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

**FORM 10-Q**

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

For the quarterly period ended March 31, 2023

☐ 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 1308**
**Menlo Park, CA 94025**
(*Address of principal executive offices) (Zip Code)*

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

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

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

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

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

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

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

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

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

As of May 11, 2023, the registrant had outstanding 2,906,926 shares of common stock.

**COHBAR, INC.**
**FORM 10-Q**
**For the Quarterly Period Ended March 31, 2023**

## PART I. FINANCIAL INFORMATION

### Item 1. Financial Statements

**CohBar, Inc.**
**Balance Sheets**

| | As of | |
|---|---|---|
| | March 31, 2023 (unaudited) | December 31, 2022 |
| **ASSETS** | | |
| **Current assets:** | | |
| Cash and cash equivalents | $ 5,392,390 | $ 5,930,731 |
| Investments | 8,688,947 | 9,806,591 |
| Vendor receivable | - | 27,500 |
| Prepaid expenses and other current assets | 237,300 | 453,681 |
| Total current assets | 14,318,637 | 16,218,503 |
| Property and equipment, net | 2,335 | 65,509 |
| Intangible assets, net | 17,776 | 18,083 |
| Other assets | 63,572 | 63,572 |
| Total assets | $ 14,402,320 | $ 16,365,667 |
| **LIABILITIES AND STOCKHOLDERS' EQUITY** | | |
| **Current liabilities:** | | |
| Accounts payable | $ 532,423 | $ 180,104 |
| Accrued liabilities | 49,513 | 327,868 |
| Accrued payroll and other compensation | 316,605 | 525,666 |
| Total liabilities | 898,541 | 1,033,638 |
| **Commitments and contingencies** | | |
| **Stockholders' equity:** | | |
| Preferred stock, $0.001 par value, Authorized 5,000,000 shares; No shares issued and outstanding as of March 31, 2023 and December 31, 2022, respectively | - | - |
| Common stock, $0.001 par value, Authorized 12,000,000 shares; Issued and outstanding 2,906,926 shares as of March 31, 2023 and Decemebr 31, 2022, respectively | 2,907 | 2,907 |
| Additional paid-in capital | 112,575,993 | 112,238,392 |
| Accumulated deficit | (99,075,121) | (96,909,270) |
| Total stockholders' equity | 13,503,779 | 15,332,029 |
| Total liabilities and stockholders' equity | $ 14,402,320 | $ 16,365,667 |

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



**CohBar, Inc.**
**Statements of Operations**
**(unaudited)**

| | For The Three Months Ended March 31, | |
|---|---|---|
| | 2023 | 2022 |
| **Revenues** | $ - | $ - |
| **Operating expenses:** | | |

| | | |
|---|---|---|
| Research and development | 1,020,739 | 1,506,308 |
| General and administrative | 1,279,273 | 1,744,918 |
| Total operating expenses | 2,300,012 | 3,251,226 |
| Operating loss | (2,300,012) | (3,251,226) |
| | | |
| **Other income (expense):** | | |
| Interest income | 134,161 | - |
| Interest expense | - | (1,824) |
| Amortization of debt discount and offering costs | - | (8,723) |
| Total other income (expense) | 134,161 | (10,547) |
| Net loss | $ (2,165,851) | $ (3,261,773) |
| Basic and diluted net loss per share | $ (0.75) | $ (1.13) |
| Weighted average common shares outstanding - basic and diluted | 2,906,926 | 2,890,878 |

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



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

| | Three Month Period Ended March 31, 2023 | | | | |
|---|---|---|---|---|---|
| | Common Stock | | Additional Paid-in- | Accumulated | Total Stockholders' |
| | Number | Amount | Capital | Deficit | Equity |
| **Balance, December 31, 2022** | **2,906,926** | **$ 2,907** | **$ 112,238,392** | **$ (96,909,270)** | **$ 15,332,029** |
| Stock-based compensation | - | - | 337,601 | - | 337,601 |
| Net loss | - | - | - | (2,165,851) | (2,165,851) |
| **Balance, March 31, 2023** | **2,906,926** | **$ 2,907** | **$ 112,575,993** | **$ (99,075,121)** | **$ 13,503,779** |

| | Three Month Period Ended March 31, 2022 | | | | |
|---|---|---|---|---|---|
| | Common Stock | | Additional Paid-in- | Accumulated | Total Stockholders' |
| | Number | Amount | Capital | Deficit | Equity |
| **Balance, December 31, 2021** | **2,877,986** | **$ 2,878** | **$ 110,339,011** | **$ (84,734,062)** | **$ 25,607,827** |
| Stock-based compensation | - | - | 456,423 | - | 456,423 |
| Sale of common stock in ATM, net | 21,404 | 21 | 200,603 | - | 200,624 |
| Net loss | - | - | - | (3,261,773) | (3,261,773) |
| **Balance, March 31, 2022** | **2,899,390** | **$ 2,899** | **$ 110,996,037** | **$ (87,995,835)** | **$ 23,003,101** |

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



**CohBar, Inc.**
**Statements of Cash Flows**
**(unaudited)**

| | For The Three Months Ended March 31, | |
|---|---|---|
| | 2023 | 2022 |
| **Cash flows from operating activities:** | | |
| Net loss | $ (2,165,851) | $ (3,261,773) |
| Adjustments to reconcile net loss to net cash used in operating activities: | | |
| Depreciation and amortization | 63,481 | 32,801 |
| Gain on disposal of assets | (22,975) | - |
| Stock-based compensation | 337,601 | 456,423 |
| Amortization of debt discount | - | 8,350 |
| Amortization of debt issuance costs | - | 373 |
| Discount on investments | 50,644 | 18,048 |
| Changes in operating assets and liabilities: | | |
| Vendor receivable | 27,500 | 173,499 |
| Prepaid expenses and other current assets | 216,381 | 151,999 |
| Accounts payable | 352,319 | 268,700 |
| Accrued liabilities | (278,355) | (59,235) |
| Accrued payroll and other compensation | (209,061) | (307,994) |
| **Net cash used in operating activities** | (1,628,316) | (2,518,809) |
| | | |
| **Cash flows from investing activities:** | | |
| Net proceeds from the sale of property and equipment | 22,975 | - |

| | | |
|---|---|---|
| Payment for security deposit | - | (6,976) |
| Purchases of investments | (8,773,000) | (21,983,000) |
| Proceeds from redemptions of investments | 9,840,000 | 21,255,000 |
| **Net cash provided by (used in) investing activities** | 1,089,975 | (734,976) |
| | | |
| **Cash flows from financing activities:** | | |
| Proceeds from the At-the-Market Offering, net | - | 200,624 |
| Repayment of promissory notes | - | (375,000) |
| **Net cash provided by (used in) financing activities** | - | (174,376) |
| | | |
| **Net decrease in cash and cash equivalents** | (538,341) | (3,428,161) |
| **Cash and cash equivalents at beginning of period** | 5,930,731 | 4,992,145 |
| **Cash and cash equivalents at end of period** | $ 5,392,390 | $ 1,563,984 |
| | | |
| **Supplemental disclosure of cash flow information:** | | |
| Cash paid for interest | $ - | $ 114,411 |

*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.

