

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

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2022

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

For the transition period from \_\_\_ to \_\_\_

Commission file number: 001-38105



**180 LIFE SCIENCES CORP**

(Exact name of registrant as specified in its charter)

**Delaware**

(State or other jurisdiction of  
incorporation or organization)

**3000 El Camino Real  
Bldg. 4, Suite 200  
Palo Alto, CA 94306**

(Address of principal executive offices)

**90-1890354**

(I.R.S. Employer  
Identification No.)

**94306**

(Zip Code)

**(650) 507-0669**

(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 \$0.0001 per share	ATNF	The NASDAQ Stock Market LLC (The NASDAQ Capital Market)
Warrants to purchase Common Stock	ATNFW	The NASDAQ Stock Market LLC (The 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 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	<input type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input checked="" type="checkbox"/>	Smaller reporting company	<input checked="" type="checkbox"/>
		Emerging growth company	<input checked="" type="checkbox"/>

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

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

As of November 9, 2022, 40,460,494 shares of common stock, par value \$0.0001 per share, were issued and outstanding.

180 LIFE SCIENCES CORP. AND SUBSIDIARIES  
FORM 10-Q  
FOR THE THREE AND NINE MONTHS ENDED SEPTEMBER 30, 2022

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PART I – FINANCIAL INFORMATION

ITEM 1. Financial Statements

180 LIFE SCIENCES CORP. AND SUBSIDIARIES  
CONDENSED CONSOLIDATED BALANCE SHEETS

	September 30, 2022 (unaudited)	December 31, 2021
<b>Assets</b>		
Current Assets:		
Cash	\$ 3,588,639	\$ 8,224,508
Prepaid expenses and other current assets	2,926,202	2,976,583
<b>Total Current Assets</b>	<b>6,514,841</b>	<b>11,201,091</b>
Intangible assets, net	1,564,860	1,948,913
In-process research and development	12,290,516	12,575,780
Goodwill	13,965,715	36,987,886
<b>Total Assets</b>	<b>\$ 34,335,932</b>	<b>\$ 62,713,670</b>
<b>Liabilities and Stockholders' Equity</b>		
Current Liabilities:		
Accounts payable	\$ 1,015,244	\$ 586,611
Accrued expenses	2,092,029	1,964,580
Accrued expenses - related parties	158,467	18,370
Loans payable - current portion	321,694	1,828,079
Loans payable - related parties	84,756	81,277
Derivative liabilities	1,052,807	15,220,367
<b>Total Current Liabilities</b>	<b>4,724,997</b>	<b>19,699,284</b>
Loans payable – non current portion	31,522	48,165
Deferred tax liability	3,504,046	3,643,526
<b>Total Liabilities</b>	<b>8,260,565</b>	<b>23,390,975</b>
Commitments and contingencies (Note 8)		
<b>Stockholders' Equity:</b>		
Preferred stock, \$0.0001 par value; 5,000,000 shares authorized; (see designations and shares authorized for Series A, Class C and Class K preferred stock)		
Class C Preferred Stock; 1 share authorized, issued and outstanding at September 30, 2022 and December 31, 2021	-	-
Class K Preferred Stock; 1 share authorized, issued and outstanding at September 30, 2022 and December 31, 2021	-	-
Common stock, \$0.0001 par value; 100,000,000 shares authorized; 39,246,011 and 34,035,925 shares issued and outstanding at September 30, 2022 and December 31, 2021, respectively	3,924	3,404
Additional paid-in capital	115,427,474	107,184,137
Accumulated other comprehensive (loss) income	(3,689,764)	817,440
Accumulated deficit	(85,666,267)	(68,682,286)
<b>Total Stockholders' Equity</b>	<b>26,075,367</b>	<b>39,322,695</b>
<b>Total Liabilities and Stockholders' Equity</b>	<b>\$ 34,335,932</b>	<b>\$ 62,713,670</b>

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

**180 LIFE SCIENCES CORP. AND SUBSIDIARIES**  
**CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS**  
**AND COMPREHENSIVE INCOME (LOSS)**  
(unaudited)

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2022	2021	2022	2021
<b>Operating Expenses:</b>				
Research and development	\$ 583,177	\$ 316,473	\$ 1,688,474	\$ 689,217
Research and development - related parties	53,347	298,879	158,401	1,287,583
General and administrative	3,418,628	3,519,605	10,405,933	8,740,067
General and administrative - related parties	-	82,519	5,261	462,081
Total Operating Expenses	<u>4,055,152</u>	<u>4,217,476</u>	<u>12,258,069</u>	<u>11,178,948</u>
Loss From Operations	<u>(4,055,152)</u>	<u>(4,217,476)</u>	<u>(12,258,069)</u>	<u>(11,178,948)</u>
<b>Other (Expense) Income:</b>				
Gain on settlement of liabilities	-	472,677	-	927,698
Other income	-	12,308	-	12,308
Interest expense	(7,348)	(5,455)	(22,117)	(130,634)
Interest (expense) income – related parties	(1,536)	(14,201)	1,495	(42,279)
Loss on extinguishment of convertible notes payable, net	-	-	-	(9,737)
Loss on impairment of goodwill	(18,872,850)	-	(18,872,850)	-
Change in fair value of derivative liabilities	1,449,908	22,043,391	14,167,560	(10,342,337)
Change in fair value of accrued issuable equity	-	-	-	(9,405)
Offering costs allocated to warrant liabilities	-	-	-	(604,118)
Total Other (Expense) Income, Net	<u>(17,431,826)</u>	<u>22,508,720</u>	<u>(4,725,912)</u>	<u>(10,198,504)</u>
<b>(Loss) Income Before Income Taxes</b>	<u>(21,486,978)</u>	<u>18,291,244</u>	<u>(16,983,981)</u>	<u>(21,377,452)</u>
Income tax benefit	-	5,612	-	16,587
<b>Net (Loss) Income</b>	<u>(21,486,978)</u>	<u>18,296,856</u>	<u>(16,983,981)</u>	<u>(21,360,865)</u>
<b>Other Comprehensive (Loss) Income:</b>				
Foreign currency translation adjustments	(1,871,072)	(530,817)	(4,507,204)	65,018
<b>Total Comprehensive (Loss) Income</b>	<u>\$ (23,358,050)</u>	<u>\$ 17,766,039</u>	<u>\$ (21,491,185)</u>	<u>\$ (21,295,847)</u>
<b>Basic and Diluted Net (Loss) Income per Common Share</b>				
Basic	\$ (0.55)	\$ 0.56	\$ (0.47)	\$ (0.70)
Diluted	<u>\$ (0.55)</u>	<u>\$ 0.23</u>	<u>\$ (0.47)</u>	<u>\$ (0.70)</u>
<b>Weighted Average Number of Common Shares Outstanding:</b>				
Basic	<u>39,181,736</u>	<u>32,727,965</u>	<u>35,803,504</u>	<u>30,491,082</u>
Diluted	<u>39,181,736</u>	<u>33,709,584</u>	<u>35,803,504</u>	<u>30,491,082</u>

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

**180 LIFE SCIENCES CORP. AND SUBSIDIARIES**  
**CONDENSED CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY**  
(unaudited)

For The Three and Nine Months Ended September 30, 2022

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
<b>Balance - January 1, 2022</b>	34,035,925	\$ 3,404	\$ 107,184,137	\$ 817,440	\$ (68,682,286)	\$ 39,322,695
<b>Shares issued for professional services to directors</b>	51,319	5	149,713	-	-	149,718
Stock based compensation	-	-	596,467	-	-	596,467
Comprehensive income (loss):						
Net income	-	-	-	-	1,563,713	1,563,713
Other comprehensive loss	-	-	-	(728,081)	-	(728,081)
<b>Balance - March 31, 2022</b>	34,087,244	\$ 3,409	\$ 107,930,317	\$ 89,359	\$ (67,118,573)	\$ 40,904,512
Shares issued for professional services to directors	44,579	4	60,623	-	-	60,627
Stock based compensation	12,000	1	795,051	-	-	795,052
Comprehensive income (loss):						
Net income	-	-	-	-	2,939,284	2,939,284
Other comprehensive loss	-	-	-	(1,908,051)	-	(1,908,051)
<b>Balance - June 30, 2022</b>	34,143,823	\$ 3,414	\$ 108,785,991	\$ (1,818,692)	\$ (64,179,289)	\$ 42,791,424
Shares issued for professional services to directors	55,112	5	60,617	-	-	60,622
Issuance of pre-funded warrants <sup>(a)</sup>	-	-	2,562,265	-	-	2,562,265
Shares issued from exercise of pre-funded warrants <sup>(a)</sup>	1,547,076	155	-	-	-	155
Shares issued in connection with July 2022 Offering <sup>(a)</sup>	3,500,000	350	3,407,140	-	-	3,407,490
Stock based compensation	-	-	611,461	-	-	611,461
Comprehensive income (loss):						
Net loss	-	-	-	-	(21,486,978)	(21,486,978)
Other comprehensive loss	-	-	-	(1,871,072)	-	(1,871,072)
<b>Balance - September 30, 2022</b>	39,246,011	\$ 3,924	\$ 115,427,474	\$ (3,689,764)	\$ (85,666,267)	\$ 26,075,367

(a) Consists of \$6,499,737 of gross proceeds from the July 2022 Offering; gross proceeds of \$3,710,000 are related to the common shares and common warrants issued and includes \$302,510 in related placement agent fees and other offering costs, and \$2,789,737 in gross proceeds are in connection with the pre-funded warrants and includes \$227,472 in related placement agent fees and other offering costs. At the end of the period, 1,547,076 pre-funded warrants were exercised at an exercise price of \$0.0001 for proceeds of \$155.

