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

FORM 10-Q

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

For the quarterly period ended March 31, 2021

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

For the transition period from to

Commission File Number 001-38326

COHBAR, INC.

(Exact name of registrant as specified in its charter)

Delaware	**26-1299952**
(State or other jurisdiction of incorporation or organization)	*(I.R.S. Employer Identification Number)*

1455 Adams Drive, Suite 2050
Menlo Park, CA 94025
(*Address of principal executive offices) (Zip Code)*

(650) 446-7888
(Registrant's telephone number, including area code)

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value $0.001 per share	CWBR	Nasdaq Capital Market

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

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

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

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

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

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

As of May 11, 2021, the registrant had outstanding 61,788,325 shares of common stock.

COHBAR, INC.
FORM 10-Q
For the Quarterly Period Ended March 31, 2021

PART I. FINANCIAL INFORMATION

Item 1. Financial Statements

CohBar, Inc.
Balance Sheets

	As of	
	March 31, 2021	**December 31, 2020**
	(unaudited)	
ASSETS		
Current assets:		
Cash	$ 1,817,354	$ 2,894,575
Investments	15,999,690	18,120,266
Prepaid expenses and other current assets	343,673	413,692
Total current assets	18,160,717	21,428,533
Property and equipment, net	357,589	394,004
Intangible assets, net	17,805	18,075
Other assets	69,620	67,403
Total assets	$ 18,605,731	$ 21,908,015
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 1,052,031	$ 727,599
Accrued liabilities	314,821	1,141,741
Accrued payroll and other compensation	816,550	853,335
Note payable, net of debt discount and offering costs of $6,509 and $15,656 as of March 31, 2021 and December 31, 2020, respectively	273,491	349,344
Total current liabilities	2,456,893	3,072,019
Notes payable, net of debt discount and offering costs of $21,800 and $26,159 as of March 31, 2021 and December 31, 2020, respectively	353,200	348,841
Total liabilities	2,810,093	3,420,860
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, $0.001 par value, Authorized 5,000,000 shares; No shares issued and outstanding as of March 31, 2021 and December 31, 2020, respectively	-	-
Common stock, $0.001 par value, Authorized 180,000,000 shares; Issued and outstanding 61,788,325 shares as of March 31, 2021 and 61,117,524 as of December 31, 2020	61,788	61,118
Additional paid-in capital	89,030,480	87,684,323
Accumulated deficit	(73,296,630)	(69,258,286)
Total stockholders' equity	15,795,638	18,487,155
Total liabilities and stockholders' equity	$ 18,605,731	$ 21,908,015

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

CohBar, Inc.
Condensed Statements of Operations
(unaudited)

	For The Three Months Ended March 31,	
	2021	2020
Revenues	$ -	$ -
Operating expenses:		
Research and development	2,654,772	1,449,872
General and administrative	1,358,679	1,831,621
Total operating expenses	4,013,451	3,281,493
Operating loss	(4,013,451)	(3,281,493)
Other income (expense):		
Interest income	3,173	35,449
Interest expense	(14,560)	(77,836)
Equity modification expense	-	(802,400)
Amortization of debt discount and offering costs	(13,506)	(91,283)
Total other expense	(24,893)	(936,070)
Net loss	$ (4,038,344)	$ (4,217,563)
Basic and diluted net loss per share	$ (0.07)	$ (0.10)
Weighted average common shares outstanding - basic and diluted	61,560,279	43,119,369

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

CohBar, Inc.
Statements of Changes in Stockholders' Equity
(unaudited)

	Three Month Period Ended March 31, 2021				
	Common Stock		Additional Paid-in- Captial	Accumulated Deficit	Total Stockholders' Equity
	Number	Amount			
Balance, December 31, 2020	**61,117,524**	**$ 61,118**	**$ 87,684,323**	**$ (69,258,286)**	**$ 18,487,155**
Stock based compensation	-	-	320,444	-	320,444
Exercise of employee stock options	623,901	624	958,223	-	958,847
Exercise of warrants	46,900	46	67,490	-	67,536
Net loss	-	-	-	(4,038,344)	(4,038,344)
Balance, March 31, 2021	**61,788,325**	**$ 61,788**	**$ 89,030,480**	**$ (73,296,630)**	**$ 15,795,638**

	Three Month Period Ended March 31, 2020				
	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity
	Number	Amount			
Balance, December 31, 2019	**43,069,418**	**$ 43,069**	**$ 61,087,082**	**$ (52,993,325)**	**$ 8,136,826**
Stock based compensation	-	-	882,645	-	882,645
Equity modification expense	-	-	802,400	-	802,400
Exercise of employee stock options	71,981	72	42,154	-	42,226
Net loss	-	-	-	(4,217,563)	(4,217,563)
Balance, March 31, 2020	**43,141,399**	**$ 43,141**	**$ 62,814,281**	**$ (57,210,888)**	**$ 5,646,534**

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

CohBar, Inc.
Statements of Cash Flows
(unaudited)

	For The Three Months Ended March 31,	
	2021	2020
Cash flows from operating activities:		
Net loss	$ (4,038,344)	$ (4,217,563)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	36,685	43,958
Stock-based compensation	320,444	882,645
Equity modification expense	-	802,400
Amortization of debt discount	12,932	87,201
Amortization of debt issuance costs	574	4,081

Discount on investments	(2,424)	-
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	70,019	63,414
Accounts payable	324,432	17,348
Accrued liabilities	(826,920)	(6,018)
Accrued payroll and other compensation	(36,785)	(104,435)
Net cash used in operating activities	(4,139,387)	(2,426,969)
Cash flows from investing activities:		
Purchases of property and equipment	-	(7,183)
Payment for security deposit	(2,217)	(3,161)
Purchases of investments	(8,029,000)	-
Proceeds from redemptions of investments	10,152,000	-
Net cash provided by (used in) investing activities	2,120,783	(10,344)
Cash flows from financing activities:		
Proceeds from exercise of warrants	67,536	-
Repayment of promissory notes	(85,000)	-
Proceeds from exercise of employee stock options	958,847	42,226
Net cash provided by financing activities	941,383	42,226
Net decrease in cash and cash equivalents	(1,077,221)	(2,395,087)
Cash at beginning of period	2,894,575	12,563,853
Cash at end of period	$ 1,817,354	$ 10,168,766
Supplemental disclosure of cash flow information:		
Cash paid for interest	$ 20,437	$ -

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

COHBAR, INC.
NOTES TO CONDENSED FINANCIAL STATEMENTS
(unaudited)

Note 1 - Business Organization and Nature of Operations

CohBar, Inc. ("CohBar," "its" or the "Company") is a clinical stage biotechnology company focused on the research and development of mitochondria based therapeutics ("MBTs"), an emerging class of drugs for the treatment of chronic and age-related diseases including nonalcoholic steatohepatitis ("NASH"), obesity, cancer, fibrotic diseases such as idiopathic pulmonary fibrosis, acute respiratory distress syndrome ("ARDS") including COVID-19 associated ARDS, type 2 diabetes mellitus and cardiovascular and neurodegenerative diseases.

The Company's primary activities include the research and development of its MBT pipeline, securing intellectual property protection for its discoveries and assets, managing collaborations and clinical trials with contract research organizations ("CROs") and raising capital to fund the Company's operations. To date, the Company has not generated any revenues from operations and does not expect to generate any revenues in the near future. The Company has financed its operations primarily with proceeds from sales of its equity securities, private placements, the exercise of outstanding warrants and stock options and the issuance of debt instruments.

The Company is monitoring the COVID-19 pandemic, which continues to rapidly evolve, and has taken steps to mitigate the potential impacts on its business. The extent to which the pandemic may impact the Company's business, preclinical studies and its clinical trial will depend on future developments, which are highly uncertain and cannot be predicted with confidence. The Company has modified its business practices by restricting nonessential travel, implementing a partial work from home policy for its employees and instituting new safety protocols for its lab to enable essential on-site work to continue. The Company expects to continue to take actions that are in the best interests of its employees and business partners. Due to the uncertainty surrounding the pandemic, the Company's visibility into the duration of these actions is limited.

The unaudited interim condensed financial statements of the Company have been prepared in accordance with United States generally accepted accounting principles ("U.S. GAAP") for interim financial information and the rules and regulations of the Securities and Exchange Commission ("SEC"). They do not include all information and footnotes required by U.S. GAAP for complete financial statements. Except as disclosed herein, there have been no material changes in the information disclosed in the notes to the financial statements for the year ended December 31, 2020, included in the Company's Annual Report on Form 10-K (the "2020 Form 10-K"), filed with the SEC on March 30, 2021. The interim unaudited condensed financial statements should be read in conjunction with those audited financial statements included in the 2020 Form 10-K. In the opinion of management, all adjustments considered necessary for fair presentation, consisting solely of normal recurring adjustments, have been made. Operating results for the three-month period ended March 31, 2021 are not necessarily indicative of the results that may be expected for the year ending December 31, 2021, or any other period.

Note 2 – Liquidity and Going Concern

As of March 31, 2021, the Company had working capital and stockholders' equity of $15,703,824 and $15,795,638, respectively. During the three months ended March 31, 2021, the Company incurred a net loss of $4,038,344 and utilized cash of $4,139,387 in its operating activities. The Company's management has evaluated whether there is substantial doubt about its ability to continue as a going concern. The Company has not generated any revenues, has incurred net losses since inception, does not expect to generate revenues in the near term and requires additional capital for its contemplated operational activities. These factors raise substantial doubt about the Company's ability to continue as a going concern for at least one year from the issuance of these financial statements. If the Company is unable to raise additional capital whenever necessary, it may be forced to decelerate or curtail its research and development activities and/or other operations until such time as additional capital becomes available. Such limitation of its activities would allow the Company to slow its rate of spending and extend its use of cash until additional capital is raised. There can be no assurance that such a plan would be successful. There is no assurance that additional financing will be available when needed or that the Company will be able to obtain such financing on reasonable terms.

Note 3 - Summary of Significant Accounting Policies

Basis of Presentation

All amounts are presented in U.S. Dollars.

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 liabilities at dates of the financial statements and the reported amounts of revenue and expenses during the periods. Actual results could differ from these estimates. The Company's significant estimates and assumptions include the fair value of financial instruments, stock-based compensation and the valuation allowance relating to the Company's deferred tax assets.

Concentrations of Credit Risk

The Company maintains deposits in a financial institution which is insured by the Federal Deposit Insurance Corporation ("FDIC"). At various times, the Company has deposits in this financial institution in excess of the amount insured by the FDIC. The Company has not experienced any losses in such accounts and believes it is not exposed to any significant credit risk.

Investments

Investments as of March 31, 2021 and December 31, 2020 consist of U.S. Treasury Bills, which are classified as held-to-maturity, totaling $15,999,690 and $18,120,266, respectively. The Company determines the appropriate balance sheet classification of its investments at the time of purchase and evaluates the classification at each balance sheet date. All of the Company's U.S. Treasury Bills mature within the subsequent twelve months from the date of purchase. Unrealized gains and losses were *de minimus*. As of March 31, 2021 and December 31, 2020, the carrying value of the Company's U.S. Treasury Bills approximates their fair value due to their short-term maturities.

Common Stock Purchase Warrants

The Company classifies as equity any contracts that (i) require physical settlement or net-share settlement or (ii) provide the Company with a choice of net-cash settlement or settlement in its own shares (physical settlement or net-share settlement) providing that such contracts are indexed to the Company's own stock. The Company classifies as assets or liabilities any contracts that (i) require net-cash settlement (including a requirement to net cash settle the contract if an event occurs and if that event is outside the Company's control), or (ii) give the counterparty a choice of net-cash settlement or settlement in shares (physical settlement or net-share settlement). The Company assesses classification of its common stock purchase warrants and other free-standing derivatives at each reporting date to determine whether a change in classification between assets, liabilities and equity is required. The Company's free-standing derivatives consist of warrants to purchase common stock that were issued in connection with its notes payable and a private offering. The Company evaluated these warrants to assess their proper classification using the applicable criteria enumerated under U.S. GAAP and determined that the common stock purchase warrants meet the criteria for equity classification in the accompanying balance sheets as of March 31, 2021 and December 31, 2020.

Note 3 - Summary of Significant Accounting Policies (continued)

Share-Based Payment

The Company accounts for share-based payments using the fair value method. For employees and directors, the fair value of the award is measured, as discussed below, on the grant date. For non-employees, fair value is generally valued based on the fair value of the services provided or the fair value of the equity instruments on the measurement date, whichever is more readily determinable. The Company has granted stock options at exercise prices equal to the closing price of the Company's common stock as reported by Nasdaq, with input from management on the date of grant. Upon exercise of an option or warrant, the Company issues new shares of common stock out of its authorized shares.

The weighted-average fair value of options and warrants has been estimated on the grant date or measurement date using the Black-Scholes pricing model. The fair value of each instrument is estimated on the grant date or measurement date utilizing certain assumptions for a risk-free interest rate, volatility and expected remaining lives of the awards. The risk-free interest rate used is the United States Treasury rate for the day of the grant having a term equal to the life of the equity instrument. Beginning with the first quarter of the year ended December 31, 2019, the fair value of stock-based payment awards issued was estimated using a volatility derived from the Company's share price. The assumptions used in calculating the fair value of share-based payment awards represent management's best estimates, but these estimates involve inherent uncertainties and the application of management judgment. As a result, if factors change and the Company uses different assumptions, the Company's stock-based compensation expense could be materially different in the future.