The Company's primary historical activities have included utilizing its mitochondria focused technology 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 recently suspended IND-enabling work on pre-clinical candidate CB5138-3, which the Company had been developing as a potential treatment of idiopathic pulmonary fibrosis and other fibrotic diseases. The decision to suspend IND-enabling work follows recently completed non-clinical formulation studies seeking to identify a formulation suitable for clinical development. In connection with the decision to suspend IND-enabling work for this candidate, the Company intends to explore development and/or partnership opportunities within the Company's peptide library and technology platform, while simultaneously exploring other strategic alternatives. In addition, the Company does not believe that the formulation of CB4211 used in the Phase 1b stage of the trial is suitable for further development. Efforts to develop an improved formulation have not been successful to date and there can be no assurances that the Company will be able to develop such a formulation.

The Company has retained Ladenburg Thalmann & Co. Inc. as a financial advisor to assist the Company in exploring strategic alternatives. Potential strategic alternatives that may be explored or evaluated as part of this process include a merger, business combination, investment into the Company, asset sale or other strategic transaction. The board of directors of the Company has not set a timetable for the conclusion of this review, nor has it made any definitive decisions related to taking any further actions or potential strategic options at this time or at all. There can be no assurance that this process will result in any such transaction, and the Company does not intend to disclose additional details unless and until it has entered into a specific transaction.

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, 2022, included in the Company's Annual Report on Form 10-K, filed with the SEC on March 9, 2023, as amended by the Company's Amendment No. 1 on Form 10-K/A, filed with the SEC on April 28, 2023 (the "2022 Form 10-K"). The interim unaudited condensed financial statements should be read in conjunction with those audited financial statements included in the 2022 Form 10-K. In the opinion of management, all adjustments considered necessary for fair presentation, consisting solely of normal recurring adjustments, have been made. Operating results for the three-month period ended March 31, 2023 are not necessarily indicative of the results that may be expected for the year ending December 31, 2023, or any other period.

**Note 2 - Liquidity and Management's Plans**

As of March 31, 2023, the Company had a cash, cash equivalents and investments balance of $14.1 million and working capital and stockholders' equity of $13.4 million and $13.5 million, respectively. During the three months ended March 31, 2023, the Company incurred a net loss of $2.2 million. Based on management's current plans (see Note 1 - Business Organization and Nature of Operations), the Company believes that its funds available will be sufficient to fund the Company's planned operating expenses and capital expenditure requirements for at least one year from the issuance of these financial statements.



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

**Note 3 - Summary of Significant Accounting Policies**

***Basis of Presentation***

All amounts are presented in U.S. Dollars.

***Use of Estimates***

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent liabilities at dates of the financial statements and the reported amounts of revenue and expenses during the periods. Actual results could differ from these estimates. The Company's significant estimates and assumptions include the fair value of financial instruments, stock-based compensation and the valuation allowance relating to the Company's deferred tax assets.

***Concentrations of Credit Risk***

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

***Investments***

Investments as of March 31, 2023 and December 31, 2022 consist of U.S. Treasury Bills, which are classified as held-to-maturity, and Certificates of Deposit totaling $8.7 million and $9.8 million as of March 31, 2023 and December 31, 2022, respectively. The Company determines the appropriate balance sheet classification of its investments at the time of purchase and evaluates the classification at each balance sheet date. All of the Company's U.S. Treasury Bills mature within the subsequent twelve months from the date of purchase. Unrealized gains and losses were *de minimus*. As of March 31, 2023 and December 31, 2022, the carrying value of the Company's U.S. Treasury Bills approximates their fair value due to their short-term maturities.





**Note 3 - Summary of Significant Accounting Policies (continued)**

***Cash Equivalents***

The Company considers all highly liquid investments with an original maturity of three months or less when purchased to be cash equivalents. As of March 31, 2023 and December 31, 2022, the Company invested $3.9 million in each of the periods in Treasury Bills that are considered cash equivalents due to their maturity date being less than three months from the date of purchase.

***Fair Value of Financial Instruments***

The Company measures the fair value of financial assets and liabilities based on the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. The Company utilizes three levels of inputs that may be used to measure fair value:

Level 1 - quoted prices in active markets for identical assets or liabilities.

Level 2 - quoted prices for similar assets and liabilities in active markets or inputs that are observable.

Level 3 - inputs that are unobservable (for example, cash flow modeling inputs based on assumptions).

The carrying amounts of cash, investments and accounts payable approximate fair value due to the short-term nature of these instruments. The amount of debt included in the accompanying balance sheets approximates its fair value because the interest rate of the notes approximates the current market interest rate.

***Common Stock Purchase Warrants***

The Company classifies as equity any contracts that (i) require physical settlement or net-share settlement or (ii) provide the Company with a choice of net-cash settlement or settlement in its own shares (physical settlement or net-share settlement) providing that such contracts are indexed to the Company's own stock. The Company classifies as assets or liabilities any contracts that (i) require net-cash settlement (including a requirement to net cash settle the contract if an event occurs and if that event is outside the Company's control), or (ii) give the counterparty a choice of net-cash settlement or settlement in shares (physical settlement or net-share settlement). The Company assesses classification of its common stock purchase warrants and other free-standing derivatives at each reporting date to determine whether a change in classification between assets, liabilities and equity is required. The Company's free-standing derivatives consist of warrants to purchase common stock that were issued in connection with its notes payable and public and private offerings. The Company evaluated these warrants to assess their proper classification using the applicable criteria enumerated under U.S. GAAP and determined that the common stock purchase warrants meet the criteria for equity classification in the accompanying balance sheets as of March 31, 2023.





**Note 3 - Summary of Significant Accounting Policies (continued)**

***Research and Development Expenses***

The Company expenses all research and development expenses as incurred. These costs include payroll, employee benefits, supplies, contracted for lab services, depreciation and other personnel-related costs associated with product development.