**For The Three and Nine Months Ended September 30, 2021**

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income		Total Stockholders' Equity
	Shares	Amount		Income	Deficit	
<b>Balance - January 1, 2021</b>	26,171,225	\$ 2,617	\$ 78,005,004	\$ 636,886	\$ (48,357,638)	\$ 30,286,869
Shares issued upon conversion of KBL debt	467,123	47	1,941,078	-	-	1,941,125
Shares issued upon conversion of 180 debt	158,383	16	432,367	-	-	432,383
Shares issued in connection with the financing, net of financing costs <sup>(a)</sup>	2,564,000	256	10,730,814	-	-	10,731,070
Offering costs allocated to warrant liabilities <sup>(b)</sup>	-	-	604,118	-	-	604,118
Warrants issued in connection with private offering, reclassified to derivative liabilities	-	-	(7,294,836)	-	-	(7,294,836)
Shares issued upon exchange of common stock equivalents	959,809	96	(96)	-	-	-
Stock based compensation:						
Common stock	197,790	20	925,384	-	-	925,404
Options	-	-	1,092,399	-	-	1,092,399
Comprehensive income (loss):						
Net loss	-	-	-	-	(16,198,585)	(16,198,585)
Other comprehensive income	-	-	-	189,348	-	189,348
<b>Balance - March 31, 2021</b>	30,518,330	\$ 3,052	\$ 86,436,232	\$ 826,234	\$ (64,556,223)	\$ 22,709,295
Shares issued to settle accounts payable	225,000	23	1,973,227	-	-	1,973,250
Impact of transfer agent reconciliation	280,509	28	(28)	-	-	-
Stock based compensation:						
Common stock	37,515	4	378,655	-	-	378,659
Options	-	-	344,095	-	-	344,095
Correction of an error	-	-	363,523	-	-	363,523
Comprehensive loss:						
Net loss	-	-	-	-	(23,459,136)	(23,459,136)
Other comprehensive income	-	-	-	406,487	-	406,487
<b>Balance - June 30, 2021</b>	31,061,354	\$ 3,106	\$ 89,495,704	\$ 1,232,721	\$ (88,015,359)	\$ 2,716,172
Shares issued in connection with the August 2021 Offering, net of financing costs	2,500,000	250	13,879,750	-	-	13,880,000
Shares issued to settle convertible det and derivative liabilities with Alpha Capital	150,000	15	1,060,485	-	-	1,060,500
Shares issued in connection with the repayment of related party loans and convertible notes	141,852	15	851,097	-	-	851,112
Shares issued upon exchange of common stock equivalents	44,240	4	(4)	-	-	-
Stock-based compensation:						
Common Stock	71,289	8	431,988	-	-	431,996
Options	-	-	434,979	-	-	434,979
Comprehensive income (loss):						
Net income	-	-	-	-	18,296,856	18,296,856
Other comprehensive loss	-	-	-	(530,817)	-	(530,817)
<b>Balance - September 30, 2021</b>	33,968,735	\$ 3,399	\$ 106,153,999	\$ 701,904	\$ (69,718,503)	\$ 37,140,799

(b) Consists of \$11,666,200 of gross proceeds from the February 2021 PIPE offering, net of placement agent fees and other cash offering costs of \$968,930. Of the \$968,930 of offering costs, \$364,812 was allocated to the common stock and \$604,118 was allocated to the warrant liabilities and expensed immediately due to their liability classification.

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

**180 LIFE SCIENCES CORP. AND SUBSIDIARIES**  
**CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS**  
(unaudited)

	<b>For the Nine Months Ended</b>	
	<b>September 30,</b>	
	<b>2022</b>	<b>2021</b>
<b>Cash Flows From Operating Activities</b>		
Net Loss	\$ (16,983,981)	\$ (21,360,865)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation:		
Shares issued for services	270,967	2,099,582
Amortization of stock options and restricted stock shares	2,002,980	1,871,473
Impairment of goodwill	18,872,850	-
Depreciation and amortization	71,396	93,139
Bad debt expense – related parties	-	338,582
Gain on settlement of liabilities	-	(927,698)
Loss on extinguishment of convertible note payable	-	9,737
Deferred tax benefit	-	(16,587)
Offering costs allocated to warrant liabilities	-	604,118
Change in fair value of derivative liabilities	(14,167,560)	10,342,337
Change in fair value of accrued issuable equity	-	9,405
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	36,340	(443,531)
Accounts payable	428,632	(5,458,875)
Accounts payable – related parties	-	(211,048)
Accrued expenses	127,449	(799,764)
Accrued expenses – related parties	140,097	(441,403)
Accrued issuable equity	-	(52,500)
Total adjustments	<u>7,783,151</u>	<u>7,016,967</u>
Net Cash Used In Operating Activities	<u>(9,200,830)</u>	<u>(14,343,898)</u>
<b>Cash Flows From Financing Activities</b>		
Shares issued for cash, net of issuance costs	-	26,666,200
Proceeds from sale of common stock and common warrants	6,499,737	-
Proceeds from exercise of pre-funded warrants	155	-
Offering costs in connection with sale of common stock and warrants	(529,982)	(2,055,130)
Repayment of loans payable	(1,491,986)	(306,361)
Repayment of loans payable – related parties	-	(431,838)
Repayment of convertible debt – related parties	-	(10,000)
Net Cash Provided By Financing Activities	<u>4,477,924</u>	<u>23,862,871</u>

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

**180 LIFE SCIENCES CORP. AND SUBSIDIARIES**  
**CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS, continued**  
**(unaudited)**

<b>Effect of Exchange Rate Changes on Cash</b>	87,037	60,283
	<u>                    </u>	<u>                    </u>
<b>Net (Decrease) Increase In Cash</b>	(4,635,869)	9,579,256
Cash - Beginning of Period	8,224,508	2,108,544
Cash - End of Period	<u>\$ 3,588,639</u>	<u>\$ 11,687,800</u>
 <b>Supplemental Disclosures of Cash Flow Information:</b>		
Cash paid during the period for income taxes	\$ -	\$ -
Cash paid during the period for interest	<u>\$ 13,423</u>	<u>\$ 31,428</u>
 <b>Non-cash investing and financing activities:</b>		
Warrants issued in connection with the private offering	\$ -	\$ 7,294,836
Shares issued to settle accounts payable	<u>\$ -</u>	<u>\$ 1,973,250</u>
Conversion of convertible debt and accrued interest into common stock	<u>\$ -</u>	<u>\$ 1,340,184</u>
Common stock issued upon exchange of notes payable and accrued interest	<u>\$ -</u>	<u>\$ 1,283,496</u>
Shares and warrants issued for Alpha settlement	<u>\$ -</u>	<u>\$ 1,156,177</u>
Security deposit applied to accounts payable	<u>\$ -</u>	<u>\$ 7,078</u>
Exchange of common stock equivalents for common stock	<u>\$ -</u>	<u>\$ 100</u>

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

**180 LIFE SCIENCES CORP. AND SUBSIDIARIES**  
**NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**  
**(Amounts in US Dollars)**  
**(unaudited)**

**NOTE 1 - BUSINESS ORGANIZATION AND NATURE OF OPERATIONS**

180 Life Sciences Corp., formerly known as KBL Merger Corp. IV (“180LS”, or together with its subsidiaries, the “Company”), was a blank check company organized under the laws of the State of Delaware on September 7, 2016. The Company was formed for the purpose of effecting a merger, share exchange, asset acquisition, share purchase, reorganization or similar business combination with one or more businesses. On November 6, 2020 (“Closing Date”), a business combination was consummated following a special meeting of stockholders, where the stockholders of the Company considered and approved, among other matters, a proposal to adopt a Business Combination Agreement. Pursuant to the Business Combination Agreement, KBL Merger Sub, Inc. merged with 180 Life Corp. (f/k/a 180 Life Sciences Corp.) (“180”), with 180 continuing as the surviving entity and becoming a wholly-owned subsidiary of the Company (“the Business Combination”). References to “KBL” refer to the Company prior to the November 6, 2020 business combination.

The Company is a clinical stage biotechnology company focused on the development of therapeutics for unmet medical needs in chronic pain, inflammation, fibrosis and other inflammatory diseases, where anti-TNF therapy will provide a clear benefit to patients, by employing innovative research, and, where appropriate, combination therapy. We have three product development platforms:

- fibrosis and anti-tumor necrosis factor (“TNF”);
- drugs which are derivatives of cannabidiol (“CBD”); and
- alpha 7 nicotinic acetylcholine receptor (“ $\alpha$ 7nAChR”).

**NOTE 2 - GOING CONCERN AND MANAGEMENT’S PLANS**

The Company has not generated any revenues and has incurred significant losses since inception. For the nine months ended September 30, 2022, the Company used cash in operations of \$9,200,830. As of September 30, 2022, the Company has an accumulated deficit of \$85,666,267 and working capital of \$1,789,844. On July 17, 2022, the Company entered into a Securities Purchase Agreement with certain purchasers, pursuant to which the Company agreed to sell an aggregate of 3,500,000 shares of common stock, pre-funded warrants to purchase up to an aggregate of 2,632,076 shares of common stock (“July 2022 Pre-Funded Warrants”), and common stock warrants to purchase up to an aggregate of 6,132,076 shares of common stock (the “July 2022 Common Warrants”), at a combined purchase price of \$1.06 per share and warrant (the “July 2022 Offering”). Aggregate gross proceeds from the July 2022 Offering were \$6,499,737 (see Note 9 – Stockholder’s Equity). The July 2022 Offering closed on July 20, 2022.

On March 11, 2020, the World Health Organization declared COVID-19 a pandemic. The extent of COVID-19’s effect on the Company’s operational and financial performance will depend on future developments, including the duration, spread and intensity of the pandemic (including any resurgences), the impact of variants of the virus that causes COVID-19, labor needs at the Company as well as in the supply chain, compliance with government or employer COVID-19 vaccine mandates and the resulting impact on available labor, and the level of social and economic restrictions imposed in the United States and abroad in an effort to curb the spread of the virus, all of which are uncertain and difficult to predict.

Management has evaluated, and will continue to evaluate, the impact of the COVID-19 pandemic on the industry and has concluded that while it is reasonably possible that the virus could have a negative effect on the Company's financial position or results of its operations, the specific impact is not readily determinable as of the date of these unaudited condensed consolidated financial statements (the "condensed consolidated financial statements"). The follow-up time for patient data and the statistical analysis for the Phase 2b Dupuytren's Contracture clinical trial was delayed as a result of COVID-19, but such follow-up and statistical analyses are now complete. The Company announced the top-line data results from the Phase 2b trial on December 1, 2021 and the data was published on April 29, 2022 in a peer-reviewed journal. The Company may experience similar delays in other clinical trials due to the continued future impact of COVID-19. The condensed consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

These condensed consolidated financial statements have been prepared under the assumption of a going concern, which assumes that the Company will be able to realize its assets and discharge its liabilities in the normal course of business. The Company's ability to continue its operations is dependent upon obtaining new financing for its ongoing operations. Future financing options available to the Company include equity financings and loans and if the Company is unable to obtain such additional financing timely, or on favorable terms, the Company may have to curtail its development, marketing and promotional activities, which would have a material adverse effect on its business, financial condition and results of operations, and it could ultimately be forced to discontinue its operations and liquidate. These matters raise substantial doubt about the Company's ability to continue as a going concern for a reasonable period of time, which is defined as within one year after the date that the condensed consolidated financial statements are issued. Realization of the Company's assets may be substantially different from the carrying amounts presented in these condensed consolidated financial statements and the accompanying condensed consolidated financial statements do not include any adjustments that may become necessary, should the Company be unable to continue as a going concern.

### **NOTE 3 - SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES**

#### **Significant Accounting Policies**

There have been no material changes to the Company's significant accounting policies as set forth in the Company's audited consolidated financial statements included in the Annual Report on Form 10-K for the year ended December 31, 2021 under Note 3 - Summary of Significant Accounting Policies, except as disclosed in this note.

