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

FORM 10-Q

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

For the quarterly period ended June 30, 2022

☐ 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 August 10, 2022, the registrant had outstanding 87,149,822 shares of common stock.

COHBAR, INC.
FORM 10-Q
For the Quarterly Period Ended June 30, 2022

PART I. FINANCIAL INFORMATION

Item 1. Financial Statements

CohBar, Inc.
Condensed Balance Sheets

	As of	
	June 30, 2022 (unaudited)	December 31, 2021
ASSETS		
Current assets:		
Cash and cash equivalents	$ 2,878,147	$ 4,992,145
Investments	17,219,179	21,253,866
Vendor receivable	-	173,499
Prepaid expenses and other current assets	1,068,133	527,380
Total current assets	21,165,459	26,946,890
Property and equipment, net	196,181	260,612
Intangible assets, net	18,696	19,309
Other assets	76,596	69,620
Total assets	$ 21,456,932	$ 27,296,431
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 308,605	$ 371,993
Accrued liabilities	76,666	196,020
Accrued payroll and other compensation	358,572	754,314
Note payable, net of debt discount and offering costs of $0 and $8,723 as of June 30, 2022 and December 31, 2021, respectively	-	366,277
Total liabilities	743,843	1,688,604
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, $0.001 par value, Authorized 5,000,000 shares; No shares issued and outstanding as of June 30, 2022 and December 31, 2021, respectively	-	-
Common stock, $0.001 par value, Authorized 180,000,000 shares; Issued and outstanding 86,981,684 shares as of June 30, 2022 and 86,339,567 as of December 31, 2021	86,982	86,340
Additional paid-in capital	111,346,910	110,255,549
Accumulated deficit	(90,720,803)	(84,734,062)
Total stockholders' equity	20,713,089	25,607,827
Total liabilities and stockholders' equity	$ 21,456,932	$ 27,296,431

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

CohBar, Inc.
Condensed Statements of Operations
(unaudited)

	For The Three Months Ended June 30,		For The Six Months Ended June 30,	
	2022	2021	2022	2021
Revenues	$ -	$ -	$ -	$ -
Operating expenses:				

Research and development	1,186,900	2,617,675	2,693,208	5,272,447
General and administrative	1,556,785	2,584,364	3,301,703	3,943,043
Total operating expenses	2,743,685	5,202,039	5,994,911	9,215,490
Operating loss	(2,743,685)	(5,202,039)	(5,994,911)	(9,215,490)
Other income (expense):				
Interest income	18,717	(33)	18,717	3,140
Interest expense	-	(10,425)	(1,824)	(24,985)
Amortization of debt discount and offering costs	-	(10,868)	(8,723)	(24,374)
Total other income (expense)	18,717	(21,326)	8,170	(46,219)
Net loss	$ (2,724,968)	$ (5,223,365)	$ (5,986,741)	$ (9,261,709)
Basic and diluted net loss per share	$ (0.03)	$ (0.08)	$ (0.07)	$ (0.15)
Weighted average common shares outstanding - basic and diluted	86,981,684	61,860,023	86,854,721	61,710,979

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

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

	Three and Six Month Periods Ended June 30, 2022				
	Common Stock		Additional Paid-in-	Accumulated	Total Stockholders'
	Number	Amount	Captial	Deficit	Equity
Balance, December 31, 2021	**86,339,567**	**$ 86,340**	**$ 110,255,549**	**$ (84,734,062)**	**$ 25,607,827**
Stock-based compensation	-	-	456,423	-	456,423
Sale of common stock in ATM, net	642,117	642	199,982	-	200,624
Net loss	-	-	-	(3,261,773)	(3,261,773)
Balance, March 31, 2022	**86,981,684**	**$ 86,982**	**$ 110,911,954**	**$ (87,995,835)**	**$ 23,003,101**
Stock-based compensation	-	-	434,956	-	434,956
Net loss	-	-	-	(2,724,968)	(2,724,968)
Balance, June 30, 2022	**86,981,684**	**$ 86,982**	**$ 111,346,910**	**$ (90,720,803)**	**$ 20,713,089**

	Three and Six Month Periods Ended June 30, 2021				
	Common Stock		Additional Paid-in-	Accumulated	Total Stockholders'
	Number	Amount	Captial	Deficit	Equity
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**
Stock-based compensation	-	-	957,558	-	957,558
Sale of common stock, net	481,102	481	621,341	-	621,822
Net loss	-	-	-	(5,223,365)	(5,223,365)
Balance, June 30, 2021	**62,269,427**	**$ 62,269**	**$ 90,609,379**	**$ (78,519,995)**	**$ 12,151,653**

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

CohBar, Inc.
Statements of Cash Flows
(unaudited)