***Share-Based Payments***

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

The weighted-average fair value of options and warrants has been estimated on the grant date or measurement date using the Black-Scholes pricing model. The fair value of each instrument is estimated on the grant date or measurement date utilizing certain assumptions for a risk-free interest rate, volatility and expected remaining lives of the awards. The risk-free interest rate used is the United States Treasury rate for the day of the grant having a term equal to the life of the equity instrument. Volatility was derived from the Company's historical share prices. 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. During the three months ended March 31, 2023, the Company did not grant any options or warrants to purchase shares of its common stock.

The Black-Scholes assumptions are as follows:

| | For the Three Months Ended March 31, | |
|---|---|---|
| | 2023 | 2022 |
| Expected life | N/A | 6.25 years |
| Risk free interest rate | N/A | 1.47% |
| Expected volatility | N/A | 92% |
| Expected dividend yield | N/A | N/A |
| Forfeiture rate | N/A | N/A |

As of March 31, 2023, total unrecognized stock compensation expense was $3.0 million, which will be recognized as those options vest over a period of approximately three 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 March 31, | |
|---|---|---|
| | 2023 | 2022 |
| Options | 252,994 | 377,905 |
| Warrants | 1,177,315 | 1,182,503 |
| Totals | 1,430,309 | 1,560,408 |

**Note 4 – Accrued Liabilities**

Accrued liabilities consist of the following:

| | As of March 31, 2023 | As of December 31, 2022 |
|---|---|---|
| Lab services & supplies | $ 7,131 | $ 160,482 |
| Professional fees | 42,382 | 167,386 |
| Total accrued liabilities | $ 49,513 | $ 327,868 |

**Note 5 - Notes Payable – Related Party**

During the three months ended March 31, 2022, the Company repaid a promissory note, held by a director of the Company, totaling $0.4 million in principal and $0.1 million in interest.

**Note 6 - Commitments and Contingencies**

***Litigations, Claims and Assessments***

The Company may from time to time be a party to litigation and subject to claims incident to the ordinary course of business. In the future, the Company may become a 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 material legal proceedings.

**Note 6 - Commitments and Contingencies (continued)**

***Licensing Agreements***

The Company was previously a party to an Exclusive License Agreement (the "2011 Exclusive Agreement") with the Regents of the University of California (the "Regents" or "Licensors"), which was terminated, effective as of April 6, 2023.

The Company is also a party to an Exclusive License Agreement (the "2013 Exclusive Agreement") with the Regents whereby the Regents granted the Company an exclusive license for the use of certain other patents. The 2013 Exclusive Agreement remains in effect for the life of the last-to-expire patent or last to be abandoned patent application, whichever is later. The Company paid the Regents an initial license issue fee of $10,000 for these other patents. The Company is also required to pay annual maintenance fees to the Licensors. Aggregate maintenance fees for the first three years following execution of the agreement were $7,500. Thereafter, the Company is required to pay maintenance fees of $5,000 annually until the first sale of a licensed product. The Company agreed to pay the Regents specified development milestone payments aggregating up to $765,000 for the first product sold under the 2013 Exclusive Agreement. Milestone payments for additional products developed and sold under the 2013 Exclusive Agreement are reduced by 50%. In addition, for the duration of the 2013 Exclusive Agreement, the Company is required to pay the Regents royalties equal to 2% of the Company's worldwide net sales of drugs, therapies or other products developed from claims covered by the licensed patent, subject to a minimum royalty payment of $75,000 annually, beginning after the first commercial sale of a licensed product. The Company is required to pay the Regents royalties ranging from8% of worldwide sublicense sales of covered products (if the sublicense is entered after commencement of Phase II clinical trials) to 12% of worldwide sublicense sales (if the sublicense is entered prior to commencement of Phase I clinical trials). The agreement also requires the Company to meet certain diligence and development milestones, including filing of an IND Application for a product covered by the agreement on or before the seventh anniversary of the agreement date. Through March 31, 2023, no royalties have been incurred under the agreement. All maintenance fees due and payable have been paid.

***Operating Leases***

The Company is a party to a lease agreement for laboratory space leased on a month-to-month basis that is part of a shared facility in Menlo Park, California. In September 2022, the Company renewed its lease for office space in Fairfield, New Jersey for an additional year at the same annual cost of $13,080 per annum.

Rent expense amounted to $0.1 million in each of the three months ended March 31, 2023 and 2022.

**Note 7 - Stockholders' Equity**

***Authorized Capital***

The Company has authorized the issuance and sale of up to17 million shares of stock, consisting of 12 million shares of common stock having a par value of $0.001 and 5 million shares of Preferred Stock having a par value of $0.001 per share. As of March 31, 2023 and December 31, 2022, 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.





**Note 7 - Stockholders' Equity (continued)**

***At-the-Market Offering***

During the year ended December 31, 2020, the Company entered into an At-the-Market Offering Sales Agreement ("ATM") with Virtu Americas, LLC, as sales agent. During the quarter ended March 31, 2022, the Company sold 23.4 thousand shares of its common stock under the ATM program for proceeds of $0.2 million, net of commissions. As of March 31, 2023, the Company had approximately $5.0 million available in its ATM program. The Company's ATM program expires in September 2023.

***Stock Options***

The Company has an incentive stock plan, the Amended and Restated 2011 Equity Incentive Plan (the "2011 Plan"), and has granted stock options to employees, non-employee directors and consultants from the 2011 Plan. Options granted under the 2011 Plan may be Incentive Stock Options or Non-statutory Stock Options, as determined by the Administrator at the time of grant. As of March 31, 2023, there were 0.2 million shares remaining available for issuance under the 2011 Plan.

During the three months ended March 31, 2023, stock options to purchase64.9 thousand shares of common stock were cancelled and returned to the option pool for future issuance.