#### **Basis of Presentation**

The accompanying unaudited condensed consolidated financial statements of the Company have been prepared on a going concern basis in accordance with accounting principles generally accepted in the United States of America (GAAP) for interim financial reporting and as required by Regulation S-X, Rule 10-01. Accordingly, they do not include all of the information and footnotes required by GAAP for complete financial statements. In the opinion of management, all adjustments (including those which are normal and recurring) considered necessary for a fair presentation of the interim financial information have been included. When preparing financial statements in conformity with GAAP, the Company must make estimates and assumptions that affect the reported amounts of assets, liabilities, revenues, expenses and related disclosures at the date of the financial statements. Actual results could differ from those estimates. Additionally, operating results for the three and nine months ended September 30, 2022, are not necessarily indicative of the results that may be expected for any other interim period or for the fiscal year ending December 31, 2022. For further information, refer to the financial statements and footnotes included in the Company's annual financial statements for the fiscal year ended December 31, 2021, which are included in the Company's annual report on Form 10-K filed with the Securities and Exchange Commission ("SEC") on March 31, 2022.

#### **Use of Estimates**

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates, judgments, and assumptions that affect the reported amounts of assets, liabilities, revenues and expenses, together with amounts disclosed in the related notes to the condensed consolidated financial statements. The Company's significant estimates and assumptions used in these condensed consolidated financial statements include, but are not limited to, the collectability of an insurance claims receivable, the fair value of financial instruments warrants, options and equity shares, the valuation of stock-based compensation, and the estimates and assumptions related to impairment analysis of goodwill and other intangible assets.

Certain of the Company's estimates could be affected by external conditions, including those unique to the Company and general economic conditions. It is reasonably possible that these external factors could have an effect on the Company's estimates and may cause actual results to differ from those estimates.

## Foreign Currency Translation

The Company's reporting currency is the United States dollar. The functional currency of certain subsidiaries was the Canadian Dollar ("CAD") (0.7874 CAD to 1 US dollar as of December 31, 2021) or British Pound ("GBP") (1.1150 and 1.3510 GBP to 1 US dollar, each as of September 30, 2022 and December 31, 2021, respectively), while expense accounts are translated at the weighted average exchange rate for the period (0.7941 CAD and 0.7992 CAD to 1 US dollar for each of the three and nine months ended September 30, 2021, respectively, 1.1772 and 1.3784 GBP to 1 US dollar for each of the three months ended September 30, 2022 and 2021, respectively, and 1.2597 and 1.3847 GBP to 1 US dollar for each of the nine months ended September 30, 2022 and 2021, respectively). Equity accounts are translated at historical exchange rates. The resulting translation adjustments are recognized in stockholders' equity as a component of accumulated other comprehensive income.

Comprehensive income (loss) is defined as the change in equity of an entity from all sources other than investments by owners or distributions to owners and includes foreign currency translation adjustments as described above. During the three months ended September 30, 2022 and 2021, the Company recorded other comprehensive loss of (\$1,871,072) and (\$530,817), respectively, as a result of foreign currency translation adjustments. During the nine months ended September 30, 2022 and 2021, the Company recorded other comprehensive (loss) income of (\$4,507,204) and \$65,018, respectively, as a result of foreign currency translation adjustments.

Foreign currency gains and losses resulting from transactions denominated in foreign currencies, including intercompany transactions, are included in results of operations. The Company recognized (\$14,031) and (\$14,151) of foreign currency transaction losses for the three and nine months ended September 30, 2022, respectively, and recognized (\$218,834) and (\$200,264) of foreign currency transaction losses for the three and nine months ended September 30, 2021, respectively. Such amounts have been classified within general and administrative expenses in the accompanying condensed consolidated statements of operations and comprehensive income (loss).

## Impairment of Long-Lived Assets and Goodwill

The Company reviews long-lived assets and certain identifiable assets for impairment whenever circumstances and situations change such that there is an indication that the carrying amounts may not be recovered. An impairment exists when the carrying value of the long-lived asset is not recoverable and exceeds its estimated fair value.

Goodwill represents the difference between the purchase price and the fair value of assets and liabilities acquired in a business combination. The Company reviews goodwill yearly, or more frequently whenever circumstances and situations change such that there is an indication that the carrying amounts may not be recovered, for impairment by initially considering qualitative factors to determine whether it is more likely than not that the fair value of a reporting unit is less than its carrying amount, including goodwill, as a basis for determining whether it is necessary to perform a quantitative analysis. If it is determined that it is more likely than not that the fair value of reporting unit is less than its carrying amount, a quantitative analysis is performed to identify goodwill impairment. If it is determined that it is not more likely than not that the fair value of the reporting unit is less than its carrying amount, it is unnecessary to perform a quantitative analysis. The Company may elect to bypass the qualitative assessment and proceed directly to performing a quantitative analysis. As of December 31, 2021, the Company elected to bypass the qualitative assessment and conducted a quantitative assessment whereby it was determined the fair value of the reporting unit (which the Company concluded was the consolidated entity), exceeded the carrying value and, accordingly, there was no impairment of goodwill.

During the quarter, the market value of the Company's single reporting unit had significantly declined and as such, the Company elected to conduct a quantitative analysis of goodwill to assess for impairment. As of September 30, 2022, the market value of the Company's publicly traded stock was \$0.67 per share; the Company determined the fair market value of its single reporting unit as of that date to be \$26,102,105, which represents the value per share multiplied by 39,251,286 shares (consisting of 39,246,011 shares of common stock outstanding as of September 30, 2022 plus 5,275 special voting shares which are exchangeable into common stock for no additional consideration). The carrying amount of the reporting unit as of September 30, 2022 was \$44,974,955 (total assets of \$53.2 million less total liabilities of \$8.2 million). As of this measurement date, the carrying value exceeded the fair market value by \$18,872,850 and as such, management determined that the goodwill of the reporting unit was impaired by this amount. To recognize the impairment of goodwill, the Company recorded a loss (which appears as an expense on the income statement) for \$18,872,850, which reduced the goodwill of its CannBioRex Pharmaceuticals Corp. ("CBR") and 180 Therapeutics LP ("180T") subsidiaries by \$11,264,612 and \$7,608,238, respectively.

The following is a summary of goodwill activity for the nine months ended September 30, 2022 for the Company's single reporting unit, which includes the recorded loss on goodwill impairment described above.

	<u>CBR Goodwill</u>	<u>180T Goodwill</u>	<u>Consolidated Goodwill</u>
<b>Balance, December 31, 2021</b>	\$ 23,749,631	\$ 13,238,255	\$ 36,987,886
Currency translation	(664,353)	-	(664,353)
<b>Balance, March 31, 2022</b>	23,085,278	13,238,255	36,323,533
Currency translation	(1,734,582)	-	(1,734,582)
<b>Balance, June 30, 2022</b>	21,350,696	13,238,255	34,588,951
Currency translation	(1,750,386)	-	(1,750,386)
Balance before impairment	19,600,310	13,238,255	32,838,565
Impairment of goodwill	(11,264,612)	(7,608,238)	(18,872,850)
<b>Balance, September 30, 2022</b>	<u>\$ 8,335,698</u>	<u>\$ 5,630,017</u>	<u>\$ 13,965,715</u>

The Company will continue to perform goodwill/intangible assets and In-Process Research and Development ("IPR&D") assets impairment testing on an annual basis, or as needed if there are changes to the composition of its reporting unit. As of September 30, 2022, there have been no changes to the composition of the reporting unit.

#### Net Income (Loss) Per Common Share

Basic net income (loss) per common share is computed by dividing net income (loss) by the weighted average number of common shares outstanding during the period. Diluted net income (loss) per common share is computed by dividing net income (loss) by the weighted average number of common shares outstanding, plus the number of additional common shares that would have been outstanding if the common share equivalents had been issued (computed using the treasury stock or if converted method), if dilutive.

The following table details the net income (loss) per share calculation, reconciles between basic and diluted weighted average shares outstanding, and presents the potentially dilutive shares that are excluded from the calculation of the weighted average diluted common shares outstanding, because their inclusion would have been anti-dilutive:

	<u>For the Three Months Ended</u> <u>September 30,</u>		<u>For the Nine Months Ended</u> <u>September 30,</u>	
	<u>2022</u>	<u>2021</u>	<u>2022</u>	<u>2021</u>
Numerator:				
Net (loss) income	\$ (21,486,978)	\$ 18,296,856	\$ (16,983,981)	\$ (21,360,865)
Less: decrease in fair value of dilutive warrants	-	10,487,783	-	-
(Loss) income available to common stockholders - diluted	<u>\$ (21,486,978)</u>	<u>\$ 7,809,073</u>	<u>\$ (16,983,981)</u>	<u>\$ (21,360,865)</u>
Weighted average shares outstanding (denominator for basic earnings per share)	<u>39,181,736<sup>(1)</sup></u>	<u>32,727,965</u>	<u>35,803,504<sup>(1)</sup></u>	<u>30,491,082</u>
Effects of dilutive securities:				
Assumed exercise of stock options, treasury stock method	-	182,727	-	-
Assumed exercise of warrants, treasury stock method	-	798,892	-	-
Dilutive potential common shares	-	981,619	-	-
Weighted average shares and assumed potential common shares (denominator for diluted earnings per share, treasury method)	<u>39,181,736<sup>(1)</sup></u>	<u>33,709,584</u>	<u>35,803,504<sup>(1)</sup></u>	<u>30,491,082</u>
Basic earnings per share	<u>\$ (0.55)</u>	<u>\$ 0.56</u>	<u>\$ (0.47)</u>	<u>\$ (0.70)</u>
Diluted earnings per share	<u>\$ (0.55)</u>	<u>\$ 0.23</u>	<u>\$ (0.47)</u>	<u>\$ (0.70)</u>

(1) This amount includes 1,085,000 of unexercised, pre-funded penny warrants.

The following common share equivalents are excluded from the calculation of weighted average common shares outstanding, because their inclusion would have been anti-dilutive:

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2022	2021	2022	2021
Options	3,259,121	436,000	3,259,121	2,066,000
Warrants	17,285,984 <sup>(1)</sup>	8,526,250	17,285,984 <sup>(1)</sup>	11,153,908
Total potentially dilutive shares	20,545,105	8,962,250	20,545,105	13,219,908

(1) This amount excludes 1,085,000 of unexercised, pre-funded warrants, which are not considered to be anti-dilutive, as they are penny warrants.

#### Warrant, Option and Convertible Instrument Valuation

The Company has computed the fair value of warrants and options using a Black-Scholes model. The expected term used for warrants is the contractual life and the expected term used for options issued is the estimated period of time that options granted are expected to be outstanding. The Company utilizes the “simplified” method to develop an estimate of the expected term of “plain vanilla” option grants. The Company is utilizing an expected volatility figure based on a review of the historical volatilities, over a period of time, equivalent to the expected life of the instrument being valued, of similarly positioned public companies within its industry. The risk-free interest rate was determined from the implied yields from U.S. Treasury zero-coupon bonds with a remaining term consistent with the expected term of the instrument being valued.

#### Subsequent Events

The Company has evaluated events that have occurred after the balance sheet date but before these condensed consolidated financial statements were issued. Based upon that evaluation, the Company did not identify any recognized or non-recognized subsequent events that would have required adjustment or disclosure in the financial statements, except as disclosed in Note 11 - Subsequent Events.