	For The Six Months Ended June 30,	
	2022	2021
Cash flows from operating activities:		
Net loss	$ (5,986,741)	$ (9,261,709)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	65,044	72,864
Stock-based compensation	891,379	1,278,002
Amortization of debt discount	8,350	23,339
Amortization of debt issuance costs	373	1,035
Discount on investments	36,687	(1,961)
Changes in operating assets and liabilities:		

Vendor receivable	173,499	-
Prepaid expenses and other current assets	(540,753)	(632,156)
Accounts payable	(63,388)	1,130,810
Accrued liabilities	(119,354)	(955,720)
Accrued payroll and other compensation	(395,742)	(121,518)
Net cash used in operating activities	(5,930,646)	(8,467,014)
Cash flows from investing activities:		
Purchases of property and equipment	-	(6,398)
Payment for security deposit	(6,976)	(2,217)
Purchases of investments	(34,140,000)	(18,251,000)
Proceeds from redemptions of investments	38,138,000	24,152,000
Net cash provided by investing activities	3,991,024	5,892,385
Cash flows from financing activities:		
Proceeds from the At-the-Market Offering, net	200,624	621,822
Proceeds from exercise of warrants	-	67,536
Repayment of promissory notes	(375,000)	(365,000)
Proceeds from exercise of employee stock options	-	958,847
Net cash (used in) provided by financing activities	(174,376)	1,283,205
Net decrease in cash and cash equivalents	(2,113,998)	(1,291,424)
Cash and cash equivalents at beginning of period	4,992,145	2,894,575
Cash and cash equivalents at end of period	$ 2,878,147	$ 1,603,151
Supplemental disclosure of cash flow information:		
Cash paid for income taxes	$ -	$ 1,332
Cash paid for interest	$ 114,411	$ 89,908

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 leveraging the power of the mitochondria and the peptides encoded in its genome to develop potential breakthrough therapeutics targeting chronic and age-related diseases with limited to no treatment options.

The Company's primary activities include utilizing its MITO+ platform to identify and develop novel peptide analogs, the research and development of its 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 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, 2021, included in the Company's Annual Report on Form 10-K (the "2021 Form 10-K"), filed with the SEC on March 29, 2022. The interim unaudited condensed financial statements should be read in conjunction with those audited financial statements included in the 2021 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 and six month periods ended June 30, 2022 are not necessarily indicative of the results that may be expected for the year ending December 31, 2022, or any other period.

Note 2 – Liquidity and Management's Plans

As of June 30, 2022, the Company had working capital and stockholders' equity of $20.4 million and $20.7 million, respectively. During the six months ended June 30, 2022, the Company incurred a net loss of $6.0 million and utilized cash of $5.9 million in its operating activities. Based on the cash and investments on hand as of June 30, 2022 of approximately $20.1 million, current budget assumptions and projected cash burn, the Company believes that it has sufficient capital to meet its operating expenses and obligations for the next twelve months from the date of this filing. However, if unanticipated difficulties or circumstances arise, the Company may require additional capital sooner to support its operations. 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 the Company's activities would allow it 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 June 30, 2022 and December 31, 2021 consist of U.S. Treasury Bills, which are classified as held-to-maturity, totaling $17.2 million and $21.3 million, 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 June 30, 2022 and December 31, 2021, 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) provided 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 June 30, 2022 and December 31, 2021.

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 accounts for performance-based share payments by measuring the fair value of the grant when the performance criteria are deemed satisfied and recognizing the associated expense at that time. The Company has granted stock options at exercise prices equal to the closing price of the Company's common stock as reported by The Nasdaq Capital Market, 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. 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 June 30,		For the Six Months Ended June 30,	
	2022	2021	2022	2021
Expected life	N/A	6.25 years	6.25 years	6.25 years
Risk free interest rate	N/A	1.06%	1.47%	1.06%
Expected volatility	N/A	91%	92%	91%
Expected dividend yield	N/A	0%	0%	0%
Forfeiture rate	N/A	0%	0%	0%

As of June 30, 2022, total unrecognized stock option compensation expense was $5.0 million, 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.

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

Note 3 - Summary of Significant Accounting Policies (continued)

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 as of June 30, 2022 and 2021:

	As of June 30,	
	2022	**2021**
Options	9,776,252	10,944,413
Warrants	35,475,075	19,368,918
Totals	45,251,327	30,313,331

Recent Accounting Pronouncements

There were no recently issued accounting standards not yet adopted which would have a material effect on the Company's consolidated financial statements or related disclosures.

Note 4 - 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 2022.

Rent expense was $0.1 million for each of the three-month periods ended June 30, 2022 and 2021. Rent expense was $0.2 million for each of the six-month periods ended June 30, 2022 and 2021.