The weighted-average Black-Scholes assumptions are as follows:

	For the Three Months Ended March 31,	
	2021	**2020**
Expected life	N/A	6.25 years
Risk free interest rate	N/A	1.61%
Expected volatility	N/A	95%
Expected dividend yield	N/A	0%
Forfeiture rate	N/A	0%

As of March 31, 2021, total unrecognized stock option compensation expense was $2,231,902, which will be recognized as those options vest over a period of approximately four years. The amount of future stock option compensation expense could be affected by any future option grants or by any option holders leaving the Company before their grants are fully vested.

NET LOSS PER SHARE OF COMMON STOCK

Basic net loss per share is computed by dividing net loss attributable to common stockholders by the weighted average number of common shares outstanding during the period. Diluted net earnings per share reflects the potential dilution that could occur if securities or other instruments to issue common stock were exercised or converted into common stock. Potentially dilutive securities are excluded from the computation of diluted net loss per share as their inclusion would be anti-dilutive and consist of the following:

COHBAR, INC.
NOTES TO CONDENSED FINANCIAL STATEMENTS
(unaudited)

Note 3 - Summary of Significant Accounting Policies (continued)

	As of March 31,	
	2021	**2020**
Options	6,805,538	7,685,377
Warrants	19,368,918	4,907,223
Totals	26,174,456	12,592,600

RECENT ACCOUNTING PRONOUNCEMENT

In December 2019, the Financial Accounting Standards Board issued ASU No. 2019-12, "Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes" ("ASU 2019-12"), which is intended to simplify the accounting for income taxes. ASU 2019-12 removes certain exceptions to the general principles in Topic 740. This guidance is effective for fiscal years beginning after December 15, 2020. ASU 2019-12 did not have an impact on the accompanying consolidated financial statements and related disclosures.

Note 4 - Accrued Liabilities

Accrued liabilities consist of:

	As of March 31, 2021	As of December 31, 2020
Lab services & supplies	$ 27,425	$ 917,194
Professional fees	106,552	44,171
Interest	156,854	162,731
Other	23,990	17,645
Total accrued liabilities	$ 314,821	$ 1,141,741

Note 5 - Commitments and Contingencies

LITIGATION, CLAIMS AND ASSESSMENTS

The Company may from time to time be party to litigation and subject to claims incident to the ordinary course of business. As the Company grows and gains prominence in the marketplace, it may become party to an increasing number of litigation matters and claims. The outcome of litigation and claims cannot be predicted with certainty, and the resolution of these matters could materially affect the Company's future results of operations, cash flows or financial position. The Company is not currently a party to any legal proceedings.

OPERATING LEASES

The Company is a party to (i) a lease agreement for laboratory space leased on a month-to month basis that is part of a shared facility in Menlo Park, California and (ii) a one-year lease agreement for office space in Fairfield, New Jersey, which expires in September 2021.

Rent expense was $102,213 and $100,136 for the three months ended March 31, 2021 and 2020, respectively.

COHBAR, INC.
NOTES TO CONDENSED FINANCIAL STATEMENTS
(unaudited)

Note 6 - Stockholders' Equity

AUTHORIZED CAPITAL

The Company has authorized the issuance and sale of up to 185,000,000 shares of stock, consisting of 180,000,000 shares of common stock having a par value of $0.001 and 5,000,000 shares of Preferred Stock having a par value of $0.001 per share. As of March 31, 2021 and 2020, there were no shares of Preferred Stock outstanding and there were no declared but unpaid dividends or undeclared dividend arrearages on any shares of the Company's capital stock.

REGISTRATION OF SHARES

During the three months ended March 31, 2021, the Company filed a registration statement for the shares issued in its private offering (the "Private Offering") with

certain promissory note holders in December 2020. The Company converted outstanding amounts under its 8% Unsecured Promissory Notes (the "2018 Notes") due in 2021 and 2022 in the Private Offering totaling an aggregate of $3,847,018 in principal and interest and issued 3,154,115 units at a price of $1.22 per unit. Each unit consists of one share of the Company's common stock and one warrant to purchase 0.75 of one share of the Company's common stock at an exercise price of $1.44 per share. Each warrant can be exercised at any time on or after June 18, 2021 and has an expiration date of June 18, 2026. Two officers of the Company participated in the Private Offering and converted an aggregate of approximately $131,000 in principal and interest into 107,000 units.

Stock Options

The Company has an incentive stock plan, the Amended and Restated 2011 Equity Incentive Plan (the "2011 Plan"), and has granted stock options to employees, non-employee directors and consultants from the 2011 Plan. Options granted under the 2011 Plan may be Incentive Stock Options or Non-statutory Stock Options, as determined by the Administrator at the time of grant. As of March 31, 2021, there were 5,169,561 shares remaining available for issuance under the 2011 Plan.

During the three months ended March 31, 2021, stock options to purchase 623,901 shares of common stock were exercised for cash proceeds of $958,847.

During the three months ended March 31, 2021, stock options to purchase 40,452 shares of common stock expired, were cancelled and returned to the option pool for future issuance.

The Company recorded stock-based compensation as follows:

	For the Three Months Ended March 31,	
	2021	2020
Research and development	$ 57,102	$ 212,429
General and administrative	263,342	670,216
Total	$ 320,444	$ 882,645

Note 6 - Stockholders' Equity (continued)

The following table represents stock option activity for the three months ended March 31, 2021:

	Stock Options		Weighted Average Exercise Price		Fair Value Vested	Contractual Life (Years)	Aggregate Intrinsic Value
	Outstanding	Exercisable	Outstanding	Exercisable			
Balance – December 31, 2020	7,469,891	5,390,431	$ 2.06	$ 1.68	$ 1.68	6.27	$ -
Granted	-	-	-	-	-	-	-
Exercised	(623,901)	-	-	-	-	-	-
Cancelled	(40,452)	-	-	-	-	-	-
Balance – March 31, 2021	6,805,538	4,923,099	$ 2.12	$ 1.77	$ 1.77	6.27	$ 1,670,751

The following table summarizes information on stock options outstanding and exercisable as of March 31, 2021:

Grant Price		Weighted Average Exercise Price	Total Outstanding	Number Exercisable	Weighted Average Remaining Contractual Term
From	To				
$ 0.26	$ 2.02	$ 0.71	2,455,621	2,286,454	4.12 years
$ 2.10	$ 4.60	$ 2.42	3,756,917	2,084,249	7.51 years
$ 5.30	$ 8.86	$ 6.25	593,000	552,396	7.09 years
	Totals		**6,805,538**	**4,923,099**	

Warrants

During the three months ended March 31, 2021, the Company granted warrants to two service providers to purchase a total of 60,000 shares of its common stock with an exercise price of $1.38 per share. Fifty thousand of these warrants were valued using the Black-Scholes option pricing model and the corresponding expense will be recognized over the vesting period of one year. Ten thousand of these warrants are performance based and will be valued and expensed at the time the performance conditions are met. The warrants have terms that range from two to three years with vesting over a one-year period.

During the three months ended March 31, 2021, warrants to purchase 46,900 shares of common stock were exercised for cash proceeds of $67,536.

During the three months ended March 31, 2021, warrants to purchase 17,000 shares of common stock expired and were cancelled.

The following table summarizes information on warrants outstanding as of March 31, 2021.

	Warrants		Weighted Average Exercise Price		Fair Value Vested	Contractual Life (Years)	Aggregate Intrinsic Value
	Outstanding	Exercisable	Outstanding	Exercisable			
Balance – December 31, 2020	19,372,818	15,495,973	$ 1.62	$ 1.61	$ 0.81	4.07	$ -
Granted	60,000	-	-	-	-	-	-
Exercised	(46,900)	-	-	-	-	-	-
Cancelled	(17,000)	-	-	-	-	-	-
Balance – March 31, 2021	19,368,918	15,440,406	$ 1.62	$ 1.65	$ 0.81	3.83	$ 882,553

COHBAR, INC.
NOTES TO CONDENSED FINANCIAL STATEMENTS
(unaudited)

Note 7 – Non-Cash Expenses

The following table details the Company's non-cash expenses included in the accompanying condensed statements of operations:

	For the Three Months Ended March 31,	
	2021	**2020**
Operating expenses:		
Stock-based compensation	$ 320,444	$ 882,645
Depreciation & amortization	36,685	43,958
Subtotal	$ 357,129	$ 926,603
Other expense:		
Amortization of debt discount	13,506	87,201
Equity expense	-	802,400
Subtotal	$ 13,506	$ 889,601
Total non-cash expenses	$ 370,635	$ 1,816,204

Note 8 – Amendments to Notes and Warrants

WARRANTS

On March 10, 2020, the Company entered into amendments (the "Amendments") with certain holders of the 2018 Notes and Nontransferable Common Stock Purchase Warrants (the "2018 Warrants"). Pursuant to the Amendments, the maturity date of the applicable 2018 Notes was extended and the expiration date of the applicable 2018 Warrants was extended from March 29, 2021 to March 29, 2022. The terms of the applicable 2018 Notes were also amended to grant the holders of such 2018 Notes a right to participate in the Private Offering and to grant resale registration rights in connection therewith. The Company recognized in Other Expenses, $209,810 of costs relating to the 2018 Warrants extension in the accompanying condensed statements of operations. On August 10, 2020, the 2018 Notes and the 2018 Warrants were further amended.

The Company determined the proper classification of the loan modification based on ASC 470-50, Debt Modifications and Extinguishments. Because the change in present value of cash flows of the modified debt is less than 10% when compared to the present value of the cash flows of the original debt, no change is required to be made to the debt in the accompanying condensed financial statements.

Also, on March 10, 2020, the Company entered into an amendment with certain holders of the Company's Common Stock Purchase Warrants (the "2017 Warrants") pursuant to which the expiration date of the applicable 2017 Warrants was extended from June 30, 2020 to September 30, 2021. The Company recognized in Other Expenses, $592,590 of costs relating to the 2017 Warrants extension in the accompanying condensed statements of operations.

Note 9 – Promissory Notes

During the three months ended March 31, 2021, the Company paid $105,437 in principal and interest for two promissory notes that matured. Two promissory notes totaling $352,110 in principal and interest are due and payable on June 30, 2021.

COHBAR, INC.
NOTES TO CONDENSED FINANCIAL STATEMENTS
(unaudited)

Note 10 – Subsequent Events

Management has evaluated subsequent events to determine if events or transactions occurring through the date on which the condensed financial statements were issued require adjustment or disclosure in the Company's condensed financial statements.

Subsequent to March 31, 2021, the Company granted options to purchase up to an aggregate of 6,222,000 shares of the Company's common stock. The options were issued at an exercise prices of either $1.35 or $1.38 per share with terms of 10 years and vesting periods ranging from approximately three to four years.

Subsequent to March 31, 2021, options to purchase an aggregate of 1,211,250 shares of the Company's common stock were forfeited and returned to the option pool for future issuance.

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

The following discussion and analysis is based upon our financial statements as of the dates and for the periods presented in this section. You should read this discussion and analysis in conjunction with the financial statements and notes thereto found in Part I, Item 1 of this Form 10-Q and our financial statements and notes thereto

included in our Annual Report on Form 10-K for the year ended December 31, 2020 (the "2020 Form 10-K"). All references to the first quarter mean the three-month period ended March 31, 2021. Unless the context otherwise requires, "CohBar," "we," "us" and "our" refer to CohBar, Inc.

Special Note Regarding Forward-Looking Statements

This report, including the "Management's Discussion and Analysis of Financial Condition and Results of Operations," contains forward-looking statements regarding future events and our future results that are based on our current expectations, estimates, forecasts and projections about our business, our potential drug candidates, our capital resources and ability to fund our operations, our results of operations, the industry in which we operate and the beliefs and assumptions of our management. Words such as "expect," "anticipate," "target," "goal," "project," "would," "could," "intend," "plan," "believe," "seek" and "estimate," variations of these words, and similar expressions are intended to identify those forward-looking statements. These forward-looking statements are only predictions and are subject to risks, uncertainties and assumptions that are difficult to predict. Therefore, actual results may differ materially from those expressed in any forward-looking statements. Factors that might cause or contribute to such differences include, but are not limited to, those discussed in this report under the section entitled "Risk Factors" in Item 1A of Part I of the 2020 Form 10-K, as supplemented or modified in our quarterly reports on Form 10-Q. We undertake no obligation to revise or update publicly any forward-looking statements for any reason, whether as a result of new information, future events or otherwise, except as may be required by law.

Overview

We are a clinical stage biotechnology company and a leader in the research and development of mitochondria based therapeutics (MBTs), an emerging class of drugs with the potential to treat a wide range of chronic and age-related diseases, including non-alcoholic steatohepatitis (NASH), obesity, fibrotic diseases including IPF, acute respiratory distress syndrome (ARDS) including COVID-19 associated ARDS, cancer, type 2 diabetes mellitus (T2D), and cardiovascular and neurodegenerative diseases. Our portfolio of programs has substantially expanded from two to five programs in the last year. This expanded pipeline greatly strengthens our belief that there are multiple therapeutic peptides that can be realized from the mitochondrial genome.

MBTs originate from almost two decades of research by our founders, resulting in their discovery of a novel group of mitochondrial-derived peptides (MDPs) encoded within the mitochondrial genome. Some of these naturally occurring MDPs and their analogs have demonstrated a range of biological activity and therapeutic potential in research models across multiple chronic and age-related diseases.