#### Recently Issued Accounting Pronouncements

Management does not believe that any recently issued, but not yet effective, accounting pronouncements, if currently adopted, would have a material effect on the Company’s unaudited condensed consolidated financial statements.

**NOTE 4 – PREPAID EXPENSES AND OTHER CURRENT ASSETS**

Prepaid expenses consist of the following as of September 30, 2022 and December 31, 2021:

	<b>September 30, 2022</b>	<b>December 31, 2021</b>
Insurance	\$ 378,009	\$ 2,151,487
Research and development expense tax credit receivable	601,265	644,513
Insurance claims receivable <sup>(1)</sup>	1,836,940	-
Professional fees	38,311	80,783
Value-added tax receivable	46,059	24,411
Taxes	25,618	25,634
Other	-	49,755
	<u>\$ 2,926,202</u>	<u>\$ 2,976,583</u>

(1) See Note 8 – Commitments and Contingencies – Legal Matters.

**NOTE 5 – ACCRUED EXPENSES**

Accrued expenses consist of the following as of September 30, 2022 and December 31, 2021:

	<b>September 30, 2022</b>	<b>December 31, 2021</b>
Consulting fees	\$ 402,315	\$ 548,281
Professional fees	26,738	252,973
Accrued legal fees <sup>(1)</sup>	218,217	300,000
Employee and director compensation	1,236,014	725,569
Research and development fees	168,172	91,737
Interest	33,523	25,433
Other	7,050	20,587
	<u>\$ 2,092,029</u>	<u>\$ 1,964,580</u>

(1) See Note 8 - Commitments and Contingencies, *Legal Matters*.

As of September 30, 2022 and December 31, 2021, accrued expenses - related parties were \$158,467 and \$18,370, respectively. See Note 10 - Related Parties for details.

## NOTE 6 - DERIVATIVE LIABILITIES

The following table sets forth a summary of the changes in the fair value of Level 3 derivative liabilities (except the Public SPAC Warrants as defined below, which are Level 1 derivative liabilities) that are measured at fair value on a recurring basis:

	<b>Warrants</b>				<b>Total</b>
	<b>Public SPAC</b>	<b>Private SPAC</b>	<b>PIPE</b>	<b>Other</b>	
Balance as of January 1, 2022	\$ 8,048,850	\$ 467,325	\$ 6,516,300	\$ 187,892	\$ 15,220,367
Change in fair value of derivative liabilities	(1,852,650)	(251,250)	(3,044,800)	(81,414)	(5,230,114)
Balance as of March 31, 2022	6,196,200	216,075	3,471,500	106,478	9,990,253
Change in fair value of derivative liabilities	(4,357,350)	(185,925)	(2,849,900)	(94,363)	(7,487,538)
Balance as of June 30, 2022	1,838,850	30,150	621,600	12,115	2,502,715
Change in fair value of derivative liabilities	(1,246,600)	(10,050)	(188,000)	(5,258)	(1,449,908)
Balance as of September 30, 2022	\$ 592,250	\$ 20,100	\$ 433,600	\$ 6,857	\$ 1,052,807

The fair value of the derivative liabilities as of September 30, 2022 and December 31, 2021 was estimated using the Black Scholes option pricing model, with the following assumptions used:

	<b>September 30, 2022</b>
Risk-free interest rate	4.16% - 4.24%
Expected term in years	1.84 - 3.40
Expected volatility	76.00% - 95.00%
Expected dividends	0%
Market Price	\$ 0.67

  

	<b>December 31, 2021</b>
Risk-free interest rate	0.85% - 1.14%
Expected term in years	2.59 - 4.15
Expected volatility	98.5%
Expected dividends	0%
Market Price	\$ 3.90

### SPAC Warrants

#### Public SPAC Warrants

Participants in KBL's initial public offering received an aggregate of 11,500,000 warrants ("Public SPAC Warrants"). Each Public SPAC Warrant entitles the holder to purchase one-half of one share of the Company's common stock at an exercise price of \$5.75 per half share (\$11.50 per whole share) until November 6, 2025, subject to adjustment. No fractional shares will be issued upon exercise of the Public SPAC Warrants. Management has determined that the Public SPAC Warrants contain a tender offer provision which could result in the Public SPAC Warrants settling for the tender offer consideration (including potentially cash) in a transaction that didn't result in a change-in-control. This feature results in the Public SPAC Warrants being precluded from equity classification. Accordingly, the Public SPAC Warrants are classified as liabilities measured at fair value, with changes in fair value each period reported in earnings. The Public SPAC Warrants were revalued on September 30, 2022 at \$592,250, which resulted in decreases of \$1,246,600 and \$7,456,600 in the fair value of the derivative liabilities during the three and nine months ended September 30, 2022, respectively.

### *Private SPAC Warrants*

Participants in KBL's initial private placement in connection with its initial public offering received an aggregate of 502,500 warrants ("Private SPAC Warrants"). Each Private SPAC Warrant entitles the holder to purchase one-half of one share of the Company's common stock at an exercise price of \$5.75 per half share (\$11.50 per whole share) until November 6, 2025, subject to adjustment. No fractional shares will be issued upon exercise of the Private SPAC Warrants. Management has determined that the Private SPAC Warrants contain a tender offer provision which could result in the Private SPAC Warrants settling for the tender offer consideration (including potentially cash) in a transaction that didn't result in a change-in-control. This feature (amongst others) results in the Private SPAC Warrants being precluded from equity classification. Accordingly, the Private SPAC Warrants are classified as liabilities measured at fair value, with changes in fair value each period reported in earnings. The Private SPAC Warrants were revalued on September 30, 2022 at \$20,100, which resulted in decreases of \$10,050 and \$447,225 in the fair value of the derivative liabilities during the three and nine months ended September 30, 2022, respectively.

### **PIPE Warrants**

On February 23, 2021, the Company issued five-year warrants (the "PIPE Warrants") to purchase 2,564,000 shares of common stock at an exercise price of \$5.00 per share in connection with a private placement offering. The PIPE Warrants did not meet the requirements for equity classification due to the existence of a tender offer provision that could potentially result in cash settlement of the PIPE Warrants that didn't meet the limited exception in the case of a change-in-control. Accordingly, the PIPE Warrants are liability-classified and the Company recorded the \$7,294,836 fair value of the PIPE Warrants, which was determined using the Black-Scholes option pricing model, as derivative liabilities. The PIPE Warrants were revalued on September 30, 2022 at \$433,600, which resulted in decreases of \$188,000 and \$6,082,700 in the fair value of the derivative liabilities during the three and nine months ended September 30, 2022, respectively.

### **Other Warrants**

#### *AGP Warrant*

In connection with the transactions contemplated by the Company's Business Combination Agreement (as amended, the "Business Combination Agreement"), dated as of July 25, 2019 (the "Business Combination"), on November 6, 2020, the Company became obligated to assume five-year warrants for the purchase of 63,658 shares of the Company's common stock at an exercise price of \$5.28 per share (the "Alliance Global Partners Warrant Liability" or "AGP Warrant Liability") that had originally been issued by KBL to an investment banking firm in connection with a prior private placement.

On March 12, 2021, the Company issued a warrant to Alliance Global Partners ("AGP" and the "AGP Warrant") to purchase up to an aggregate of 63,658 shares of the Company's common stock at a purchase price of \$5.28 per share, subject to adjustment, in full satisfaction of the AGP Warrant Liability. The exercise of the AGP Warrant is limited at any given time to prevent AGP from exceeding beneficial ownership of 4.99% of the then total number of issued and outstanding shares of the Company's common stock upon such exercise. The warrant is exercisable at any time between May 2, 2021 and May 2, 2025. The AGP Warrant did not meet the requirements for equity classification due to the existence of a tender offer provision that could potentially result in cash settlement of the AGP Warrant that did not meet the limited exception in the case of a change-in-control. Accordingly, the AGP Warrant will continue to be liability-classified. The AGP Warrant was revalued on September 30, 2022 at \$6,633, which resulted in decreases of \$3,762 and \$137,698 in the fair value of the derivative liabilities during the three and nine months ended September 30, 2022, respectively.

## Alpha Warrant

In connection with that certain Mutual Release and Settlement Agreement dated July 31, 2021 (agreed to on July 29, 2021) between the Company and Alpha Capital Anstalt (“Alpha” and the “Alpha Settlement Agreement”), the Company issued a three-year warrant for the purchase of 25,000 shares of the Company’s common stock at an exercise price of \$7.07 per share (the “Alpha Warrant Liability” and the “Alpha Warrant”). The exercise of shares of the Alpha Warrant is limited at any given time to prevent Alpha from exceeding a beneficial ownership of 4.99% of the then total number of issued and outstanding shares of the Company’s common stock upon such exercise. The warrant is exercisable until August 2, 2024. The Alpha Warrant did not meet the requirements for equity classification due to the existence of a tender offer provision that could potentially result in cash settlement of the Alpha Warrant that did not meet the limited exception in the case of a change-in-control. Accordingly, the Alpha Warrant is liability-classified and the Company recorded the \$95,677 fair value of the Alpha Warrant, which was determined using the Black-Scholes option pricing model, as a derivative liability. The Alpha Warrant was revalued on September 30, 2022 at \$224, which resulted in decreases of \$1,496 and \$43,337 in the fair value of the derivative liabilities during the three and nine months ended September 30, 2022, respectively.

### Warrant Activity

A summary of the warrant activity (including certain warrants granted in August 2021 and July 2022 as part of private offerings, both of which are equity-classified) during the nine months ended September 30, 2022 is presented below:

	Number of Warrants	Weighted Average Exercise Price	Weighted Average Remaining Life in Years	Intrinsic Value
Outstanding, December 31, 2021	11,153,908	\$ 9.06	4.1	\$ -
Issued	8,764,152	0.74	5.3	1,750,067
Exercised	(1,547,076)	0.0001	-(1)	(1,028,651)
Cancelled	-	-	-	-
Expired	-	-	-	-
Outstanding, September 30, 2022	<u>18,370,984</u>	<u>\$ 5.77</u>	<u>3.8<sup>(1)</sup></u>	<u>\$ 721,417</u>
Exercisable, September 30, 2022	<u>12,238,908</u>	<u>\$ 8.13</u>	<u>3.0</u>	<u>721,417</u>

(1) Note that the July 2022 Pre-funded Warrants are exercisable until they are exercised in full and have no expiration date; as such, they have been excluded from this calculation.

A summary of outstanding and exercisable warrants as of September 30, 2022 is presented below:

Warrants Outstanding		Warrants Exercisable	
Exercise Price	Number of Shares	Weighted Average Remaining Life in Years	Number of Shares
\$ 5.00	2,564,000	3.4	2,564,000
\$ 5.28	63,658	2.6	63,658
\$ 7.07	25,000	1.8	25,000
\$ 7.50	2,500,000	3.9	2,500,000
\$ 11.50	6,001,250	3.1	6,001,250
\$ 1.06	6,132,076	-(1)	-(1)
\$ 0.0001	1,085,000	-(2)	1,085,000
	<u>18,370,984</u>	<u>3.3 (1) (2)</u>	<u>12,238,908</u>

(1) Note that the July 2022 Common Warrants are exercisable for 5 years following the initial exercise date, which is six months following the closing of the July 2022 Offering, or January 20, 2023.