Note 5 - Stockholders' Equity

Authorized Capital

The Company has authorized the issuance and sale of up to 185.0 million shares of stock, consisting of 180.0 million shares of common stock having a par value of $0.001 and 5.0 million shares of Preferred Stock having a par value of $0.001 per share. As of June 30, 2022 and December 31, 2021, 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.

At the Company's annual meeting of stockholders in June 2022, the stockholders approved an amendment to the Company's certificate of incorporation to effect a reverse stock split by a ratio not to exceed 1:30, with the exact ratio to be set by the Company's board of directors in its sole discretion, and approved an amendment to the Company's certificate of incorporation to effectively increase the number of authorized shares of common stock of the Company.

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

Note 5 - Stockholders' Equity (continued)

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 June 30, 2022, there were 4.4 million shares remaining available for issuance under the 2011 Plan.

During the six months ended June 30, 2022, stock options to purchase 0.4 million shares of common stock were granted at an exercise price of $0.43 per share. The stock options have a term of ten years and are subject to vesting based on continuous service of the awardee over a period of four years. The stock options have an aggregate grant date fair value of $0.1 million.

During the six months ended June 30, 2022, stock options to purchase 1.6 million 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 June 30,		For the Six Months Ended June 30,	
	2022	2021	2022	2021
Research and development	$ 17,601	$ 119,627	$ 46,409	$ 176,730
General and administrative	417,355	837,931	844,970	1,101,272
Total	$ 434,956	$ 957,558	$ 891,379	$ 1,278,002

The following table represents stock option activity for the six months ended June 30, 2022:

	Stock Options		Weighted Average Exercise Price		Fair Value	Contractual	Aggregate
	Outstanding	Exercisable	Outstanding	Exercisable	Vested	Life (Years)	Intrinsic Value
Balance – December 31, 2021	10,992,335	6,126,901	$ 1.71	$ 1.58	$ 1.58	6.27	$ -
Granted	375,000	-	-	-	-	-	-
Exercised	-	-	-	-	-	-	-
Cancelled	(1,591,083)	-	-	-	-	-	-
Balance – June 30, 2022	9,776,252	5,579,545	$ 1.64	$ 1.46	$ 1.46	6.26	$ -

Note 5 - Stockholders' Equity (continued)

The following table summarizes information on stock options outstanding and exercisable as of June 30, 2022:

Grant Price		Weighted Average	Total	Number	Weighted Average Remaining
From	To	Exercise Price	Outstanding	Exercisable	Contractual Term
$ 0.26	$ 2.02	$ 1.17	7,923,085	3,830,440	7.65 years
$ 2.10	$ 4.60	$ 2.74	1,410,167	1,306,105	5.71 years
$ 5.30	$ 8.86	$ 6.44	443,000	443,000	5.85 years
		Totals	**9,776,252**	**5,579,545**	

WARRANTS

During the six months ended June 30, 2022, warrants to purchase0.2 million shares of common stock expired and were cancelled.

The following table summarizes information on warrants outstanding as of June 30, 2022:

	Warrants		Weighted Average Exercise Price		Fair Value	Contractual Life	Aggregate Intrinsic
	Outstanding	Exercisable	Outstanding	Exercisable	Vested	(Years)	Value
Balance – December 31, 2021	35,634,075	35,629,908	$ 1.04	$ 1.04	$ 0.53	4.38	$ -
Granted	-	-	-	-	-	-	-
Exercised	-	-	-	-	-	-	-
Cancelled	(159,000)	-	-	-	-	-	-
Balance – June 30, 2022	35,475,075	35,475,075	$ 1.03	$ 1.03	$ 0.61	3.90	$ -

Note 6 – At-the-Market Offering

In May 2020, the Company entered into an At-the-Market Offering Sales Agreement (the "ATM") with Virtu Americas, LLC as sales agent. During the six months ended June 30, 2022, the Company sold 0.6 million shares of its common stock under the ATM program for proceeds of $0.2 million, net of commissions.

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 June 30,		For the Six Months Ended June 30,	
	2022	2021	2022	2021
Operating expenses:				
Stock-based compensation	$ 434,956	$ 957,558	$ 891,379	$ 1,278,002
Depreciation & amortization	32,244	36,179	65,044	72,864
Subtotal	$ 467,200	$ 993,737	$ 956,423	$ 1,350,866
Other expense:				

Amortization of debt discount	-	10,407	8,350	23,339
Subtotal	$ -	$ 10,407	$ 8,350	$ 23,339
Total non-cash expenses	$ 467,200	$ 1,004,144	$ 964,773	$ 1,374,205

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

Note 8 – Promissory Notes

During the six months ended June 30, 2022, the Company repaid a promissory note, held by a director of the Company, totaling $0.5 million in principal and interest.

During the six months ended June 30, 2021, the Company paid $0.1 million in principal and interest for two promissory notes that matured.