We are focused on building our organization, enhancing our scientific and management teams and their capabilities, planning and strategy, raising capital and the research and development of our MDPs. Our research efforts have focused on discovering and evaluating our MDPs for potential development as MBT drug candidates.

Our efforts have resulted in the identification of more than 100 previously unidentified peptides encoded within the mitochondrial genome and generated over 1,000 analogs. Many of these MDPs and their analogs have demonstrated various degrees of biological activity in cell based and/or animal models relevant to a wide range of diseases, such as NASH, obesity, fibrotic diseases, ARDS, cancer, and other diseases.

Clinical Program: Our first clinical candidate, CB4211, is a potential treatment for NASH and obesity. It is a novel peptide initially developed from a MOTS-c MDP. In July 2018, we initiated a Phase 1a/1b clinical study of CB4211. In November 2019, the double-blind, placebo-controlled Phase 1a stage was completed and the blinded safety and tolerability data supported advancement to the Phase 1b stage of the study. The study was designed to initially assess the safety, tolerability and pharmacokinetics of CB4211 following single and multiple-ascending doses in healthy subjects. In November 2019, we initiated recruitment for the Phase 1b stage, which is designed to assess the safety, tolerability and activity of CB4211 in obese subjects with non-alcoholic fatty liver disease (NAFLD). Assessments will include changes in liver fat assessed by MRI-PDFF, body weight and biomarkers relevant to NASH and obesity. On March 30, 2020, we announced a delay in the completion of our Phase 1b study due to the COVID-19 pandemic. The delay was a result of a pause by some of our clinical research organization partners in all of their activities related to the study in response to COVID-19. On July 7, 2020, we announced the resumption of our Phase 1b study. In March 2021, we completed the enrollment for the Phase 1b clinical trial. While topline data is expected to be released in July 2021, it is dependent upon a number of factors and therefore, we cannot predict with certainty the exact timing of such release. Based on positive clinical results and additional funding from potential partnerships and general fundraising, we plan to initiate preparations for a Phase 2 study of CB4211 in 2021 and initiate a Phase 2 study in 2022.

Preclinical Programs: Our preclinical pipeline has substantially expanded from two to four programs in the last year, including one for IPF and other fibrotic diseases, one for COVID-19 associated acute respiratory distress syndrome and two for cancer. Our research efforts have further identified and focused on certain MDPs and their analogs that have demonstrated therapeutic potential for treating indications related to those diseases in preclinical models.

- ***CB5138 Analogs for IPF and other Fibrotic Diseases:*** Our discovery efforts have identified CB5138 Analogs, a family of novel peptides with potential for use as treatments for fibrotic diseases. In co-cultures of human lung cells, CB5138-1 decreased the expression of key fibrosis biomarkers, including alpha smooth muscle actin (αSMA), and collagen types I and III. CB5138-1 also decreased the transformation of healthy lung cells into fibrotic cells after induction by TGF-beta1, resulting in reduced production of the fibrotic components αSMA and pro-collagen I alpha 1. In vivo, CB5138-1 decreased lung fibrosis and inflammation in both the prophylactic mouse model of IPF, initiating treatment with the peptide immediately after fibrosis induction by bleomycin, and in the therapeutic mouse model of IPF, starting peptide treatment one week after induction. In addition, using the more exacting therapeutic model of IPF, two new analogs of CB5138 (CB5138-2 and CB5138-3) significantly reduced lung fibrosis assessed by the Ashcroft Score, reduced inflammation, and decreased fibrosis-related changes in lung weight, collagen deposition in lung tissue, and collagen secretion into lung fluid. In addition, we have demonstrated that a CB5138 Analog has enhanced effects when combined with nintedanib, the leading treatment for IPF, suggesting potential utility for combination therapy in IPF. In the first quarter of 2021, we identified CB5138-3 as the lead clinical candidate in this program and our goal is to initiate IND-enabling activities with the potential to file an IND in 2022.

- ***CB5064 Analogs for ARDS, including COVID-19 Associated ARDS:*** Our internal discovery efforts have identified CB5064 Analogs, a family of peptides that are agonists of the apelin receptor with potential for use as therapeutics for COVID-19 associated ARDS and ARDS in general. In May 2020, we initiated testing of CB5064 Analogs in preclinical models of ARDS. In the preclinical studies, acute lung injury was induced in mice by administration of lipopolysaccharide (LPS), a bacterial toxin that produces similar symptoms to other causes of ARDS, including fluid accumulation and cytokine secretion. A single dose of CB5064 Analog was administered one hour prior to the LPS exposure and effects on lung weight and levels of pro-inflammatory cytokines were measured at 4 hours after LPS exposure. Treatment with CB5064 Analogs reduced fluid accumulation in the lungs and a corresponding broad reduction in levels of key pro-inflammatory cytokines secreted into the lung fluid, when compared to treatment with a placebo control. We previously demonstrated the beneficial effects of this novel family of peptides on glucose tolerance, insulin sensitivity and weight loss in an obese mouse model of T2D, as presented at the American Diabetes Association in 2019. In January 2021, we signed a Non-Clinical Evaluation Agreement (NCEA) with the National Institute of Allergy and Infectious Diseases (NIAID) initiating a collaboration to evaluate the potential of CB5064 Analogs for the treatment of COVID-19 associated ARDS. We are currently performing the required studies in this program. Based on successful outcomes of those studies and additional funding, we plan to nominate a clinical candidate and initiate pre-IND work in 2021, with the longer-term goal of initiating a Phase 1 study.

- ***CB5046 Analogs for Cancer and Other Disease Indications:*** Our internal discovery efforts have identified CB5046 Analogs, a family of novel potent and selective peptide inhibitors of CXCR4, a key chemokine receptor involved in tumor growth, metastasis and avoidance of immune surveillance that is overexpressed in 75% of human tumors. CXCR4 is also involved in localization of healthy stem cells and in certain genetic diseases. We have demonstrated positive effects of one of the CB5046 Analogs when administered in combination with chemotherapy in an animal model of aggressive melanoma. We are screening multiple peptide analogs for in vitro activity and, based on successful outcomes from those studies and additional funding, we plan to explore the potential for use initially in stem cell mobilization and hematologic cancers.

- ***MBT3 Analogs for Cancer Immunotherapy:*** Our discovery efforts have identified a novel peptide family, MBT3 Analogs. We have demonstrated the enhanced killing of cancer cells by human immune cells in the presence of an MBT3 Analog, and plan to further explore the therapeutic potential of this analog family for treatment of cancer, subject to resource availability and the requirements of our more-advanced programs.

We have financed our operations primarily with proceeds from sales of our equity securities, including our initial public offering, private placements of our securities, public sales of our securities and the exercise of outstanding warrants and stock options, as well as through a debt offering. Since our inception through March 31, 2021, our operations have been funded with an aggregate of approximately $77.4 million from the sale and issuance of equity instruments and debt.

Since inception, we have incurred significant operating losses. Our net losses were $4,038,344 and $4,217,563 for the quarters ended March 31, 2021 and 2020, respectively. We incurred $370,635 and $1,816,204 in non-cash expenses during the quarters ended March 31, 2021 and 2020, respectively. Our net losses excluding non-cash expenses were $3,667,709 and $2,401,359 for the quarters ended March 31, 2021 and 2020, respectively. As of March 31, 2021, we had an accumulated deficit of $73,296,630. We expect to continue to incur significant expenses and operating losses over the next several years. Our net losses may fluctuate significantly from quarter to quarter and from year to year. Although we anticipate incurring increasing expenses as we advance CB4211 through the clinic and as we conduct preclinical development of our other research peptides, the extent of that increase is uncertain at this time and subject to change due to the ongoing COVID-19 pandemic and other factors.

Financial Operations Review

Revenue

To date, we have not generated any revenue from product sales and do not expect to generate any revenue from the sale of products in the near future. In the future, we will seek to generate revenue from product sales, either directly or under any future licensing, development or similar relationship with a strategic partner.

Research and Development Expenses

Research and development expenses consist primarily of costs incurred for our research activities, including our drug discovery efforts, and the development of our product candidates, which include:

- employee-related expenses including salaries, benefits and stock-based compensation expense;
- expenses incurred under agreements with third parties, including contract research organizations (CROs) that conduct research and development and preclinical activities on our behalf and the cost of consultants;
- the cost of laboratory equipment, supplies and manufacturing MBT test materials; and
- depreciation and other personnel-related costs associated with research and product development.

We record all research and development expenses as incurred. We expect our research and development expenses to increase in the year ending December 31, 2021 compared to the year ended December 31, 2020, as we incur additional costs related to our clinical activities and for discovery, evaluation and optimization of other MDPs as potential MBT drug candidates.

Our Research Programs

Our research and development programs include activities in support of the clinical development of our lead MBT candidate program, CB4211, as well as the operation of our platform technology related to the discovery and development of new MBTs, evaluation of newly discovered MDPs, design of novel improved analogs, evaluation of their therapeutic potential and optimization of their characteristics as potential MBT drug development candidates. Depending on factors of capability, cost, efficiency and intellectual property rights, we conduct our research programs at our laboratory facility, or externally, pursuant to contractual arrangements with CROs or under collaborative arrangements with academic institutions.

The success of our research programs and the timing of those programs and the possible development of research peptides into drug candidates is highly uncertain. As such, at this time, we cannot reasonably estimate or know the nature, timing or estimated costs of the efforts that will be necessary to complete research and development of a commercial drug. We are also unable to predict when, if ever, we will receive material net cash inflows from our operations. This is due to the numerous risks and uncertainties associated with developing medicines, including the uncertainty of:

- developing appropriate manufacturing processes and formulations;
- establishing an appropriate safety profile with toxicology studies;
- obtaining appropriate regulatory approval for conducting clinical trials;
- successfully designing, enrolling and completing clinical trials;
- receiving marketing approvals from applicable regulatory authorities;
- establishing commercial manufacturing capabilities or making arrangements with third-party manufacturers;
- obtaining and enforcing patent and trade secret protection for our product candidates;

- launching commercial sales of the products, if and when approved, whether alone or in collaboration with others;
- receiving desirable payor reimbursement and formulary access for potential drugs that are approved and commercially launched; and
- maintaining an acceptable safety profile of the products following approval.

A change in the outcome of any of these variables with respect to the development of any of our product candidates would significantly change the costs and timing associated with the development of that product candidate.

Research and development activities are central to our business model. Most of our potential MBT drug candidates are in early stages of investigational research. Candidates in later stages of clinical development generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later-stage clinical trials. We expect research and development costs to increase for the foreseeable future as our product candidate development programs progress. However, we do not believe that it is possible at this time to accurately project total program-specific expenses through commercialization. There are numerous factors associated with the successful commercialization of any of our product candidates, including future trial design and various regulatory requirements, many of which cannot be determined with accuracy at this time based on our stage of development. Additionally, future commercial and regulatory factors beyond our control may impact our clinical development programs and plans.

General and Administrative Expenses

General and administrative expenses consist primarily of salaries and other related costs, including stock-based compensation, for personnel in executive, finance and administrative functions. Other significant costs include legal fees relating to patent and corporate matters and fees for accounting and consulting services and directors' and officers' insurance. We anticipate that our general and administrative expenses will increase in the year ending December 31, 2021 as we plan to expand our business.

Results of Operations

The following table sets forth our results of operations for the periods presented. The period-to-period comparison of financial results is not necessarily indicative of financial results to be achieved in future periods.

	For The Three Months Ended March 31,		Change	
	2021	2020	$	%
Operating expenses:				
Research and development	$ 2,654,772	$ 1,449,872	$ 1,204,900	83%
General and administrative	1,358,679	1,831,621	(472,942)	-26%
Total operating expenses	$ 4,013,451	$ 3,281,493	$ 731,958	22%

Comparison of Three Months Ended March 31, 2021 and 2020

Research and development expenses were $2,654,772 in the three months ended March 31, 2021 compared to $1,449,872 in the prior year period, an increase of $1,204,900, or 83%. The increase in research and development expenses was primarily due to an increase of $1,176,580 in expenses associated with our research programs focused on continuing the development of our peptides and a $195,585 increase in clinical trial costs due to the timing of those expenses. The increase in research and development costs was partially offset by a decrease of $155,326 in stock-based compensation costs. Though we expect research and development expenses to increase in the coming quarters as we plan to continue advancing our lead MBT candidate program through our clinical trial and evaluating and optimizing other MDPs as potential MBT drug candidates, the extent of that increase is unknown at this time and subject to change based on successful outcomes of our studies, the amount of capital available to us and the uncertainties related to the COVID-19 pandemic.

General and administrative expenses were $1,358,679 in the three months ended March 31, 2021 compared to $1,831,621 in the prior year period, a decrease of $472,942, or 26%. The decrease in general and administrative expenses was primarily due to a decrease of $406,874 in stock-based compensation. Though we expect general and administrative expenses for the year ending December 31, 2021 to be higher in comparison to the prior year as we incur the increased costs for such items as noted above, the extent of that increase is unknown at this time and subject to change based on the amount of capital available to us and uncertainties related to the COVID-19 pandemic.

Liquidity and Capital Resources

As of March 31, 2021, we had a cash balance of $1,817,354. We maintain our cash in a checking and savings account on deposit with a banking institution in the United States.