(2) Note that the July 2022 Pre-funded Warrants are exercisable until they are exercised in full and have no expiration date; as such, they have been excluded from this calculation.

## NOTE 7 - LOANS PAYABLE

### Loans Payable

The following table summarizes the activity of loans payable during the nine months ended September 30, 2022:

	Principal Balance at December 31, 2021	Forgiveness	Principal Repaid in Cash	Adjustment	Effect of Foreign Exchange Rates	Principal Balance at September 30, 2022
Paycheck Protection Program	\$ 41,312	\$ -	\$ (41,312)	\$ -	\$ -	\$ -
Bounce Back Loan Scheme	61,169	-	(6,711)	-	(12,000)	42,458
First Assurance Funding	1,618,443	-	(1,443,963)	(14,042)(1)	-	160,438
Other loans payable	155,320	-	-	(5,000)(2)	-	150,320
Total loans payable	<u>\$ 1,876,244</u>	<u>\$ -</u>	<u>\$ (1,491,986)</u>	<u>\$ (19,042)</u>	<u>\$ (12,000)</u>	<u>\$ 353,216</u>
Less: loans payable - current portion	1,828,079					321,694
Loans payable - noncurrent portion	<u>\$ 48,165</u>					<u>\$ 31,522</u>

(1) Note that this amount was related to finance charges and was reclassified.

(2) Note that this amount was reclassified to related party payables.

During the three months ended September 30, 2022, the Company paid \$481,321 and \$2,692 in partial satisfaction of the First Assurance Funding loan and the Bounce Back Loan Scheme, respectively. During the nine months ended September 30, 2022, the Company paid an aggregate of \$1,443,963 and \$6,711 in partial satisfaction of the First Assurance Funding loan and the Bounce Back Loan Scheme, respectively, and paid \$41,312 in full satisfaction of the Paycheck Protection Program loan.

### Loans Payable – Related Parties

The below table summarizes the activities of loans payable – related parties during the nine months ended September 30, 2022 (see Note 10 – Related Parties for additional details):

	Principal Balance at December 31, 2021	Reclass from Loans Payable	Effect of Foreign Exchange Rates	Principal Balance at September 30, 2022
Loans payable issued between September 18, 2019 through November 4, 2020	<u>\$ 81,277</u>	<u>\$ 5,000</u>	<u>\$ (1,521)</u>	<u>\$ 84,756</u>

### Interest Expense on Loans Payable

For the three months ended September 30, 2022 and 2021, the Company recognized interest expense associated with loans payable of \$7,348 and \$2,315, respectively, and interest expense — related parties associated with loans payable of \$1,536 and \$10,566, respectively. During the nine months ended September 30, 2022 and 2021, the Company recognized interest expense associated with loans payable of \$22,117 and \$20,498, respectively, and interest income (expense) — related parties associated with loans payable of \$1,495 and (\$30,898), respectively.

As of September 30, 2022, the Company had accrued interest and accrued interest — related parties associated with loans payable of \$32,914 and \$16,676, respectively. As of December 31, 2021, the Company had accrued interest and accrued interest — related parties associated with loans payable of \$24,212 and \$812, respectively. See Note 10 — Related Parties for additional details.

## NOTE 8 - COMMITMENTS AND CONTINGENCIES

### Litigation and Other Loss Contingencies

The Company records liabilities for loss contingencies arising from claims, assessments, litigation, fines, penalties and other sources when it is probable that a liability has been incurred and the amount of the loss can be reasonably estimated. The Company has no liabilities recorded for loss contingencies as of December 31, 2021. See Legal Matters – *Action Against Former Executive of KBL* below for information related to a September 30, 2022 accrual.

### Legal Matters

#### *Action Against Former Executive of KBL*

On September 1, 2021, the Company initiated legal action in the Chancery Court of Delaware against Dr. Marlene Krauss, the Company's former Chief Executive Officer and director ("Dr. Krauss") and two of her affiliated companies, KBL IV Sponsor, LLC and KBL Healthcare Management, Inc. (collectively, the "KBL Affiliates") for, among other things, engaging in unauthorized monetary transfers of the Company's assets, non-disclosure of financial liabilities within the Company's Consolidated Financial Statements, issuing shares of stock without proper authorization; and improperly allowing stockholder redemptions to take place. The Company's complaint alleges causes of action against Dr. Krauss and/or the KBL Affiliates for breach of fiduciary duties, ultra vires acts, unjust enrichment, negligence and declaratory relief, and seeks compensatory damages in excess of \$11,286,570, together with interest, attorneys' fees and costs. There can be no assurance that the Company will be successful in its legal actions. As of September 30, 2022, the Company has a legal accrual of \$218,217 recorded to cover the legal expenses of the former executives of KBL.

On October 5, 2021, Dr. Krauss and the KBL Affiliates filed an Answer, Counterclaims and Third-Party Complaint (the "Krauss Counterclaims") against the Company and twelve individuals who are, or were, directors and/or officers of the Company, i.e., Marc Feldmann, Lawrence Steinman, James N. Woody, Teresa DeLuca, Frank Knuettel II, Pamela Marrone, Lawrence Gold, Donald A. McGovern, Jr., Russell T. Ray, Richard W. Barker, Shoshana Shendelman and Ozan Pamir (collectively, the "Third-Party Defendants"). On October 27, 2021, the Company and Ozan Pamir filed an Answer to the Krauss Counterclaims, and all of the other Third-Party Defendants filed a Motion to Dismiss as to the Third-Party Complaint.

On January 28, 2022, in lieu of filing an opposition to the Motion to Dismiss, Dr. Krauss and the KBL Affiliates filed a Motion for leave to file amended counterclaims and third-party complaint, and to dismiss six of the current and former directors previously named, i.e., to dismiss Teresa DeLuca, Frank Knuettel II, Pamela Marrone, Russell T. Ray, Richard W. Barker and Shoshana Shendelman. The Motion was granted by stipulation and, on February 24, 2022, Dr. Krauss filed an amended Answer, Counterclaims and Third-Party Complaint (the "Amended Counterclaims"). In essence, the Amended Counterclaims allege (a) that the Company and the remaining Third-Party Defendants breached fiduciary duties to Dr. Krauss by making alleged misstatements against Dr. Krauss in SEC filings and failing to register her shares in the Company so that they could be traded, and (b) the Company breached contracts between the Company and Dr. Krauss for registration of such shares, and also failed to pay to Dr. Krauss the amounts alleged to be owing under a promissory note in the principal amount of \$371,178, plus an additional \$300,000 under Dr. Krauss's resignation agreement. The Amended Counterclaims seek unspecified amounts of monetary damages, declaratory relief, equitable and injunctive relief, and attorney's fees and costs.

On March 16, 2022, Donald A. McGovern, Jr. and Lawrence Gold filed a Motion to Dismiss the Amended Counterclaims against them, and the Company and the remaining Third-Party Defendants filed an Answer to the Amended Counterclaims denying the same. On April 19, 2022, Dr. Krauss stipulated to dismiss all of her counterclaims and allegations against both Donald A. McGovern, Jr. and Lawrence Gold, thereby mooted their Motion to Dismiss the Amended Counterclaims against them. The Company and the Third-Party Defendants intend to continue to vigorously defend against all of the Amended Counterclaims, however, there can be no assurance that they will be successful in the legal defense of such Amended Counterclaims. In April 2022, Donald A. McGovern, Jr. and Lawrence Gold were dismissed from the lawsuit as parties. Discovery has not yet commenced in the case.

### *Action Against the Company by Dr. Krauss*

On August 19, 2021, Dr. Krauss initiated legal action in the Chancery Court of Delaware against the Company. The original Complaint sought expedited relief and made the following two claims: (1) it alleged that the Company is obligated to advance expenses including, attorney's fees, to Dr. Krauss for the costs of defending against the SEC and certain Subpoenas served by the SEC on Dr. Krauss; and (2) it alleged that the Company is also required to reimburse Dr. Krauss for the costs of bringing this lawsuit against the Company. On or about September 3, 2021, Dr. Krauss filed an Amended and Supplemental Complaint (the "Amended Complaint") in this action, which added the further claims that Dr. Krauss is also allegedly entitled to advancement by the Company of her expenses, including attorney's fees, for the costs of defending against the Third-Party Complaint in the Tyche Capital LLC action referenced below, and the costs of defending against the Company's own Complaint against Dr. Krauss as described above. On or about September 23, 2021, the Company filed its Answer to the Amended Complaint in which the Company denied each of Dr. Krauss' claims and further raised numerous affirmative defenses with respect thereto.

On November 15, 2021, Dr. Krauss filed a Motion for Summary Adjudication as to certain of the issues in the case, which was opposed by the Company. A hearing on such Motion was held on December 7, 2021, and, on March 7, 2022, the Court issued a decision in the matter denying the Motion for Summary Adjudication in part and granting it in part. The Court then issued an Order implementing such a decision on March 29, 2022. The parties are now engaging in proceedings set forth in that implementing Order. The Court granted Dr. Krauss's request for advancement of some of the legal fees which Dr. Krauss requested in her Motion, and the Company was required to pay a portion of those fees while it objects to the remaining portion of disputed fees. These legal fees have been accrued on the Company's balance sheet as of September 30, 2022. On October 10, 2022, Dr. Krauss filed an Application to compel the Company to pay the full amount of fees requested by Dr. Krauss for May-July 2022, and to modify the Court's Order. The Company has filed its Opposition thereto, but no hearing has yet been scheduled by the Court for the Application. Notwithstanding any requirement by the Court for the Company to advance attorneys' fees to Dr. Krauss, no adjudication has yet been made as to whether Dr. Krauss will ultimately be entitled to permanently retain such advancements. The Company is seeking payment for a substantial portion of such amounts from its director and officers' insurance policy, of which no assurance can be provided that the directors and officers insurance policy will cover such amounts. See "*Declaratory Relief Action Against the Company by AmTrust International*" below.

### *Action Against Tyche Capital LLC*

The Company commenced and filed an action against defendant Tyche Capital LLC ("Tyche") in the Supreme Court of New York, in the County of New York, on April 15, 2021. In its Complaint, the Company alleged claims against Tyche arising out of Tyche's breach of its written contractual obligations to the Company as set forth in a "Guarantee And Commitment Agreement" dated July 25, 2019, and a "Term Sheet For KBL Business Combination With CannBioRex" dated April 10, 2019 (collectively, the "Subject Guarantee"). The Company alleges in its Complaint that, notwithstanding demand having been made on Tyche to perform its obligations under the Subject Guarantee, Tyche has failed and refused to do so, and is currently in debt to the Company for such failure in the amount of \$6,776,686, together with interest accruing thereon at the rate set forth in the Subject Guarantee.