The Company recorded stock-based compensation expense as follows:

| | For the Three Months Ended March 31, | |
|---|---|---|
| | 2023 | 2022 |
| Research and development | $ 11,772 | $ 28,808 |
| General and administrative | 325,829 | 427,615 |
| Total | $ 337,601 | $ 456,423 |

The following table represents stock option activity for the three months ended March 31, 2023:

| | Stock Options | | Weighted Average Exercise Price | | Weighted Average Fair Value Vested | Weighted Average Contractual Life (Years) | Aggregate Intrinsic Value |
|---|---|---|---|---|---|---|---|
| | Outstanding | Exercisable | Outstanding | Exercisable | | | |
| Balance – December 31, 2022 | 317,857 | 194,853 | $ 44.53 | $ 38.53 | $ 38.53 | 6.99 | $ - |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Granted | - | - | - | - | - | - | - |
| Exercised | - | - | - | - | - | - | - |
| Cancelled | (64,863) | - | - | - | - | - | - |
| Balance – March 31, 2023 | 252,994 | 195,192 | $ 46.03 | $ 40.21 | $ 40.21 | 6.63 | $ - |

The following table summarizes information on stock options outstanding and exercisable as of March 31, 2023:

| Grant Price | | Weighted Average Exercise Price | Total Outstanding | Number Exercisable | Weighted Average Remaining Contractual Term |
|---|---|---|---|---|---|
| From | To | | | | |
| $ 6.00 | $ 60.60 | $ 35.90 | 220,259 | 146,796 | 6.58 years |
| $ 63.00 | $ 138.00 | $ 83.16 | 21,301 | 36,962 | 4.07 years |
| $ 159.00 | $ 181.20 | $ 172.14 | 11,434 | 11,434 | 4.84 years |
| | | **Totals** | **252,994** | **195,192** | |



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

**Note 7 - Stockholders' Equity (continued)**

***Warrants***

The following table represents warrant activity for the three months ended March 31, 2023:

| | Warrants | | Weighted Average Exercise Price | | Fair Value Vested | Contractual Life (Years) | Aggregate Intrinsic Value |
|---|---|---|---|---|---|---|---|
| | Outstanding | Exercisable | Outstanding | Exercisable | | | |
| Balance – December 31, 2022 | 1,178,169 | 1,178,169 | $ 30.67 | $ 30.67 | $ 17.83 | 3.41 | $ - |
| Granted | - | - | - | - | - | - | - |
| Exercised | - | - | - | - | - | - | - |
| Cancelled | (854) | - | - | - | - | - | - |
| Balance – March 31, 2023 | 1,177,315 | 1,177,315 | $ 30.66 | $ 30.66 | $ 17.79 | 3.16 | $ - |

During the three months ended March 31, 2023, warrants to purchase0.9 thousand shares of common stock expired and were cancelled.

***Employee Stock Purchase Plan***

The Company has an Employee Stock Purchase Plan ("ESPP") in which it purchases shares with the amounts accumulated during the offering period from employee directed payroll deferrals. Purchases of the Company's common stock are equal to 85% of the closing market price of its common stock on the first day or last day of the offering period, whichever is lower. As of March 31, 2023, there were 10.5 thousand shares remaining available for issuance under the ESPP plan.

**Note 8 – Non-Cash Expenses**

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

| | For the Three Months Ended March 31, | |
|---|---|---|
| | 2023 | 2022 |
| **Operating expenses:** | | |
| Stock-based compensation | $ 337,601 | $ 456,423 |
| Depreciation & amortization | 63,481 | 32,801 |
| **Subtotal** | $ 401,082 | $ 489,224 |
| **Other expense:** | | |
| Amortization of debt discount | - | 8,350 |
| **Subtotal** | $ - | $ 8,350 |
| **Total non-cash expenses** | $ 401,082 | $ 497,574 |

**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 and determined no such adjustments were necessary.



**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, 2022 as amended by the Company's Amendment No. 1 on Form 10-K/A, filed with the SEC on April 28, 2023 (the "2022 Form 10-K"). All references to the first quarter mean the three-month period ended March 31, 2023. Unless the context otherwise requires, "CohBar," "we," "us" and "our" refer to CohBar, Inc.*

**Special Note Regarding Forward-Looking Statements**

*This report, including without limitation the sections entitled "Risk Factors" and the "Management's Discussion and Analysis of Financial Condition and Results of Operations," contain forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. For this purpose, any statements contained herein are not statements of historical fact, including without limitation, statements regarding future events and our future results, our results of operations, 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, may be deemed forward-looking statements. Without limiting the foregoing, words such as "may," "will," "should," "expect," "anticipate," "target," "goal," "project," "would," "could," "intend," "plan," "believe," "seek" and "estimate," variations of these words, and similar expressions are intended to identify these 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 2022 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. 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 what has traditionally been thought of as mitochondrial function.

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 technology platform. We expect our research and development expenses to decrease in the coming quarters as we continue to explore strategic alternatives. However, we do not believe that it is possible at this time to accurately project our research and development costs.

Historically, we have financed our operations primarily with proceeds from sales of our equity securities, including our initial public offering, private placements of our securities, a debt offering, public sales of our securities and the exercise of outstanding warrants and stock options. Since our inception through March 31, 2023, our operations have been funded with an aggregate of approximately $97.3 million from the sale and issuance of equity instruments and debt, including the proceeds from the exercise of warrants and stock options.



Since inception, we have incurred significant operating losses. Our net losses were $2.2 million and $3.3 million for the three months ended March 31, 2023 and 2022, respectively. We incurred $0.4 million and $0.5 million in non-cash expenses during the three months ended March 31, 2023 and 2022, respectively. Our net losses excluding non-cash expenses were $1.8 million and $2.8 million for the three months ended March 31, 2023 and 2022, respectively. As of March 31, 2023, we had an accumulated deficit of $99.1 million. Dependent upon our ultimate determination of whether or not to pursue any potential strategic alternative, significant expenses and operating losses over the next several years may continue to occur. Our net losses may fluctuate significantly from quarter to quarter and from year to year.

**Recent Developments**

We recently suspended IND-enabling work on pre-clinical candidate CB5138-3, which we had been developing as a potential treatment of idiopathic pulmonary fibrosis and other fibrotic diseases. The decision to suspend IND-enabling work follows recently completed non-clinical formulation studies seeking to identify a formulation suitable for clinical development. In connection with the decision to suspend IND-enabling work for this candidate, we intend to explore development and/or partnership opportunities within our peptide library and technology platform, while simultaneously exploring other strategic alternatives. In addition, we do not believe that the formulation of CB4211 used in the Phase 1b stage of the trial is suitable for further development. Efforts to develop an improved formulation have not been successful to date and there can be no assurances that we will be able to develop such a formulation.

We have retained Ladenburg Thalmann & Co. Inc. as a financial advisor to assist the Company in exploring strategic alternatives. Potential strategic alternatives that may be explored or evaluated as part of this process include a merger, business combination, investment into the Company, asset sale or other strategic transaction. Our board of directors has not set a timetable for the conclusion of this review, nor has it made any definitive decisions related to taking any further actions or potential strategic options at this time or at all. There can be no assurance that this process will result in any such transaction and the Company does not intend to disclose additional details unless and until it has entered into a specific transaction. See also "Risk Factors—Risks Related to Strategic Alternative Process and Potential Strategic Transaction".