As of March 31, 2021, we had working capital and stockholders' equity of $15,703,824 and $15,795,638, respectively. During the three months ended March 31, 2021, we incurred a net loss of $4,038,344. Our management has evaluated whether there is substantial doubt about our ability to continue as a going concern. We have not generated any revenues, incurred net losses since inception, do not expect to generate revenues in the near term and we require additional capital for our contemplated operational activities. These factors raise substantial doubt about our ability to continue as a going concern for at least one year from the issuance of these financial statements. If we are unable to raise additional capital whenever necessary, we may be forced to decelerate or curtail our research and development activities and/or other operations until such time as additional capital becomes available. Such limitation of our activities would allow us to slow our rate of spending and extend our use of cash until additional capital is raised. There can be no assurance that such a plan will be successful. There is no assurance that additional financing will be available when needed or that we will be able to obtain such financing on reasonable terms.

Cash Flows from Operating Activities

Net cash used in operating activities for the three months ended March 31, 2021 and 2020 was $4,139,387 and $2,426,969, respectively. The cash used in operations for the three months ended March 31, 2021 was primarily due to our reported net loss of $4,038,344. The cash used in operations for the three months ended March 31, 2020 was primarily due to our reported net loss of $4,217,563, partially offset by $1,820,285 in stock-based compensation, depreciation and amortization expense and the equity modification expense in the prior year quarter

Cash Flows from Investing Activities

Net cash provided by investing activities was $2,120,783 in the three months ended March 31, 2021 and was due to the timing of the maturity of our investments partially offset by the purchases of new investments. Net cash used in investing activities was $10,344 in the three months ended March 31, 2020 and was due to the purchases of property and equipment and a payment of an additional security deposit for additional rental space at our lab facility in Menlo Park, California.

Cash Flows from Financing Activities

Net cash provided by financing activities in the three months ended March 31, 2021 and 2020 was $941,383 and $42,226, respectively. Cash provided by financing activities in the three months ended March 31, 2021 was due to the proceeds received from the exercise of stock options and warrants partially offset by the repayment of promissory notes. Cash provided by financing activities in the three months ended March 31, 2020 was due to the proceeds received from the exercise of stock options.

Contractual Obligations

We are a party to (i) a lease agreement for laboratory space leased on a month-to month basis that is part of a shared facility in Menlo Park, California and (ii) a one-year lease agreement for office space in Fairfield, New Jersey, which expires in September 2021.

Rent expense was $102,213 and $100,136 for the three months ended March 31, 2021 and 2020, respectively.

Off-Balance Sheet Arrangements

We did not have any off-balance sheet financing arrangements at March 31, 2021.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

As a smaller reporting company as defined by the rules and regulations of the SEC, we are not required to provide this information.

Item 4. Evaluation of Disclosure Controls and Procedures

In accordance with Rule 13a-15 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), as of the end of the period covered by this Quarterly Report on Form 10-Q, our management evaluated, with the participation of our Chief Executive Officer and our Chief Financial Officer, the effectiveness of our disclosure controls and procedures (as defined in Rule 13a-15(e) and Rule 15d-15(e) under the Exchange Act). Based upon their evaluation of these disclosure controls and procedures, our management, including the Chief Executive Officer and Chief Financial Officer, have concluded that our disclosure controls and procedures were effective as of the end of the period covered by this report.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting identified in connection with the evaluation required by Rule 13a-15(d) and 15d-15(d) of the Exchange Act that occurred during the three months ended March 31, 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

We may from time to time be party to litigation and subject to claims incident to the ordinary course of business. As we grow and gain prominence in the marketplace, we may become party to an increasing number of litigation matters and claims. The outcome of litigation and claims cannot be predicted with certainty, and the resolution of these matters could materially affect our future results of operations, cash flows or financial position. We are not currently a party to any legal proceedings.

Item 1A. Risk Factors

Summary of Risk Factors

An investment in our common stock involves various risks, and prospective investors are urged to carefully consider the matters discussed in the section titled "Risk Factors" prior to making an investment in our common stock. These risks include, but are not limited to, the following:

- Substantial doubt exists as to our ability to continue as a going concern. Our ability to continue as a going concern is uncertain and we will need additional funding and may be unable to raise additional capital when needed, which would force us to delay, reduce or eliminate our research and development activities.
- The outbreak of the novel strain of coronavirus, SARS-CoV-2, which causes COVID-19, could adversely impact our business, including our clinical trials and preclinical studies.
- We have had a history of losses and no revenue.
- We are an early-stage biotechnology company and may never be able to successfully develop marketable products or generate any revenue. We have a very limited relevant operating history upon which an evaluation of our performance and prospects can be made. There is no assurance that our future operations will result in profits. If we cannot generate sufficient revenues, we may suspend or cease operations.
- If we fail to demonstrate efficacy or safety in our research and clinical trials, our future business prospects, financial condition and operating results will be materially adversely affected.
- If our current and any future clinical trials are delayed, suspended or terminated, we may be unable to develop our product candidates on a timely basis, which would adversely affect our ability to obtain regulatory approvals, increase our development costs and delay or prevent commercialization of any approved products.
- If we do not achieve our projected development goals in the time frames we announce and expect, the commercialization of our products may be delayed and, as a result, our stock price may decline.
- Our future success depends on key members of our scientific team and our ability to attract, retain and motivate qualified personnel.

- We may seek to establish development and commercialization collaborations, and, if we are not able to establish them on commercially reasonable terms, we may have to alter our development and commercialization plans.

- We may not be successful in our efforts to identify or discover potential drug development candidates.

- Our research and development plans will require substantial additional future funding which could impact our operational and financial condition. Without the required additional funds, we will likely cease operations.

- Even if we are able to develop our potential drugs, we may not be able to obtain regulatory approval, or if approved, we may not be able to generate significant revenues or successfully commercialize our products, which will adversely affect our financial results and financial condition, and we will have to delay or terminate some or all of our research and development plans, which may force us to cease operations.

- If we do not maintain the support of qualified scientific collaborators, our revenue, growth and profitability will likely be limited, which would have a material adverse effect on our business.

- We expect to rely on third parties to conduct our clinical trials and some aspects of our research and preclinical testing. These third parties may not perform satisfactorily, including failing to meet deadlines for the completion of such trials, research or preclinical testing.

- We contract with third parties for the manufacture of our peptide materials for research and preclinical testing and expect to continue to do so for any future product candidate advanced to clinical trials and commercialization. This reliance on third parties increases the risk that we will not have sufficient quantities of our research peptide materials, product candidates or medicines, or that such supply will not be available to us at an acceptable cost, which could delay, prevent or impair our research, development or commercialization efforts.

- We may not be able to develop drug candidates, market or generate sales of our products to the extent anticipated. Our business may fail, and investors could lose all of their investment in our Company.

- Interim and preliminary or topline data from our clinical trials that we announce or publish from time to time may change as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final data.

- We expect to expand our drug development and regulatory capabilities, and as a result, we may encounter difficulties in managing our growth, which could disrupt our operations.

- The use of any of our products in clinical trials may expose us to liability claims, which may cost us significant amounts of money to defend against or pay out, causing our business to suffer.

CohBar operates in an environment that involves a number of risks and uncertainties. The risks and uncertainties described in this Quarterly Report on Form 10-Q are not the only risks and uncertainties that we face. Additional risks and uncertainties that presently are not considered material or are not known to us, and therefore are not mentioned herein, may impair our business operations. If any of the risks described in this Quarterly Report on Form 10-Q actually occur, our business, operating results and financial position could be adversely affected.

Risks Related to Our Financial Position and Need for Additional Capital

Substantial doubt exists as to our ability to continue as a going concern. Our ability to continue as a going concern is uncertain and we will need additional funding and may be unable to raise additional capital when needed, which would force us to delay, reduce or eliminate our research and development activities.

Substantial doubt exists as to our ability to continue as a going concern. Our ability to continue as a going concern is uncertain and dependent on our ability to obtain additional financing. We have expended and continue to expend substantial funds in connection with our product development, clinical trial and regulatory approval activities.

Our operations to date have consumed substantial amounts of cash, and we expect our capital and operating expenditures to continue to increase in the next few years. We may not be able to generate significant revenues for several years, if at all. Until we can generate significant revenues, if ever, we expect to satisfy our future cash needs through equity or debt financing, and/or through any future development collaborations with commercial partners. We cannot be certain that additional funding will be available on acceptable terms, or at all. We have no committed source of additional capital and, in light of our current market capitalization, it may be more difficult to raise the amount of capital needed to support planned development of our product candidates. In addition, the ongoing COVID-19 pandemic has led to, and may continue to create, global economic disruption, uncertainty and volatility in the global financial markets. These effects may make it increasingly difficult to raise additional capital. If we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we may be required to significantly delay, reduce the scope of, or eliminate one or more of our research and development activities. If we are unable to secure additional capital, a Phase 2 clinical trial of CB4211 will be delayed or discontinued. We could also be required to seek collaborators for our product candidate at an earlier stage than otherwise would be desirable or on terms that are less favorable than might otherwise be available or relinquish or license on unfavorable terms our rights to such product candidates.

The outbreak of the novel strain of coronavirus, SARS-CoV-2, which causes COVID-19, could adversely impact our business, including our clinical trials and preclinical studies.

Public health crises such as pandemics or similar outbreaks could adversely impact our business. In response to the global COVID-19 pandemic, we have modified our business practices by restricting nonessential travel, implementing a partial work from home policy for our employees and instituting new safety protocols for our lab to enable essential on-site work to continue. We continue to monitor the impact of COVID-19 on ongoing activities at our external research and development partner sites.

Timely enrollment in our clinical trials is dependent upon global clinical trial sites, which may be adversely affected by global health matters, such as pandemics. We are currently conducting a clinical trial for our lead product candidate in the United States, which is currently, and may continue to be, affected by COVID-19. For example, enrollment for our CB4211 Phase 1b study was delayed due to suspension of study activities at some of our clinical sites. Although enrollment resumed, we have experienced delays and withdrawals in enrollment due to COVID-19. These and any additional delays in our CB4211 Phase 1b study could increase our development costs, delay or prevent the availability of topline data expected to be available from the trial, delay our product development and regulatory submission process, result in the termination of the trial or make it difficult to raise additional capital.

As a result of the COVID-19 outbreak, or similar pandemics, we may experience disruptions that could severely impact our business, clinical trials and preclinical studies, including:

- delays or difficulties in recruiting, enrolling and retaining patients in our clinical trials;
- delays or difficulties in clinical site initiation, including difficulties in recruiting clinical site investigators and clinical site staff;
- delays or disruptions in non-clinical experiments and investigational new drug application-enabling good laboratory practice standard toxicology studies due to unforeseen circumstances in the supply chain;
- increased rates of patients withdrawing from our clinical trials following enrollment as a result of contracting COVID-19, being forced to quarantine or not accepting home health visits;
- diversion of healthcare resources away from the conduct of clinical trials, including the diversion of hospitals serving as our clinical trial sites and hospital staff supporting the conduct of our clinical trials;
- interruption of key clinical trial activities, such as clinical trial site data monitoring, due to limitations on travel imposed or recommended by federal or state governments, employers and others or interruption of clinical trial subject visits and study procedures (particularly any procedures that may be deemed non-essential), which may impact the integrity of subject data and clinical study endpoints;
- interruption or delays in the operations of the U.S. Food and Drug Administration (FDA) and comparable foreign regulatory agencies, which may impact approval timelines;
- limitations on employee resources that would otherwise be focused on the conduct of our preclinical studies and clinical trials, including because of sickness of employees or their families, the desire of employees to avoid contact with large groups of people, an increased reliance on working from home or mass transit disruptions;
- disruptions in the supply chain and the manufacture or shipment of both drug substance and finished drug product for our product candidates for preclinical testing and clinical trials;

- interruption of, or delays in receiving, supplies of our product candidates from our contract manufacturing organizations due to staffing shortages, production slowdowns or stoppages and disruptions in delivery systems; and
- reduced ability to engage with the medical, investor and partnering communities due to the cancellation of conferences scheduled throughout the year.

In addition, the trading prices for our common stock and other biopharmaceutical companies have been highly volatile as a result of the COVID-19 pandemic and the resulting impact on economic activity. As a result, we may face difficulties raising capital through sales of our common stock or other equity-linked securities, and any such sales may be on unfavorable terms to us and potentially dilutive to existing stockholders.

The extent to which the pandemic may impact our business, clinical trials and preclinical studies will depend on future developments, which are highly uncertain and cannot be predicted with confidence, such as the duration of the pandemic, the impact of vaccinations, travel restrictions and actions to contain the virus or treat its impact, such as social distancing and quarantines or lock-downs in the United States and other countries, business closures or business disruptions and the effectiveness of actions taken in the United States and other countries to contain and treat the disease.

We have had a history of losses and no revenue.

We have generated substantial accumulated losses since our inception. We have not generated any revenues from our operations to date and do not expect to generate any revenue in the near future. As a result, our management expects the business to continue to experience negative cash flow for the foreseeable future. We can offer no assurance that we will ever operate profitably or that we will generate positive cash flow in the future.

Until we can generate significant revenues, if ever, we expect to satisfy our future cash needs through equity or debt financing. We will need to raise additional funds, and such funds may not be available on commercially acceptable terms, if at all. If we are unable to raise funds on acceptable terms, we may not be able to execute our business plan, take advantage of future opportunities, or respond to competitive pressures or unanticipated requirements. This may seriously harm our business, financial condition and results of operations. In the event we are not able to continue operations, investors will likely suffer a complete loss of their investments in our securities.