On or about May 17, 2021, Tyche responded to the Company's Complaint by filing an Answer and Counterclaims against the Company alleging that it was the Company, rather than Tyche, that had breached the Subject Guarantee. Tyche also filed a Third-Party Complaint against six third-party defendants, including three members of the Company's management, Sir Marc Feldmann, Dr. James Woody, and Ozan Pamir (collectively, the "Individual Company Defendants"), claiming that they allegedly breached fiduciary duties to Tyche with regards to the Subject Guarantee. In that regard, on June 25, 2021, each of the Individual Company Defendants filed a Motion to Dismiss Tyche's Third-Party Complaint against them.

On November 23, 2021, the Court granted the Company's request to issue an Order of attachment against all of Tyche's shares of the Company's stock that had been held in escrow. In so doing, the Court found that the Company had demonstrated a likelihood of success on the merits of the case based on the facts alleged in the Company's Complaint.

On February 18, 2022, Tyche filed an Amended Answer, Counterclaims and Third-Party Complaint. On March 22, 2022, the Company and each of the Individual Company Defendants filed a Motion to Dismiss all of Tyche's claims. A hearing on such Motion to Dismiss was held on August 25, 2022, and the Court granted the Motion to Dismiss entirely as to each of the Individual Company Defendants, and also as to three of the four Counterclaims brought against the Company, only leaving Tyche's declaratory relief claim. On September 9, 2022, Tyche filed a Notice of Appeal as to the Court's decision, which has not yet been briefed or adjudicated. On August 26, 2022, Tyche filed a Motion to vacate or modify the Company's existing attachment Order against Tyche's shares of the Company's stock held in escrow. The Company has filed its Opposition thereto, and a hearing on such Motion has been set for January 5, 2023. The Company and the Individual Company Defendants intend to continue to vigorously defend against all of Tyche's claims, however, there can be no assurance that they will be successful in the legal defense of such claims. Written discovery proceedings have commenced among the parties.

### *Action Against Ronald Bauer & Samantha Bauer*

The Company and two of its wholly-owned subsidiaries, Katexco Pharmaceuticals Corp. and CannBioRex Pharmaceuticals Corp. (collectively, the “Company Plaintiffs”), initiated legal action against Ronald Bauer and Samantha Bauer, as well as two of their companies, Theseus Capital Ltd. and Astatine Capital Ltd. (collectively, the “Bauer Defendants”), in the Supreme Court of British Columbia on February 25, 2022. The Company Plaintiffs are seeking damages against the Bauer Defendants for misappropriated funds and stock shares, unauthorized stock sales, and improper travel expenses, in the combined sum of at least \$4,395,000 CAD [\$3,178,025 USD] plus the additional sum of \$2,721,036 USD. The Bauer Defendants filed an answer to the Company Plaintiffs’ claims on May 6, 2022. There can be no assurance that the Company Plaintiffs will be successful in this legal action.

### *Declaratory Relief Action Against the Company by AmTrust International*

On June 29, 2022, AmTrust International Underwriters DAC (“AmTrust”), which was the premerger directors and officers insurance policy underwriter for KBL, filed a declaratory relief action against the Company in the U.S. District Court for the Northern District of California (the “Declaratory Relief Action”) seeking declaration of AmTrust’s obligations under the directors and officers insurance policy. In the Declaratory Relief Action, AmTrust is claiming that as a result of the merger the Company is no longer the insured under the subject insurance policy, notwithstanding the fact that the fees which the Company seeks to recover from AmTrust relate to matters occurring prior to the merger.

On September 20, 2022, the Company filed its Answer and Counterclaims against AmTrust for bad faith breach of AmTrust’s insurance coverage obligations to the Company under the subject directors and officers insurance policy, and seeking damages of at least \$2 million in compensatory damages, together with applicable punitive damages. In addition, the Company brought a Third-Party Complaint against its excess insurance carrier, Freedom Specialty Insurance Company (“Freedom”) seeking declaratory relief that Freedom will also be required to honor its policy coverage as soon as the amount of AmTrust’s insurance coverage obligations to the Company have been exhausted. On October 25, 2022, AmTrust filed its Answer to the Company’s Counterclaims, however, Freedom’s response to the Third-Party Complaint is not yet due. As of September 30, 2022, the Company has recorded an insurance claims receivable of \$1,836,940, which it believes is the net recoverable amount advanced to former directors and officers of the Company as of September 30, 2022. While the Company believes it has a strong case against AmTrust, there can be no assurance that the Company will prevail in this action.

## **NOTE 9 – STOCKHOLDERS’ EQUITY**

### **Common Stock**

#### *Common Stock Issued for Services*

During the three and nine months ended September 30, 2022, the Company issued an aggregate 55,112 and 151,010, respectively, of immediately vested shares of the Company’s common stock as compensation to consultants, directors, and officers, with an aggregate issuance date fair value of \$60,622 and \$270,967, respectively, which was charged immediately to the condensed consolidated statement of operations for the three and nine months ended September 30, 2022.

### **Restricted Stock Shares**

During the three and nine months ended September 30, 2022, the Company issued zero and 12,000 restricted shares of the Company’s common stock, or Restricted Stock Shares, as of the end of both periods as compensation to consultants with an issuance date fair value of zero and \$48,600 as of the end of both periods. Per the two year consulting agreement which evidences the issuance of the 12,000 restricted shares during the nine months ended September 30, 2022, the Restricted Stock Shares are issued at the beginning of the contract term and annually and vest monthly over a period of 24 months. The Company recognized stock-based compensation expense related to the amortization of the Restricted Stock Shares of \$6,075 and \$20,250 for the three and nine months ended September 30, 2022.

Below is a table summarizing the Restricted Stock Shares granted and outstanding as of and for the nine months ended September 30, 2022:

	Unvested Restricted Stock	Weighted Average Grant Date FV Price
Unvested as of January 1, 2022	-	\$ -
Granted	12,000	4.05
Vested	5,000	4.05
Unvested as of September 30, 2022	7,000	4.05
Total unrecognized expense remaining	\$ 28,350	
Weighted-average years expected to be recognized over	1.25	-

### Stock Options

A summary of the option activity during the nine months ended September 30, 2022 is presented below:

	Number of Options	Weighted Average Exercise Price	Weighted Average Remaining Term (Years)	Intrinsic Value
Outstanding, January 1, 2022	2,741,000	4.77	9.4	70,500
Granted	518,121	1.36	-	-
Exercised	-	-	-	-
Expired	-	-	-	-
Forfeited	-	-	-	-
Outstanding, September 30, 2022	3,259,121	4.23	8.8	\$ -
Exercisable, September 30, 2022	1,660,057	4.16	8.7	\$ -

For options issued during the nine months ended September 30, 2022, the assumptions used in the Black Scholes valuation method were as follows:

Risk-free interest rate	2.88%
Expected term in years	5.00-5.77
Expected volatility	91.00%
Expected dividends	0%

A summary of outstanding and exercisable stock options as of September 30, 2022 is presented below:

Stock Options Outstanding		Stock Options Exercisable	
Exercise Price	Number of Shares	Weighted Average Remaining Life in Years	Number of Shares
\$ 2.49	50,000	8.2	50,000
\$ 4.43	1,580,000	8.4	983,111
\$ 7.56	436,000	8.8	127,167
\$ 3.95	675,000	9.2	301,042
\$ 1.36	518,121	9.6	198,737
	3,259,121	8.7	1,660,057

The Company recognized stock-based compensation expense of \$672,083 and \$2,273,947 for the three and nine months ended September 30, 2022, respectively, related to the issuance of shares to consultants and directors for services provided, as well as for the amortization of stock options and restricted stock shares. Expense of \$584,237 and \$1,959,919 is included within general and administrative expenses on the condensed consolidated statements of operations for the three and nine month periods, respectively, and expense of \$87,846 and \$314,028 is included within research and development expenses on the condensed consolidated statements of operations for the three and nine month periods, respectively. The full amount of stock-based compensation recognized for the three and nine month periods ended September 30, 2022 is considered to be related party expense. Stock-based compensation expense related to the amortization of stock options for the three and nine months ended September 30, 2021 was \$434,979 and \$1,871,473, respectively; these expenses were included within general and administrative expenses or research and development expenses on the condensed consolidated statement of operations for both of those periods. The full amount of stock-based compensation recognized for the three and nine month periods ended September 30, 2021, respectively, was considered to be related party expense. As of September 30, 2022, there was \$4,827,266 of unrecognized stock-based compensation expense related to stock options that will be recognized over the weighted average remaining vesting period of 2.3 years, as well as \$28,350 of unrecognized expense related to Restricted Stock Shares that will be recognized over the weighted average remaining vesting period of 1.3 years.

#### *July 2022 Offering*

On July 17, 2022, the Company entered into a Securities Purchase Agreement with certain purchasers, pursuant to which the Company agreed to sell an aggregate of 3,500,000 shares of common stock, pre-funded warrants to purchase up to an aggregate of 2,632,076 shares of common stock (“July 2022 Pre-Funded Warrants”), and common stock warrants to purchase up to an aggregate of 6,132,076 shares of common stock (the “July 2022 Common Warrants”), at a combined purchase price of \$1.06 per share and warrant (the “July 2022 Offering”). Aggregate gross proceeds from the July 2022 Offering were \$6,499,737. The July 2022 Offering closed on July 20, 2022.

The July 2022 Pre-Funded Warrants have an exercise price equal to \$0.0001, are immediately exercisable and are subject to customary anti-dilution adjustments for stock splits or dividends or other similar transactions. The exercise price of the July 2022 Pre-Funded Warrants will not be subject to adjustment as a result of subsequent equity issuances at effective prices lower than the then-current exercise price. The July 2022 Pre-Funded Warrants are exercisable until they are exercised in full. The July 2022 Pre-Funded Warrants are subject to a provision prohibiting the exercise of such July 2022 Pre-Funded Warrants to the extent that, after giving effect to such exercise, the holder of such July 2022 Pre-Funded Warrants (together with the holder’s affiliates, and any other persons acting as a group together with the holder or any of the holder’s affiliates), would beneficially own in excess of 9.99% of the Company’s outstanding common stock (which may be increased or decreased, with 61 days prior written notice by the holder). Although the July 2022 Pre-Funded Warrants have a tender offer provision, the July 2022 Pre-Funded Warrants were determined to be equity-classified because they met the limited exception in the case of a change-in-control. Because the July 2022 Pre-Funded Warrants are equity-classified, the placement agent fees and offering expenses will be accounted for as a reduction of additional paid in capital.

