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

FORM 10-Q

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

For the quarterly period ended June 30, 2021

		or		
□ TR	ANSITION REPORT PURSUANT TO SE	CTION 13 OR 15 (d) OF THE SECU	URITIES EXCHANGE ACT	T OF 1934
	For the transition period from	to		
	Comr	nission File Number: 000-55347		
		delmada Therapeutics, Inc. of registrant as specified in its charter))	
	Nevada		45-5401931	
`	State or Other Jurisdiction of		(I.R.S. Employer	
Ir	ncorporation or Organization)		Identification No.)	
88	30 Third Avenue, 12th Floor			
(Addr.	New York, NY ess of Principal Executive Offices)		(Zip Code)	
(Addit	ess of Filicipal Executive Offices)		(Zip Code)	
	(Registrant's 7	(646) 876-3459 Gelephone Number, Including Area Cod	łe)	
	(Registration)	erephone rumber, merading rirea coe		
	(Former Name, Former Addre	N/A ss and Former Fiscal Year, if Changed S	Since Last Report)	
	(1 office 1 value, 1 office 1 value	ss and Former Fiscar Tear, if Changea	since East Report)	
Securities registered p	oursuant to Section 12(b) of the Act:			
Title of 6	each class	Trading Symbol(s)	Name of each exc	change on which registered
Common stock, \$0.00	01 par value per share	RLMD	The NASDAC) Global Select Market
	rk whether the registrant (1) has filed all rep such shorter period that the registrant was red			
	rk whether the registrant has submitted electhis chapter) during the preceding 12 months			
	rk whether the registrant is a large accelerated of "large accelerated filer," "accelerated filer,			
Large accelerated filer		Acceler	rated filer	
Non-accelerated filer			reporting company ng growth company	
	h company, indicate by check mark if the reg s provided pursuant to Section 13(a) of the Ex		nded transition period for con	nplying with any new or revised
Indicate by check mar	k whether the registrant is a shell company (a	s defined in Rule 12b-2 of the Exchang	ge Act). □ Yes ⊠ No	
As of August 6, 2021,	there were 17,472,986 shares of common sto	ck, \$0.001 par value per share, outstand	ding.	

Relmada Therapeutics, Inc. Index

		Page Number
PART I - FI	INANCIAL INFORMATION	
Item 1.	Condensed Consolidated Financial Statements	1
	Condensed Consolidated Balance Sheets as of June 30, 2021 (unaudited) and December 31, 2020	1
	<u>Unaudited Condensed Consolidated Statements of Operations for the Three and Six Months Ended June 30, 2021 and 2020</u>	2
	<u>Unaudited Condensed Consolidated Statements of Stockholders' Equity for the Six Months Ended June 30, 2021 and 2020</u>	3
	<u>Unaudited Condensed Consolidated Statements of Cash Flows for the Six Months Ended June 30, 2021 and 2020</u>	4
	Notes to Unaudited Condensed Consolidated Financial Statements	5
Item 2.	Management's Discussion and Analysis of Financial Condition and Results of Operation	14
Item 3.	Quantitative and Qualitative Disclosures About Market Risk	22
Item 4.	Controls and Procedures	22
PART II - C	OTHER INFORMATION	
Item 1.	Legal Proceedings	23
Item 1A.	Risk Factors	23
Item 2.	Unregistered Sales of Equity Securities and Use of Proceeds	23
Item 3.	Defaults Upon Senior Securities	23
Item 4.	Mine Safety Disclosures	23
Item 5.	Other Information	23
Item 6.	Exhibits	24
SIGNATUR	RES	25

PART I - FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

Relmada Therapeutics, Inc. Condensed Consolidated Balance Sheets

		As of		As of
	June 30, 2021		г	Nagambar 21
		(unaudited)	L	December 31, 2020
Assets	_	(unaudited)	_	2020
Current assets:				
Cash and cash equivalents	\$	4,669,345	\$	2,495,397
Short-term investments	Ψ	104,399,140	Ψ	114,595,525
Lease payments receivable – short term		82,845		79,457
Prepaid expenses		1,548,880		903,190
Total current assets		110,700,210		118,073,569
Fixed assets, net of accumulated depreciation		-		1,258
Other assets		25,000		25,000
Lease payments receivable – long term		44,090		86,377
Total assets	\$	110,769,300	\$	118,186,204
Commitments and Contingencies (See Note 8)				
Liabilities and Stockholders' Equity				
Current liabilities:				
Accounts payable	\$	10,455,922	\$	8,346,475
Accrued expenses		3,460,821		4,256,983
Total current liabilities		13,916,743		12,603,458
	_		_	,,
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, 50,000,000 shares authorized, 17,468,819 and 16,332,939 shares issued and outstanding,				
respectively		17,469		16,333
Additional paid-in capital		324,917,516		284,881,716
Accumulated deficit		(228,082,428)		(179,315,303)
Total stockholders' equity		96,852,557		105,582,746
Total liabilities and stockholders' equity	\$	110,769,300	\$	118,186,204

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

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

	Three months ended June 30,				Six months ended June 30,			
		2021 2020			2021		2020	
Operating expenses:								
Research and development	\$	17,331,507	\$	5,323,953	\$	31,353,734	\$	9,831,737
General and administrative		9,130,373		7,433,249		17,513,349		12,899,903
Total operating expenses		26,461,880		12,757,202		48,867,083		22,731,640
Loss from operations	_	(26,461,880)		(12,757,202)	_	(48,867,083)		(22,731,640)
Other (expenses) income:								
Interest/investment income, net		322,807		404,004		742,781		811,657
Realized (loss) gain on short-term investments		(123,590)		12,810		(176,379)		(158,801)
Unrealized (loss) gain on short-term investments		(289,281)		1,221,947		(466,444)	_	287,027
Total other (expenses) income		(90,064)		1,638,761		99,958	_	939,883
Net loss	\$	(26,551,944)	\$	(11,118,441)	\$	(48,767,125)	\$	(21,791,757)
Loss per common share – basic and diluted	\$	(1.56)	\$	(0.73)	\$	(2.90)	\$	(1.45)
Weighted average number of common shares outstanding – basic and diluted		17,054,646		15,323,051		16,814,991		15,030,641

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

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

Common Stock

Par Value

Shares

Six months ended June 30,	2021
Additional	
Paid-in	A

Capital

Accumulated

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
			Six mo	onths	ended June 30,	202	0	
					Additional			
Common Stock Paid-in Accumulated								
	Commo	on Stoc	k		Paid-in	4	Accumulated	
	Shares		Par Value		Paid-in Capital	_	Accumulated Deficit	 Total
Balance - December 31, 2019				\$		\$		\$ Total 115,678,294
Balance - December 31, 2019 Stock based compensation	Shares	I	Par Value	\$	Capital		Deficit	\$
· · · · · · · · · · · · · · · · · · ·	Shares	I	Par Value	\$	Capital 235,522,746		Deficit	\$ 115,678,294
Stock based compensation	Shares 14,457,013	I	Par Value 14,457	\$	Capital 235,522,746 5,039,362		Deficit	\$ 115,678,294 5,039,362
Stock based compensation Warrant exercised for cash	Shares 14,457,013 447,107	I	Par Value 14,457 447	\$	Capital 235,522,746 5,039,362 3,041,726		Deficit	\$ 115,678,294 5,039,362
Stock based compensation Warrant exercised for cash Cashless warrant exercise	Shares 14,457,013 447,107 34,114	I	Par Value 14,457 447 34	\$	Capital 235,522,746 5,039,362 3,041,726 (34)		Deficit	\$ 115,678,294 5,039,362 3,042,173
Stock based compensation Warrant exercised for cash Cashless warrant exercise Options exercised	Shares 14,457,013 447,107 34,114	I	Par Value 14,457 447 34	\$	Capital 235,522,746 5,039,362 3,041,726 (34)		Deficit (119,858,909)	\$ 115,678,294 5,039,362 3,042,173 73,020
Stock based compensation Warrant exercised for cash Cashless warrant exercise Options exercised Net loss	Shares 14,457,013 447,107 34,114 2,434	I	Par Value 14,457 447 34 3 -	\$	Capital 235,522,746 5,039,362 3,041,726 (34) 73,017		Deficit (119,858,909) (10,673,316)	\$ 115,678,294 5,039,362 3,042,173 - 73,020 (10,673,316)
Stock based compensation Warrant exercised for cash Cashless warrant exercise Options exercised Net loss Balance - March 31, 2020	Shares 14,457,013 447,107 34,114 2,434	I	Par Value 14,457 447 34 3 -	\$	Capital 235,522,746 5,039,362 3,041,726 (34) 73,017 - 243,676,817		Deficit (119,858,909) (10,673,316)	\$ 115,678,294 5,039,362 3,042,173 - 73,020 (10,673,316) 113,159,533
Stock based compensation Warrant exercised for cash Cashless warrant exercise Options exercised Net loss Balance - March 31, 2020 Stock based compensation	Shares 14,457,013 447,107 34,114 2,434 14,940,668	I	2ar Value 14,457 447 34 3 - 14,941	\$	Capital 235,522,746 5,039,362 3,041,726 (34) 73,017 - 243,676,817 7,302,513		Deficit (119,858,909) (10,673,316) (130,532,225)	\$ 115,678,294 5,039,362 3,042,173 73,020 (10,673,316) 113,159,533 7,302,513
Stock based compensation Warrant exercised for cash Cashless warrant exercise Options exercised Net loss Balance - March 31, 2020 Stock based compensation Warrant exercised for cash	Shares 14,457,013 447,107 34,114 2,434 14,940,668 368,364	I	Par Value 14,457 447 34 3 - 14,941 368	\$	Capital 235,522,746 5,039,362 3,041,726 (34) 73,017 243,676,817 7,302,513 2,576,735		Deficit (119,858,909) (10,673,316) (130,532,225)	\$ 115,678,294 5,039,362 3,042,173 73,020 (10,673,316) 113,159,533 7,302,513
Stock based compensation Warrant exercised for cash Cashless warrant exercise Options exercised Net loss Balance - March 31, 2020 Stock based compensation Warrant exercised for cash Cashless warrant exercise	Shares 14,457,013 447,107 34,114 2,434 14,940,668 368,364 1,840	I	Par Value 14,457 447 34 3 - 14,941 368 2	\$	Capital 235,522,746 5,039,362 3,041,726 (34) 73,017 - 243,676,817 7,302,513 2,576,735 (2)		Deficit (119,858,909) (10,673,316) (130,532,225)	\$ 115,678,294 5,039,362 3,042,173 73,020 (10,673,316) 113,159,533 7,302,513 2,577,103
Stock based compensation Warrant exercised for cash Cashless warrant exercise Options exercised Net loss Balance - March 31, 2020 Stock based compensation Warrant exercised for cash Cashless warrant exercise Options exercised	Shares 14,457,013 447,107 34,114 2,434 14,940,668 368,364 1,840 113,281	I	Par Value 14,457 447 34 3 - 14,941 368 2 113	\$	Capital 235,522,746 5,039,362 3,041,726 (34) 73,017		Deficit (119,858,909) (10,673,316) (130,532,225)	\$ 115,678,294 5,039,362 3,042,173

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

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

		Six month June		led
		2021		2020
Cash flows from operating activities	0	(40.7(7.105)	Φ	(21.701.757)
Net loss	\$	(48,767,125)	\$	(21,791,757)
Adjustments to reconcile net loss to net cash used in operating activities:		1.258		2,075
Depreciation expense Stock-based compensation		14,119,660		,
Realized loss on short-term investments		176.379		12,341,875 158,801
Unrealized loss (gain) on short-term investments		,		,
(C)		466,444		(287,027)
Change in operating assets and liabilities: Lease payment receivable		38,899		35,782
		(645,690)		183,329
Prepaid expenses		2,109,447		/
Accounts payable				442,506
Accrued expenses	_	(796,162)		535,997
Net cash used in operating activities		(33,296,890)		(8,378,419)
Cash flows from investing activities				
Purchase of short-term investments		(56,872,459)		(62,364,176)
Sale of short-term investments		66,426,021		22,393,644
Net cash provided by (used) in investing activities		9,553,562		(39,970,532)
Cash flows from financing activities				
Principal payments of notes payable		_		(110,247)
Proceeds from issuance of common stock		23,458,050		19,855,018
Proceeds from options exercised for common stock		517,271		530,643
Proceeds from warrants exercised for common stock		1,941,955		5,619,276
Net cash provided by financing activities	_	25,917,276	_	25,894,690
1 , 0			_	
Net increase/(decrease) in cash and cash equivalents		2,173,948		(22,454,261)
Cash and cash equivalents at beginning of the period	_	2,495,397		36,278,519
Cash and cash equivalents at end of the period	\$	4,669,345	\$	13,824,258
Supplemental disclosure of cash flow information:				
Cash paid during the period for:	*		Φ	051
Interest	\$	-	\$	954
Non-cash investing and financing activities:				
Cashless exercise of warrants for common stock	\$	-	\$	36

The accompanying notes are an integral part of these 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, 2020 and notes thereto contained in the Company's Annual Report on Form 10-K.

Liquidity

As shown in the accompanying financial statements, the Company incurred negative operating cash flows of \$33,296,890 for the six months ended June 30, 2021 and has an accumulated deficit of \$228,082,428 from inception through June 30, 2021. At June 30, 2021, the Company had cash and short term investments of \$109,068,485.