**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.

***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 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 have historically included activities in support of the clinical development of our product candidates that were based on mitochondria peptides, as well as the operation of our platform technology related to the discovery and development of novel therapeutics derived from the mitochondrial genome. Depending on factors of capability, cost, efficiency and intellectual property rights, we have historically conducted 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; 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 and have historically primarily focused on potential drug candidates 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 our research and development expenses to decrease in the coming quarters as we continue to explore strategic alternatives. However, we do not believe that it is possible at this time to accurately project our research and development costs.

***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 fluctuate in the coming quarters depending on the timing and magnitude of costs associated with our evaluation of potential strategic alternatives.



**Results of Operations**

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

| | For The Three Months Ended March 31, | | Change | |
|---|---|---|---|---|
| | 2023 | 2022 | $ | % |
| **Operating expenses:** | | | | |
| Research and development | $ 1,020,739 | $ 1,506,308 | $ (485,569) | -32% |
| General and administrative | 1,279,273 | 1,744,918 | (465,645) | -27% |
| Total operating expenses | $ 2,300,012 | $ 3,251,226 | $ (951,214) | -29% |

***Comparison of Three Months Ended March 31, 2023 and 2022***

*Research and development* expenses were $1.0 million in the three months ended March 31, 2023 compared to $1.5 million in the prior year period, a decrease of approximately $0.5 million, or 32%. The decrease in research and development expenses was primarily due to a decrease of $0.2 million in expenses associated with our research programs and clinical trial related costs of our CB4211 program due to the timing of those expenses, a $0.2 million decrease in consulting services due to less reliance on outside consultants and a $0.1 million decrease in lab supplies because of less purchases in the current year period.

*General and administrative expenses* were $1.3 million in the three months ended March 31, 2023 compared to $1.7 million in the prior year period, a decrease of approximately $0.4 million, or 27%. The decrease in general and administrative expenses was primarily due to a decrease of $0.3 million in professional fees primarily related to lower legal fees in the current year period related to the expenses of protecting our intellectual property portfolio and a $0.1 million decrease in stock-based compensation costs.

**Liquidity and Capital Resources**

As of March 31, 2023, we had cash, cash equivalents and investments totaling $14.1 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. Our ATM program expires in September 2023.

As of March 31, 2023, we had working capital and stockholders' equity of $13.4 million and $13.5 million, respectively. During the three months ended March 31, 2023, we incurred a net loss of $2.2 million. Based on management's current plans (see Recent Developments above), we believe that our funds available will be sufficient to fund our planned operating expenses and capital expenditure requirements for at least one year from the issuance of these financial statements.



***Cash Flows from Operating Activities***

Net cash used in operating activities for the three months ended March 31, 2023 and 2022 was $1.6 million and $2.5 million, respectively. The cash used in operations for the three months ended March 31, 2023 was primarily due to our reported net loss of $2.2 million, partially offset by the total of non-cash expenses of $0.4 million. The cash used in operations for the three months ended March 31, 2022 was primarily due to our reported net loss of $3.3 million, partially offset by the total of non-cash expenses of $0.5 million.

***Cash Flows from Investing Activities***

Net cash provided by investing activities was $1.1 million in the three months ended March 31, 2023 and was primarily due to the maturities of our investments, partially offset by the purchases of our investments. Net cash used in investing activities was $0.7 million in the three months ended March 31, 2022 and was primarily due to the timing of the purchases of our investments, partially offset by the maturities of our investments.

***Cash Flows from Financing Activities***

No net cash was used in or provided from financing activities in the three months ended March 31, 2023. Net cash used in financing activities in the three months ended March 31, 2022 was $0.2 million due to the repayment of a promissory note, partially offset by the proceeds received from our ATM program.

***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 2023.

Rent expense was $0.1 million for each of the three months ended March 31, 2023 and 2022.

**Critical Accounting Estimates**

Management's discussion and analysis of our financial condition and results of operations is based on our condensed consolidated financial statements, which have been prepared in accordance with GAAP. The preparation of these financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements, as well as the reported expenses incurred during the reporting periods. Our estimates are based on our historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions and any such differences may be material. We believe that the accounting policies disclosed are critical to understanding our historical and future performance, as these policies relate to the more significant areas involving management's judgments and estimates.

During the three months ended March 31, 2023, there were no material changes to our critical accounting estimates or in the methodology used for estimates from those described in "Management's Discussion and Analysis of Financial Condition and Results of Operations" included in our Annual Report on Form 10-K for the year ended December 31, 2022.



**Item 3. Quantitative and Qualitative Disclosures About Market Risk**

As a smaller reporting company, we are not required to provide the information requested by this item pursuant to Item 305(e) of Regulation S-K.

**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 on this evaluation, our Chief Executive Officer and Chief Financial Officer concluded as of the end of the period covered by this report that our disclosure controls and procedures were not effective due to a material weakness. The material weakness relates to a lack of segregation of duties as we currently have only one employee assigned to positions that involve processing financial information. As a result, not all of our journal entries and account reconciliations have been reviewed by someone other than the preparer, heightening the risk of error or fraud.

**Changes in Internal Control over Financial Reporting**

Other than the material weakness described above, there were no changes in our internal control over financial reporting identified in connection with the evaluation required by Rule 13a-15(d) and 15d-15(d) of the Exchange Act that occurred during the three months ended March 31, 2023 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

**Plan for Remediation of the Material Weakness in Internal Control over Financial Reporting**

Our management intends to remediate this material weakness in internal control over financial reporting in the coming quarters by hiring additional personnel/assigning additional personnel to positions that involve processing financial information to segregate duties in the review of journal entries and account reconciliations so that such entries and reconciliations are reviewed by someone other than the preparer.

If we are unable to remediate the material weakness, or other control deficiencies are identified, we may not be able to report our financial results accurately, prevent fraud or file our periodic reports as a public company in a timely manner. Due to our small size and limited resources, segregation of duties may not always be possible and may not be economically feasible. As a result, we have not been able to take steps to improve our internal controls over financial reporting during the quarter ended March 31, 2023. We continue to evaluate the effectiveness of internal controls and procedures on an on-going basis. However, there can be no assurance of when, if ever, we will be able to remediate the identified material weaknesses. See Item 1A of Part II "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" for more details.