Note 9 – 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 June 30, 2022, the Company granted stock options to purchase a total of 0.2 million shares of the Company's common stock with an exercise price of $0.197 per share. The stock options have a term of ten years with vesting over a four-year period.

Subsequent to June 30, 2022, the Company issued 168,138 shares of common stock at a price of $0.1488 per share pursuant to its Employee Stock Purchase Plan (the "ESPP"). Two officers of the Company participated in the ESPP.

Subsequent to June 30, 2022, warrants to purchase 130,000 shares of the Company's common stock expired.

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, 2021 (the "2021 Form 10-K"). All references to the second quarter mean the three-month period ended June 30, 2022, and all references to the first six months of 2022 and 2021 mean the six-month periods ended June 30, 2022 and 2021, respectively. 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 2021 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 leveraging the power of the mitochondria and the peptides encoded in its genome to develop potential breakthrough therapeutics targeting chronic and age-related diseases with limited to no treatment options. Our novel approach is built on the key insights of our founders that certain mitochondrially encoded peptides produce effects that are not limited to local regulation within the mitochondria and may have important roles to play in critical systemic biological pathways. Many of these effects are quite distinct from traditional mitochondrial function such as energy production and metabolism, involving diverse processes including inflammation, fibrosis and cell signaling.

We believe we have achieved a leading position in exploring the mitochondrial genome and its utility for the development of novel therapeutics, including world-renowned expertise in mitochondrial biology, a broad intellectual property estate with more than 65 patent applications filed, key opinion leaders and disciplined drug discovery and development processes. Our proprietary processes of identifying nucleic acid sequences encoding native peptides in the mitochondrial genome, developing and optimizing novel analogs of these natural mitochondrial derived peptides ("MDPs"), as well as developing and conducting proprietary screens to identify and characterize the activities of these peptides are referred to as our Mito+ platform. We are using our Mito+ platform to identify and develop novel modified versions of natural peptides, which we call analogs, to treat a variety of serious conditions, with a focus on chronic diseases involving inflammation and fibrosis. We believe that the mitochondrial genome may be transformative in the field of drug discovery and that our novel peptide analogs may become a new and major class of drugs with broad therapeutic application. We are currently advancing a pipeline of novel peptide analogs through varying stages of development: CB5138-3 for idiopathic pulmonary fibrosis ("IPF"), CB4211 for the treatment of nonalcoholic steatohepatitis ("NASH") and obesity, and several preclinical and discovery-stage programs.

Our Programs

- ***CB5138-3****:* In 2021, we nominated our second clinical candidate, CB5138-3, a first-in-class therapeutic under development for the treatment of idiopathic pulmonary fibrosis and other fibrotic diseases. Our CB5138-3 product candidate has shown positive preclinical results, with significant anti-fibrotic and anti-inflammatory properties in models of IPF. In addition, we believe CB5138-3 has the potential to provide a better safety and tolerability profile than currently approved IPF drugs, which are poorly tolerated with significant gastrointestinal and/or skin toxicity. When combined with our promising preclinical data, we believe CB5138-3 could provide important clinical and commercial advantages over current standard of care. This program is currently in IND-enabling studies. To date, we have not seen any notable systemic toxicity in rodent or non-human primate studies. Due to additional planned formulation work, we plan to file an Investigational New Drug ("IND") Application in the second half of 2023 and begin a first-in-human study shortly thereafter.

- ***CB4211:*** Our most advanced clinical candidate, CB4211, is a first-in-class therapeutic under development for the treatment of NASH and obesity. In August 2021, we released positive topline data from our Phase 1a/1b clinical study of CB4211. The Phase 1b stage of this study was designed to assess the safety, tolerability, and activity of CB4211 in obese subjects with nonalcoholic fatty liver disease. The study met its primary endpoint as CB4211 was well-tolerated and appeared safe with no serious adverse events. The evaluation of the exploratory endpoints in the Phase 1b portion of the trial showed significant reductions from baseline in key biomarkers of liver damage, ALT and AST, and in glucose levels in the CB4211 group compared to placebo after four weeks of treatment, with a trend towards lower body weight. We believe the positive clinical data from our CB4211 trial is an important validation of our overall approach to drug discovery, serving as a proof point that novel analogs of peptides encoded in the mitochondrial genome can impact systemic biological pathways in humans while having an attractive safety and tolerability profile. We have been working to further improve the formulation for CB4211 and intend to partner this program before moving forward into further clinical trials.

- ***CB5064 Analogs*****:** Our discovery efforts have identified CB5064 Analogs, a family of peptides that are agonists of the apelin receptor. By utilizing the protective apelin signaling pathway, our CB5064 Analogs have the potential to address a variety of unmet medical needs such as our initial target of Acute Respiratory Distress Syndrome ("ARDS"). We believe our CB5064 Analogs could be effective in ARDS from a variety of different causes, such as bacterial or viral pneumonia, including COVID-19 associated ARDS. In a preclinical mouse model of ARDS, 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.