Relmada has funded its past operations through equity raises and most recently in 2021 raised net proceeds from the sale of common stock of \$23,458,050 through our ATM offering and \$1,941,955 through the exercise of warrants. The Company also raised an additional \$517,271 during the six months ended June 30, 2021 from the exercises of options.

Management believes that the Company's existing cash and cash equivalents 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 trials will not be incurred until such additional financing is raised. Further, additional financing related to subsequent 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 consolidated financial statements.

NOTE 2 - SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (continued)

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) virus. 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 the valuation of stock-based compensation expenses and recorded amounts related to income taxes.

Cash and Cash Equivalents

The Company considers cash deposits and all highly liquid investments with a maturity of three months or less when purchased to be cash equivalents. The Company's cash deposits are held at two high-credit-quality financial institutions. The Company's cash deposits at these institutions exceed 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). The Company has adopted Financial Accounting Standards Board (FASB) Accounting Standard Update (ASU) 2016-01, *Financial Instruments* which requires substantially all equity investments in 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 consolidated statement of operations. Short term investment activity is presented in the investing activities section on the consolidated statement of cash flows.

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.

Fixed Assets

Fixed assets are stated at cost less accumulated depreciation. Fixed assets are comprised of computers and software. Depreciation is calculated using the straight-line method over the estimated useful life of the assets. Computers and software have an estimated useful life of three years.

NOTE 2 - SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (continued)

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 leases for office space. The Company does not recognize a lease liability or right-of-use asset on the balance sheet for short-term leases. Instead, the Company recognizes short-term lease payments as an expense on a straight-line basis over the lease term. A short-term lease is defined as a lease that, at the commencement date, has a lease term of 12 months or less and does not include an option to purchase the underlying asset that the lessee is reasonably certain to exercise.

Fair Value of Financial Instruments

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

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

Level 1 Inputs - Unadjusted quoted prices in active markets for identical assets or liabilities that the reporting entity has the ability to access at the measurement date.

Level 2 Inputs - Inputs other than quoted prices included in Level 1 that are observable for the asset or liability, either directly or indirectly. These might include quoted prices for similar assets or liabilities in 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).

The Company's short-term investment instruments of \$104,399,140 at June 30, 2021 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 an unrealized loss of \$289,281 and \$466,444 included in other income for the three and six months ended June 30, 2021, respectively. The Company recorded an unrealized gain of \$1,221,947 and \$287,027 included in other income for the three and six months ended June 30, 2020, respectively.

Income Taxes

The Company accounts for income taxes using the asset and liability method. Accordingly, deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between financial statement carrying amounts of existing assets and liabilities and their respective tax bases. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in the tax rate is recognized in income or expense in the period that the change is effective. Tax benefits are recognized when it is probable that the deduction will be sustained. A valuation allowance is established when it is more likely than not that all or a portion of a deferred tax asset will either expire before the Company is able to realize the benefit, or that future deductibility is uncertain. As of June 30, 2021 and December 31, 2020, 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.

NOTE 2 - SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (continued)

The Company files a U.S. Federal income tax return and various state returns. Uncertain tax positions taken on the Company's tax returns will be accounted for as liabilities for unrecognized tax benefits. The Company will recognize interest and penalties, if any, related to unrecognized tax benefits in general and administrative expenses in the statements of operations. There were no liabilities recorded for uncertain tax positions at June 30, 2021 and December 31, 2020. The open tax years, subject to potential examination by the applicable taxing authority, for the Company are from June 30, 2018 forward.

Research and Development

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

Stock-Based Compensation

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

Net Loss per Common Share

Basic net 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 net 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 Class A convertible preferred stock, Series A preferred stock, restricted stock awards, 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 six months ended June 30, 2021 and 2020, 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):

	Six month	is ended
	June 30,	June 30,
	2021	2020
Stock options	5,158,956	4,134,575
Common stock warrants	2,755,083	2,905,369
Total	7,914,039	7,039,944

NOTE 2 - SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (continued)

Recent Accounting Pronouncements

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 is currently in the process of evaluating the impact of this new guidance on the condensed consolidated financial statements and the related disclosures.

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):

	June 30,		ecember 31,
	 2021		2020
Insurance	\$ 1,325,400	\$	527,600
Research and Development	135,600		291,800
Legal	11,000		11,000
Other	 76,900		72,800
Total	\$ 1,548,900	\$	903,200

NOTE 4 - FIXED ASSETS

Fixed assets, net of accumulated depreciation, consisted of the following (rounded to nearest \$00):

	Useful lives	June 30, 2021]	December 31, 2020
Computer and Software	3 years	\$	16,700	\$	16,700
Less: accumulated depreciation			(16,700)		(15,400)
Fixed Assets		\$	-	\$	1,300

For the six months ended June 30, 2021 and 2020, the Company recognized depreciation expense of approximately \$1,300 and \$2,100, respectively.

NOTE 5 - ACCRUED EXPENSES

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

	June 30,		ecember 31,
	 2021		2020
Research and development	\$ 2,181,000	\$	2,183,800
Professional fees	138,800		150,900
Accrued bonus	650,200		1,444,900
Accrued vacation	414,400		351,200
Other	 76,400		126,200
Total	\$ 3,460,800	\$	4,257,000

NOTE 6 - STOCKHOLDERS' EQUITY

Common Stock

During the six months ended June 30, 2021, the Company issued 335,550 shares of common stock, for cash exercises of warrants for proceeds of \$1.941,955.

During the six months ended June 30, 2021, the Company also issued 148,656 shares of common stock for cash exercises of options for proceeds of \$517,271.

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 may 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 is not obligated to sell any shares under the agreement. During the six months ended June 30, 2021, the Company issued 651,674 shares of common stock for net cash proceeds of approximately \$23,500,000 under the agreement. During the six months ended June 30, 2020 the Company issued 427,700 shares of common stock for net cash proceeds of approximately \$19,900,000 under the agreement.

Options and Warrants

In December 2014, the Board of Directors adopted and the shareholders approved Relmada's 2014 Stock Option and Equity Incentive Plan, as amended, which allows for the granting of 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 shareholders approved Relmada's Board of Director approved 2021 Equity Incentive Plan which allows for the granting of 1,500,000 options or other stock awards.

These combined plans allow for the granting of up to 6,652,942 options or stock awards.

Stock options are exercisable generally for a period of 10 years from the date of grant and generally vest over four years. As of June 30, 2021, there were 1,493,986 shares available for future grants under the combined Equity Incentive Plans.

As of June 30, 2021, 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 employee option awards for share-based compensation in its option-pricing model.

On January 6, 2021, the Company awarded a total of 1,490,000 options to employees and directors with an exercise price of \$33.43 and a 10-year term vesting over a 4-year period. The options granted include time based vesting grants and performance vesting based on the Company's achievement of performance metrics. The options have an aggregate fair value of \$39.7 million calculated using the Black-Scholes option-pricing model. Variables used in the Black-Scholes option-pricing model include: (1) discount rate of 0.59% (2) expected life of 6.25 years, (3) expected volatility of 101%, and (4) zero expected dividends. As of June 30, 2021, four performance metrics for 364,000 options were met. Vesting of such options is subject to the passage of time. At June 30, 2021, the Company incurred expense of \$1,154,180 related to these options.

On February 18, 2021, the Company awarded a total of 25,000 options to an employee with an exercise price of \$35.15 and a 10-year term, vesting over a 4-year period. The options have an aggregate fair value of \$701,000 calculated using the Black-Scholes option-pricing model. Variables used in the Black-Scholes option-pricing model include: (1) discount rate of 0.75% (2) expected life of 6.25 years, (3) expected volatility of 101%, and (4) zero expected dividends.

At June 30, 2021, the Company has unrecognized stock-based compensation expense of approximately \$78.4 million related to unvested stock options over the weighted average remaining service period of 3.00 years.

NOTE 6 - STOCKHOLDERS' EQUITY (continued)

<u>Options</u>

A summary of the changes in options during the six months ended June 30, 2021 is as follows:

			Weighted	
		Weighted	Average	
		Average	Remaining	
		Exercise	Contractual	Aggregate
	Number of	Price For	Term	Intrinsic
	Options	Share	(Years)	Value
Outstanding and expected to vest at December 31, 2020	3,905,737	\$ 24.32	8.40	\$ 48,952,339
Granted	1,515,000	\$ 33.46	9.53	\$ -
Exercised	(148,656)	\$ 3.48	-	\$ -
Forfeited	(113,125)	\$ 34.47		\$ <u>-</u>
Outstanding and expected to vest at June 30, 2021	5,158,956	\$ 27.38	8.44	\$ 44,581,203
Options exercisable at June 30, 2021	1,785,828	\$ 21.90	7.70	\$ 25,677,980

Warrants

A summary of the changes in outstanding warrants during the six months ended June 30, 2021 is as follows:

	Number of Shares	Weighted Average Exercise Price Per Share
Outstanding and vested at December 31, 2020	2,670,633	\$ 9.11
Granted	420,000	\$ 33.39
Exercised	(335,550)	\$ 5.79
Outstanding at June 30, 2021	2,755,083	\$ 13.22
Vested at June 30, 2021	2,335,864	\$ 9.74

At June 30, 2021, the Company had approximately \$13.3 million of unrecognized compensation expense related to outstanding warrants.

On January 6, 2021, the Company awarded a total of 400,000 warrants to consultants with an exercise price of \$33.43 and a 10-year term, vesting over 4-year period. The warrants granted include time based vesting grants and performance vesting based on the Company's achievement of performance metrics. The warrants have an aggregate fair value of \$10.6 million calculated using the Black-Scholes option-pricing model. Variables used in the Black-Scholes option-pricing model include: (1) discount rate of 0.59% (2) expected life of 6.25 years, (3) expected volatility of 101%, and (4) zero expected dividends. As of June 30, 2021, four performance metrics for 140,000 warrants were met. Vesting of such options is subject to the passage of time. At June 30, 2021, the Company incurred expense of \$443,916 related to these warrants.

On June 18, 2021, the Company awarded a total of 10,000 warrants to a consultant with an exercise price of \$30.90 and a 5-year term, vesting over a 1-year period. The warrants granted are time based vesting. The warrants have an aggregate fair value of \$190,401 calculated using the Black-Scholes option-pricing model. Variables used in the Black-Scholes option-pricing model include: (1) discount rate of 0.47% (2) expected life of 3.00 years, (3) expected volatility of 100%, and (4) zero expected dividends.

On June 25, 2021, the Company awarded a total of 10,000 warrants to a consultant with an exercise price of \$34.35 and a 5-year term, vesting over a 1-year period. The warrants granted are time based vesting. The warrants have an aggregate fair value of \$211,653 calculated using the Black-Scholes option-pricing model. Variables used in the Black-Scholes option-pricing model include: (1) discount rate of 0.48% (2) expected life of 3.00 years, (3) expected volatility of 100%, and (4) zero expected dividends.

At June 30, 2021, the aggregate intrinsic value of warrants vested and outstanding was approximately \$52.4 and \$52.5, respectively.

At December 31, 2020, the aggregate intrinsic value of warrants vested and outstanding was approximately \$61.0 and \$61.2 million, respectively.

NOTE 6 - STOCKHOLDERS' EQUITY (continued)

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 six months ended June 30, 2021 and 2020 (rounded to nearest \$00):

	S	Six Months		Six Months
		Ended		Ended
		June 30,		June 30,
		2021		2020
Research and development	\$	2,506,700	\$	3,122,500
General and administrative		11,613,000		9,219,400
Total	\$	14,119,700	\$	12,341,900

NOTE 7 - 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. On March 6, 2021, the remaining vested options were forfeited. The agreement also contains customary confidentiality, release, and non-disparagement provisions, and the Company agreed to pay 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 shall have 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. The agreement also contains customary confidentiality, release, and non-disparagement provisions, and the Company agreed to pay accrued vacation time totaling approximately \$28,940.

NOTE 8 - 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 is currently developing 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 August 10, 2021, no discussions are active between the Company and Wonpung.

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

Third Party Licensor

Based upon a prior acquisition, the Company assumed an obligation to pay third parties (Dr. Charles E. Inturrisi and Dr. Paolo Manfredi – see below): (A) royalty payments up to 2% on net sales of licensed products that are not sold by sublicensee and (B) on each and every sublicense earned royalty payment received by licensee from its sublicensee on sales of license product by sublicensee, the higher of (i) 20% of the royalties received by licensee; or (ii) up to 2% of net sales of sublicensee. The Company will also make milestone payments of up to \$4 or \$2 million, for the first commercial sale of product in the field that has a single active pharmaceutical ingredient, and for the first commercial sale of product in the field of product that has more than one active pharmaceutical ingredient, respectively. As of June 30, 2021, the Company has not generated any revenue related to this license agreement.

NOTE 8 - COMMITMENTS AND CONTINGENCIES (continued)

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 d-methadone 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 d-methadone. 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 June 30, 2021, no events have occurred, and the Company continues to pay Licensor \$45,000 every three months.

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.

Lawsuit Brought by Previous Employee

On July 15, 2020, an employee of the Company filed a Complaint alleging unequal pay based on gender and other employment-based claims. On April 9, 2021, the Company settled this Complaint for an amount immaterial to the consolidated financial statements.