The July 2022 Common Warrants have an exercise price equal to \$1.06 per share, are exercisable 6 months following the closing of the July 2022 Offering (the “Initial Exercise Date”) and are subject to customary anti-dilution adjustments for stock splits or dividends or other similar transactions. The exercise price of the July 2022 Common Warrants will not be subject to adjustment as a result of subsequent equity issuances at effective prices lower than the then-current exercise price. The July 2022 Common Warrants are exercisable for 5 years following the Initial Exercise Date. The July 2022 Common Warrants are subject to a provision prohibiting the exercise of such July 2022 Common Warrants to the extent that, after giving effect to such exercise, the holder of such July 2022 Common Warrants (together with the holder’s affiliates, and any other persons acting as a group together with the holder or any of the holder’s affiliates), would beneficially own in excess of 4.99% of the Company’s outstanding common stock (which may be increased or decreased, with 61 days prior written notice by the holder). Although the July 2022 Common Warrants have a tender offer provision, the July 2022 Common Warrants were determined to be equity-classified because they met the limited exception in the case of a change-in-control. Because the July 2022 Common Warrants are equity-classified, the placement agent fees and offering expenses will be accounted for as a reduction of additional paid in capital.

As of September 30, 2022, 1,547,076 of the July 2022 Pre-Funded Warrants have been exercised for a value of \$155; there are 1,085,000 unexercised July 2022 Pre-Funded Warrants remaining as of the end of the period. No July 2022 Common Warrants have been exercised as of September 30, 2022.

## **NOTE 10 - RELATED PARTIES**

### **Accrued Expenses - Related Parties**

Accrued expenses - related parties was \$158,467 as of September 30, 2022 and consists of \$16,676 of interest accrued on loans due to a certain investor in the Company and \$141,791 of accrued consulting fees for services provided by certain directors and consultants of the Company. Accrued expenses - related parties of \$18,370 as of December 31, 2021, consists of interest accrued on loans and convertible notes due to certain officers and directors of the Company.

### **Loans Payable - Related Parties**

Loans payable - related parties totaled \$84,756 and \$81,277 as of September 30, 2022 and December 31, 2021, respectively. See Note 7 - Loans Payable for more information.

### **Research and Development Expenses - Related Parties**

Research and Development Expenses – Related Parties of \$53,347 and \$298,879 during the three months ended September 30, 2022 and 2021, respectively, and \$158,401 and \$1,287,583 during the nine months ended September 30, 2022 and 2021, respectively, are related to consulting and professional fees paid to current or former officers, directors or greater than 5% stockholders, or affiliates thereof.

### **General and Administrative Expenses - Related Parties**

General and Administrative Expenses – Related Parties during the three months ended September 30, 2022 and 2021 were \$0 and \$82,519, respectively. These expenses relate to professional fees paid to current or former officers, directors or greater than 5% stockholders, or affiliates thereof. General and Administrative Expenses – Related Parties during the nine months ended September 30, 2022 and 2021 were \$5,261 and \$462,081, respectively. These expenses relate to professional fees paid to current or former officers, directors or greater than 5% stockholders, or affiliates thereof.

## **Interest (Expense) Income - Related Parties**

During the three and nine months ended September 30, 2022, the Company recorded (\$1,536) and \$1,495, respectively, of interest (expense) income - related parties related to loans from greater than 5% stockholders or affiliates of the Company.

During the three months and nine months ended September 30, 2021, the Company recorded \$14,201 and \$42,279, respectively, of interest expense - related parties, of which \$3,633 and \$11,380, respectively, related to interest on certain convertible notes held by officers and directors of the Company and \$10,567 and \$30,899, respectively, related to interest expense on loans from officers, directors greater than 5% stockholders, or affiliates thereof, of the Company.

## **NOTE 11 - SUBSEQUENT EVENTS**

### *Oxford University Research Agreement*

On October 24, 2022, the Company entered into a new research agreement with Oxford University related to the license agreement signed in November 2021, whereby it was granted rights to certain patents related to the HMGB1 molecule for liver regeneration. Pursuant to this agreement, the term of the contract is for one year, beginning on January 1, 2023; the financial terms of the contract are a commitment of £125,000 per quarter, with the first payment due in April 2023. Any outstanding amounts will earn interest at a rate of 4% per annum.

### *Directors' Compensation*

On October 31, 2022, the Board of Directors of the Company approved the issuance of 129,483 shares of \$0.0001 par value common stock, in lieu of cash compensation, to certain independent directors under the Company's 2022 Omnibus Incentive Plan as consideration for services rendered during the third quarter of 2022. The shares were valued at the closing sales price on October 31, 2022, the date such issuances were approved by the Board of Directors.

### *Exercise of July 2022 Pre-funded Warrants*

On November 1, 2022, the remainder, or 1,085,000, of the July 2022 Pre-Funded Warrants were exercised for a value of \$109; there are no remaining outstanding July 2022 Pre-Funded Warrants.

### *Notice of a Special Meeting of Stockholders to Effect a Reverse Stock Split*

On November 4, 2022, the Company filed a Pre-Schedule 14A with the SEC providing notice of a special meeting of stockholders of the Company on December 15, 2022 to approve an amendment to the Second Amended and Restated Certificate of Incorporation, as amended, to effect a reverse stock split of the issued and outstanding shares common stock, par value \$0.0001 per share, by a ratio of between one-for-four to one-for-twenty, inclusive, with the exact ratio to be set at a whole number to be determined by the Board of Directors or a duly authorized committee thereof in its discretion, at any time after the approval of the amendment and prior to December 15, 2023.

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

### CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q ("Report"), including "Management's Discussion and Analysis of Financial Condition and Results of Operations," contains forward-looking statements, within the federal securities laws, including the Private Securities Litigation Reform Act of 1995, regarding future events and the future results of the Company that are based on current expectations, estimates, forecasts, and projections about the industry in which the Company operates and the beliefs and assumptions of the management of the Company. Words such as "expects," "anticipates," "targets," "goals," "projects," "intends," "plans," "believes," "seeks," "estimates," variations of such words, and similar expressions are intended to identify such 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 and adversely 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 elsewhere in this Report, including under "Risk Factors", and in other reports the Company files with the Securities and Exchange Commission ("SEC"), including the Company's Annual Report on Form 10-K for the year ended December 31, 2021, as filed with the SEC on March 31, 2022 (under the heading "Risk Factors" and in other parts of that report), and include, but are not limited to, statements about:

- Expectations for the clinical and preclinical development, manufacturing, regulatory approval, and commercialization of our product candidates;
- the uncertainties associated with the clinical development and regulatory approval of the Company's drug candidates, including potential delays in the enrollment and completion of clinical trials, issues raised by the U.S. Food and Drug Administration (FDA) and the U.K. Medicines and Healthcare products Regulatory Agency (MHRA);
- regulatory developments in the United States and foreign countries;
- our success in retaining or recruiting, or changes required in, our officers, key employees or directors;
- current negative operating cash flows and our potential ability to obtain additional financing to advance our business and the terms of any further financing, which may be highly dilutive and may include onerous terms;
- the continued impact of the COVID-19 pandemic on our business operations and our research and development initiatives;
- the accuracy of our estimates regarding expenses, future revenues and capital requirements;
- the Company's reliance on third parties to conduct its clinical trials, enroll patients, and manufacture its preclinical and clinical drug supplies;
- the ability to come to mutually agreeable terms with such third parties and partners, and the terms of such agreements;
- estimates of patient populations for the Company's planned products;
- unexpected adverse side effects or inadequate therapeutic efficacy of drug candidates that could limit approval and/or commercialization, or that could result in recalls or product liability claims;
- the Company's ability to fully comply with numerous federal, state and local laws and regulatory requirements, as well as rules and regulations outside the United States, that apply to its product development activities;
- challenges and uncertainties inherent in product research and development, including the uncertainty of clinical success and of obtaining regulatory approvals; uncertainty of commercial success;
- the ability of the Company to execute its plans to develop and market new drug products and the timing and costs of these development programs;
- high inflation, increasing interest rates and economic downturns, including potential recessions, as well as macroeconomic, geopolitical, health and industry trends, pandemics, acts of war (including the ongoing Ukraine/Russian conflict) and other large-scale crises;
- estimates of the sufficiency of our existing capital resources combined with future anticipated cash flows to finance our operating requirements;
- our ability to maintain our listing on NASDAQ (including that we are not currently in compliance with NASDAQ's continued listing requirements); and
- other risks and uncertainties, including those listed under "Risk Factors", below.

All forward-looking statements speak only at the date of the filing of this Report. The reader should not place undue reliance on these forward-looking statements. Although we believe that our plans, intentions and expectations reflected in or suggested by the forward-looking statements we make in this Report are reasonable, we provide no assurance that these plans, intentions or expectations will be achieved. We disclose important factors that could cause our actual results to differ materially from our expectations under “Risk Factors” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and elsewhere in this Report and our Annual Report on Form 10-K for the year ended December 31, 2021. These cautionary statements qualify all forward-looking statements attributable to us or persons acting on our behalf. Except as required by law, we assume no obligation to update or revise these forward-looking statements for any reason, even if new information becomes available in the future.

#### *General Information*

The following discussion is based upon our unaudited Condensed Consolidated Financial Statements included elsewhere in this Report, which have been prepared in accordance with U.S. generally accepted accounting principles. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses, and related disclosure of contingencies. We base our estimates on historical experience and on various other assumptions that we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions. Factors that could cause or contribute to these differences include those discussed below and elsewhere in this Report, and in other reports we file with the SEC, and in our most recent Annual Report on Form 10-K. All references to years relate to the calendar year ended December 31<sup>st</sup> of the particular year.

This information should be read in conjunction with the interim unaudited condensed consolidated financial statements and the notes thereto included in this Quarterly Report on Form 10-Q, and the audited financial statements and notes thereto and “Part II. Other Information – Item 7. Management’s Discussion and Analysis of Financial Condition and Results of Operations”, contained in our Annual Report on Form 10-K for the year ended December 31, 2021, filed with the Securities and Exchange Commission on March 31, 2022 (the “Annual Report”).

Certain capitalized terms used below and otherwise defined below, have the meanings given to such terms in the footnotes to our unaudited condensed consolidated financial statements included above under “Part I – Financial Information” – “Item 1. Financial Statements”.

Please see the section entitled “Glossary” beginning on page ii of our Annual Report for a list of abbreviations and definitions commonly used in the pharmaceutical and biotechnology industry which are used throughout this Report.

Our logo and some of our trademarks and tradenames are used in this Report. This Report also includes trademarks, tradenames and service marks that are the property of others. Solely for convenience, trademarks, tradenames and service marks referred to in this Report may appear without the ®, ™ and SM symbols. References to our trademarks, tradenames and service marks are not intended to indicate in any way that we will not assert to the fullest extent under applicable law our rights or the rights of the applicable licensors if any, nor that respective owners to other intellectual property rights will not assert, to the fullest extent under applicable law, their rights thereto. We do not intend the use or display of other companies’ trademarks and trade names to imply a relationship with, or endorsement or sponsorship of us by, any other companies.