- ***Discovery Efforts:*** Our discovery efforts have resulted in the identification of multiple unique and previously unidentified peptides encoded within the mitochondrial genome. Many of these natural sequences and their novel analogs have demonstrated various degrees of biological activity in cell based and/or animal models relevant to a wide range of diseases. Our research efforts have identified and focused on certain of these novel analogs that have demonstrated greatest therapeutic potential. We plan to further explore these peptide families for the potential treatment of a variety of diseases, subject to resource availability and the requirements of our more-advanced programs.

Business Overview

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 June 30, 2022, our operations have been funded with an aggregate of approximately $97.3 million from the sale and issuance of equity instruments and debt.

Since inception, we have incurred significant operating losses. Our net losses were $6.0 million and $9.3 million for the six months ended June 30, 2022 and 2021, respectively. We incurred $1.0 million and $1.4 million in non-cash expenses during the six months ended June 30, 2022 and 2021, respectively. Our net losses excluding non-cash expenses were $5.0 million and approximately $7.9 million for the six months ended June 30, 2022 and 2021, respectively. As of June 30, 2022, we had an accumulated deficit of $90.7 million. Although we anticipate incurring expenses consistent with prior periods, our net losses may fluctuate significantly from quarter to quarter and from year to year and are subject to the ongoing COVID-19 pandemic, the timing of our clinical trial expenses 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 MDP and proprietary analog test materials; and
- depreciation and other personnel-related costs associated with research and product development.

We record all research and development expenses as incurred.

Our Research Programs

Our research and development programs include activities in support of our continuing evaluation of CB5138-3 in IPF and CB4211 in NASH and obesity, as well as the operation of our platform technology related to the discovery and development of additional novel analogs, evaluation of newly discovered natural sequences, design of novel improved analogs, evaluation of their therapeutic potential and optimization of their characteristics as potential 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 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 we incur costs related to our IND-enabling studies and potential initial clinical costs for our CB5138-3 program in addition to general program costs and the discovery, evaluation and optimization of novel analogs as potential drug candidates. 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 remain relatively constant in the year ending December 31, 2022.

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 June 30,		Change	
	2022	2021	$	%
Operating expenses:				
Research and development	$ 1,186,900	$ 2,617,675	$ (1,430,775)	-55%
General and administrative	1,556,785	2,584,364	(1,027,579)	-40%
Total operating expenses	$ 2,743,685	$ 5,202,039	$ (2,458,354)	-47%

Comparison of Three Months Ended June 30, 2022 and 2021

Research and development expenses were $1.2 million in the three months ended June 30, 2022 compared to $2.6 million in the prior year period, a decrease of $1.4 million, or 55%. The decrease in research and development expenses was primarily due to a decrease of $0.7 million associated with the timing of our research programs focused on continuing the development of our peptides and a $0.7 million decrease in clinical trial costs due to the timing of those expenses.

General and administrative expenses were $1.6 million in the three months ended June 30, 2022 compared to $2.6 million in the prior year period, a decrease of $1.0 million, or 40%. The decrease in general and administrative expenses was primarily due to a $0.9 million decrease in compensation costs and stock-based compensation costs primarily related to the departure of our former CEO in the prior year period.

	For The Six Months Ended June 30,		Change	
	2022	2021	$	%
Operating expenses:				
Research and development	$ 2,693,208	$ 5,272,447	$ (2,579,239)	-49%
General and administrative	3,301,703	3,943,043	(641,340)	-16%
Total operating expenses	$ 5,994,911	$ 9,215,490	$ (3,220,579)	-35%

Comparison of Six Months Ended June 30, 2022 and 2021

Research and development expenses were $2.7 million in the six months ended June 30, 2022 compared to $5.3 million in the prior year period, a decrease of $2.6

million, or 49%. The decrease in research and development expenses was primarily due to a decrease of $1.6 million associated with the timing of our research programs focused on continuing the development of our peptides and a $1.0 million decrease in clinical trial costs due to the timing of those expenses. Though we expect research and development expenses to increase in the coming quarters as we incur the costs of the IND-enabling activities and clinical trial for CB5138-3, and continue evaluating and optimizing other potential 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 $3.3 million in the six months ended June 30, 2022 compared to $3.9 million in the prior year period, a decrease of $0.6 million, or 16%. The decrease in general and administrative expenses was primarily due to $0.6 million decrease in compensation costs and stock-based compensation costs primarily due to the departure of our former CEO in the prior year period.

Liquidity and Capital Resources

As of June 30, 2022, we had cash, cash equivalents and investments totaling $20.1 million. We maintain our cash in a checking and savings account on deposit with a banking institution in the United States.