Leases and Sublease

The Company's corporate headquarters are located at 880 Third Avenue, 12th Floor, New York, New York 10022 pursuant to a lease agreement for a period of one year. In accordance with ASC 842, *Leases*, the Company has elected the practical expedient and recognizes rent expense evenly over the 12 months. The monthly rent is approximately \$8,800. For the six months ended June 30, 2021 and 2020, the Company recognized lease expense of approximately \$38,700 and \$83,000, respectively.

On June 8, 2017, the Company entered into an Amended and Restated License Agreement with Actinium. Pursuant to the terms of the agreement, Actinium will continue to license 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 shall have at any time during the term of this agreement the right to purchase the FFE for \$496,914, less any previously paid license fees. The license of FFE qualifies 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 six months ended June 30, 2021 and 2020, the Company recognized lease income of approximately \$6,300 and \$9,400, respectively. As of June 30, 2021, the balance of unearned interest income was approximately \$8,600.

Contractual Obligations

The following tables sets forth our contractual obligations for the next five years and thereafter:

		Less than					More than
	Total	1 year		1 - 2 years	3 - 5 years		5 years
Office lease	\$ 52,800	\$ 52,800	\$	-	\$	-	\$ -
Total obligations	\$ 52,800	\$ 52,800	\$	-	\$	-	\$ -

NOTE 9 - OTHER POST-RETIREMENT BENEFIT PLAN

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

The employees choose an amount from various investment options for both their contributions and the Company's matching contribution. The Company's contribution expense was approximately \$78,800 and \$27,800 for the six months ended June 30, 2021 and 2020, respectively.

NOTE 10 - SUBSEQUENT EVENTS

Subsequent to June 30, 2021, 4,167 outstanding warrants were exercised for total cash proceeds of approximately \$25,000.

On July 12, 2021, the Company awarded a total of 10,000 warrants to a consultant with an exercise price of \$34.77 and a 5 year term, vesting over a 1-year period.

On July 16, 2021, the Company executed a license agreement with Arbormentis, LLC with an upfront fee of approximately \$15 million, consisting of a mix of cash and equity, in addition to potential milestone payment totaling in excess of \$150 million. The license agreement is filed as exhibit 10.2 to this Report. 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.

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 "Description of Business," "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 an NCE 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 adequate antidepressant treatments with an antidepressant medication.

In the REL-1017-202 study, 62 subjects, average age 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: the Montgomery-Asberg Depression Rating Scale (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 4 Day 7					Day 14	
	LS						LS			LS		
	Means			LS Means			Means			Means		
	Difference	P-value	d	Difference	P-value	d	Difference	P-value	d	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 also observed in the Phase 1 studies. Subjects experienced 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, we 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 major depressive disorder (MDD).

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

- The Phase 3 program consists of two sister, two-arm, placebo-controlled clinical trials. Each trial will be conducted in 55 clinical sites in the United States and will
 include approximately 400 MDD patients with inadequate response to standard antidepressants in their current depression episode. 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 Montgomery and Asberg Depression Rating Scale (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 1st, 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. Patients who complete RELIANCE I and RELIANCE II will be eligible to rollover into the long-term, open-label study, which is also expected to include subjects who had not previously participated in a REL-1017 clinical trial.

Psilocybin License Agreement

In July 2021, we executed a License Agreement with Arbomentis, LLC which gives us the development and commercial rights to a novel psilocybin and derivate program. Under the terms of the agreement, we will pay Arbormentis an up-front fee of \$15 million consisting of a mix of cash and warrants to purchase the Company's common stock, in addition to potential milestone payments totaling in excess of \$150 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 us but is perpetual and not terminable by the licensor absent material breach of its terms by us. We will collaborate with Arbormentis 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. Importantly, neuroplasticity plays a key role in the activity of REL-1017, Relmada's lead program. Dr. Paolo Manfredi, our Acting Chief Scientific Officer and co-inventor of REL-1017, and Dr. Marco Pappagallo, our Acting Chief Medical Officer, are among the scientists affiliated with Arbormentis.

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

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, 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 maximum tolerated dose, showed a highly statistically significant difference in abuse potential versus oxycodone with p-values less than 0.001.

Results are detailed in the table below.

		REL-1017	REL-1017	REL-1017	Oxycodone
	Placebo	25 mg	75 mg	150 mg	40 mg
Mean Emax for Drug Liking	51.7	53.0	58.2	64.9	85.0
P-value for Difference vs. oxycodone 40 mg	< 0.001	< 0.001	< 0.001	< 0.001	-

These highly statistically significant data clearly demonstrate a very meaningful difference between REL-1017 and oxycodone at all three tested doses. These results, along with previously published literature, confirm the lack of opioid effects of REL-1017.

Key Upcoming Anticipated Milestones

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

- Results of IV ketamine human abuse potential study in the fourth quarter of 2021.
- Results of RELIANCE I and RELIANCE II adjunctive MDD trials in the first half of 2022.

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 one of the marketed products for depression, esketamine (marketed by Johnson and Johnson as Spravato), an in-clinic nasal spray treatment can demonstrate rapid antidepressant effects, while the other currently approved products can take two to four 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 planning to evaluate the utility of esmethadone as a front line monotherapy treatment for MDD.

Additionally, other indications that Relmada may explore in the future, include, restless leg syndrome and other glutamatergic system activation related diseases.

Our Corporate History and Background

We are a clinical-stage, publicly traded biotechnology company developing NCEs and novel versions of proven 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 \$48,767,125 for the six months ended June 30, 2021. At June 30, 2021, we have an accumulated deficit of \$228,082,428.

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 and business advisors, including recognized experts in the fields of depression, 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 an NDA submission will consist of conducting a full clinical development program. We plan to also generate intellectual property (IP) that will further protect our products from competition. We will 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) and Spravato® (Johnson & Johnson).

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. We have also secured an Orphan Drug Designation from the FDA for d-methadone for "the treatment of postherpetic neuralgia", which, upon NDA approval, carry 7-year FDA Orphan Drug marketing exclusivity. In the European Union, some of our 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 in the E.U. We believe an extensive intellectual property estate of US and foreign patents and applications will protect our technology and products once our patent applications for our products are approved.

Key Strengths

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

- Compelling lead product opportunity, esmethadone 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, the primary endpoint at 7 days, with onset of action seen at 4 days, and the effect carrying through to 14 days (7 days post-treatment).
- Active on-going Phase 3 program, with two mirror-sister Phase 3 registration studies currently enrolling for the treatment of Major Depressive Disorder (MDD), with open-label safety extension study also currently on-going.
- Successful Phase 1 safety studies of esmethadone and strong clinical activity signal in depression established in three independent animal models.

- Potential in additional multiple indications in underserved markets with large patient population, such as MDD, 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: approved and filed patent applications provide coverage beyond 2033. In addition, some of our drugs, including esmethadone have also been designated as Orphan Drugs by the FDA, thereby providing seven years of market exclusivity at launch.

Available Information

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

Results of Operations

For the Three Months Ended June 30, 2021 versus June 30, 2020

	Tł	Three Months Ended June 30, 2021		Three Months Ended June 30, 2020		Increase (Decrease)
Operating Expenses						
Research and development	\$	17,331,507	\$	5,323,953	\$	12,007,554
General and administrative		9,130,373		7,433,249		1,697,124
Total	\$	26,461,880	\$	12,757,202	\$	13,704,678

Research and Development Expense

Research and development expense for the three months ended June 30, 2021 was approximately \$17,331,500 compared to \$5,324,000 for the three months ended June 30, 2020, an increase of approximately \$12,007,500. The increase was primarily due to:

- Increase in study costs of \$10,325,500 associated with the execution of our Phase 2 and 3 studies;
- Decrease in manufacturing and drug storage costs of \$161,900;
- Decrease in compensation expense of \$270,500 due to a decrease in research and development employees and their related bonuses;
- An increase in stock-based compensation expense of \$584,800;
- Increase in other research expenses of \$1,529,600 primarily associated with the addition of consultants contracted to assist in the execution of our Phase 3 trials.

General and Administrative Expense

General and administrative expense for the three months ended June 30, 2021 was approximately \$9,130,400 compared to \$7,433,200 for the three months ended June 30, 2020, an increase of approximately \$1,697,200. The increase was primarily due to:

- Increase in compensation expense of \$497,200 related to the hiring of two additional employees;
- Increase in stock-based compensation expense of \$381,100 primarily related to options granted to employees, as well as the hiring of two additional employees;
- Increase in other general and administrative expenses of \$818,900 primarily due to an increase in consulting services.

Other Income (Expense)

Interest / investment income was approximately \$322,800 and \$404,000 for the three months ended June 30, 2021 and 2020, respectively. Realized loss on short-term investments was approximately \$123,600 for the three months ended June 30, 2021 compared to a realized gain of approximately \$12,800 for the three months ended June 30, 2020. Unrealized loss on short-term investments was approximately \$289,300 for the three months ended June 30, 2021 compared to an unrealized gain of approximately \$1,221,900 for the three months ended June 30, 2020.

Net Loss

The net loss for the Company for the three months ended June 30, 2021 and 2020 was approximately \$26,551,900 and \$11,118,400, respectively. The Company had loss per share of basic and diluted \$1.56 and 0.73 for the three months ended June 30, 2021 and 2020, respectively.

Income Taxes

The Company did not provide for income taxes for the three months ended June 30, 2021 and 2020, since there was a loss and a full valuation allowance against all deferred tax assets.

Results of Operations

For the Six Months Ended June 30, 2021 versus June 30, 2020

	S	Ended E		Six Months Ended June 30,		Increase
		2021		2020		(Decrease)
Operating Expenses						
Research and development	\$	31,353,734	\$	9,831,737	\$	21,521,997
General and administrative		17,513,349		12,899,903		4,613,446
Total	\$	48,867,083	\$	22,731,640	\$	26,135,443

Research and Development Expense

Research and development expense for the six months ended June 30, 2021 was approximately \$31,353,700 compared to \$9,831,700 for the six months ended June 30, 2020, an increase of approximately \$21,522,000. The increase was primarily due to:

- Increase in study costs of \$18,063,400 associated with the execution of our Phase 2 and 3 studies;
- Increase in manufacturing and drug storage costs of \$666,900;
- Decrease in pre-clinical and toxicology expenses of \$212,300;
- Decrease in compensation expense of \$223,700 due to a decrease in research and development employees and their related bonuses;
- A decrease in stock-based compensation expense of \$615,800 primarily related the separation agreement with Ottavio Vitolo through which we incurred expenses of approximately \$1,500,000 in 2020;
- Increase in other research expenses of \$3,843,500 primarily associated with the addition of consultants contracted to assist in the execution of our Phase 3 trials.

General and Administrative Expense

General and administrative expense for the six months ended June 30, 2021 was approximately \$17,513,300 compared to \$12,899,900 for the six months ended June 30, 2020, an increase of approximately \$4,613,400. The increase was primarily due to:

- Increase in compensation expense of \$516,800 related to the hiring of two additional employees;
- Increase in stock-based compensation expense of \$2,393,700 related to the hiring of two additional employees;
- Increase in other general and administrative expenses of \$1,702,900 primarily due to an increase in consulting services.

Other Income (Expense)

Interest / investment income was approximately \$742,800 and \$811,700 for the six months ended June 30, 2021 and 2020, respectively. Realized loss on short-term investments was approximately \$176,400 and \$158,800 for the six months ended June 30, 2021 and 2020, respectively. Unrealized loss on short-term investments was approximately \$466,400 for the six months ended June 30, 2021 compared to an unrealized gain of approximately \$287,000 for the six months ended June 30, 2020.

Net Loss

The net loss for the Company for the six months ended June 30, 2021 and 2020 was approximately \$48,767,100 and \$21,791,800 respectively. The Company had loss per share of basic and diluted \$2.90 and \$1.45 for the six months ended June 30, 2021 and 2020, respectively.

Income Taxes

The Company did not provide for income taxes for the six months ended June 30, 2021 and 2020, since there was a loss and a full valuation allowance against all deferred tax assets.

Liquidity

As shown in the accompanying financial statements, the Company incurred negative operating cash flows of \$33,296,890 for the six months ended June 30, 2021 and has an accumulated deficit of \$228,082,428 from inception through June 30, 2021. At June 30, 2021, the Company had cash and short term investments of \$109,068,485.

Relmada has funded its past operations through equity raises and most recently in 2021 raised net proceeds from the sale of common stock of \$23,458,050 through our ATM offering and \$1,941,955 through the exercise of warrants. The Company also raised an additional \$517,271 during the six months ended June 30, 2021 from the exercises of options.

Management believes that it has sufficient funding to continue ongoing operations for at least 12 months from the issuance of the accompanying condensed consolidated quarterly financial statements. Since June 30, 2021 and to date, the Company has received approximately \$25,000 in warrant exercises, which resulted in the Company having approximately \$97.7 million in cash, cash equivalents and short term investments at August 10, 2021. Based on its budgeted cash flow requirements, the Company believes these funds are sufficient to fund its ongoing operations for at least 12 months after the filing of these condensed consolidated quarterly financial statements. The Company expects that the burn rate for that time frame, will range between \$75 and \$85 million.