## 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**

Investing in our common stock involves significant risks. You should carefully consider the risks and uncertainties described below, together with all of the other information in this Quarterly Report on Form 10-Q, including "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our audited financial statements and related notes, and other filings we have made and make in the future with the Securities and Exchange Commission. If any of the following risks are realized, our business, financial condition, results of operations and prospects could be materially and adversely affected. In such case, the trading price of our common stock would likely decline, and you may lose all or part of your investment. Below is a summary of some of the risks we face:

- we may not be successful in identifying and implementing any strategic alternatives, including a potential merger, business combination, investment into the Company, asset sale or other strategic transaction, and any such strategic transaction that we may consummate in the future could have negative consequences;
- even if we are successful in completing a strategic alternative, we may be exposed to other operational and financial risks;
- our ability to consummate a strategic alternative depends upon our ability to retain our employees required to consummate such transaction;
- we may become involved in securities litigation that could divert management's attention and harm our business, and insurance coverage may not be sufficient to cover all costs and damages;
- if we decide to dissolve and liquidate, the amount of cash that may be available for distribution to our stockholders is uncertain;
- we have had a history of losses and no revenue;
- we are an early-stage biotechnology company and may never be able to successfully develop marketable products or generate any revenue. We have a limited relevant operating history upon which an evaluation of our performance and prospects can be made. There is no assurance that our future operations will result in profits. If we cannot generate sufficient revenues, we may suspend or cease operations;
- if we fail to demonstrate efficacy or safety in any future 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 future 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;
- our future success depends on our Chief Executive Officer and our Chief Financial Officer;
- 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 have not been successful to date in our efforts to develop commercially viable formulations in our product candidates;
- we may not be successful in our efforts to develop commercially viable formulations for our product candidates;
- our future 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;
- if we do not achieve any future projected development goals in the time frames we announce and expect, the commercialization of any such future products may be delayed and, as a result, our stock price may decline;
- even if we are able to develop future potential drug candidates, 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;
- even if we are successful in developing future drug candidates, we may not be able to market or generate sales of such future 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 future 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;

- any future 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, better tolerated, less costly, more easily administered or offer other advantages over any product we seek to market;

- the use of any of our future 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;



- 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;

- i f 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; and

- if we are not able to comply with the applicable continued listing requirements or standards of Nasdaq, our common stock could be delisted;

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 Strategic Alternative Process and Potential Strategic Transaction**

***We may not be successful in identifying and implementing any strategic alternatives, including a potential merger, business combination, investment into the Company, asset sale or other strategic transaction, and any such strategic transaction that we may consummate in the future could have negative consequences.***

On November 17, 2022, we announced our retention of Ladenburg Thalmann & Co. Inc. as a financial advisor to assist us in exploring strategic alternatives. Potential strategic alternatives that may be explored or evaluated as part of this process include a merger, business combination, investment into the Company, asset sale or other strategic transaction. Our board of directors has not set a timetable for the conclusion of this review, nor has it made any definitive decisions related to taking any further actions or potential strategic options at this time or at all.

The process of continuing to evaluate these strategic alternatives is costly, time-consuming and complex, and we have incurred, and may in the future incur, significant costs related to this continued evaluation, such as legal and accounting fees and expenses and other related charges. We may also incur additional unanticipated expenses in connection with this process. A considerable portion of these costs will be incurred regardless of whether any such course of action is implemented or transaction is completed, decreasing the remaining cash available for use in our business.

Potential counterparties in a strategic transaction involving our Company may place minimal or no value on our assets. Further, the development and any potential commercialization of our product candidates will require substantial additional cash to fund the costs associated with conducting the necessary preclinical and clinical testing and obtaining regulatory approval. Consequently, any potential counterparty in a strategic transaction involving our Company may choose not to spend additional resources and continue to utilize the Company's peptide library and technology platform and may attribute little or no value, in such a transaction, to those product assets.



There can be no assurance that any particular course of action, business arrangement or transaction, or series of transactions, will be pursued, successfully consummated, lead to increased stockholder value, or achieve the anticipated results. If we are unable to consummate a strategic transaction, our board of directors may decide to pursue a dissolution and liquidation.

***Even if we are successful in completing a strategic alternative, we may be exposed to other operational and financial risks.***

Although there can be no assurance that a strategic alternative will result from the process we have undertaken to identify and evaluate strategic alternatives, the negotiation and consummation of any such transaction will require significant time on the part of our management, which results in disruption to our business.

The negotiation and consummation of any such transaction may also require more time or greater cash resources than we anticipate and expose us to other operational and financial risks, including:

- increased near-term and long-term expenditures;

- exposure to unknown liabilities;

- higher than expected acquisition or integration costs;

- incurrence of substantial debt or dilutive issuances of equity securities to fund future operations;

- write-downs of assets or goodwill or incurrence of non-recurring, impairment or other charges;

- increased amortization expenses;

- difficulty and cost in combining the operations and personnel of any acquired business with our operations and personnel;

- impairment of relationships with key suppliers or customers of any acquired business due to changes in management and ownership;

- inability to retain key employees of our Company or any acquired business; and

- possibility of future litigation.

Any of the foregoing risks could have a material adverse effect on our business, financial condition and prospects.

***Our ability to consummate a strategic alternative depends on our ability to retain our employees required to consummate such transaction.***

Our ability to consummate a strategic alternative depends upon our ability to retain our employees required to consummate such a transaction, the loss of whose services may adversely impact the ability to consummate such transaction. If we are unable to successfully retain these employees, we are at risk of a disruption to our exploration and consummation of a strategic alternative as well as business operations.

***We may become involved in securities litigation that could divert management's attention and harm the Company's business, and insurance coverage may not be sufficient to cover all costs and damages.***

In the past, securities litigation has often followed certain significant business transactions, such as the sale of a company or announcement of any other strategic transaction, or the announcement of negative events, such as negative results from clinical trials. We may be exposed to such litigation even if no wrongdoing occurred. Litigation is usually expensive and diverts management's attention and resources, which could adversely affect our business and cash resources and our ability to consummate a potential strategic alternative or the ultimate value our stockholders receive in any such transaction.



***If we decide to dissolve and liquidate our Company, the amount of cash that may be available for distribution to our stockholders is uncertain.***

If our board of directors decides to pursue a dissolution and liquidation of our Company, the amount of cash that may be available for distribution to our stockholders is uncertain. This amount will depend on the resolution of our financial commitments and contingent liabilities and the timing of the decision to liquidate. Our financial commitments and contingent liabilities include: (i) personnel costs, including severance; (ii) contractual obligations to vendors and clinical study sites; and (iii) non-cancelable lease obligations.