On May 27, 2020, we entered into an At-the-Market Offering Sales Agreement (the "ATM") with Virtu Americas, LLC, as sales agent. In connection with the ATM, we filed a prospectus supplement on March 29, 2022, pursuant to which we may currently sell shares of common stock with an aggregate offering price of up to $5.0 million.

During the six months ended June 30, 2022, we sold 0.6 million shares of our common stock under our ATM program for proceeds of $0.2 million, net of commissions.

As of June 30, 2022, we had working capital and stockholders' equity of $20.4 million and $20.7 million, respectively. During the six months ended June 30, 2022, we incurred a net loss of $6.0 million. Based on cash and investments on hand as of June 30, 2022 of approximately $20.1 million and our projected cash burn, we believe that we have sufficient capital to meet our operating expenses and obligations for the next twelve months from the date of this filing. However, if unanticipated difficulties or circumstances arise, we may require additional capital sooner to support our operations. 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 would 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 six months ended June 30, 2022 and 2021 was $5.9 million and $8.5 million, respectively. The cash used in operations for the six months ended June 30, 2022 was primarily due to our reported net loss of $6.0 million. The cash used in operations for the six months ended June 30, 2021 was primarily due to our reported net loss of $9.3 million, partially offset by an increase in accounts payable of $1.1 million due to the timing of invoices received during the quarter.

Cash Flows from Investing Activities

Net cash provided by investing activities was $4.0 million in the six months ended June 30, 2022 and was primarily due to the redemptions of investments during the period. Net cash provided by investing activities was $5.9 million in the six months ended June 30, 2021 and was primarily due to the redemptions of investments during the period.

Cash Flows from Financing Activities

Net cash used in and provided by financing activities in the six months ended June 30, 2022 and 2021 was $0.2 million and $1.3 million, respectively. Cash used in financing activities in the six months ended June 30, 2022 was due to the repayment of promissory notes partially offset by the proceeds received from sales under our ATM program. Cash provided by financing activities in the six months ended June 30, 2021 was due to proceeds received from the sales of common stock under our ATM program and the exercise of stock options and warrants partially offset by the repayment of promissory notes.

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 2022.

Rent expense was $0.1 million for each of the three-month periods ended June 30, 2022 and 2021. Rent expense was $0.2 million for each of the six-month periods ended June 30, 2022 and 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 June 30, 2022 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

Item 1. Legal Proceedings

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:

- we are an early-stage biotechnology company and may never be able to successfully develop marketable products or generate any revenue. We have a 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 have had a history of losses and no revenue;
- the outbreak of SARS-CoV-2, which causes COVID-19, and the ongoing COVID-19 pandemic, could adversely impact our business, including our clinical trials and preclinical studies;
- 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 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;
- we may not be successful in our efforts to develop commercially viable formulations for our product 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; and
- 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.

We operate 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

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 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 our novel analogs and progressing our most advanced drug candidate into and through clinical studies. We have not generated any revenues to date. All of our novel peptide analogs 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 novel peptide analogs will ever be approved by the FDA. Typically, it takes 10 to 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.

The outbreak of SARS-CoV-2, which causes COVID-19, and the ongoing COVID-19 pandemic, 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 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. These and any additional delays in our clinical trials 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;
- 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;
- delays in the ability to initiate certain preclinical studies in a timely fashion due to shortages in the availability of suitable animals for such studies;
- 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 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;
- 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, including rising interest rates and inflation. As COVID-19 transitions from a pandemic to an endemic disease, we are uncertain about its ongoing effect on both domestic and worldwide economic activity, which may continue to be unpredictable. 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 emergence of novel variants of SARS-CoV-2, the impact of vaccinations and vaccination rates, 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. For example, primarily due to COVID-19 related restrictions and disruption, we have experienced delays in shipping raw materials to our partners in China, which has delayed certain of our investigational new drug application-enabling activities.

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 our novel peptide analogs in non-clinical studies, as well as in clinical trials. Non-clinical studies involve testing potential drug candidates 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, our Phase 1a/1b trial of CB4211, our most advanced drug candidate, involved, and we expect that our other early clinical trials will involve, small patient populations. Because of these small sample sizes, the results of these early clinical trials, including the topline data from our CB4211 Phase 1a/1b trial, may not be indicative of future results.