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

	Six Months	Six Months
	Ended	Ended
	June 30,	June 30,
	2021	2020
Cash used in operating activities	\$ (33,296,890)	\$ (8,378,419)
Cash provided by/(used in) investing activities	9,553,562	(39,970,532)
Cash provided by financing activities	25,917,276	25,894,690
Net increase/(decrease) in cash and cash equivalents	\$ 2,173,948	\$ (22,454,261)

For the six months ended June 30, 2021, cash used in operating activities was \$33,296,890 primarily due to the net loss of \$48,767,125, prepaid expense of \$645,690, accrued expenses of \$796,162 offset by non-cash stock compensation charges of \$14,119,660, accounts payable of \$2,109,447, unrealized loss of \$466,444, and realized loss of \$176,379.

For the six months ended June 30, 2020, cash used in operating activities was \$8,378,419 primarily due to the net loss of \$21,791,757, offset by non-cash stock compensation charges of \$12,341,875, prepaid expense of \$183,329, accounts payable of \$442,506, unrealized gain of \$287,027, realized loss of \$158,801, and accrued expenses of \$535,997.

For the six months ended June 30, 2021, cash provided by investing activities was \$9,553,562 related to the net purchase and sale of short-term investments.

For the six months ended June 30, 2020, cash used in investing activities was \$39,970,532 related to the net purchase and sale of short-term investments.

Net cash provided by financing activities for the six months ended June 30, 2021 was \$25,917,276 due to proceeds from options exercised for common stock of \$517,271, proceeds from warrants exercised for common stock of \$1,941,955, and sales of common stock of \$23,458,050.

Net cash provided by financing activities for the six months ended June 30, 2020 was \$25,894,690 due to proceeds from options exercised for common stock of \$530,643, proceeds from warrants exercised for common stock of \$5,619,276, and sales of common stock of \$19,855,018, partially offset by payments of notes payable of \$110,247.

Effects of Inflation

Our assets are primarily monetary, consisting of cash and cash equivalents. Because of their liquidity, these assets are not directly affected by inflation. Because we intend to retain and continue to use our equipment, we believe that the incremental inflation related to replacement costs of such items will not materially affect our operations. 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.

Off-Balance Sheet Arrangements

We do not have any off-balance sheet arrangements that have or are reasonably likely to have a current or future effect on our financial condition, changed in financial condition, revenues or expenses, results of operations, liquidity, capital expenditures or capital resources or capital resources that is material to investors.

Commitments and Contingencies

Please refer to Note 10 in our Annual Report on Form 10-K for the year ended December 31, 2020 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, 2020. 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 consolidated financial statements are presented in accordance with U.S. GAAP, and all applicable U.S. GAAP accounting standards effective as of June 30, 2021 have been taken into consideration in preparing the unaudited consolidated financial statements. The preparation of unaudited consolidated financial statements requires estimates and assumptions that affect the reported amounts of assets, liabilities, expenses and related disclosures. Some of those estimates are subjective and complex, and, consequently, actual results could differ from those estimates. The following accounting policies and estimates have been highlighted as significant because changes to certain judgments and assumptions inherent in these policies could affect our consolidated financial statements:

- · Research and development expenses, and
- Stock-based compensation expenses

We base our estimates, to the extent possible, on historical experience. Historical information is modified as appropriate based on current business factors and various assumptions that we believe are necessary to form a basis for making judgments about the carrying value of assets and liabilities. We evaluate our estimates on an on-going basis and make changes when necessary. Actual results could differ from our estimates.

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, 2020.

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

We carried out an evaluation, under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, of the effectiveness of the design and operation of our disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the Exchange Act). Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by an issuer in the reports that it files or submits under the Exchange Act is accumulated and communicated to the issuer's management, including its principal executive and principal financial officers, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure. Based upon our evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures are effective as of June 30, 2021, in ensuring that material information that we are required to disclose in reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission rules and forms.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting, as such term is defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act, during the three months ended June 30, 2021 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.

Lawsuit Brought by Previous Employee

On July 15, 2020, an employee of the Company filed a Complaint alleging unequal pay based on gender and other employment-based claims. On April 9, 2021, the Company settled this Complaint for an amount immaterial to the consolidated financial statements.

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, 2020, which include more detailed risk factors related to COVID-19.

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

On June 18, 2021, the Company issued warrants to purchase 10,000 shares of common stock to a consultant for services pursuant to a consulting agreement, with an exercise price of \$30.90 and a 5-year term, vesting over a 1-year period. The warrants granted are time-based vesting. The issuance of these warrants was exempt from registration under the Securities Act pursuant to Section 4(1)(2) thereof and/or Rule 506 thereunder, as not involving any public offering.

On June 25, 2021, the Company issued warrants to purchase 10,000 shares of common stock to a consultant for services pursuant to a consulting agreement, with an exercise price of \$34.35 and a 5-year term, vesting over a 1-year period. The warrants granted are time-based vesting. The issuance of these warrants was exempt from registration under the Securities Act pursuant to Section 4(1)(2) thereof and/or Rule 506 thereunder, as not involving any public offering.

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						
10.1	Relmada Therapeutics, Inc. 2021 Equity Incentive Plan	Exhibit 10.1 to Current Report on Form 8-K filed on May 20, 2021						
10.2	<u>License Agreement dated as of July 16, 2021, between Arbormentis, LLC and Relmada Therapeutics, Inc.*</u>	Filed Herewith						
31.1	Certification of the Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002	Filed herewith						
31.2	Certification of the Principal Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002	Filed herewith						
32.1	Certification of the Chief Executive Officer pursuant to U.S.C. Section 1350 as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002**	Furnished herewith						
32.2	Certification of the Principal Financial Officer pursuant to U.S.C. Section 1350 as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002**	Furnished herewith						
101.INS	Inline XBRL Instance Document.	Filed herewith						
101.SCH	Inline XBRL Taxonomy Extension Schema Document.	Filed herewith						
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document.	Filed herewith						
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document.	Filed herewith						
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document.	Filed herewith						
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document.	Filed herewith						
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101).	Filed herewith						

^{*} Certain information identified by [***] has been omitted from this exhibit because it is both not material and is the type that the registrant treats as private or confidential.

^{**} 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: August 10, 2021 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)

Certain information identified by [***] has been omitted from this exhibit because it is both not material and is the type that the registrant treats as private or confidential.

LICENSE AGREEMENT

BETWEEN

RELMADA THERAPEUTICS, INC.

AND

ARBORMENTIS, LLC

.

LICENSE AGREEMENT

This agreement ("Agreement") is entered into as of July 16, 2021 (the "<u>Effective Date</u>"), by and between Arbormentis, LLC, a Delaware limited liability company ("<u>Licensor</u>") and Relmada Therapeutics, Inc., a Nevada corporation ("<u>Licensee</u>").

RECITALS

WHEREAS, Dr. Paolo Manfredi, along with other inventors, developed certain inventions regarding the Licensed Compounds in the context of psychiatric use, and established Licensor as a new company to hold and license such inventions;

WHEREAS, Dr. Manfredi and the other inventors assigned and transferred all of their right, title, and interest in the Licensed Technology to Licensor;

WHEREAS, subject to the terms and conditions of this Agreement, Licensor and Licensee desire to enter into this Agreement for Licensor to license the use of Licensed Technology relating to the Licensed Compounds to Licensee;

WHEREAS, Licensee acknowledges Licensor's expertise relating to the development of the Licensed Compounds and, concurrently with the execution of this Agreement, will enter into a Consulting Agreement with Licensor (the "Consulting Agreement") pursuant to which Licensee will engage Licensor to provide advisory services relating to the development of the Licensed Compound and Licensed Product;

NOW THEREFORE, in consideration of the mutual covenants set forth herein, Licensor and Licensee further agree as follows:

ARTICLE 1. DEFINITIONS

The terms, as defined herein, shall have the same meanings in both their singular and plural forms.

- 1.1 "Affiliate" of a Party shall mean any Person in which such Party owns or controls, directly or indirectly, at least fifty percent (50%) of the outstanding stock, membership units, or other voting rights, or in which such Party is owned or controlled by, or is under common control with such Party, directly or indirectly, by at least fifty percent (50%) of the outstanding stock, membership units, or other voting rights; but in any country where the local law does not permit foreign equity participation of at least fifty percent (50%), then an Affiliate includes any company in which such Party owns or controls, is under common control with, or is owned or controlled by, directly or indirectly, the maximum percentage of outstanding stock, membership units, or voting rights permitted by local law. [***].
- 1.2 "Applicable Law" shall mean the applicable provisions of any and all national, supranational, regional, state and local laws, treaties, statutes, rules, regulations, administrative codes, guidances, ordinances, judgments, decrees, directives, injunctions, orders, permits of or from any court, arbitrator, Regulatory Authority, Governmental Authority or authority having jurisdiction over or related to the subject item, including the U.S. Federal Food, Drug and Cosmetic Act, GCP, GLP, GMP, Anti-Corruption Laws and Export Control Laws.

- 1.3 "Bankruptcy Code" shall mean title 11 of the United States Code, as amended from time to time.
- 1.4 "<u>Commercialization</u>" shall mean any and all activities related to pre-marketing, launching, marketing, promotion (including advertising and detailing), labeling, bidding and listing, pricing and reimbursement, distribution, storage, handling, offering for sale, selling, having sold, importing, having imported, exporting, having exported, distributing, having distributed, providing customer service and support, conducting medical affairs, conducting post-marketing safety surveillance and reporting of or otherwise commercializing or exploiting Licensed Products. "<u>Commercialize</u>" and "<u>Commercializing</u>" have the correlative meanings.
- 1.5 "Commercially Reasonable Efforts" shall mean with respect to the efforts to be expended by Licensee in connection with a particular activity or objective to be conducted under this Agreement, that level of efforts that Licensee would normally use, in the exercise of its prudent scientific and business judgment, for the development and/or commercialization of a comparable pharmaceutical product for a similar patient population at a similar stage of its development or commercialization, taking into account all relevant scientific, commercial, business and other factors, including issues of safety and efficacy, expected and approved product labeling, expected and actual cost and time to develop, expected and actual profitability, expected and actual return on investment, expected and actual competitiveness of Third Party alternative products (including generic products) in the marketplace, the nature and extent of expected and actual market exclusivity (including Patent coverage and regulatory exclusivity), the expected likelihood of marketing approval, the expected and actual pricing and level of reimbursement, and the expected and actual amounts of marketing and promotional expenditures required. Commercially Reasonable Efforts shall be determined on a country-by-country basis and it is anticipated that the level of effort and resources that constitute "Commercially Reasonable Efforts" with respect to a particular country will change over time.
- 1.6 "Control" or "Controlled" means, with respect to any Patent, non-public information, materials, data, results and technology, or other intellectual property rights, that a Party has the legal authority or right (whether by ownership, license or otherwise) to grant a license, sublicense, access or other right (as applicable) under such Patent, non-public information, materials, data, results and technology, or other intellectual property rights to the other Party on the terms and conditions set forth herein, in each case without breaching the terms of any agreement with a Third Party.
- 1.7 "Cover" shall mean, with respect to a claim of a Patent and a Licensed Product, that such claim would be infringed, absent a license, by the manufacture, use, offer for sale, sale or importation of such Licensed Product (considering claims of patent applications to be issued as then pending).

- 1.8 "Development" shall mean all activities that relate to the development of Licensed Products or to (a) obtaining, maintaining or expanding Regulatory Approval of a Licensed Product, or (b) developing the ability to manufacture clinical and commercial quantities of a Licensed Product. This includes: (i) preclinical testing, toxicology, and clinical trials; (ii) preparation, submission, review, and development of data or information for the purpose of submission to a Governmental Authority to obtain, maintain or expand Regulatory Approval of a Licensed Product; and (iii) manufacturing process development and scale-up, bulk production and fill/finish work associated with the supply of a Licensed Product for preclinical testing and clinical trials, and related quality assurance and technical support activities. "Develop" has a correlative meaning.
- 1.9 "FDA" shall mean the U.S. Food and Drug Administration, or any successor entity thereto performing similar functions.
- 1.10 "Field" shall mean any and all indications and uses.
- 1.11 "First Commercial Sale" shall mean on a country-by-country basis, the first commercial transfer or disposition for monetary value of a Licensed Product in a country in the Territory for use or consumption by a Third Party end user, in each case, after Regulatory Approval for such Product has been obtained in such country.
- 1.12 "Generic Product" shall mean respect to a particular Licensed Product and a particular country, any pharmaceutical product that: (a) contains the same active pharmaceutical ingredient(s) as such Licensed Product, (b) is approved by the Regulatory Authority in such country as a substitutable generic for such Licensed Product or otherwise is approved in a manner that relied on or incorporated data submitted by Licensee, its Affiliates or Sublicensees, in connection with the regulatory filings for such Licensed Product, including through an ANDA or an application under §505(b)(2) of the U.S. Federal Food, Drug and Cosmetic Act, or any enabling legislation thereof, or any similar procedure outside the United States, in each case now or in the future; and (c) is sold in such country by a Person other than Licensee, its Affiliates or Sublicensees.
- 1.13 "Government Authority" shall mean multi-national, federal, state, local, municipal, provincial or other governmental authority of any nature (including any governmental division, prefecture, subdivision, department, agency, bureau, branch, office, commission, counsel, court or other tribunal).
- 1.14 "IND" shall mean an Investigational New Drug application, as defined in the U.S. Federal Food, Drug and Cosmetic Act and the regulations promulgated thereunder, or the equivalent application to the equivalent agency in any other regulatory jurisdiction, the filing of which is necessary to initiate or conduct clinical testing of a pharmaceutical product in humans in such jurisdiction, in each case with respect to a Licensed Product for use within the Field.
- 1.15 "Indication" shall mean a separate and distinct disease, disorder or medical condition for which a Licensed Product can be used to diagnose, treat or prevent, which use is the subject of a separate MAA approval for a distinct labeling supported by data from at least one pivotal clinical trial not previously submitted to the applicable Regulatory Authority. For clarity, subpopulations or patients with a primary disease or condition, however stratified, shall not be deemed to be separate "Indications" for the purposes of this Agreement, including stratification by stages or progression (including precursor condition), particular combinations of symptoms associated with the primary disease or condition, prior treatment courses, response to prior treatment, different lines of treatment, family history, clinical history, phenotype, age (e.g. adult and pediatric) or other stratification. In addition, combination treatments with the Licensed Product and another product of an Indication shall not be deemed to be separate "Indication" for the purpose of this Agreement.

