 19, 2022, the investor net exercised all 1,452,016 prefunded warrants, with 1,451,795 shares of common stock issued and the remaining 221 warrants being cancelled. Both the issuance of the warrants and the issuance of the shares of common stock upon their exercise were exempt from registration under the Securities Act of 1933, as amended, under Section 3(a)(9) thereof.

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 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.

SIGNATURES

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

Date: November 10, 2022	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)

Exhibit 31.1

CERTIFICATION OF CHIEF EXECUTIVE OFFICER
PURSUANT TO
RULE 13a-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF
THE SARBANES-OXLEY ACT OF 2002

I, Sergio Traversa, certify that:

1. I have reviewed this Report on Form 10-Q of Relmada Therapeutics, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods present in this report;

4. I and the other certifying officer are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financing reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. I and the other certifying officer have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involved management or other employees who have a significant role in the registrant's internal control over financial reporting.

Relmada Therapeutics, Inc.

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

November 10, 2022

Exhibit 31.2

CERTIFICATION OF PRINCIPAL FINANCIAL AND ACCOUNTING OFFICER
PURSUANT TO
RULE 13a-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF
THE SARBANES-OXLEY ACT OF 2002

I, Maged Shenouda, certify that:

1. I have reviewed this Report on Form 10-Q of Relmada Therapeutics, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods present in this report;

4. I and the other certifying officer are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financing reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. I and the other certifying officer have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involved management or other employees who have a significant role in the registrant's internal control over financial reporting.

Relmada Therapeutics, Inc.

By: /s/ Maged Shenouda
Maged Shenouda
Chief Financial Officer

November 10, 2022

Exhibit 32.1

CERTIFICATION OF CHIEF EXECUTIVE OFFICER
PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report of Relmada Therapeutics, Inc. (the “Company”) on Form 10-Q for the quarterly period ended September 30, 2022 as filed with the Securities and Exchange Commission on the date hereof (the “Report”), I, Sergio Traversa, Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

2. The information contained in the Report fairly presents, in all material respects, the consolidated financial condition and results of consolidated operations of the Company.

Relmada Therapeutics, Inc.

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

November 10, 2022

Exhibit 32.2

CERTIFICATION OF PRINCIPAL FINANCIAL AND ACCOUNTING OFFICER
PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report of Relmada Therapeutics, Inc. (the “Company”) on Form 10-Q for the quarterly period ended September 30, 2022, as filed with the Securities and Exchange Commission on the date hereof (the “Report”), I, Maged Shenouda, Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

2. The information contained in the Report fairly presents, in all material respects, the consolidated financial condition and results of operations of the Company.

/s/ Maged Shenouda

Maged Shenouda
Chief Financial Officer
(Principal Financial Officer)

November 10, 2022