Risks Related to Discovery, Development and Commercialization

If 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 planned or future clinical trials that will cause regulatory agencies, institutional review boards, or us to suspend or delay a trial. For example, in November 2018, we announced the temporary suspension of the Phase 1a/1b clinical trial for CB4211 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 this trial due to 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. While we announced the resumption of our Phase 1b study in July 2020, our clinical activities could be delayed again in the future. Additionally, the FDA's review of any prior or future submissions related to completed, ongoing, or planned clinical trials of our product candidates, or future information requests from the FDA could result in the delay or suspension of any ongoing or planned clinical trials 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 timely performance by our contract research organizations ("CROs") and other vendors, positive clinical and preclinical results, our ability to develop commercially viable formulations for our product candidates, the addition of a corporate partner for our 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 biopharmaceutical 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 and Chief Financial Officer who are 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, Kenneth Cundy resigned from his role of Chief Scientific Officer effective March 31, 2022. Any changes in business strategies can create uncertainty, may negatively impact our ability to execute our business strategy quickly and effectively and may ultimately be unsuccessful. The impact of hiring new executives may not be immediately realized.

We rely on 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. In addition, 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.

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 biopharmaceutical companies in connection with the development or commercialization of our potential drug candidates. For example, we intend to partner CB4211 before moving this program forward into further clinical trials. There is no guarantee that we will be able to establish a partnership for the CB4211 program on favorable terms, if at all. If we are unable to establish such a partnership, our CB4211 program may be delayed or terminated, which may cause our stock price to decline or otherwise result in adverse effects on our business.

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 reimbursement rates for such product candidates, 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 biopharmaceutical 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 and novel analogs 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 novel peptide analogs 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;

- we may not be able to identify the mechanism of action for potential drug candidates, which may make it more difficult to develop and commercialize such drug candidates due to the potential desire of the FDA and other regulatory bodies, potential partners, physicians and patients to understand such mechanism of action; 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, properties that make them difficult or impossible to formulate in a commercial fashion, 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 progress our most advanced drug candidate through clinical development or identify other novel peptide analogs that are suitable for preclinical and clinical development, we will not be able to generate 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.

We may not be successful in our efforts to develop commercially viable formulations for our product candidates.

Our product candidates are comprised of novel peptide analogs. We expect that our product candidates will need to be delivered via subcutaneous injection and may cause local injection site reactions ("ISRs"), which is a common finding in peptide therapeutic product candidates. While not necessarily adverse to patients' health, ISRs could substantially limit the commercial appeal of our product candidates, and we may decide or be required to perform additional preclinical studies or to halt or delay further clinical development of our product candidates. For example, in November 2018, we announced a temporary suspension of the Phase 1a stage of our Phase 1a/1b clinical study of CB4211 to address mild, but persistent ISRs. In March 2022, we announced that we had seen ISRs at the higher dose levels in our nonhuman primate toxicology studies for CB5138-3 and were delaying the filing of our IND in that program in part to address these ISRs. It is possible that other product candidates that we identify will also result in ISRs. Our approach to address these ISRs is to develop novel formulations that decrease or eliminate these reactions. If we are unable to successfully develop such formulations, we may decide to abandon those drug candidates. Our efforts to identify alternate drug candidates that do not cause ISRs will take additional time and expense and may not be successful.

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 cost and 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 or at all, 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;

- we may not be able to develop commercially viable formulations for our potential drug candidates;
- our potential drugs may prove to be too expensive to manufacture or administer to patients;
- our potential drugs may have routes of administration that are less convenient or acceptable 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. For example, we experienced delays in receiving the data from our third-party CRO conducting our CB4211 Phase 1b study, which delayed our analysis and release of topline data.

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, or 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

Even if we are successful in developing drug candidates, we may not be able to 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, safer, 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 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 IPF, diabetes, cancer, and other diseases for which our potential product candidates may be indicated. 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 (i.e., are administered via methods other than subcutaneous injection) 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 that 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, and the results of those 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. If any of our drug candidates are used in 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 may be 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 cGMP, 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 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 drug candidates comprised of novel analogs 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 United States 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.

- There can be no assurance that any of our patent applications, including any 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 our 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 price of our common stock may be volatile and fluctuate substantially, which could result in substantial losses for holders of our common stock.

The market price of our common stock has been and is likely to continue to be volatile. The stock market in general, and the market for biotechnology companies in particular has experienced extreme volatility that has often been unrelated to the operating performance of particular companies. The market price for our common stock may be influenced by many factors, including:

- results of preclinical studies or clinical trials of our product candidates or those of our competitors:
- unanticipated or serious safety concerns related to the use of any of our product candidates;
- challenges in developing commercially viable formulations for our product candidates;
- adverse regulatory decisions, including failure to receive regulatory approval for any of our product candidates;
- the success of competitive drugs or technologies;
- regulatory or legal developments in the United States and other countries applicable to our product candidates;

- the size and growth of our prospective patient populations;
- developments concerning our collaborators, our external manufacturers or in-house manufacturing capabilities;
- inability to obtain adequate product supply for any product candidate for preclinical studies, clinical trials or future commercial sale or inability to do so at acceptable prices;
- developments or disputes concerning patent applications, issued patents or other proprietary rights;
- the recruitment or departure of key personnel;
- the level of expenses related to any of our product candidates or clinical development programs;
- the results of our efforts to discover, develop, acquire or in-license additional product candidates or drugs;
- actual or anticipated changes in estimates as to financial results, development timelines or recommendations by securities analysts or publications of research reports about us or our industry;
- variations in our financial results or those of companies that are perceived to be similar to us;
- changes in the structure of healthcare payment systems;
- market conditions in the biotechnology sector;
- our cash position or the announcement or expectation of additional financing efforts;
- the impact of inflation, including wage inflation;
- general economic, industry and market conditions; and
- other factors, including those described in this "Risk Factors" section, many of which are beyond our control.