We are an early-stage biotechnology company and may never be able to successfully develop marketable products or generate any revenue. We have a very limited relevant operating history upon which an evaluation of our performance and prospects can be made. There is no assurance that our future operations will result in profits. If we cannot generate sufficient revenues, we may suspend or cease operations.

We are an early-stage company. Our operations to date have been limited to organizing and staffing our Company, business planning, raising capital, identifying MDPs for further research, developing our intellectual property portfolio, performing research on identified MDPs and advancing our lead MBT candidate into and through clinical studies. We have not generated any revenues to date. All of our MBTs are in the concept, research or early clinical stages. Moreover, we cannot be certain that our research and development efforts will be successful or, if successful, that our MBTs will ever be approved by the FDA. Typically, it takes 10-12 years to develop one new medicine from the time it is discovered to when it is available for treating patients, and longer timeframes are not uncommon. Even if approved, our products may not generate commercial revenues. We have no relevant operating history upon which an evaluation of our performance and prospects can be made. We are subject to all of the business risks associated with a new enterprise, including, but not limited to, risks of unforeseen capital requirements, failure of potential drug candidates either in research, preclinical testing or in clinical trials, and failure to establish business relationships and competitive advantages against other companies. If we fail to become profitable, we may be forced to suspend or cease operations.

If we fail to demonstrate efficacy or safety in our research and clinical trials, our future business prospects, financial condition and operating results will be materially adversely affected.

The success of our research and development efforts will greatly depend on our ability to demonstrate efficacy of MBTs in non-clinical studies, as well as in clinical trials. Non-clinical studies involve testing potential MBTs in appropriate non-human disease models to demonstrate efficacy and safety. Regulatory agencies evaluate these data carefully before they will approve clinical testing in humans. If certain non-clinical data reveals potential safety issues or the results are inconsistent with an expectation of the potential drug's efficacy in humans, the program may be discontinued or the regulatory agencies may require additional testing before allowing human clinical trials. This additional testing will increase program expenses and extend timelines. We may decide to suspend further testing on our potential drugs if, in the judgment of our management and advisors, the non-clinical test results do not support further development.

Moreover, success in research, preclinical testing and early clinical trials does not ensure that later clinical trials will be successful, and we cannot be sure that the results of later clinical trials will replicate the results of prior clinical trials and non-clinical testing. The clinical trial process may fail to demonstrate that our potential drug candidates are safe for humans and effective for indicated uses. This failure would cause us to abandon a drug candidate and may delay development of other potential drug candidates. Any delay in, or termination of, our non-clinical testing or clinical trials will delay the filing of an investigational new drug application and new drug application with the FDA or the equivalent applications with pharmaceutical regulatory authorities outside the United States and, ultimately, our ability to commercialize our potential drugs and generate product revenues. In addition, we expect that our early clinical trials will involve small patient populations. Because of the small sample size, the results of these early clinical trials may not be indicative of future results.

Risks Related to Discovery, Development and Commercialization

If our current and any future clinical trials are delayed, suspended or terminated, we may be unable to develop our product candidates on a timely basis, which would adversely affect our ability to obtain regulatory approvals, increase our development costs and delay or prevent commercialization of any approved products.

We cannot predict whether we will encounter problems with our ongoing, planned or any future clinical trials that will cause regulatory agencies, institutional review boards, or us to suspend or delay a trial. For example, in November 2018, the Company announced the temporary suspension of the Phase 1 clinical trial for CB4211, our lead MBT candidate, in order to address injection site reactions, and we resumed the trial in June 2019. In November 2019, we announced the completion of the Phase 1a portion of the clinical trial and the commencement of the recruiting phase of the final Phase 1b stage of the study. However, in March 2020, we announced a delay in the completion of our Phase 1b study for NASH and obesity. The delays were caused by a pause by some of our clinical research organization partners in all of their activities related to the study in response to developments relating to the COVID-19 pandemic. We announced the resumption of our Phase 1b study in July 2020. In response to a routine annual development safety update report (the "DSUR") we submitted to the FDA on August 6, 2020, the FDA requested additional details regarding injection site reaction safety data presented in the DSUR. The additional information was provided to the FDA. FDA's review of this information or future information requests could result in the delay or suspension of our Phase 1b study to address any concerns. Clinical trials and clinical data collection protocols can be delayed for a variety of reasons, including:

- unanticipated consequences of the formulation of the product candidate requiring us to pause the trial to investigate alternative formulations;
- the occurrence of unacceptable drug-related side effects or adverse events experienced by participants in our clinical trials;
- discussions with the FDA regarding the scope or design of our clinical trials and clinical data collection protocols;
- delays or the inability to obtain required approvals from institutional review boards or other responsible entities at clinical sites selected for participation in our existing or future clinical trials;
- adverse findings in clinical or nonclinical studies related to the safety of our product candidates in humans;

- the amendment of clinical trial or data collection protocols to reflect changes in regulatory requirements and guidance or other reasons, as well as subsequent re-examination of amendments of clinical trial or data collection protocols by institutional review boards or other responsible bodies; and
- the need to repeat or conduct additional clinical trials as a result of inconclusive or negative results, failure to replicate positive early clinical data in subsequent clinical trials, failure to deliver an efficacious dose of a product candidate, poorly executed testing, a failure of a clinical site to adhere to the clinical protocol, an unacceptable study design or other problems.

In addition, a clinical trial or development program may be suspended or terminated by us, institutional review boards, the FDA or other responsible bodies due to a number of factors, including:

- failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols;
- inspection of the clinical trial operations or trial sites by the FDA or other regulatory authorities resulting in the imposition of a clinical hold;
- inability to resume a suspended trial in a timely manner (which we cannot predict with certainty), if at all;
- unforeseen safety issues or any determination that a trial presents unacceptable health risks;
- inability to deliver an efficacious dose of a product candidate; and
- lack of adequate funding to continue the clinical trial.

If the results of our clinical trials are not available when we expect or if we encounter any delay in the analysis of data from our clinical trials, we may be unable to conduct additional clinical trials on the schedule we anticipate. Many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of a product candidate. Any delays in completing a clinical trial could increase our development costs, delay or prevent the availability of topline data expected to be available from the trial, delay our product development and regulatory submission process or make it difficult to raise additional capital.

If we do not achieve our projected development goals in the time frames we announce and expect, the commercialization of our products may be delayed and, as a result, our stock price may decline.

From time to time, we estimate the timing of the anticipated accomplishment of various scientific, clinical, regulatory and other product development goals, which we sometimes refer to as milestones. These milestones may include the commencement or completion of scientific studies and clinical trials and the submission of regulatory filings. From time to time, we may publicly announce the expected timing of some of these milestones. All of these milestones are and will be based on numerous assumptions, including positive clinical and preclinical results, the addition of a corporate partner for the CB4211 program, and sufficient funding from partnering and general fundraising. The actual timing of these milestones can vary dramatically compared to our estimates, in some cases for reasons beyond our control. If we do not meet these milestones as publicly announced, or at all, our revenue may be lower than expected, the commercialization of our products may be delayed or never achieved and, as a result, our stock price may decline.

Our future success depends on key members of our management and scientific teams and our ability to attract, retain and motivate qualified personnel.

Recruiting and retaining qualified senior management and scientific, clinical, and operations management and personnel will be critical to our success. We may not be able to attract and retain these personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel. We also experience competition for the hiring of scientific and clinical personnel from universities and research institutions.

We are highly dependent on our key management and scientific teams, including our Chief Executive Officer, Chief Financial Officer and Chief Scientific Officer who are all employed "at will," meaning they may terminate the employment relationship at any time. We do not maintain "key person" insurance for any of the key members of our team. The loss of the services of any of these persons could impede the achievement of our research, development and commercialization objectives. We have in the past and may in the future continue to experience changes in our executive management team resulting from the departure of executives or subsequent hiring of new executives, which may be disruptive to our business. For example, effective May 3, 2021, Joseph Sarret assumed the role of Chief Executive Officer and Steven Engle resigned from his position as Chief Executive Officer. We anticipate that we will experience a transitional period as Dr. Sarret becomes fully integrated into his new role, and such transition may have a disruptive impact on our ability to implement our business strategy and could have a material adverse effect on our business. Any changes in business strategies can create uncertainty, may negatively impact our ability to executive our business strategy quickly and effectively and may ultimately be unsuccessful. The impact of hiring new executives may not be immediately realized.

Our consultants and advisors, including our founders, may be employed by employers other than us and may have commitments under consulting or advisory contracts with other entities that may limit their availability to us. Our founders, Dr. Pinchas Cohen and Dr. Nir Barzilai, are members of our board of directors and provide oversight and guidance on scientific, research and development topics in that capacity. In addition, we rely on other consultants and advisors from time to time, including drug discovery and development advisors, to assist us in formulating our research and development strategy. Agreements with these advisors typically may be terminated by either party, for any reason, on relatively short notice.

We may seek to establish development and commercialization collaborations, and, if we are not able to establish them on commercially reasonable terms, we may have to alter our development and commercialization plans.

Our potential drug development programs and the potential commercialization of our drug candidates will require substantial additional cash to fund expenses. We may decide to collaborate with pharmaceutical or biotechnology companies in connection with the development or commercialization of our potential drug candidates.

We face significant competition in seeking appropriate collaborators. Whether we reach a definitive collaboration agreement will depend, among other things, upon our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator's evaluation of a number of factors. Those factors may include the design or results of clinical trials, the likelihood of approval by the FDA or similar regulatory authorities outside the United States, the potential market for the subject product candidate, the costs and complexities of manufacturing and delivering such product candidate to patients, the potential of competing products, the existence of uncertainty with respect to our ownership of technology, which can exist if there is a challenge to such ownership without regard to the merits of the challenge, and industry and market conditions generally. The collaborator may also consider alternative product candidates or technologies for similar disease indications on which to collaborate, and whether such alternative collaboration project could be more attractive than one with us for our product candidate.

There are a limited number of large pharmaceutical companies with whom we could potentially collaborate, and collaborations are complex and time-consuming to negotiate and document. We may not be able to negotiate collaborations on a timely basis, on acceptable terms or at all. If we are unable to do so, we may have to curtail the development of the product candidate for which we are seeking to collaborate, reduce or delay its development program or one or more of our other development programs, delay its potential commercialization or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to increase our expenditures to fund development or commercialization activities on our own, we may need to obtain additional capital, which may not be available to us on acceptable terms or at all. If we do not have sufficient funds, we may not be able to further develop our product candidates or bring them to market and generate product revenue.

We may not be successful in our efforts to identify or discover potential drug development candidates.

A key element of our strategy is to identify and test MDPs that play a role in cellular processes underlying our targeted disease indications. A significant portion of the research that we are conducting involves emerging scientific knowledge and drug discovery methods. Our drug discovery efforts may not be successful in identifying MBTs that are useful in treating disease. Our research programs may initially show promise in identifying potential drug development candidates, yet fail to yield candidates for preclinical and clinical development for a number of reasons, including:

- the research methodology used may not be successful in identifying appropriate potential drug development candidates; or
- potential drug development candidates may, on further study, be shown not to be effective in humans, or to have unacceptable toxicities, harmful side effects or other characteristics that indicate that they are unlikely to be medicines that will receive marketing approval and achieve market acceptance.

Research programs to identify new product candidates require substantial technical, financial and human resources. We may choose to focus our efforts and resources on a potential product candidate that ultimately proves to be unsuccessful. As a result, we may forego or delay pursuit of opportunities with other product candidates or for other disease indications that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to timely capitalize on viable commercial products or profitable market opportunities. If we are unable to advance our lead MBT candidate through clinical development or identify other MBTs that are suitable for preclinical and clinical development, we will not be able to obtain product revenues in future periods, which likely would result in significant harm to our financial position and negatively affect our ability to continue our operations.

Our research and development plans will require substantial additional future funding which could impact our operational and financial condition. Without the required additional funds, we will likely cease operations.

It will take several years before we are able to develop potentially marketable products, if at all. Our research and development plans will require substantial additional capital to:

- conduct research, preclinical testing and human studies;
- manufacture any future drug development candidate or product at pilot and commercial scale; and

- establish and develop quality control, regulatory, and administrative capabilities to support these programs.

Our future operating and capital needs will depend on many factors, including:

- the pace of scientific progress in our research programs and the magnitude of these programs;
- the scope and results of preclinical testing and human studies;
- the time and costs involved in obtaining regulatory approvals;
- the time and costs involved in preparing, filing, prosecuting, securing, maintaining and enforcing intellectual property rights;
- competing technological and market developments;
- our ability to establish additional collaborations;
- changes in any future collaborations;
- the cost of manufacturing our drug products; and
- the effectiveness of efforts to commercialize and market our products.

We base our outlook regarding the need for funds on many uncertain variables. Such uncertainties include the success of our research and development initiatives, regulatory approvals, the timing of events outside our direct control such as negotiations with potential strategic partners, and other factors. Any of these uncertain events can significantly change our cash requirements as they determine such one-time events as the receipt or payment of major milestones and other payments.

Additional funds will be required to support our operations, and if we are unable to obtain them on favorable terms, we may be required to cease or reduce further research and development of our drug product programs, sell or abandon some or all of our intellectual property, merge with another entity or cease operations.