**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 or one or more strategic alternatives (as discussed above). 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. We have not been able to identify suitable formulations for our CB4211 or CB5138-3 product candidates and there can be no assurances that we will be able to develop suitable formulations for any future product candidates. Moreover, we cannot be certain that any research and development efforts that we may undertake in the future will be successful or, if successful, that our novel peptide analogs will ever be approved by the FDA. 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, evaluating and implementing a strategic alternative (as discussed above), failure of potential drug candidates either in research, preclinical testing or in clinical trials, and failure to establish business relationships and competitive advantages against other companies. If we fail to become profitable, we may be forced to suspend or cease operations.



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

The success of any future 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. For example, in December 2022, we announced that we had suspended further IND-enabling activities for our CB5138-3 product candidate due to challenges in identifying a suitable formulation for clinical development.

Moreover, success in future 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. Any future 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, future non-clinical testing or clinical trials will delay the filing of any future 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 any 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 any future early clinical trials that we may conduct 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 future 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 future clinical trials that will cause regulatory agencies, institutional review boards, or us to suspend or delay a trial. We have experienced delays in both our CB4211 and CB5138-3 programs. Our Phase 1a/1b clinical trial for CB4211 was suspended in November 2018 in order to address injection site reactions, and was delayed again in March 2020 due to impacts of the COVID-19 pandemic. Our planned IND filing for our CB5138-3 product candidate was delayed from the second half of 2022 to the second half of 2023 due to the observation of injection site reactions in our preclinical toxicology studies. Ultimately, our efforts to mitigate these injection site reactions by improving the formulation for this product candidate were unsuccessful and in December 2022, we announced that we had suspended further IND-enabling activities for this peptide.



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 future 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 future clinical trials are not available when we expect or if we encounter any delay in the analysis of data from our future 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 future clinical trials may also ultimately lead to the denial of regulatory approval of a future 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 product development and regulatory submission process or make it difficult to raise additional capital.



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

From time to time, we have estimated 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 have publicly announced and may in the future publicly announce the expected timing of some of these milestones. All of these milestones have been and will be based on numerous assumptions, including timely performance by our CROs and other vendors, positive clinical and preclinical results, our ability to develop commercially viable formulations for our product candidates, and sufficient funding from partnering and general fundraising. The actual timing of these milestones have varied dramatically compared to our estimates, in some cases for reasons beyond our control. For example, we initially projected that we would have topline results from our 1a/1b clinical trial for CB4211 trial in early 2019. The trial was substantially delayed, and we did not release topline results for this study until August of 2021. For our CB5138-3 product candidate, we initially projected that we would file an IND for this program in the second half of 2022. We later revised this estimate to the second half of 2023 and, in December 2022, we announced the suspension of IND-enabling activities for this program due to challenges in identifying a suitable formulation for clinical development. The delays in each of these programs resulted in declines in our stock price. If we fail to meet future 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 our Chief Executive Officer and Chief Financial Officer.***

We are highly dependent on 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. 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. The loss of the services of our Chief Executive Officer or Chief Financial Officer could impede our ongoing exploration of strategic alternatives, as discussed above.

***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 future drug development programs and the potential commercialization of our future 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 future drug candidates.

We face significant competition in seeking appropriate collaborators. Whether we reach a definitive collaboration agreement will depend, among other things, upon our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator's evaluation of a number of factors. Those factors may include the expected efficacy, safety and tolerability of the subject product candidate, 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 strength of our data supporting the mechanism of action of the subject product candidate, 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 future 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 future product candidates or bring them to market and generate product revenue.

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

A key element of our strategy has been to identify and test MDPs and novel analogs that play a role in cellular processes underlying our targeted disease indications. Any 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 example, in December 2022, we announced that we had suspended further IND-enabling activities for our CB5138-3 product candidate due to challenges in identifying a suitable formulation for clinical development. Similarly, we have not been able to identify a formulation for CB4211 that would be suitable to move it forward to the next stage of clinical development. There are a number of reasons why any future research efforts may not yield appropriate development candidates, 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.

***We have not been successful to date 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. To date, we have not been able to identify suitable formulations for our CB4211 or CB5138-3 product candidates. It is possible that other product candidates that we may 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 as we have done with CB5138-3. Any efforts to identify alternate drug candidates that do not cause ISRs would take additional time and expense and may not be successful.



***Our future research and development plans will require substantial additional 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 future 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;
- develop and manufacture devices compatible with our drug products that are suitable for use by patients to inject our drug products on a chronic basis; 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 future 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;
- the complexity of any delivery device that we develop for use in combination with our drug products;
- competing technological and market developments;
- our ability to establish additional collaborations;
- changes in any future collaborations;
- the cost of manufacturing any drug products and any related delivery device; and
- the cost and effectiveness of efforts to commercialize and market any products.

We base our outlook regarding the need for funds on many uncertain variables. Such uncertainties include the initiation and success of any future 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 future 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 FUTURE POTENTIAL DRUG CANDIDATES, 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 of our future 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 future potential drug candidate will be approved for marketing. There are many reasons that we may fail in our efforts to develop our future potential drug candidates. These include:

- the possibility that preclinical testing or clinical trials may show that our potential drugs are ineffective and/or cause undesirable or 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;
- we may not understand the mechanism of action of our potential drugs, which could negatively impact our ability to recruit patients to participate in the clinical trials necessary for regulatory approval of our potential drugs;
- 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, the costs of any delivery device used in combination with our drug products may result in an overall manufacturing cost that is not competitive with competing products that do not require a delivery device;
- 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 future 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 future research and development, we may not be able to successfully develop potential drug candidates in the future. If this happens, our business will be adversely affected.

***We expect to rely on third parties to conduct any future clinical trials and some aspects of any future 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 expect to rely on third parties to conduct some aspects of our future research and expect to rely on third parties to conduct additional aspects of our future 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 future product research and development activities.

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

**Risks Related to Product Development and Regulatory Approval**

***Even if we are successful in developing future drug candidates, we may not be able to market or generate sales of such future 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 any future potential drug candidates and receiving regulatory clearances to market our potential products, our ability to successfully penetrate the market and generate sales of such future 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, have better safety or tolerability profiles 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 future 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 future clinical trials. Interim data from future 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 future 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, better tolerated, less costly, more easily administered or offer other advantages over any product we seek to market.***

There are numerous therapies currently marketed to treat IPF, diabetes, cancer, and other diseases for which our future 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 future product candidates for which we obtain market approval. New products may also become available that provide efficacy, safety, tolerability, convenience and other benefits that are not provided by currently marketed therapies. As a result, they may provide significant competition for any of our future 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, better tolerated, 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.