- 1.16 "Licensed Compound" shall mean Psilocybin, [***] and any and all derivatives.
- 1.17 "Licensed Know-How" shall mean any and all non-public information, materials, data, results and technology that are Controlled by Licensor or its Affiliates at any time during the Term that is (a) directly related to any Licensed Compound or Licensed Product or (b) otherwise necessary or reasonably useful for the development, manufacture, commercialization or other exploitation of any Licensed Compound or Licensed Product.
- 1.18 "<u>Licensed Patents</u>" shall mean all Patents Controlled by Licensor or its Affiliates at any time during the Term that: (a) claim or cover any Licensed Compound and Licensed Product, including composition of matter, method of make and use thereof, or (b) are otherwise necessary or reasonably useful for the development, manufacture, commercialization or other exploitation of any Licensed Compound or Licensed Product. The Licensed Patents existing as of the Effective Date are set forth in Appendix A.
- 1.19 "Licensed Product" shall mean any pharmaceutical preparation containing a Licensed Compound, alone or in combination with one or more additional active ingredients.
- 1.20 "Licensed Technology" shall mean Licensed Patents and Licensed Know-How.
- 1.21 "Manufacture" and "Manufacturing" shall mean all activities related to the synthesis, making, production, processing, purifying, formulating, filling, finishing, packaging, labeling, shipping, and holding of the any Licensed Product or any intermediate thereof, including process development, process qualification and validation, scale-up, pre-clinical, clinical and commercial production and analytic development, product characterization, stability testing, quality assurance, and quality control.
- 1.22 "Marketing Approval Application" (or "MAA") shall mean application to the appropriate Regulatory Authority for approval to market a Licensed Product in any particular jurisdiction, including an NDA in the U.S.
- 1.23 "NDA" means a New Drug Application, as defined in the U.S. Federal Food, Drug and Cosmetic Act, as amended, and applicable regulations promulgated thereunder by the FDA.

- 1.24 "Net Sales" shall mean the total of the gross invoice prices of Licensed Products sold, leased or transferred by or on behalf of Licensee, a Sublicensee, or any of their respective Affiliates, or any combination thereof, less the sum of the following actual and customary deductions where applicable and separately listed: cash, trade, or quantity discounts; sales, use, tariff, import/export duties or other excise taxes imposed on particular sales (except for value-added and income taxes imposed on the sales of Licensed Product in foreign countries); transportation charges; or credits to customers because of rejections or returns. In the event that Licensee, a Sublicensee or an Affiliate of Licensee or Sublicensee receives non-cash consideration for any Licensed Products, or in the case of non-arm's length transaction with a non-Affiliate third party, Net Sales shall be calculated based on the fair market value of such Licensed Product, assuming an arm's length transaction made in the ordinary course of business. Notwithstanding the foregoing, Net Sales shall not include the transfer or disposition of the Licensed Product (a) for use in Development, including clinical trials; (b) as donation, sample, or expanded access programs; (c) among Licensee, its Affiliates and Sublicensee for subsequent resale.
 - If a Licensed Product contains any active ingredient(s) that is not a Licensed Compound, then the Net Sales of such Licensed Product (a "Combination Product"), for the purpose of calculating sales milestone and royalties payments owed under this Agreement, shall be the Net Sales attributable to the Licensed Compound, which shall be calculated as follows: first, the actual Net Sales of such Combination Product shall be determined using the above provisions, and then such amount shall be multiplied by the fraction A/(A+B), where A is the invoice price (during the relevant time period in the relevant country) of the Licensed Product that contains only the Licensed Compound at its Active Ingredient when sold separately in finished form (the "Mono Product"), and B is the total invoice price (during the relevant time period in the relevant country) of other active ingredient(s) in the Combination Product when sold separately in finished form. If there is no separate sale of either the Mono Product or other active ingredient(s), then A and B shall be their fair market values as reasonably determined by Licensee.
- 1.25 "Party" means Licensor or Licensee, individually; and "Parties" means Licensor and Licensee, collectively.
- 1.26 "Patent" shall mean any and all patents, pending patents, patent applications (whether registered or unregistered) and equivalents of any of the foregoing including certificates of invention, and any and all divisions, continuations, provisional applications, continuations-in-part, continued prosecution applications, requests for continued examinations, additions, renewals, extension, re-examinations, reissues, supplementary protection certificates, and all United States and foreign counterparts of any the foregoing.
- 1.27 "Patent Costs" shall mean all out-of-pocket expenses for the preparation, filing, prosecution, and maintenance of all United States and foreign patents included in Licensed Patents. Patent Costs shall also include reasonable out-of-pocket expenses for patentability opinions, inventorship review and determination, preparation and prosecution of patent applications, re-examination, re-issue, interference, opposition activities related to Patents in the Licensed Patents.

- 1.28 "Person" shall mean any natural person or any legal entity, including, without limitation, corporations, partnerships, associations, commissions, boards, agencies, and any other business or governmental entity or associations.
- 1.29 "Phase 2 Clinical Study" shall mean a human clinical trial of a Licensed Product, the principal purpose of which is to evaluate the effectiveness and/or safety of such Licensed Product in the target patient population, as described in 21 C.F.R. § 312.21(b), as amended from time to time, or the corresponding foreign regulations.
- 1.30 "Phase 3 Clinical Study" shall mean a human clinical trial of a Licensed Product, the principal purpose of which is to establish safety and efficacy in patients with the disease being studied and that would satisfy the requirements under 21 C.F.R. §312.21(c) for the U.S., as amended from time to time, or the corresponding foreign regulations for a comparable filing with a comparable Regulatory Authority.
- 1.31 "Pricing and Reimbursement Approval" means, with respect to any country or jurisdiction in the Territory in which Governmental Authorities determine the pricing at which a Licensed Product will be reimbursed, the approval, agreement, determination or decision by the applicable Governmental Authorities establishing the pricing and reimbursement status for such Licensed Product.
- 1.32 "Regulatory Approval" means all approvals, licenses, registrations or authorizations of any governmental entity that are necessary for the manufacturing, use, storage, import, transport and sale of Licensed Products in a regulatory jurisdiction, including in each case, Pricing and Reimbursement Approval.
- 1.33 "Regulatory Authority" shall mean any national (e.g., the FDA) or, supra-national (e.g., the EC or the EMA), or other governmental entity in any jurisdiction of the world involved in the granting of Regulatory Approval for pharmaceutical products.
- 1.34 "Regulatory Filing" means all approvals, licenses, registrations, submissions and authorizations made to or received from a Regulatory Authority in a jurisdiction necessary for or in connection with the development, manufacture and/or commercialization of a pharmaceutical product, including any INDs, Marketing Approval Applications and Regulatory Approvals. As used herein, "Regulatory Filing" also includes all correspondence with Regulatory Authorities (and their agents) regarding Licensed Products, including all submissions, meeting minutes, reports and other items exchanged between or under authority from Licensee or its licensors with respect to a Licensed Product, or the Development, Manufacture, Commercialization or exploitation thereof.
- 1.35 "Sublicense" shall mean an agreement into which Licensee enters with a third party that is not an Affiliate for the purpose of (a) granting certain rights; (b) granting an option to certain rights; or (c) forbearing the exercise of any rights, granted to Licensee under this Agreement after the Effective Date.
- 1.36 "Sublicensee" shall mean a third party that is not an Affiliate with whom Licensee enters into a Sublicensee.

- 1.37 "Territory" shall mean worldwide except for Asia, [***].
- 1.38 "Third Party" means any Person other than other than a Party or an Affiliate of a Party.
- 1.39 "Valid Claim" shall mean any claim in an issued and unexpired Licensed Patents which has not been held unenforceable, unpatentable or invalid by a decision of a court or other governmental agency of competent jurisdiction, and which has not been admitted to be invalid or unenforceable through abandonment, reissue, disclaimer or otherwise

ARTICLE 2. GRANTS/COLLABORATION

2.1 License.

- (a) Subject to the terms and conditions of this Agreement, Licensor hereby grants to Licensee, and Licensee hereby accepts, an exclusive (even as to Licensor and its Affiliates), royalty-bearing, sublicenseable license, under the Licensed Technology to Develop, Manufacture, have Manufactured, to use and have used, to sell and have sold, to offer for sale and have offered for sale, and to import and have imported Licensed Compounds and Licensed Products in the Field in the Territory (the "<u>License</u>").
- (b) Licensee may extend the rights granted above to an Affiliate pursuant to a written agreement provided that (i) such agreement shall include, to the extent applicable, an obligation of the Affiliate to comply with all rights and obligations due to Licensor pursuant to this Agreement; (ii) such agreement shall contain a provision prohibiting the Affiliate from directly or indirectly licensing, sublicensing or otherwise granting its rights thereunder to any third party without first obtaining Licensor's written consent, which shall not be unreasonably withheld and shall be limited to the terms relating to compliance of such Affiliate with rights and obligations due to Licensor pursuant to this Agreement (it being understood that Licensor's consent right shall not extend to specific business and financial terms of Licensee's extension of rights to an Affiliate, and that Licensee shall have the right in its sole discretion to decide such business and financial terms); (iii) Licensee shall provide Licensor with a copy of such agreement and any amendment thereto within thirty (30) days of such agreement or amendment, which copy may be redacted to remove sensitive business and financial terms not related to the compliance with the rights and obligations due to Licensor pursuant to this Agreement; and (iv) Licensee and any such Affiliate shall be jointly and severally liable to Licensor for any material violation of the Affiliate's aforementioned obligation to comply with rights and obligations due to Licensor pursuant to this Agreement.

2.2 Sublicense.

(a) The License granted in Section 2.1 includes the right of Licensee to grant Sublicenses to third parties other than Affiliates, provided and on the express condition that (i) such Sublicenses shall include, to the extent applicable, an obligation of Sublicensee to comply with all rights and obligations due to Licensor pursuant to this Agreement; (ii) such Sublicenses shall contain a provision prohibiting the Sublicensee from sublicensing its rights thereunder without first obtaining Licensor's prior written consent, which shall not be unreasonably withheld and shall be limited to the portion of such Sublicense relating to the compliance with rights and obligations due to Licensor pursuant to this Agreement by the Sublicensee to which rights are sublicensed under such Sublicense (it being understood that Licensor's consent right shall not extend to specific business and financial terms of any Sublicense, which shall remain subject to Licensee's consent, in their sole discretion); (iii) Licensee shall provide Licensor with a copy of each Sublicense issued and any amendment thereto within thirty (30) days of such Sublicense or amendment, which copy may be redacted to remove sensitive business and financial terms not related to the compliance with the rights and obligations due to Licensor pursuant to this Agreement; and (iv) Licensee shall collect and guarantee payment of all payments due, directly or indirectly, to Licensor from Sublicensees.

(b) Sublicenses granted by Licensee shall survive termination of this Agreement under Section 7.1 and Licensor's rights to the Licensed Technology shall be subject to any such Sublicenses, provided that such Sublicenses provide that in the event of such termination of this Agreement, the Sublicensee shall recognize Licensor as the beneficiary of the Licensee's rights and obligations under the Sublicense and shall make all payments otherwise due to Licensee thereunder to Licensor. Sublicenses granted by Licensee shall automatically terminate if Licensee terminates this Agreement pursuant to Section 8.4.

2.3 Technology Transfer.

- (a) Promptly following the Effective Date and in any event no later than thirty (30) days thereafter, Licensor shall, and shall use diligent efforts to cause any Affiliates to, transfer all Licensed Know-How to Licensee in existence as of the Effective Date.
- (b) Without limiting Section 2.3(a), if from time to time during the Term of this Agreement, Licensee learns or believes that a particular item of Licensed Know-How has not been provided to Licensee, then upon request by Licensee, Licensor shall, and shall use diligent efforts to cause any Affiliates, to promptly transfer to Licensee all such Licensed Know-How that has not previously been provided to Licensee hereunder.
- (c) Licensor shall provide Licensee with reasonable levels of technical consulting and assistance in connection with the development of the Licensed Compound and Licensed Product, as set forth in the Consulting Agreement.
- (d) Licensor agrees to cooperate with Licensee such that Licensee may enjoy to the fullest extent the rights conveyed under this Agreement. Following the Effective Date, Licensor shall deliver to Licensee such further information and documents and shall execute and deliver to Licensee such further instruments and agreements as Licensee shall reasonably request to consummate or confirm the transactions provided for in this Agreement, to accomplish the purpose of this Agreement, or to confer on Licensee the benefits of this Agreement. Licensee shall reimburse or pay Licensor for all actual and reasonable third party out-of-pocket expenses incurred by Licensor in the course of complying with this Section 2.3(d), within thirty (30) days of Licensor's request.
- (e) For the avoidance of doubt, the rights and obligations of Licensor and Licensee with respect to collaboration set forth in this Section 2.3 are applicable only to the extent that exercise and/or performance of them is not rendered impossible, unfeasible, or impracticable by the death, illness, disability, or incapacitation of Dr. Paolo Manfredi.