Even if we are able to develop our potential drugs, we may not be able to obtain regulatory approval, or if approved, we may not be able to generate significant revenues or successfully commercialize our products, which will adversely affect our financial results and financial condition, and we will have to delay or terminate some or all of our research and development plans, which may force us to cease operations.

All our potential drug candidates will require extensive additional research and development, including preclinical testing and clinical trials, as well as regulatory approvals, before we can market them. We cannot predict if or when any potential drug candidate we intend to develop will be approved for marketing. There are many reasons that we may fail in our efforts to develop our potential drug candidates. These include:

- the possibility that preclinical testing or clinical trials may show that our potential drugs are ineffective and/or cause harmful side effects or toxicities;
- our potential drugs may prove to be too expensive to manufacture or administer to patients;
- our potential drugs may fail to receive necessary regulatory approvals from the FDA or foreign regulatory authorities in a timely manner, or at all;
- even if our potential drugs are approved, we may not be able to produce them in commercial quantities or at reasonable costs;
- even if our potential drugs are approved, they may not achieve commercial acceptance;
- even if our potential drugs are approved and commercially launched, they may not receive desirable payor reimbursement and formulary access;
- regulatory or governmental authorities may apply restrictions to any of our potential drugs, which could adversely affect their commercial success; and
- the proprietary rights of other parties may prevent us or our potential collaborative partners from marketing our potential drugs.

If we fail to develop our potential drug candidates, our financial results and financial condition will be adversely affected, we will have to delay or terminate some or all of our research and development plans and may be forced to cease operations.

Risks Related to Our Reliance on Third Parties

If we do not maintain the support of qualified scientific collaborators, our revenue, growth and profitability will likely be limited, which would have a material adverse effect on our business.

We will need to maintain our existing relationships with leading scientists and/or establish new relationships with scientific collaborators. We believe that such relationships are pivotal to establishing products using our technologies as a standard of care for various disease indications. There is no assurance that our founders, scientific advisors or research partners will continue to work with us or that we will be able to attract additional research partners. If we are not able to establish scientific relationships to assist in our research and development, we may not be able to successfully develop our potential drug candidates. If this happens, our business will be adversely affected.

We expect to rely on third parties to conduct our clinical trials and some aspects of our research and preclinical testing. These third parties may not perform satisfactorily, including failing to meet deadlines for the completion of such trials, research or preclinical testing.

We currently rely on third parties to conduct some aspects of our research and expect to continue to rely on third parties to conduct additional aspects of our research and preclinical testing, as well as any future clinical trials. Any of these third parties may terminate their engagements with us at any time. If we need to enter into alternative arrangements, it would delay our product research and development activities.

Our reliance on these third parties for research and development activities will reduce our control over these activities but will not relieve us of our responsibilities. For example, we will remain responsible for ensuring that each of our clinical trials is conducted in accordance with the general investigational plan and protocols for the trial. Moreover, the FDA requires us to comply with standards, commonly referred to as Good Clinical Practices, for conducting, recording and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of trial participants are protected. We also are required to register ongoing clinical trials and post the results of completed clinical trials on a government-sponsored database, ClinicalTrials.gov, within certain timeframes. Failure to do so can result in fines, adverse publicity and civil and criminal sanctions.

Furthermore, these third parties may also have relationships with other entities, some of which may be our competitors. If these third parties do not successfully carry out their contractual duties, meet expected deadlines or conduct our clinical trials in accordance with regulatory requirements or our stated protocols, we will not be able to obtain, or may be delayed in obtaining, marketing approvals for our drug candidates and will not be able to, or may be delayed in our efforts to, successfully commercialize our medicines.

We currently rely, and expect to continue to rely, on other third parties to store and distribute drug supplies for our clinical trials. Any performance failure on the part of our distributors could delay clinical development or marketing approval of our drug candidates or commercialization of our products, producing additional losses and depriving us of potential product revenue.

We contract with third parties for the manufacture of our peptide materials for research and preclinical testing and expect to continue to do so for any future product candidate advanced to clinical trials and commercialization. This reliance on third parties increases the risk that we will not have sufficient quantities of our research peptide materials, product candidates or medicines, or that such supply will not be available to us at an acceptable cost, which could delay, prevent or impair our research, development or commercialization efforts.

We do not have manufacturing facilities adequate to produce our research peptide materials or supplies of any future product candidate. We currently rely, and expect to continue to rely, on third-party manufacturers for the manufacture of our peptide materials, our current and any future product candidates for preclinical and clinical testing, and for commercial supply of any of these product candidates for which we or future collaborators obtain marketing approval. We do not have long term supply agreements with any third-party manufacturers, and we purchase our research peptides on a purchase order basis.

We may be unable to establish any agreements with third-party manufacturers or to do so on acceptable terms. Even if we are able to establish agreements with third-party manufacturers, reliance on third-party manufacturers entails additional risks, including:

- reliance on the third party for producing the peptide materials or product candidates according to the detailed specifications;
- reliance on the third party for regulatory compliance and quality assurance;
- the possible breach of the manufacturing agreement by the third party;
- the possible termination or nonrenewal of the agreement by the third party at a time that is costly or inconvenient for us; and
- reliance on the third party for regulatory compliance, quality assurance, and safety and pharmacovigilance reporting.

Third-party manufacturers may not be able to comply with current good manufacturing practices ("cGMP") as enforced by the FDA, regulations or similar regulatory requirements outside the United States. Our failure, or the failure of our third-party manufacturers, to comply with applicable regulations could result in us being subject to sanctions, including fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of product candidates or medicines, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of our medicines and harm our business and results of operations.

Any drug candidate that we may develop may compete with other drug candidates and products for access to manufacturing facilities. There are a limited number of manufacturers that operate under cGMP regulations and that might be capable of manufacturing for us.

Our current and anticipated future dependence upon others for the manufacture of our investigational materials or future product candidates or medicines may adversely affect our future profit margins and our ability to commercialize any medicines that receive marketing approval on a timely and competitive basis.

Risks Related to Product Development and Regulatory Approval

We may not be able to develop drug candidates, market or generate sales of our products to the extent anticipated. Our business may fail, and investors could lose all of their investment in our Company.

Assuming that we are successful in developing our potential drug candidates and receiving regulatory clearances to market our potential products, our ability to successfully penetrate the market and generate sales of those products may be limited by a number of factors, including the following:

- if our competitors receive regulatory approvals for and begin marketing similar products in the United States, the European Union ("EU"), Japan and other territories before we do, greater awareness of their products as compared to ours will cause our competitive position to suffer;
- information from our competitors or the academic community indicating that current products or new products are more effective or offer compelling other benefits than our future products could impede our market penetration or decrease our future market share; and
- the pricing and reimbursement environment for our future products, as well as pricing and reimbursement decisions by our competitors and by payers, may have an effect on our revenues.

If any of these occur, our business could be adversely affected.

Interim and preliminary or topline data from our clinical trials that we announce or publish from time to time may change as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final data.

From time to time, we may publish interim topline or preliminary data from our clinical trials. Interim data from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. Preliminary or topline data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary or topline data we previously published. As a result, interim and preliminary data should be viewed with caution until the final data are available. Adverse differences between interim or preliminary or topline data and final data could significantly harm our reputation and business prospects.

Any product candidate we are able to develop and commercialize would compete in the marketplace with existing therapies and new therapies that may become available in the future. These competitive therapies may be more effective, less costly, more easily administered or offer other advantages over any product we seek to market.

Although there are no currently approved therapies for the treatment of NAFLD or NASH, there are numerous therapies in development, including those in clinical trials that are more advanced than ours. Additionally, there are numerous therapies currently marketed to treat diabetes, cancer, Alzheimer's disease and other diseases for which our potential product candidates may be indicated. For example, if we develop an approved treatment for T2D, it would compete with several classes of drugs for T2D that are approved to improve glucose control. These include the insulin sensitizers pioglitazone (Actos) and rosiglitazone (Avandia), which are administered as oral once daily pills, and metformin, which is sometimes called an insulin sensitizer and is available as a generic once daily formulation. If we develop an approved treatment for Alzheimer's disease, it would compete with approved therapies such as donepezil (Aricept), galantamine (Razadyne), memantine (Namenda) and rivastigmine (Exelon). These therapies are varied in their design, therapeutic application and mechanism of action and may provide significant competition for any of our product candidates for which we obtain market approval. New products may also become available that provide efficacy, safety, convenience and other benefits that are not provided by currently marketed therapies. As a result, they may provide significant competition for any of our product candidates for which we obtain market approval. Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are more conveniently administered or stored or are less expensive than any products that we may develop. Our competitors also may obtain FDA or other regulatory approval for their products more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market. In addition, our ability to compete may be affected in many cases by insurers' or other third-party payers' reimbursement polices seeking to encourage the use of existing products which are generic or are otherwise less expensive to provide.

We expect to expand our drug development and regulatory capabilities, and as a result, we may encounter difficulties in managing our growth, which could disrupt our operations.

We expect to experience significant growth in the scope of our operations, particularly in the areas of drug development and commercialization and regulatory affairs. To manage our anticipated future growth, we must continue to implement and improve our managerial, operational and financial systems, expand our facilities and continue to recruit and train additional qualified personnel, which we may not be able to attract. We expect that if our drug candidates continue to progress into and in development, we may require significant additional investment in personnel, management systems and resources, particularly in the build out of our clinical and commercial capabilities. Over the next several years, we may experience significant growth in the number of our employees and the scope of our operations, particularly in the areas of drug development, regulatory affairs and sales and marketing. Due to our limited financial resources and our limited operating history, we may not be able to effectively manage the expected expansion of our operations. The physical expansion of our operations may lead to significant costs and may divert our management and business development resources. Any inability to manage growth could delay the execution of our business plans or disrupt our operations.

The use of any of our products in clinical trials may expose us to liability claims, which may cost us significant amounts of money to defend against or pay out, causing our business to suffer.

The nature of our business exposes us to potential liability risks inherent in the testing, manufacturing and marketing of our products. Our leading product candidate, CB4211, is currently in clinical trials, and if any of our drug candidates enter into clinical trials, or if any of our drug candidates become marketed products, they could potentially harm people or allegedly harm people, possibly subjecting us to costly and damaging product liability claims. Some of the patients who participate in clinical trials are already ill when they enter a trial or may intentionally or unintentionally fail to meet the exclusion criteria. The waivers we obtain may not be enforceable and may not protect us from liability or the costs of product liability litigation. Although we obtained product liability insurance, which we believe is adequate, we are subject to the risk that our insurance will not be sufficient to cover claims. We anticipate that we will need to increase our insurance coverage if we successfully commercialize any product candidate. The insurance costs along with the defense or payment of liabilities above the amount of coverage could cost us significant amounts of money and management distraction from other elements of the business, decrease demand for any product candidates that we may develop, injure our reputation and attract significant negative media attention, and lead to the withdrawal of clinical trial participants, causing our business to suffer. We may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise.

Compliance with laws and regulations pertaining to the privacy and security of health information may be time consuming, difficult and costly, particularly in light of increased focus on privacy issues in countries around the world, including the United States and the EU.

We are subject to various domestic and international privacy and security regulations. The confidentiality, collection, use and disclosure of personal data, including clinical trial patient-specific information, are subject to governmental regulation generally in the country that the personal data were collected or used. In the United States, we are subject, or expect to be subject, to various state and federal privacy and data security regulations, including but not limited to the Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), as amended by the Health Information Technology for Economic and Clinical Health Act of 2009. HIPAA mandates, among other things, the adoption of uniform standards for the electronic exchange of information in common health care transactions, as well as standards relating to the privacy and security of individually identifiable health information, which require the adoption of administrative, physical and technical safeguards to protect such information. In the EU, personal data includes any information that relates to an identified or identifiable natural person with health information carrying additional obligations, including obtaining the explicit consent from the individual for collection, use or disclosure of the information. In addition, the protection of and cross-border transfers of such data out of the EU has become more stringent with the EU's General Data Protection Regulation which came into effect in May 2018. Furthermore, the legislative and regulatory landscape for privacy and data protection continues to evolve, and there has been an increasing amount of focus on privacy and data protection issues. The United States and the EU and its member states continue to issue new privacy and data protection rules and regulations that relate to personal data and health information. Compliance with these laws may be time consuming, difficult and costly. If we fail to comply with applicable laws, regulations or duties relating to the use, privacy or security of personal data, we could be subject to the imposition of significant civil and criminal penalties, be forced to alter our business practices and suffer reputational harm.

We may not be able to obtain agreement with regulatory authorities regarding an acceptable development plan for our product candidates, the outcome of our clinical trials may not be favorable or, even if favorable, regulatory authorities may not find the results of our clinical trials to be sufficient for marketing approval.