***The use of any of our future product candidates 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 potential products. If any of our future drug candidates are used in clinical trials, or if any of our future 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 future product candidates, the outcome of our future clinical trials may not be favorable or, even if favorable, regulatory authorities may not find the results of our future clinical trials to be sufficient fo 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 if any future pivotal clinical trials for a specific indication were to 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 future 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 future 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 future 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 future product candidates under applicable regulatory requirements. The denial or delay of any such approval would delay commercialization of our future 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 future 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 future 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 future product candidates, which would significantly harm our business, financial condition, results of operations and prospects.



***Any future 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 future product candidates, when and if any of them are approved.***

Our future 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 future 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 future 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 business.***

We own or exclusively license patents and patent applications related to our MDPs and potential drug candidates comprised of novel analogs. 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 other aspects of our business than they otherwise would, which could increase our operating expenses and delay any future 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).

- 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 any future 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 taking 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. For example, we concluded as of the end of the first quarter of 2023 that our disclosure controls and procedures were not effective due to a material weakness. The material weakness relates to a lack of segregation of duties as we currently have only one employee assigned to positions that involve processing financial information. As a result, not all of our journal entries and account reconciliations have been reviewed by someone other than the preparer, heightening the risk of error or fraud. There can be no assurance of when, if ever, we will be able to remediate the identified material weaknesses. The presence of this or other material weaknesses could result in an adverse reaction in the financial markets due to a loss of confidence in the reliability of our 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"). If material weaknesses or deficiencies in our internal controls exist and go undetected or unremedied, our 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 have managed, and may in the future continue to 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 potentially 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.

***Public health crises such as pandemics or similar outbreaks could adversely impact our business.***

Public health crises such as pandemics or similar outbreaks could adversely impact our business.

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 the macroeconomic environment, including rising interest rates, inflation and recessionary fears. Future public health crises, including pandemics or similar outbreaks such as COVID-19, may adversely impact our business, strategy and financial condition. The extent to which any public health crises impacts our business, strategy or financial condition will depend on future developments, which are highly uncertain and cannot be predicted with confidence, such as the emergence of novel variants, the impact of vaccinations and vaccination rates, travel restrictions and actions to contain new outbreaks or resurgences 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 resurgences or novel variants.

***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 can be 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 future product candidates or those of our competitors:
- unanticipated or serious safety concerns related to the use of any of our future product candidates;
- challenges in developing commercially viable formulations for our future product candidates;
- adverse regulatory decisions, including failure to receive regulatory approval for any of our future product candidates;
- the success of competitive drugs or technologies;
- regulatory or legal developments in the United States and other countries applicable to our future product candidates;
- the size and growth of our prospective patient populations;
- developments concerning our future collaborators, our external manufacturers or in-house manufacturing capabilities;
- inability to obtain adequate product supply for any future 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 future 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 rising inflation, including wage inflation;
- general macroeconomic, industry, geopolitical and market conditions; and
- other factors, including those described in this "Risk Factors" section, many of which are beyond our control.



***If we are not able to comply with the applicable continued listing requirements or standards of Nasdaq, our common stock could be delisted.***

Our common stock is currently listed on Nasdaq. To maintain this listing, we must satisfy continued listing requirements and standards. There can be no assurances that we will be able to comply with the applicable listing requirements and standards. For example, in November 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 had to 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 had not regained 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. On September 23, 2022, we executed a reverse stock split of our common stock at a ratio of 1-for-30. In response to their non-compliance notification on May 10, 2022, and as a result of the reverse stock split, we received notification from The Nasdaq Stock Market Listing Qualifications Staff on October 7, 2022, that we were in compliance with its minimum bid price requirement and the matter was closed.

If our common stock is delisted from Nasdaq and is not eligible for quotation or listing on another market or exchange, including as a result of our failure to meet the bid price requirement, trading of our shares of common stock could be conducted only in the over-the-counter market or on an electronic bulletin board established for unlisted securities. In such event, it would likely become more difficult to dispose of, or obtain accurate price quotations for, shares of our common stock.

***Our business could be negatively affected as a result of significant stockholders or potential stockholders attempting to effect changes or acquire control over th Company, which could cause us to incur significant expense, hinder execution of our business strategy and impact the trading value of our securities.***

Our stockholders may from time-to-time attempt to effect changes, engage in proxy solicitations or advance stockholder proposals. Responding to proxy contests and other actions by activist shareholders can be costly and time-consuming, disrupting our operations and diverting the attention of our board of directors and senior management from the pursuit of business strategies. Any of these impacts could materially and adversely affect our business and operating results. Further, the market price of our common stock, which has been trading below book value, could be subject to significant fluctuation or otherwise be adversely affected by the events, risks and uncertainties described above.



***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 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.

***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 macroeconomic conditions and geopolitical uncertainty 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, such as the inflationary environment, financial institution instability and recessionary fears, in the global financial markets and due to geopolitical uncertainty, such as the ongoing conflict in Ukraine and rising tensions between China and Taiwan. 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 had 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 weakened ability to raise additional capital when needed on acceptable terms, if at all. A weak or declining economy could also strain our future 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 macroeconomic climate, geopolitical uncertainty and financial market conditions could adversely impact our business.

***We maintain our cash at financial institutions. The failure of financial institutions could adversely affect our ability to pay our operational expenses or make other payments.***

Our cash is held at banking institutions in non-interest-bearing and interest-bearing accounts. If such banking institutions were to fail, similar to Silicon Valley Bank in March 2023, we could lose access to our accounts or our assets held in our accounts or our access to our accounts or assets may be materially delayed. Any material loss that we may experience in the future or inability for a material time period to access our cash and cash equivalents could have an adverse effect on our ability to pay our operational expenses or make other payments, which could adversely affect our business.



***We or the future third parties upon whom we may 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, and potential future 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, and potential future 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**

Not applicable.

**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: May 15, 2023

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 generally accepted accounting principles;

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

   d. Disclosed in this report any change in the registrant's internal control over 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; and

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

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

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

May 15, 2023
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 generally accepted accounting principles;

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

   d. Disclosed in this report any change in the registrant's internal control over 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; and

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

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

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

May 15, 2023
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 the best of our knowledge, the Quarterly Report on Form 10-Q for the quarter ended March 31, 2023 (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. To the best of our knowledge, the information contained in the Form 10-Q fairly presents, in all material respects, the financial condition and results of operations of the Company.

May 15, 2023
Date

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

May 15, 2023
Date

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