ARTICLE 3. DEVELOPMENT AND COMMERCIALIZATION ACTIVITIES

- 3.1 **Development Responsibility**. From and after the Effective Date, Licensee will have the exclusive right to conduct, and be solely responsible for all aspects of, the Development of Licensed Products including manufacturing the Licensed Products, setting the regulatory strategy for seeking Regulatory Approvals for Licensed Products in the Field in the Territory, and seeking and obtaining Regulatory Approvals. As between the Parties, Licensee shall bear all of its costs and expenses incurred in connection with such Development activities.
- 3.2 **Regulatory Responsibility**. Licensee shall prepare and own all Regulatory Filings (including all INDs, NDAs, MAAs and Regulatory Approvals) for each Licensed Product in the Field in the Territory. Licensor shall not submit any Regulatory Filings for Licensed Products in the Territory without the prior written consent of Licensee. Except as expressly requested by Licensee in writing, Licensor shall not communicate with respect to the Licensed Products with any Regulatory Authority, unless so required to comply with Applicable Laws, in which case Licensor shall promptly notify Licensee of such requirement under Applicable Laws, shall submit any proposed communication to Licensee for prior approval or, if not practicable or legally permitted, shall provide Licensee with a copy or summary thereof as soon as reasonably practicable thereafter.
- 3.3 Development Diligence. Licensee, directly and/or through its Affiliates or Sublicensees, shall use Commercially Reasonable Efforts to Develop the Licensed Compounds and Licensed Products in the Field in the Territory.
- 3.4 Manufacturing. Licensee directly and/or through its Affiliates and/or one or more Third Parties, including a designated contract manufacturer, shall have the sole and exclusive right and responsibility for Manufacturing Licensed Products for clinical and commercial use in the Territory.
- 3.5 Commercialization. As between the Parties, Licensee shall have the exclusive right to conduct, and be solely responsible for all aspects of, the Commercialization of Licensed Products in the Field in the Territory, including: (a) developing and executing a commercial launch and pre-launch plan, (b) negotiating with applicable Governmental Authorities regarding the price and reimbursement status of Licensed Products; (c) marketing and promotion; (d) booking sales and distribution and performance of related services; (e) handling all aspects of order processing, invoicing and collection, inventory and receivables; (f) providing customer support, including handling medical queries, and performing other related functions; (g) conforming its practices and procedures to Applicable Laws relating to the marketing, detailing and promotion of Licensed Products in the Territory; and (h) Manufacturing of Licensed Products for commercial use. As between the Parties, Licensee shall bear all of its costs and expenses incurred in connection with such Commercialization activities.

10

- 3.6 Commercial Diligence. Licensee, directly or through one or more Sublicensee, shall use Commercially Reasonable Efforts to Commercialize each Licensed Product for which it has obtained Regulatory Approval in the Territory.
- 3.7 **Product Trademarks**. As between the Parties, Licensee shall have the sole and exclusive right to determine and own the trademarks to be used with respect to the Commercialization of the Licensed Products in the Field in the Territory, which branding may vary by country and Licensed Product. Licensee may, directly or through one or more Affiliates or Third Parties, register, maintain, enforce and defend such trademarks in the Territory, where and how it determines appropriate.

ARTICLE 4. CONSIDERATION

4.1 Upfront Payment; Warrant.

- (a) In consideration for the License and other rights granted herein to Licensee, as well as other promises and agreements herein, Licensee shall pay Licensor within thirty (30) days following the Effective Date, a nonrefundable payment of [***]Dollars (USD \$[***])..
- (b) Concurrently with the execution of this Agreement, the Parties have entered into that certain Common Stock Purchase Warrant Agreement, pursuant to which Licensee has issued Licensor a warrant to purchase [***] shares of Licensee at the price and subject to other terms and conditions set forth therein.

4.2 Milestone Payments.

(a) **Milestone Payments**. Licensee shall pay to Licensor the milestone payments set forth below following the first achievement by Licensee, and/or any of its Affiliates or Sublicensees, of the corresponding milestone events defined below with respect to a Licensed Product containing Psilocybin to achieve such event (each, a "Psilocybin Milestone Payment" and "Psilocybin Milestone Event," respectively).

Psilocybin Milestone Event	Psilocybin Milestone Payment
[***]	\$2.0 million
[***]	\$7.5 million
First Patient dosed in Phase 3 Clinical Trial in each Indication	\$25 million
US NDA approval for each Indication	\$50 million
Aggregate annual Net Sale reach \$200 million	\$25 million
Aggregate annual Net Sale reach \$400 million	\$25 million
Aggregate annual Net Sale reach \$600 million	\$25 million

Licensee shall pay to Licensor the milestone payments set forth below following the first achievement by Licensee, and/or any of its Affiliates or Sublicensees, of the corresponding milestone events defined below with respect to a Licensed Product containing [***] to achieve such event (each, a "[***] Milestone Payment" and "[***] Milestone Event," respectively).

Aggregate annual Net Sale reach \$200 million	\$25 million
Aggregate annual Net Sale reach \$400 million	\$25 million
Aggregate annual Net Sale reach \$600 million	\$25 million

The Psilocybin Milestone Payments and [***] Milestone Payments set forth above are one time payments, except for those marked with an asterisk, which shall be paid once for each Indication but no more than four (4) Indications. If the Development of a Licensed Product fails or is abandoned in a particular Indication, any milestone payment already paid for such Indication may be credited against the milestone payment payable for any subsequent Indications.

Licensee shall notify Licensor in writing within thirty (30) days after the first achievement of any milestone set forth in this Section 4.2 (provided that, in the case of sales milestone, the notice for the achievement of such sales milestone shall be delivered together with the royalty reports under Section 5.1 for the time period during which such sales milestone is achieved), and shall pay to Licensor the corresponding milestone payment within thirty (30) days after the receipt of the invoice issued by Licensor after the receipt of the notice for the achievement of such milestone.

4.3. Royalty Payments.

- (a) Subject to the terms and conditions of this Agreement, in consideration for the rights and licenses granted under this Agreement, Licensee shall pay to Licensor a royalty at the rate of [***] percent ([***]%) of Licensee's Net Sales on a Licensed Product-by-Licensed Product basis.
- (b) On a product-by-product and country-by-country basis, royalty payments would commence upon the First Commercial Sale of a Licensed Product in such country and would terminate upon the latest of: (a) the date on which the sale of such Licensed Product without the licenses granted hereunder would no longer infringe a Valid Claim in such country and (b) ten (10) years after the First Commercial Sale of such Licensed Product in such country ("**Royalty Term**").

4.4 Royalty Adjustments.

(a) If Licensee, its Affiliate or Sublicensee becomes obligated to make payment to a Third Party with respect to intellectual property rights owned or controlled by
such Third Party reasonably necessary for or utilized in the Manufacture, use or sale of the Licensed Product ("Third Party Payments"), Licensee may deduct fifty percentage of the Licensed Product ("Third Party Payments"), Licensee may deduct fifty percentage of the Licensed Product ("Third Party Payments"), Licensee may deduct fifty percentage of the Licensed Product ("Third Party Payments"), Licensee may deduct fifty percentage of the Licensed Product ("Third Party Payments"), Licensee may deduct fifty percentage of the Licensed Product ("Third Party Payments"), Licensee may deduct fifty percentage of the Licensed Product ("Third Party Payments"), Licensee may deduct fifty percentage of the Licensed Product ("Third Party Payments"), Licensee may deduct fifty percentage of the Licensed Product ("Third Party Payments"), Licensee may deduct fifty percentage of the Licensed Product ("Third Party Payments"), Licensee may deduct fifty percentage of the Licensed Product ("Third Party Payments"), Licensee may deduct fifty percentage of the Licensed Product ("Third Party Payments"), Licensee may deduct fifty percentage of the Licensed Product ("Third Party Payments"), Licensee may deduct fifty percentage of the Licensed Product ("Third Party Payments"), Licensee may deduct fifty percentage of the Licensed Product ("Third Party Payments"), Licensee may deduct fifty percentage of the License of the Lic
(50%) of the amount payable to each such Third Party from the amounts payable to Licensor under this ARTICLE 4; provided that such deduction shall not reduce the amount
so payable to Licensor to less than fifty percent (50%) of the amount that would otherwise be due hereunder. Licensee may carry forward to subsequent calendar quarters an
deductions that it was not able to deduct as a result of the foregoing proviso.

- (b) [***].
- (c) [***].
- (d) [***].

4.5 Payments.

- (a) Consideration in the form of royalties payable to Licensor pursuant to Section 4.4(a) hereunder (whether direct or indirect from a Sublicensee or an Affiliate) shall be paid by Licensee quarterly on or before March 31, June 30, September 30, and December 31 of each calendar year. Each such payment shall be for royalties under Section 4.4 accrued within Licensee's most recently completed calendar quarter (which, for the avoidance of doubt, is the quarter preceding the one in which the payment is due). For the avoidance of doubt, royalties shall accrue when payments on which royalties are due are received by Licensee.
- (b) Royalties earned on Net Sales occurring or under Sublicenses granted pursuant to this Agreement in any country outside the United States shall not be additionally reduced by Licensee for any taxes, fees, or other charges imposed by the government of such country on the payment of royalty income, except that all payments made by Licensee in fulfillment of Licensor's tax liability in any particular country may be credited against earned royalties or fees due Licensor for that country provided that the same is documented as such in a manner acceptable to the United States Internal Revenue Service. Licensee shall pay all bank charges resulting from the transfer of such royalty payments.
- (c) All payments hereunder shall be made in U.S. dollars, but Licensor may opt to receive the earned royalties or fees in the foreign currency of the country outside the United States and provide Licensee written notice thereof. If royalties are to be paid in U.S. dollars on Net Sales recorded in a foreign currency, the amount owed will be calculated according to the currency exchange rate against U.S. dollars of the day the royalties are being paid.

4.6 Late Payments. In the event royalty, reimbursement, and/or fee payments are not received by Licensor when due, Licensee shall pay to Licensor interest charges at a rate of ten percent (10%) per year. Such interest shall be calculated from the date payment was due until actually received by Licensor.

ARTICLE 5. REPORTS AND RECORDS

5.1 Reports.

- (a) **Copies of Agreements/Documentation**. In addition to the disclosure of agreements with Affiliates pursuant to <u>Section 2.1(b)</u> and Sublicenses pursuant to <u>Section 2.2(a)</u>, Licensee shall provide Licensor with redacted copies of any agreements and any amendments thereto relating to the rights granted herein within thirty (30) days of such agreements or amendments.
- (b) Commercialization Reports. After the First Commercial Sale of a Licensed Product anywhere in the Territory, Licensee shall submit to Licensor quarterly reports on or before each February 28, May 31, August 31 and November 30 of each year. Each report shall cover Licensee's (and each Affiliate's and Sublicensee's) most recently completed calendar quarter (which, for the avoidance of doubt, is the quarter preceding the one in which the report is due) and shall show:
- (i) the gross sales and Net Sales during the most recently completed calendar quarter and the royalties, in US dollars or foreign currency where applicable, payable with respect thereto;
 - (ii) the number of each type of Licensed Product sold;
 - (iii) whether any sales milestone is achieved;
 - (iv) the method used to calculate the royalties;
 - (v) the exchange rates used, if any;
 - (vi) relevant business and corporate development efforts relating to the rights granted in this Agreement.

Licensee shall provide the above information using the form as shown in Appendix B and include information on the date of the First Commercial Sale of each additional Licensed Product or in each additional country. If no sales of Licensed Products have been made and no Sublicense revenue has been received by Licensee during any reporting period, Licensee shall so report.

5.2 Records and Audits.

(a) Licensee shall keep, and shall require its Affiliates and Sublicensees to keep, accurate and correct records of all Licensed Products manufactured, used, and sold. Such records shall be retained by Licensee and its Affiliates and Sublicensees for at least five (5) years following a given reporting period.