In the United States, the FDA generally requires two adequate and well-controlled pivotal clinical trials to approve a new drug application ("NDA"). Furthermore, for full approval of an NDA, the FDA requires a demonstration of efficacy based on a clinical benefit endpoint. The FDA may grant accelerated approval based on a surrogate endpoint reasonably likely to predict clinical benefit. Even though our pivotal clinical trials for a specific indication may achieve their primary endpoints and are reasonably believed by us to be likely to predict clinical benefit, the FDA may not accept the results of such trials or approve our product candidates on an accelerated basis, or at all. It is also possible that the FDA may refuse to accept for filing and review any regulatory application we submit for regulatory approval in the United States. Even if our regulatory application is accepted for review, there may be delays in the FDA's review process and the FDA may determine that such regulatory application does not contain adequate clinical or other data or support the approval of our product candidate. In such a case, the FDA may issue a complete response letter that may require that we conduct and/or

complete additional clinical trials and preclinical studies or provide additional information or data before it will reconsider an application for approval. Any such requirements may be substantial, expensive and time-consuming, and there is no guarantee that we will continue to pursue such application or that the FDA will ultimately decide that any such application supports the approval of our product candidate. Furthermore, the FDA may also refer any regulatory application to an advisory committee for review and recommendation as to whether, and under what conditions, the application should be approved. While the FDA is not bound by the recommendation of an advisory committee, it considers such recommendations carefully when making decisions. Delay or failure to obtain, or unexpected costs in obtaining, the regulatory approval necessary to bring a potential product to market could decrease our ability to generate sufficient revenue to maintain our business.

The regulatory approval process is lengthy, expensive and uncertain, and we may be unable to obtain regulatory approval for our product candidates under applicable regulatory requirements. The denial or delay of any such approval would delay commercialization of our product candidates and adversely impact our ability to generate revenue, our business and our results of operations.

The development, research, testing, manufacturing, labeling, approval, selling, import, export, marketing, promotion and distribution of drug products are subject to extensive and evolving regulation by federal, state and local governmental authorities in the United States, principally the FDA, and by foreign regulatory authorities, which regulations differ from country to country. Neither we nor any future collaborator is permitted to market any of our product candidates in the United States until we receive regulatory approval of an NDA from the FDA.

Obtaining regulatory approval of an NDA can be a lengthy, expensive and uncertain process. Prior to obtaining approval to commercialize our product candidate in the United States or abroad, we or our collaborators must demonstrate with substantial evidence from well-controlled clinical trials, and to the satisfaction of the FDA or other foreign regulatory authorities, that such product candidates are safe and effective for their intended uses. The number of nonclinical studies and clinical trials that will be required for regulatory approval varies depending on the product candidate, the disease or condition that the product candidate is designed to address, and the regulations applicable to any particular product candidate.

Results from nonclinical studies and clinical trials can be interpreted in different ways. Even if we believe the nonclinical or clinical data for our product candidates are promising, such data may not be sufficient to support approval by the FDA and other regulatory authorities. Administering product candidates to humans may produce undesirable side effects, which could interrupt, delay or halt clinical trials and result in the FDA or other regulatory authorities denying approval of a product candidate for any or all indications. The FDA may also require us to conduct additional studies or trials for our product candidates either prior to or post-approval, such as additional clinical pharmacology studies or safety or efficacy studies or trials, or it may object to elements of our clinical development program such as the primary endpoints or the number of subjects in our clinical trials.

The FDA or any foreign regulatory bodies can delay, limit or deny approval of our product candidates or require us to conduct additional nonclinical or clinical testing or abandon a program for many reasons, including:

- the FDA or the applicable foreign regulatory authority's disagreement with the design or implementation of our clinical trials;
- negative or ambiguous results from our clinical trials or results that may not meet the level of statistical significance required by the FDA or comparable foreign regulatory authorities for approval;
- serious and unexpected drug-related side effects experienced by participants in our clinical trials;
- our inability to demonstrate to the satisfaction of the FDA or the applicable foreign regulatory authority that our product candidates are safe and effective for the proposed indication;
- the FDA's or the applicable foreign regulatory authority's disagreement with the interpretation of data from nonclinical studies or clinical trials;
- our inability to demonstrate the clinical and other benefits of our product candidates outweigh any safety or other perceived risks;
- the FDA's or the applicable foreign regulatory authority's requirement for additional nonclinical studies or clinical trials;
- the FDA's or the applicable foreign regulatory authority's disagreement regarding the formulation, labeling and/or the specifications of our product candidates;
- the FDA's or the applicable foreign regulatory authority's failure to approve the manufacturing processes or facilities of third-party manufacturers with which we contract;
- the potential for approval policies or regulations of the FDA or the applicable foreign regulatory authorities to significantly change in a manner rendering our clinical data insufficient for approval; or
- the FDA or the applicable foreign regulatory authority's disagreement with the sufficiency of the clinical, non-clinical and/or quality data in the NDA or comparable marketing authorization application.

Of the large number of drugs in development, only a small percentage successfully complete the FDA or other regulatory approval processes and are commercialized. The lengthy development and approval process as well as the unpredictability of future clinical trial results may result in our failing to obtain regulatory approval to market our product candidates, which would significantly harm our business, financial condition, results of operations and prospects.

Any product candidate for which we obtain marketing approval will be subject to extensive post-marketing regulatory requirements and could be subject to post-marketing restrictions or withdrawal from the market, and we may be subject to penalties if we fail to comply with regulatory requirements or if we experience unanticipated problems with our product candidates, when and if any of them are approved.

Our product candidates and the activities associated with their development and potential commercialization, including their testing, manufacturing, recordkeeping, labeling, storage, approval, advertising, promotion, sale and distribution, are subject to comprehensive regulation by the FDA and other U.S. and international regulatory authorities. These requirements include submissions of safety and other post-marketing information and reports, registration and listing requirements, requirements relating to manufacturing, including current cGMPs, quality control, quality assurance and corresponding maintenance of records and documents, including periodic inspections by the FDA and other regulatory authorities and requirements regarding the distribution of samples to providers and recordkeeping.

The FDA may also impose requirements for costly post-marketing studies or clinical trials and surveillance to monitor the safety or efficacy of any approved product. The FDA closely regulates the post-approval marketing and promotion of drugs and biologics to ensure drugs and biologics are marketed only for the approved disease indications and in accordance with the provisions of the approved labeling. The FDA imposes stringent restrictions on manufacturers' communications regarding use of their products. If we promote our product candidates in a manner inconsistent with FDA-approved labeling or otherwise not in compliance with FDA regulations, we may be subject to enforcement action. Violations of the Federal Food, Drug, and Cosmetic Act relating to the promotion of prescription drugs may lead to investigations alleging violations of federal and state healthcare fraud and abuse laws, as well as state consumer protection laws and similar laws in international jurisdictions.

In addition, later discovery of previously unknown adverse events or other problems with our product candidates, manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may yield various results, including:

- restrictions on such product candidates, manufacturers or manufacturing processes;
- restrictions on the labeling or marketing of a product;
- restrictions on product distribution or use;
- requirements to conduct post-marketing studies or clinical trials;
- warning or untitled letters;
- withdrawal of any approved product from the market;
- refusal to approve pending applications or supplements to approved applications that we submit;
- recall of product candidates;
- restrictions on product distribution or use;
- fines, restitution or disgorgement of profits or revenues;
- suspension or withdrawal of marketing approvals;
- refusal to permit the import or export of our product candidates;
- product seizure; and
- injunctions or the imposition of civil or criminal penalties.

Non-compliance with European requirements regarding safety monitoring or pharmacovigilance, and with requirements related to the development of products for the pediatric population, can also result in significant financial penalties. Similarly, failure to comply with the EU's requirements regarding the protection of personal information can also lead to significant penalties and sanctions.

THE PATENT POSITIONS OF BIOPHARMACEUTICAL PRODUCTS ARE COMPLEX AND UNCERTAIN, AND WE MAY NOT BE ABLE TO PROTECT OUR PATENTED OR OTHER INTELLECTUAL PROPERTY. IF WE CANNOT PROTECT THIS PROPERTY, WE MAY BE PREVENTED FROM USING IT, OR OUR COMPETITORS MAY USE IT, AND OUR BUSINESS COULD SUFFER SIGNIFICANT HARM. ALSO, THE TIME AND MONEY WE SPEND ON ACQUIRING AND ENFORCING PATENTS AND OTHER INTELLECTUAL PROPERTY WILL REDUCE THE TIME AND MONEY WE HAVE AVAILABLE FOR OUR RESEARCH AND DEVELOPMENT, POSSIBLY resulting in a slow down or cessation of our research and development.

We own or exclusively license patents and patent applications related to our MDPs and potential MBTs and we anticipate continuing to develop our intellectual property portfolio. However, neither patents nor patent applications ensure the protection of our intellectual property for a number of reasons, including the following:

- The United States Supreme Court rendered a decision in Molecular Pathology vs. Myriad Genetics, Inc., 133 S.Ct. 2107 (2013) ("Myriad"), in which the court held that naturally occurring DNA segments are products of nature and not patentable as compositions of matter. On March 4, 2014, the U.S. Patent and Trademark Office ("USPTO") issued guidelines for examination of such claims that, among other things, extended the Myriad decision to any natural product. Since MDPs are natural products isolated from cells, the USPTO guidelines may affect allowability of some of our patent claims (pertaining to natural MDP sequences) that are filed in the USPTO but are not yet issued. Further, while the USPTO guidelines are not binding on the courts, it is likely that as the law of subject matter eligibility continues to develop, Myriad will be extended to natural products other than DNA. Thus, our issued U.S. patent claims directed to MDPs as compositions of matter may be vulnerable to challenge by competitors who seek to have our claims rendered invalid. While Myriad and the USPTO guidelines described above will affect our patents only in the United States, there is no certainty that similar laws or regulations will not be adopted in other jurisdictions.

- Competitors may interfere with our patenting process in a variety of ways. Competitors may claim that they invented the claimed invention prior to us. Competitors may also claim that we are infringing their patents and restrict our freedom to operate. Competitors may also contest our patents and patent applications, if issued, by showing in various patent offices that, among other reasons, the patented subject matter was not original, was not novel or was obvious. In litigation, a competitor could claim that our patents and patent applications are not valid or enforceable for a number of reasons. If a court agrees, we would lose some or all of our patent protection.

- As a company, we have no meaningful experience with competitors interfering with our patents or patent applications. In order to enforce our intellectual property, we may need to file a lawsuit against a competitor. Enforcing our intellectual property in a lawsuit can take significant time and money. We may not have the resources to enforce our intellectual property if a third party infringes an issued patent claim. Infringement lawsuits may require significant time and money resources. If we do not have such resources, for patents that we have licensed from a third party, the licensor is not obligated to help us enforce our patent rights. If the licensor does take action by filing a lawsuit claiming infringement, we will not be able to participate in the suit and therefore will not have control over the proceedings or the outcome of the suit.

- Because of the time, money and effort involved in obtaining and enforcing patents, our management may spend less time and resources on developing potential drug candidates than they otherwise would, which could increase our operating expenses and delay product programs.

- Our licensed patent applications directed to the composition and methods of using MOTS-c, an MDP, and SHLP-6, which we consider as a research peptide for the potential treatment of cancer, have not yet been issued. There can be no assurance that these or our other licensed patent applications will result in the issuance of patents, and we cannot predict the breadth of claims that may be allowed in our currently pending patent applications or in patent applications we may file or license from others in the future.

- Issuance of a patent may not provide much practical protection. If we receive a patent of narrow scope, then it may be easy for competitors to design products that do not infringe our patent(s).

- We have limited ability to expand coverage of our licensed patent related to SHLP-2 and our licensed patent application related to SHLP-6 outside of the United States. The lack of patent protection in international jurisdictions may inhibit our ability to advance MBT drug candidates in these markets.

- If a court decides that the method of manufacture or use of any of our drug candidates infringes on a third-party patent, we may have to pay substantial damages for infringement.

- A court may prohibit us from making, selling or licensing a potential drug candidate unless the patent holder grants a license. A patent holder is not required to grant a license. If a license is available, we may have to pay substantial royalties or grant cross licenses to our patents, and the license terms may be unacceptable.

- Redesigning our potential drug candidates so that they do not infringe on other patents may not be possible or could require substantial funds and time.

It is also unclear whether our trade secrets are adequately protected. While we use reasonable efforts to protect our trade secrets, our employees or consultants may unintentionally or willfully disclose our information to competitors. Enforcing a claim that someone illegally obtained and is using our trade secrets is expensive and time consuming, and the outcome is unpredictable. In addition, courts outside the United States are sometimes less willing to protect trade secrets. Our competitors may independently develop equivalent knowledge, methods and know-how. We may also support and collaborate in research conducted by government organizations, hospitals, universities or other educational institutions. These research partners may be unable or unwilling to grant us exclusive rights to technology or products derived from these collaborations prior to entering into the relationship.

If we do not obtain required intellectual property rights, we could encounter delays in our drug development efforts while we attempt to design around other patents or even be prohibited from developing, manufacturing or selling potential drug candidates requiring these rights or licenses. There is also a risk that disputes may arise as to the rights to technology or potential drug candidates developed in collaboration with other parties.

General Risk Factors

If we fail to establish and maintain proper and effective internal control over financial reporting in the future, our ability to produce accurate and timely financial statements could be impaired, which could harm our operating results, investors' views of us and, as a result, the value of our common stock.

The Sarbanes-Oxley Act requires, among other things, that we maintain effective internal controls for financial reporting and disclosure controls and procedures and that we furnish a report by management on, among other things, the effectiveness of our internal control over financial reporting. This assessment needs to include disclosure of any material weaknesses identified by our management in our internal control over financial reporting. A material weakness is a deficiency, or combination of deficiencies, in internal control over financial reporting that results in more than a reasonable possibility that a material misstatement of annual or interim financial statements will not be prevented or detected on a timely basis. Section 404 of the Sarbanes-Oxley Act also generally requires an attestation from our independent registered public accounting firm on the effectiveness of our internal control over financial reporting. However, for as long as we are not an accelerated filer or large accelerated filer, we intend to take advantage of the exemption permitting us not to comply with the independent registered public accounting firm attestation requirement.