The price of our common stock does not meet the requirements for continued listing on Nasdaq. If we fail to regain compliance with the minimum listing requirements, our common stock will be subject to delisting. Our ability to publicly or privately sell equity securities and the liquidity of our common stock could be adversely affected if our common stock is delisted.

The continued listing standards of Nasdaq require, among other things, that the minimum bid price of a listed company's stock be at or above $1.00. If the closing minimum bid price is below $1.00 for a period of more than 30 consecutive trading days, the listed company will fail to be in compliance with Nasdaq's listing rules and, if it does not regain compliance within the grace period, will be subject to delisting. As previously reported, on November 10, 2021, we received a notice from the Nasdaq Listing Qualifications Department notifying us that for 30 consecutive trading days, the bid price of our common stock had closed below the minimum $1.00 per share requirement. In accordance with Nasdaq's listing rules, we were afforded a grace period of 180 calendar days, or until May 9, 2022, to regain compliance with the bid price requirement. In order to regain compliance, the bid price of our common stock must close at a price of at least $1.00 per share for a minimum of 10 consecutive trading days.

On May 10, 2022, Nasdaq notified us that we did not regain compliance by May 9, 2022, but that Nasdaq had granted us an additional 180 day period to regain compliance because we met the continued listing requirement for market value of publicly held shares and all other applicable Nasdaq listing requirements (other than the minimum closing bid price requirement) and we provided written notice to Nasdaq of our intention to cure the deficiency during the second compliance period, by effecting a reverse stock split, if necessary. Pursuant to the May 10, 2022 letter from Nasdaq and additional grace period granted thereby, we now have until November 7, 2022 to regain compliance with Nasdaq's $1.00 minimum bid requirement. At our 2022 annual meeting of stockholders held on June 15, 2022, our stockholders approved, among other things, an amendment to our certificate of incorporation to effect a reverse stock split by a ratio not to exceed 1-for-30. Our board of directors may effect such amendment and reverse stock split, in its sole discretion and at a ratio set at its sole discretion, at any time prior to our annual meeting of stockholders in 2023 and intends to effect the amendment and reverse stock split prior to November 7, 2022.

We cannot provide any guarantee that we will regain compliance during the grace period or be able to maintain compliance with Nasdaq's listing requirements in the future. If we are not able to regain compliance during the grace period, or any extension of the grace period for which we may be eligible, our common stock will be subject to delisting. Delisting from Nasdaq could adversely affect our ability to raise additional financing through the public or private sale of equity securities, would significantly affect the ability of investors to trade our securities and would negatively affect the value and liquidity of our common stock. Delisting could also have other negative results, including the potential loss of confidence by employees, the loss of institutional investor interest and fewer business development opportunities.

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 Nasdaq 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, rules regarding the diversity of our board of directors 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 Nasdaq or another stock exchange could be adversely affected.

We are also subject to more stringent state law requirements. For example, under California law Senate Bill 826 ("SB 826") we were required to have at least three female directors on our board of directors and under California law Assembly Bill 979 ("AB 979") we were required to have one director from an "underrepresented community" starting December 31, 2021, and will be required to have two additional directors from an "underrepresented community" starting 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. On April 1, 2022, the Los Angeles Superior Court declared AB 979 unconstitutional and on May 13, 2022, declared SB 826 unconstitutional. Although it is unclear whether these decisions may be appealed, the State of California is currently precluded from enforcing AB 979 and SB 826. However, in the event these decisions are appealed and the requirements are enforceable, 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 common stock.

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

New U.S. legislation or regulations that 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 that 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 and the recent and ongoing armed conflict in Ukraine may have similar impacts on the global financial 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. In addition, the long-term effects of climate change on general economic conditions and the biopharmaceutical industry in particular are unclear, and may heighten or intensify existing risk of natural disasters. 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, directors, 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, directors, 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 or director 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	Inline XBRL Instance Document
101.SCH	Inline XBRL Taxonomy Extension Schema Document
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104	Cover Page Interactive Data File (formatted as Inline XBRL, and contained in Exhibit 101)

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: August 15, 2022

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.

August 15, 2022
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.

August 15, 2022
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 June 30, 2022 (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.

August 15, 2022
Date

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

August 15, 2022
Date

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