- (b) Upon reasonable notice from Licensor to Licensee, Licensee shall make (and shall cause its Affiliates and/or Sublicensees to make) all records set forth in Section 5.2(a) available at Licensee's offices during normal business hours for inspection at Licensor's expense (except as otherwise provided in this Section 5.2(b)) by a Certified Public Accountant selected by Licensor for the sole purpose of verifying reports and payments or other compliance issues. Such accountant shall keep any information learned during or related to the audit confidential as provided in Section 5.3 and shall not disclose to Licensor any information other than information relating to the accuracy of payments and disclosures made under this Agreement or other compliance issues. In the event that any such inspection shows an under reporting and underpayment in excess of five percent (5%) for any six-month (6-month) period, then Licensee shall pay the cost of the inspection and/or audit as well as any additional sum that would have been payable to Licensor had Licensee reported correctly, plus an interest charge at a rate of fifteen percent (15%) per year. Such interest shall be calculated from the date the correct payment was due to Licensor up to the date when such payment is actually made by Licensee. For underpayment not in excess of five percent (5%) for any six-month (6-month) period, Licensee shall pay the difference within thirty (30) days without interest charge or inspection/audit cost.
- 5.3 Confidentiality. Licensor and its accountants conducting any audit or inspection shall keep any copies of Sublicenses, other agreements, amendments, financial statements, reports, or other information materials provided or disclosed by Licensee pursuant to this Agreement, including those provided under Sections 2.1, 2.2, 5.1, or 5.2 and any information learned during or related to an audit or inspection pursuant to Section 5.2 confidential, except if (a) such information is or becomes publicly known and available through no fault of Licensor or it accountants, (b) such information becomes known to Licensor and/or its accountants by a third party that has a lawful right to disclose the same, (c) Licensee consents to Licensor's and/or its accountants' disclosure of such information, (d) if such information is independently developed by Licensor and/or its accountants prior to acquiring such information from Licensee, and (e) if Licensor and/or its accountants are compelled by applicable law, a court, governmental authority, or regulatory authority to disclose such information; provided that Licensor and/or its accountants shall provide reasonable advance written notice of such required disclosure to Licensee, and use reasonable efforts to secure confidential treatment or protective order to prevent or limit such disclosure.

ARTICLE 6. PATENT MATTERS

6.1 Ownership of Inventions. Inventorship of inventions made under this Agreement shall be determined in accordance with the rules of inventorship under U.S. patent laws, and ownership of such inventions shall follow inventorship. As between the Parties, Licensee (or its Affiliate) shall solely own all inventions made solely by Licensee personnel, and Licensor (or its Affiliate) shall solely own all inventions made solely by personnel of Licensor. The Parties (or their respective Affiliates) shall jointly own all inventions made jointly by personnel of both Licensee and Licensor; provided that, subject to the rights and licenses granted under and the restrictions set forth in this Agreement, each Party may practice and exploit any such joint invention and/or any jointly owned Patent, including, without limitation, in connection with its development, manufacture and/or commercialization of products, without the consent of, or a duty of accounting to, the other Party, and each Party hereby waives any right it may have under Applicable Law to require such consent or accounting.

6.2 Patent Prosecution and Maintenance.

- (a) Licensee shall be responsible for the reasonable Patent Costs related to PCT/US2020/021400 and related Licensed Patents in the Territory, and shall reimburse Licensor for such Patent Costs within sixty (60) days after the receipt of an invoice and supporting documents from Licensor.
- (b) Provided that Licensee has reimbursed Licensor for Patent Costs in accordance with Section 6.2 of this Agreement, Licensor shall diligently file, prosecute, and maintain the United States and, if available, foreign, the Licensed Patents using counsel of Licensor's choice. Notwithstanding the previous sentence, Licensor cannot make any assurances regarding the granting of any patent by any patent office. Licensor shall provide Licensee with copies of all relevant documentation relating to such prosecution, and Licensee shall keep this documentation confidential. Licensor shall have the right consult and review all material Patent filings in advance of any deadline, submission to or action with any patent office. Licensor shall furnish to Licensee copies of all relevant drafts and documents of such Licensed Patent reasonably in advance of such consultation for Licensee's review. Licensor shall provide to Licensee copies of all patent office submissions and correspondence relevant to such Licensed Patent within a reasonable amount of time following submission or receipt thereof by Licensor. Licensor shall consider in good faith any reasonable and timely comments provided by Licensee in connection with the prosecution and maintenance of such Patents Rights.
- (c) Licensor shall amend any patent application in the Licensed Patent to include or file a new application relating to the Licensed Technology (which for the avoidance of doubt, would be part of the Licensed Patent), containing, as appropriate, claims reasonably requested by Licensee to protect the products contemplated to be sold as Licensed Products by Licensee under this Agreement.
- (d) Licensee may elect to terminate its reimbursement obligations under Section 6.2 with respect to any Patent upon three (3) months' written notice to Licensor. Licensor shall use reasonable efforts to curtail further Patent Costs for such Patent when such notice of termination is received from Licensee. Licensor, in its sole discretion and at its sole expense, may continue prosecution and maintenance of said Patent. However, Licensee shall have no further license with respect thereto, Licensor shall be the sole owner all right, title and interest in such Patent, and any rights thereto granted by Licensee to any Affiliate or Sublicensee of Licensee shall cease unless said Affiliate or Sublicensee agrees in writing to assume Licensee's reimbursement obligations to Licensor with respect to such Patent. If Licensee does not cure any material non-payment of any portion of Patent Costs with respect to any Patent within sixty (60) days after receiving written notice of the non-payment from Licensor, said non-payment may be deemed by Licensor as an election by Licensee to terminate its reimbursement obligations with respect to such Patent and its license with respect thereto. Licensor is not obligated to, but may, file, prosecute, or maintain Licensed Patents outside of countries where they exist or to file, prosecute, or maintain Licensed Patent to which Licensee has terminated its license hereunder, with the exception that Licensor shall file, prosecute, and maintain Licensed Patent in additional countries in which they do not already exist at the reasonable request of Licensee, at Licensee's cost.

(e) Licensee shall have the sole right to file, prosecute and maintain Patents claiming inventions made solely by Licensee. The Parties shall jointly file, prosecute and maintain Patents claiming inventions made jointly by Licensee and Licensor.

6.3 Patent Infringement.

- (a) In the event that Licensor or Licensee learns of infringement of potential commercial significance of any Patent licensed under this Agreement, the knowledgeable party will provide the other (i) with written notice of such infringement and (ii) with any evidence of such infringement available to it (the "Infringement Notice"). Neither Licensor nor Licensee will notify a third party (including the infringer) of infringement or put such third party on notice of the existence of any Licensed Patent without first obtaining consent of the other. Both Licensor and Licensee will use their diligent efforts to cooperate with each other to terminate such infringement without litigation.
- (b) If infringing activity of potential commercial significance by the infringer has not been abated within ninety (90) days following the date the Infringement Notice takes effect (or earlier as reasonably determined by Licensee in order to protect the Licensed Product), Licensee may, at its sole cost and expense, institute suit for patent infringement against the infringer. Licensor may voluntarily join such suit (at Licensor's own expense for costs and any reasonable legal fees of counsel selected by Licensor) but may not thereafter commence suit against the infringer for the acts of infringement that are the subject of Licensee's suit or any judgment rendered in that suit. Licensee may not join Licensor in a suit initiated by Licensor without Licensor's prior written consent. However, notwithstanding the foregoing, even if Licensor withholds such consent, if a court requires Licensee to join Licensor in a suit or states that it will dismiss Licensee's suit unless Licensor is joined, Licensor agrees that Licensee may join Licensor the suit upon five (5) days' written notice to Licensor. If Licensor is so joined in the suit without its prior written consent pursuant to the preceding sentence or is involuntarily joined in the suit, Licensee shall pay any costs incurred by Licensor arising out of such suit, including but not limited to, any reasonable legal fees of counsel that Licensor selects and retains to represent it in the suit.
- (c) If, within one hundred twenty (120) days following the date the Infringement Notice takes effect, infringing activity of potential commercial significance by the infringer has not been abated and if Licensee has not brought suit against the infringer, Licensor may institute suit for patent infringement against the infringer. If Licensor institutes such suit, Licensee may not join such suit unless Licensor consents to the same and may not thereafter commence suit against the infringer for the acts of infringement that are the subject of Licensor's suit or any judgment rendered in that suit.
- (d) Subject to Section 6.3(f), recoveries from actions brought pursuant to Section 6.3(b) or (c) shall belong to the party bringing suit. Legal actions brought jointly by Licensor and Licensee shall be at the Parties' joint expense and all recoveries shall be shared equally by them.

- (e) Any agreement made by Licensee for purposes of settling litigation or other dispute shall comply with the requirements for Sublicenses in this Agreement.
- (f) Each party will cooperate with the other in litigation proceedings instituted hereunder but at the expense of the party who initiated the suit (unless such suit is being jointly prosecuted by the parties, in which case expenses shall be shared by the Parties equally).
- (g) Any litigation proceedings will be controlled by the party bringing the suit, except that Licensor may, at Licensor's own cost and expense, be represented by counsel of its choice in any suit brought by Licensee.
- 6.5 **Patent Marking.** Licensee shall mark all Licensed Products made, used, or sold under the terms of this Agreement, or their containers, in accordance with the applicable patent marking laws, if any.

ARTICLE 7. GOVERNMENTAL MATTERS

- 7.1 **Governmental Approval or Registration.** If this Agreement or any associated transaction is required by the law of any nation to be either approved or registered with any governmental agency, Licensee shall assume all legal obligations to do so. Licensee shall notify Licensor if it becomes aware that this Agreement is subject to a United States or foreign government reporting or approval requirement. Licensee shall make all necessary filings and pay all costs including fees, penalties, and all other out-of-pocket costs associated with such reporting or approval process.
- 7.2 Export Control Laws. Licensee shall observe all applicable United States and foreign laws with respect to the transfer of Licensed Products and related technical data to foreign countries, including, without limitation, the International Traffic in Arms Regulations and the Export Administration Regulations.

ARTICLE 8. TERM AND TERMINATION

- 8.1 **Term**. This Agreement shall commence on the Effective Date and, unless terminated earlier pursuant to ARTICLE 8, shall continue in full force and effect on a Licensed Product-by-Licensed Product and country-by-country basis until the expiration of the applicable Royalty Term ("**Term**"). Upon expiration of this Agreement with respect to a Licensed Product in a country, the license granted to Licensee shall continue and become fully paid-up, perpetual and irrevocable with respect to such Licensed Product in such country.
- 8.2 **Termination for Material Breach.** If either Party materially breaches this Agreement at any time, the non-breaching Party shall have the right to terminate this Agreement by written notice to the breaching Party, if such material breach is not cured within ninety (90) days after written notice is given by the non-breaching Party to the breaching Party specifying the breach. Notwithstanding the foregoing, to the extent any material breach is limited to a particular country, then the non-breach Party shall only have the right to terminate this Agreement with respect to such country.

- 8.3 **Termination for Bankruptcy**. Either Party shall have the right to terminate this Agreement upon written notice to the other Party: (a) if such other Party is declared insolvent or bankrupt by a court of competent jurisdiction; (b) if a voluntary or involuntary petition in bankruptcy is filed in any court of competent jurisdiction against such other Party and such petition is not dismissed within ninety (90) days after filing; (c) if such other Party shall make or execute an assignment of substantially all of its assets for the benefit of creditors; or (d) substantially all of the assets of such other Party are seized or attached and not released within ninety (90) days thereafter.
- 8.4 **Termination by Licensee.** Licensee shall have the right to terminate this Agreement, in its entirety or on a country-by-country basis, for convenience, without cause, and for any or no reason on not less than ninety (90) days' prior written notice to Licensor.
- 8.5 **Termination by Licensor**. Licensor shall have the right to terminate this Agreement, in its entirety, in the event that Licensee materially breaches the Consulting Agreement referenced in the recitals and fails to cure such breach within ninety (90) days after written notice is given by Licensor to Licensee specifying the breach.

8.6 Effect of Termination.

- (a) Any termination under Article 8 shall not relieve either Party of any obligation or liability accrued under this Agreement prior to termination, or rescind any payment made to Licensor by Licensee prior to the time termination becomes effective. Termination shall not affect in any manner any rights of either Party under this Agreement that have accrued prior to termination.
- (b) Within thirty (30) days after the Effective Date of any such termination, each Party shall promptly return to the other Party, or delete or destroy, all confidential information of the other Party; provided that (i) each Party may retain copies of the confidential information of the other Party to the extent necessary to perform its obligations or exercise its rights that survive expiration or termination of this Agreement; (ii) each Party may retain one copy of the confidential information of the other Party in its secure legal archives solely for purposes of monitoring compliance with its continuing obligations hereunder and (iii) neither Party shall be required to transfer or destroy any electronically stored confidential information made as a matter of the receiving Party's routine information technology backup.
- (c) All rights and licenses granted to Licensee under this Agreement shall terminate and revert to Licensor, provided that if this Agreement is only terminated with respect to one or more countries, only the rights and licenses with respect to such country or countries shall terminate and revert to Licensor.
- (c) Upon termination of this Agreement, Licensee (and any Affiliates and Sublicensees) may dispose of all previously made or partially made Licensed Product within a period of one hundred and twenty (120) days of the effective date of such termination provided that the sale of such Licensed Product by Licensee, its Sublicensees, or Affiliates shall be subject to the terms of this Agreement, including but not limited to the rendering of reports and payment of royalties required under this Agreement.

8.7 **Survival on Termination.** The following Sections and Articles shall survive the termination of this Agreement: Sections 2.2(b), 5.2, 5.3, 6.1, 8.6, 8.7, 9.2, 9.3, and Article 11.