Our compliance with Section 404 will require us to document and evaluate our internal control over financial reporting, which is both costly and challenging. In this regard, we will need to continue to dedicate internal resources, potentially engage outside consultants and adopt a detailed work plan to assess and document the adequacy of internal control over financial reporting, continue steps to improve control processes as appropriate, validate through testing that controls are functioning as documented and implement a continuous reporting and improvement process for internal control over financial reporting. Despite our efforts, there is a risk that we will not be able to conclude that our internal control over financial reporting is effective as required by Section 404. If we identify one or more material weaknesses, it could result in an adverse reaction in the financial markets due to a loss of confidence in the reliability of our consolidated financial statements. In addition, if we are not able to continue to meet these requirements, we may not be able to remain listed on The Nasdaq Capital Market ("Nasdaq").

As we continue to grow, we expect to hire additional personnel and may utilize external temporary resources to implement, document and modify policies and procedures to maintain effective internal controls. However, it is possible that we may identify deficiencies and weaknesses in our internal controls. If material weaknesses or deficiencies in our internal controls exist and go undetected or unremediated, our consolidated financial statements could contain material misstatements that, when discovered in the future, could cause us to fail to meet our future reporting obligations and cause the price of our common stock to decline.

Significant disruptions of information technology systems or security breaches could adversely affect our business.

We are increasingly dependent upon information technology systems, infrastructure and data to operate our business. In the ordinary course of business, we collect, store and transmit large amounts of confidential information (including, among other things, trade secrets or other intellectual property, proprietary business information and personal information). It is critical that we do so in a secure manner to maintain the confidentiality and integrity of such confidential information. We also have outsourced elements of our operations to third parties, and as a result we manage a number of third-party vendors who may or could have access to our confidential information. Attacks on information technology systems are increasing in their frequency, levels of persistence, sophistication and intensity, and they are being conducted by increasingly sophisticated and organized groups and individuals with a wide range of motives and expertise. The size and complexity of our information technology systems, and those of third-party vendors with whom we contract, and the large amounts of confidential information stored on those systems, make such systems vulnerable to service interruptions or to security breaches from inadvertent or intentional actions by our employees, third-party vendors, and/or business partners, or from cyber-attacks by malicious third parties. Cyber-attacks could include the deployment of harmful malware, ransomware, denial-of-service attacks, social engineering and other means to affect service reliability and threaten the confidentiality, integrity and availability of information.

Significant disruptions of our information technology systems, or those of our third-party vendors, or security breaches could adversely affect our business operations and/or result in the loss, misappropriation and/or unauthorized access, use or disclosure of, or the prevention of access to, confidential information, including, among other things, trade secrets or other intellectual property, proprietary business information and personal information, and could result in financial, legal, business and reputational harm to us.

Any failure or perceived failure by us or any third-party collaborators, service providers, contractors or consultants to comply with our privacy, confidentiality, data security or similar obligations to third parties, or any data security incidents or other security breaches that result in the unauthorized access, release or transfer of sensitive information, including personally identifiable information, may result in governmental investigations, enforcement actions, regulatory fines, litigation or public statements

against us, could cause third parties to lose trust in us or could result in claims by third parties asserting that we have breached our privacy, confidentiality, data security or similar obligations, any of which could have a material adverse effect on our reputation, business, financial condition or results of operations. Moreover, data security incidents and other security breaches can be difficult to detect, and any delay in identifying them may lead to increased harm. While we have implemented data security measures intended to protect our information technology systems and infrastructure, there can be no assurance that such measures will successfully prevent service interruptions or data security incidents.

If securities or industry analysts do not publish or cease publishing research or reports about us, our business or our market, or if they change their recommendations regarding our stock adversely, our stock price and trading volume could decline.

The trading market for our common stock will be influenced by the research and reports that industry or securities analysts may publish about us, our business, our market or our competitors. If any of the analysts who may cover us change their recommendation regarding our stock adversely, or provide more favorable relative recommendations about our competitors, our stock price would likely decline. If any analysts who may cover us were to cease coverage of our Company or fail to regularly publish reports on us, we could lose visibility in the financial markets, which in turn could cause our stock price or trading volume to decline.

The market price of our common stock may be highly volatile.

The market for our common stock has been characterized by significant price volatility when compared to more established issuers, and we expect that it will continue to be so for the foreseeable future. The market price of our common stock is likely to be volatile for a number of reasons. First, our common stock is likely to be sporadically and/or thinly traded. As a consequence of this lack of liquidity, the trading of relatively small quantities of common stock by our stockholders may disproportionately influence the price of the common stock in either direction. The price of the common stock could, for example, decline precipitously if even a relatively small number of shares are sold on the market without commensurate demand, as compared to a market for shares of an established issuer which could better absorb those sales without adverse impact on its share price. Second, we are a speculative investment due to our lack of profits to date and substantial uncertainty regarding our ability to develop and commercialize a drug product from our new or existing technologies. As a consequence of this enhanced risk, more risk-adverse investors may, under the fear of losing all or most of their investment in the event of negative news or lack of progress, be more inclined to sell their shares on the market more quickly and at greater discounts than would be the case with the shares of an established issuer. We cannot make any predictions or projections as to what the prevailing market price for our common stock will be at any time or as to what effect the sale of common stock or the availability of common stock for sale at any time will have on the prevailing market price.

Our management owns, and could acquire, a significant percentage of our outstanding common stock. If the ownership of our common stock continues to be highly concentrated in management, it may prevent other stockholders from influencing significant corporate decisions.

As of March 31, 2021, our executive officers and directors own, as a group, approximately 22% of the outstanding shares of our common stock. Additionally, our executive officers and directors own, as a group, options and warrants exercisable for approximately 10% of our outstanding common stock, assuming exercise of such options and warrants. As a result, our management could exert significant influence over matters requiring stockholder approval, including the election of our board of directors, the approval of mergers and other extraordinary transactions, as well as the terms of any of these transactions. This concentration of ownership could have the effect of delaying or preventing a change in our control or otherwise discouraging a potential acquirer from attempting to obtain control of us, which could in turn have an adverse effect on the fair market value of our Company and our common stock. These actions may be taken even if they are opposed by our other stockholders.

The requirements of being a public company may strain our resources, divert management's attention and require us to disclose information that is helpful to competitors, make us more attractive to potential litigants and make it more difficult to attract and retain qualified personnel.

As a public company, we are subject to the reporting requirements of the Securities Act of 1933, as amended, the Exchange Act, the Sarbanes-Oxley Act, the Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010, and applicable Canadian securities rules and regulations. Despite recent reforms made possible by the JOBS Act, compliance with these rules and regulations creates significant legal and financial compliance costs and makes some activities difficult, time-consuming or costly. The Exchange Act and applicable Canadian provincial securities legislation require, among other things, that we file annual, quarterly and current reports with respect to our business and operating results.

Additionally, the Sarbanes-Oxley Act and the related rules and regulations of the SEC and the Nasdaq Capital Market require us to implement particular corporate governance practices and adhere to a variety of reporting requirements and complex accounting rules. Among other things, we are subject to rules regarding the independence of the members of our board of directors and committees of the board and their experience in finance and accounting matters and certain of our executive officers are required to provide certifications in connection with our quarterly and annual reports filed with the SEC. The perceived personal risk associated with these rules may deter qualified individuals from accepting these positions. Accordingly, we may be unable to attract and retain qualified officers and directors. If we are unable to attract and retain qualified officers and directors, our business and our ability to maintain the listing of our shares of common stock on the Nasdaq or another stock exchange could be adversely affected.

We are also subject to more stringent state law requirements. For example, under California law, we will be required to have at least three female directors on our board of directors and one director from an "underrepresented community" by December 31, 2021, and an additional director from an "underrepresented community" by December 31, 2022. A director from an "underrepresented community" means a director who self-identifies as Black, African American, Hispanic, Latino, Asian, Pacific Islander, Native American, Native Hawaiian, Alaska Native, gay, lesbian, bisexual or transgender. If we fail to comply with either of these requirements, we could be fined by the California Secretary of State, our reputation may be adversely affected and certain investors may divest their holdings in our stock.

Changes in U.S. federal income and other tax laws could adversely affect us.

New U.S. legislation or regulations which could affect our tax burden could be enacted by the U.S. government. We cannot predict the timing or extent of such tax-related developments which could have a negative impact on our financial results. Additionally, we use our best judgment in attempting to quantify and reserve for these tax obligations. However, a challenge by a taxing authority, our ability to utilize tax benefits such as carryforwards or tax credits, or a deviation from other tax-related assumptions could have a material adverse effect on our business, results of operations, or financial condition.

Unfavorable global economic conditions could adversely affect our business, financial condition or results of operations.

Our results of operations could be adversely affected by general conditions in the global economy and in the global financial markets. For example, the global financial crisis caused extreme volatility and disruptions in the capital and credit markets. A severe or prolonged economic downturn, such as a global financial crisis, could result in a variety of risks to our business, including, weakened demand for our product candidates and our ability to raise additional capital when needed on acceptable terms, if at all. A weak or declining economy could also strain our suppliers, possibly resulting in supply disruptions. Any of the foregoing could harm our business, and we cannot anticipate all of the ways in which the current economic climate and financial market conditions could adversely impact our business.

We or the third parties upon whom we depend may be adversely affected by natural disasters, and our business continuity and disaster recovery plans may not adequately protect us from a serious disaster.

Natural disasters could severely disrupt our operations and have a material adverse effect on our business, results of operations, financial condition and prospects. For example, our corporate headquarters are located in the San Francisco Bay Area, which has experienced both severe earthquakes and the effects of wildfires. We do not carry earthquake insurance. If an earthquake, wildfire, other natural disaster, power outage or other event occurred that prevented us from using all or a significant portion of our headquarters, that damaged critical infrastructure or that otherwise disrupted operations, it may be difficult or, in certain cases, impossible for us to continue our business for a substantial period of time. The disaster recovery and business continuity plans we have in place may prove inadequate in the event of a serious disaster or similar event. We may incur substantial expenses as a result of the limited nature of our disaster recovery and business continuity plans, which could have a material adverse effect on our business.

Our employees, principal investigators, CROs and consultants may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements and insider trading.

We are exposed to the risk of fraud or other misconduct by our employees, principal investigators, consultants and commercial partners. Misconduct by these parties could include intentional failures to comply with the regulations of FDA and non-U.S. regulators, provide accurate information to the FDA and non-U.S. regulators, comply with healthcare fraud and abuse laws and regulations in the United States and abroad, report financial information or data accurately or disclose unauthorized activities to us. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Such misconduct could also involve the improper use of information obtained in the course of clinical studies, which could result in regulatory sanctions and cause serious harm to our reputation. We have adopted a code of ethics, but it is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant fines or other sanctions.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds

Sales of Unregistered Securities

None.

Use of Proceeds from Registered Securities

None.

Item 3. Defaults Upon Senior Securities

None.

Item 4. Mine Safety Disclosures

None.

Item 5. Other Information

None.

Item 6. Exhibits

The following exhibits are filed herewith and this list is intended to constitute the exhibit index.

Exhibit Number	Description
31.1	Certification of Principal Executive Officer Pursuant to Rule 13-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934 as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
31.2	Certification of Principal Financial Officer Pursuant to Rule 13-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934 as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32.1	Certification of Principal Executive Officer and Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema Document
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	XBRL Taxonomy Extension Label Linkbase Document
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) 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 on.

Date: May 17, 2021 By: /s/ Jeffrey F. Biunno

Jeffrey F. Biunno
Chief Financial Officer, Treasurer and Secretary
(Principal Financial Officer)

EXHIBIT 31.1

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Joseph Sarret, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of CohBar, 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 presented in this report;

4. The registrant's other certifying officer and I 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 general 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 financial 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.

5. The registrant’s other certifying officer and I 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 involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

May 17, 2021
Date

By: /s/ Joseph Sarret
Joseph Sarret
Chief Executive Officer
(Principal Executive Officer)

EXHIBIT 31.2

CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Jeffrey F. Biunno, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of CohBar, 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 presented in this report;

4. The registrant's other certifying officer and I 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 general 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 financial 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.

5. The registrant's other certifying officer and I 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 involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

May 17, 2021
Date

By: /s/ Jeffrey F. Biunno
Jeffrey F. Biunno
Chief Financial Officer
(Principal Financial Officer)

EXHIBIT 32.1

CERTIFICATION PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002
(Subsection (a) and (b) of Section 1350, Chapter 63 of Title 18, United States Code)

Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (Subsections (a) and (b) of Section 1350, Chapter 63 of Title 18, United States Code), the undersigned officers of CohBar, Inc., a Delaware corporation (the "Company"), do hereby certify that:

1. To our knowledge, the Quarterly Report on Form 10-Q for the quarter ended March 31, 2021 (the "Form 10-Q") of the Company fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

2. The information contained in the Form 10-Q fairly presents, in all material respects, the financial condition and results of operations of the Company.

May 17, 2021
Date

By: /s/ Joseph Sarret
Joseph Sarret
Chief Executive Officer
(Principal Executive Officer)

May 17, 2021
Date

By: /s/ Jeffrey F. Biunno
Jeffrey F. Biunno
Chief Financial Officer
(Principal Financial and Accounting Officer)