ARTICLE 9. LIMITED WARRANTY AND INDEMNIFICATION

9.1 Limited Warranty.

- (a) Licensor warrants that it has the lawful right to grant this License. Licensor further warrants and represents that it has not entered and will not enter into any license, contract or understanding in conflict with the terms and provisions of this Agreement whether in part or in their entirety, including, without limitation, the exclusive rights and License to Licensee.
- (b) Licensor warrants and represents that it owns the Licensed Technology free and clear of any lien and encumbrance, and that no other Person, has an ownership right or interest therein. Appendix A includes all Licensed Patents existing as of the Effective Date. There is no pending or, to Licensor's knowledge, alleged or threatened, adverse actions, claims, suits or proceedings against Licensor or its Affiliates involving the Licensed Technology, including any opposition, interference or re-examination relating to Licensed Patents.
- (c) Except as expressly provided in Sections 9.1(a) and (b) above, the license granted herein is provided "AS IS" and without WARRANTY OF MERCHANTIBILITY or WARRANTY OF FITNESS FOR A PARTICULAR PURPOSE or any other warranty, express or implied. Licensor makes no representation or warranty that the Licensed Products, Licensed Compounds, or the use of Licensed Technology will not infringe any other patent or other proprietary rights.
- (d) In no event shall Licensor be liable for any incidental, special or consequential damages resulting from exercise of the License granted herein or the use of the Licensed Technology, Licensed Compound, or Licensed Product.
 - (e) Nothing in this Agreement shall be construed as:
 - (i) a warranty or representation by Licensor as to the validity or scope of any Licensed Patent;
- (ii) a warranty or representation that anything made, used, sold, or otherwise disposed of under any license granted in this Agreement is or shall be free from infringement of patents of third parties;
 - (iii) an obligation to bring or prosecute actions or suits against third parties for patent infringement except as provided in Section 5.2 hereof; or

(iv) conferring by implication, estoppel, or otherwise any license or rights under any patents of Licensor other than Licensed Patent as defined in this Agreement.

9.2 Indemnification.

- (a) Licensee shall indemnify and hold harmless each of Licensor, its Affiliates, and the directors, officers, shareholders and employees of such entities and the successors and assigns of any of the foregoing (the "Licensor Indemnitees"), from and against any and all liabilities, damages, penalties, fines, costs, expenses (including, reasonable attorneys' fees and other expenses of litigation) ("Liabilities") incurred by any Licensor Indemnitee as a result of any claims, actions, suits or proceedings brought by a Third Party (a "Third Party Claim") against a Licensor Indemnitee, arising from, or occurring as a result of: (a) the Development, Manufacture or Commercialization of any Licensed Product by Licensee, its Affiliates or Sublicensees and (b) any breach by Licensee of this Agreement; except to the extent such Third Party Claims fall within the scope of Licensor's indemnification obligations set forth in Section 9.2(b) below or result from the fault, recklessness or willful misconduct of a Licensor Indemnitee.
- (b) Licensor shall indemnify and hold harmless each of Licensee, its Affiliates and Sublicensees and the directors, officers and employees of Licensee, its Affiliates and Sublicensees and the successors and assigns of any of the foregoing (the "Licensee Indemnitees"), from and against any and all Liabilities incurred by any Licensee Indemnitee as a result of any Third Party Claims against an Licensee Indemnitee, arising from, or occurring as a result of (a) the Development, Manufacture or Commercialization of any Licensed Product by Licensor, its Affiliates or (sub)licensees prior to the Effective Date; (b) any breach of this Agreement by Licensor; except to the extent such Third Party Claims fall within the scope of Licensee's indemnification obligations set forth in Section 9.2(a) above or result from the fault, recklessness or willful misconduct of an Licensee Indemnitee.
- (c) A Party that intends to claim indemnification under this ARTICLE 9 (the "Indemnitee") shall promptly notify the other Party (the "Indemnitor") in writing of any Third Party Claim, in respect of which the Indemnitee intends to claim such indemnification, and the Indemnitor shall have sole control of the defense and/or settlement thereof. The indemnity arrangement in this Section 9.2(c) shall not apply to amounts paid in settlement of any action with respect to a Third Party Claim, if such settlement is effected without the consent of the Indemnitor, which consent shall not be withheld or delayed unreasonably. The failure to deliver written notice to the Indemnitor within a reasonable time after the commencement of any action with respect to a Third Party Claim shall not relieve such Indemnitor of its indemnification obligation to the Indemnitee under this Section 9.2, except to the extent that such failure is prejudicial to its ability to defend such action.
- 9.3 Limitation of Liability. NEITHER PARTY SHALL BE LIABLE TO THE OTHER PARTY FOR ANY SPECIAL, CONSEQUENTIAL, OR INDIRECT DAMAGES ARISING FROM OR RELATING TO ANY BREACH OF THIS AGREEMENT, REGARDLESS OF ANY NOTICE OF THE POSSIBILITY OF SUCH DAMAGES. NOTWITHSTANDING THE FOREGOING, NOTHING IN THIS SECTION 9.3 IS INTENDED TO OR SHALL LIMIT OR RESTRICT THE INDEMNIFICATION RIGHTS OR OBLIGATIONS OF ANY PARTY UNDER SECTION 9.2(a) OR 9.2(b), AND THE FOREGOING LIMITATIONS SHALL NOT APPLY WITH RESPECT TO DAMAGES AVAILABLE FOR A PARTY'S BREACH OF CONFIDENTIALITY OBLIGATIONS.

9.4 Insurance

- (a) Licensee, at its sole cost and expense, shall insure its activities in connection with the work under this Agreement and obtain, keep in force and maintain insurance or an equivalent program of self-insurance as follows:
- (i) comprehensive or commercial general liability insurance (contractual liability included) with limits of at least: (A) each occurrence, [***] dollars (US\$[***]); (B) products/completed operations aggregate, [***] dollars (US\$[***]); (C) personal and advertising injury,[***] dollars (US\$[***]); and (D) general aggregate (commercial form only), [***] dollars (US\$[***]); and
 - (ii) the coverage and limits referred to above shall not in any way limit the liability of Licensee.
- (b) Licensee shall (and shall cause its Affiliates and/or Sublicensees, as applicable, to), within ninety (90) days of the Effective Date (or the execution date of any agreement with an Affiliate and/or a Sublicensee), furnish Licensor with certificates of insurance showing compliance with all requirements. Such certificates shall: (i) indicate that Licensor has been endorsed as an additionally insured party under the coverage referred to above; and (ii) include a provision that the coverage shall be primary.

ARTICLE 10. [***]

ARTICLE 11. MISCELLANEOUS PROVISIONS

- 11.1 Correspondence. Any notice, invoice or payment required to be given to either party under this Agreement shall be deemed to have been properly given and effective:
 - (a) on the date of delivery if delivered in person;
- (b) one (1) day after delivery to the respective addresses given below, or to such other address as is designated by written notice given to the other party if sent via an overnight delivery service or express mail;
 - (c) one (1) day after the successful transmission in pdf file format if sent by electronic mail using the Internet; or

(d) five (5) days after mailing if mailed by first-class or certified mail, postage paid, to the respective addresses given below, or to such other address as is designated by written notice given to the other party.

If sent to Licensee:

Relmada Therapeutics, Inc. 750 Third Avenue, 9th Floor New York, NY 10017

Attention: Sergio Traversa, Pharm.D., Chief Executive Officer

TEL: 917 405 1305 FAX: (315) 624-7359

EMAIL: st@relmada.com

If sent to Licensor:

For all correspondence except payments -

[***]

For all payments -

[***]

Licensee is responsible for all bank charges of wire transfer of funds for payments. Such bank charges shall not be deducted from total amount due to Licensor.

11.2 Assignability.

(b) This Agreement is not assignable in any way by either Party without the written consent of the other Party, except expressly as follows: each Party may without prior written consent of the other Party, but with two (2) business days prior written notice thereof, assign this Agreement as a whole (but not in part) and the rights and obligations and interests granted herein to any bona fide third party purchaser of substantially all of such Party's assets or substantially all of such Party's equity, or to any successor entity resulting from any merger, reverse merger, or consolidation of such Party with or into such entity; provided in each case, that the assignee and/or surviving entity agrees in writing to be bound by the terms of this Agreement for the benefit of the other Party. In addition, Licensor may assign its right to receive payments under Article 4 without Licensee's prior written consent.

(c) This Agreement is a license of the type described by Section 365(c)(1) of the Bankruptcy Code.

- (d) Any assignment, agreement, or other transaction attempted or entered into in violation of this Section 9.2 shall be deemed null and void and have no legal effect.
- 11.3 No Waiver. No waiver by either party of any breach or default of any covenant or agreement set forth in this Agreement shall be deemed a waiver as to any subsequent and/or similar breach or default.
- 11.4 **Failure to Perform.** In the event of a failure of performance due under this Agreement and if it becomes necessary for either party to undertake legal action against the other on account thereof, then the prevailing party shall be entitled to reasonable attorney's fees in addition to costs and necessary disbursements.
- 11.5 **Governing Laws.** This Agreement shall be governed by, and construed in accordance with (A) the laws of the United States, in respect to trademark and patent issues, except that the scope and validity of any foreign Patent or trademark shall be governed by the applicable laws of the country of the Patent or trademark, and (B) in all other respects, including as to validity (except for patent and trademark issues), interpretation and effect, by the laws of the State of New York without giving effect to the conflict of laws rules thereof.
- 11.6 Force Majeure. Except for monetary obligations hereunder, a party to this Agreement may be excused from any performance required herein if such performance is rendered impossible or unfeasible due to any catastrophe or other major event beyond its reasonable control, including, without limitation, war, riot, and insurrection; laws, proclamations, edicts, ordinances, or regulations; strikes, lockouts, or other serious labor disputes; and floods, fires, explosions, pandemics or other natural disasters, provided that the nonperforming part uses commercially reasonable efforts to avoid or remove such causes for non-performance. When such events have abated, the non-performing party's obligations herein shall resume.
- 11.7 **Headings.** The headings of the several sections are inserted for convenience of reference only and are not intended to be a part of or to affect the meaning or interpretation of this Agreement.
- 11.8 Entire Agreement. This Agreement sets forth the entire Agreement and understanding between the parties, and incorporates and merges therein all prior discussions, understandings and arrangements, expressed or implied, oral or written, between the parties, and neither party should be bound by any conditions, definitions, warranties or representations, with respect to the subject matter of this Agreement, other than as expressly provided in this Agreement, unless and other than expressly set forth in writing and executed by Licensor and Licensee (or their successors or assigns).
- 11.9 Amendments. No amendment or modification of this Agreement shall be valid or binding on the parties unless made in writing and signed on behalf of each party.
- 11.10 **Severability.** In the event any provision of this Agreement should be held invalid, illegal, or unenforceable in any jurisdiction, the Parties shall negotiate in good faith a valid, legal and enforceable substitute provision that most nearly reflects the original intent of the Parties and all other provisions of this Agreement shall remain in full force and effect in such jurisdiction. Such invalidity, illegality or unenforceability shall not affect the validity, legality or enforceability of such provision in any other jurisdiction.
- 11.11 Counterparts; Other Matters. This Agreement may be executed in any number of counterparts, each of which shall be deemed an original, and all of which together shall constitute one and the same instrument. Signatures to this Agreement delivered by facsimile or similar electronic transmission will be deemed to be binding as originals. This Agreement is established in the English language. Any translation in another language shall be deemed for convenience only and shall never prevail over the original English version.

IN WITNESS WHEREOF, Licensor and Licensee caused this Agreement to be duly executed as of the Effective Date.

Arbormentis, LLC By: [***] Date: LICENSEE RELMADA THERAPEUTICS, INC. By: [***]

LICENSOR

Date:

7/16/21

25

Appendix A - Patents and Patent Applications

Title	Country	Patent Number	Application Number
Compositions and methods of use comprising substances with neural	PCT		PCT Serial No. US2020/021400
plasticity actions administered at non-psychedelic/psychotomimetic dosages			
and formulations			Filed 3/6/2020

Appendix B - Commercialization Report

Company Name

Reporting Period (mm / dd / yyyy) From / / Through / / /					Date of first sale of	r ACTUAL (mm / dd / yyyy) lle of uct(s) / /	
Please list al	l trade names	for product(s) incorporati	ng licensed rights whether or no	ot you had sales during this re	porting period.		
Docket #	Country	Number of Units Sold	Gross Sales by Country	Net Sales by Country* (A)	Royalty Rate*	Total Royalties by Country (A*B)	
						_	
 * Please refer to the license agreement for: applicable royalty rate, please provide as decimal; how Net Sales should be calculated; applicable share of sublicense fees; 		Royalty Subtotal Minimum Royalty Payment* Total Royalty Owed Total Sublicense Fees*					
 application of minimum royalty rate If sales were in a currency other than United States Dollars, please specify exchange rate used 		(y	Total Payment				

Your Reference No

Number of sublicenses g	granted during the reporting			Number of sublicenses terminated or expired during the		
period				reporting period		
Granted Sub-Licensee C	Granted Sub-Licensee Company Name(s) (please list below) Terminated S		Terminated Sub-	-Licensee Company Name(s) (please list below)		
Total Number of active s	sublicenses during reporting perio	d				
Other Licensed Product	ts in the pipeline					
Product Name		D	eve	lopmental Stage		
Product Name		D	eve	lopmental Stage		
Product Name		D	Developmental Sta			
Product Name Devel		lopmental Stage				
Report Prepared & Approved By						
Name (Please Print)		Title	tle		Email	
Signature	·		Date (mm/dd/yyyy)			
						//

Sublicense Activity (if applicable)

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.

/s/ Sergio Traversa

Sergio Traversa Chief Executive Officer (principal executive officer)

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.

/s/ Maged Shenouda

Maged Shenouda Chief Financial Officer (principal financial officer)

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 June 30, 2021, 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.

/s/ Sergio Traversa

Sergio Traversa Chief Executive Officer (principal executive officer)

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 June 30, 2021, 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)