The market data and certain other statistical information used throughout this Report are based on independent industry publications, reports by market research firms or other independent sources that we believe to be reliable sources. Industry publications and third-party research, surveys and studies generally indicate that their information has been obtained from sources believed to be reliable, although they do not guarantee the accuracy or completeness of such information. We are responsible for all of the disclosures contained in this Report, and we believe these industry publications and third-party research, surveys and studies are reliable. While we are not aware of any misstatements regarding any third-party information presented in this Report, their estimates, in particular, as they relate to projections, involve numerous assumptions, are subject to risks and uncertainties, and are subject to change based on various factors, including those discussed under, and incorporated by reference in, the section entitled “Item 1A. Risk Factors” of this Report. These and other factors could cause our future performance to differ materially from our assumptions and estimates. Some market and other data included herein, as well as the data of competitors as they relate to the Company, is also based on our good faith estimates.

See also “Cautionary Statement Regarding Forward-Looking Statements”, above, which includes information on forward-looking statements used herein and other matters which are applicable to this Report, including, but not limited to this “Item 2. Management’s Discussion and Analysis of Financial Condition and Results of Operations.”

Unless the context requires otherwise, references to the “Company,” “we,” “us,” “our,” “180 Life,” “180LS” and “180 Life Sciences Corp.” refer specifically to 180 Life Sciences Corp. and its consolidated subsidiaries. References to “KBL” refer to the Company prior to the November 6, 2020 Business Combination.

In addition, unless the context otherwise requires and for the purposes of this Report only:

“CAD” refers to Canadian dollars;

“Exchange Act” refers to the Securities Exchange Act of 1934, as amended;

“£” or “GBP” refers to British pounds sterling;

“SEC” or the “Commission” refers to the United States Securities and Exchange Commission; and

“Securities Act” refers to the Securities Act of 1933, as amended.

#### *Additional Information*

We file annual, quarterly, and current reports, proxy statements and other information with the SEC. Our SEC filings are available to the public over the Internet at the SEC’s website at [www.sec.gov](http://www.sec.gov) and are available for download, free of charge, soon after such reports are filed with or furnished to the SEC, on the “Investors”—“SEC Filings”—“All SEC Filings” page of our website at [www.180lifesciences.com](http://www.180lifesciences.com). Copies of documents filed by us with the SEC are also available from us without charge, upon oral or written request to our Secretary, who can be contacted at the address and telephone number set forth on the cover page of this Report. Our website address is [www.180lifesciences.com/](http://www.180lifesciences.com/). The information on, or that may be accessed through, our website is not incorporated by reference into this Report and should not be considered a part of this Report.

#### *Going Concern and Management Liquidity Plans*

As of September 30, 2022, we had an accumulated deficit of \$85,666,267 and working capital of \$1,789,844. In addition, for the nine months ended September 30, 2022, \$9,200,830 of cash was used in operations and total cash decreased by \$4,635,869. The accompanying condensed consolidated financial statements have been prepared assuming the Company will continue as a going concern. As we are not generating revenues, we need to raise a significant amount of capital in order to pay our debts and cover our operating costs. While the Company raised money in August 2021 and July 2022 (see Note 2 – Going Concern and Management’s Plans), we expect to require additional funding in the future and there is no assurance that we will be able to raise additional needed capital or that such capital will be available under favorable terms.

We are subject to all the substantial risks inherent in the development of a new business enterprise within an extremely competitive industry. Due to the absence of a long-standing operating history and the emerging nature of the markets in which we compete, we anticipate operating losses until we can successfully implement our business strategy, which includes all associated revenue streams. We may never achieve profitable operations or generate significant revenues.

We currently have a minimum monthly cash requirement spend of approximately \$900,000. We believe that in the aggregate, we will require significant additional capital funding to support and expand the research and development and marketing of our products, fund future clinical trials, repay debt obligations, provide capital expenditures for additional equipment and development costs, payment obligations, office space and systems for managing the business, and cover other operating costs until our planned revenue streams from products are fully-implemented and begin to offset our operating costs, if ever.

Since our inception, we have funded our operations with the proceeds from equity and debt financings. We have experienced liquidity issues due to, among other reasons, our limited ability to raise adequate capital on acceptable terms. We have historically relied upon the issuance of equity and promissory notes that are convertible into shares of our common stock to fund our operations and have devoted significant efforts to reduce that exposure. We anticipate that we will need to issue equity to fund our operations and repay our outstanding debt for the foreseeable future. If we are unable to achieve operational profitability or we are not successful in securing other forms of financing, we will have to evaluate alternative actions to reduce our operating expenses and conserve cash.

The accompanying condensed consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America on a going concern basis, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. Accordingly, the consolidated financial statements do not include any adjustments relating to the recoverability of assets and classification of liabilities that might be necessary should the Company be unable to continue as a going concern. The consolidated financial statements included in this report also include a going concern footnote.

Additionally, wherever possible, our Board of Directors will attempt to use non-cash consideration to satisfy obligations. In many instances, we believe that the non-cash consideration will consist of restricted shares of our common stock, preferred stock or warrants to purchase shares of our common stock. Our Board of Directors has authority, without action or vote of the shareholders, but subject to NASDAQ rules and regulations (which generally require shareholder approval for any transactions which would result in the issuance of more than 20% of our then outstanding shares of common stock or voting rights representing over 20% of our then outstanding shares of stock), to issue all or part of the authorized but unissued shares of common stock, preferred stock or warrants to purchase such shares of common stock. In addition, we may attempt to raise capital by selling shares of our common stock, possibly at a discount to market in the future. These actions will result in dilution of the ownership interests of existing shareholders, may further dilute common stock book value, and that dilution may be material. Such issuances may also serve to enhance existing management's ability to maintain control of us, because the shares may be issued to parties or entities committed to supporting existing management.

#### *Organization of MD&A*

Our Management's Discussion and Analysis of Financial Condition and Results of Operations (the "MD&A") is provided in addition to the accompanying consolidated financial statements and notes to assist readers in understanding our results of operations, financial condition, and cash flows. MD&A is organized as follows:

- **Business Overview and Recent Events.** A summary of the Company's business and certain material recent events.
- **Significant Financial Statement Components.** A summary of the Company's significant financial statement components.
- **Results of Operations.** An analysis of our financial results comparing the three and nine months ended September 30, 2022 and 2021.
- **Liquidity and Capital Resources.** An analysis of changes in our balance sheets and cash flows and discussion of our financial condition.
- **Critical Accounting Policies and Estimates.** Accounting estimates that we believe are important to understanding the assumptions and judgments incorporated in our reported financial results and forecasts.

#### *Business Overview and Recent Events*

On November 6, 2020 ("Closing Date"), the Business Combination was consummated following a special meeting of stockholders, where the stockholders of KBL considered and approved, among other matters, a proposal to adopt a Business Combination Agreement. Pursuant to the Business Combination Agreement, KBL Merger Sub, Inc. merged with 180, with 180 continuing as the surviving entity and becoming a wholly-owned subsidiary of KBL. As part of the Business Combination, KBL issued 17,500,000 shares of common stock and equivalents to the stockholders of 180, in exchange for all of the outstanding capital stock of 180. The Business Combination became effective November 6, 2020 and in connection therewith, 180 filed a Certificate of Amendment of its Certificate of Incorporation in Delaware to change its name to 180 Life Corp., and KBL changed its name to 180 Life Sciences Corp.

Following the closing of the Business Combination, we transitioned our operations to those of 180, which is a clinical stage biotechnology company headquartered in Palo Alto, California, focused on the development of therapeutics for unmet medical needs in chronic pain, inflammation, fibrosis and other inflammatory diseases, where anti-TNF therapy will provide a clear benefit to patients, by employing innovative research, and, where appropriate, combination therapy. We have three product development platforms:

- fibrosis and anti-tumor necrosis factor ("TNF");
- drugs which are derivatives of cannabidiol ("CBD"); and
- alpha 7 nicotinic acetylcholine receptor ("α7nAChR").

We have several future product candidates in development, including one product candidate which has recently completed a successful Phase 2b clinical trial in the United Kingdom for Dupuytren's Contracture, a condition that affects the development of fibrous connective tissue in the palm of the hand. 180 was founded by several world-leading scientists in the biotechnology and pharmaceutical sectors.

We intend to invest resources to successfully complete the clinical programs that are underway, discover new drug candidates, and develop new molecules to build on our existing pipeline to address unmet clinical needs. The product candidates are designed via a platform comprised of defined unit operations and technologies. This work is performed in a research and development environment that evaluates and assesses variability in each step of the process in order to define the most reliable production conditions.

We may rely on third-party contract manufacturing organizations ("CMOs") and other third parties for the manufacturing and processing of the product candidates in the future. We believe the use of contract manufacturing and testing for the first clinical product candidates is cost-effective and has allowed us to rapidly prepare for clinical trials in accordance with our development plans. We expect that third-party manufacturers will be capable of providing and processing sufficient quantities of these product candidates to meet anticipated clinical trial demands.

#### *July 2022 Offering*

On July 17, 2022, the Company entered into a Securities Purchase Agreement with certain purchasers, pursuant to which the Company agreed to sell an aggregate of 3,500,000 shares of common stock, pre-funded warrants to purchase up to an aggregate of 2,632,076 shares of common stock ("July 2022 Pre-Funded Warrants"), and common stock warrants to purchase up to an aggregate of 6,132,076 shares of common stock (the "July 2022 Common Warrants"), at a combined purchase price of \$1.06 per share and warrant (the "July 2022 Offering"). Aggregate gross proceeds from the July 2022 Offering were \$6,499,737. The July 2022 Offering closed on July 20, 2022.

The July 2022 Pre-Funded Warrants have an exercise price equal to \$0.0001, are immediately exercisable and are subject to customary anti-dilution adjustments for stock splits or dividends or other similar transactions. The exercise price of the July 2022 Pre-Funded Warrants will not be subject to adjustment as a result of subsequent equity issuances at effective prices lower than the then-current exercise price. The July 2022 Pre-Funded Warrants are exercisable until they are exercised in full. The July 2022 Pre-Funded Warrants are subject to a provision prohibiting the exercise of such July 2022 Pre-Funded Warrants to the extent that, after giving effect to such exercise, the holder of such July 2022 Pre-Funded Warrants (together with the holder's affiliates, and any other persons acting as a group together with the holder or any of the holder's affiliates), would beneficially own in excess of 9.99% of the Company's outstanding common stock (which may be increased or decreased, with 61 days prior written notice by the holder). Although the July 2022 Pre-Funded Warrants have a tender offer provision, the July 2022 Pre-Funded Warrants were determined to be equity-classified because they met the limited exception in the case of a change-in-control. Because the July 2022 Pre-Funded Warrants are equity-classified, the placement agent fees and offering expenses will be accounted for as a reduction of additional paid in capital.

The July 2022 Common Warrants have an exercise price equal to \$1.06 per share, are exercisable 6 months following the closing of the July 2022 Offering (the “Initial Exercise Date”) and are subject to customary anti-dilution adjustments for stock splits or dividends or other similar transactions. The exercise price of the July 2022 Common Warrants will not be subject to adjustment as a result of subsequent equity issuances at effective prices lower than the then-current exercise price. The July 2022 Common Warrants are exercisable for 5 years following the Initial Exercise Date. The July 2022 Common Warrants are subject to a provision prohibiting the exercise of such July 2022 Common Warrants to the extent that, after giving effect to such exercise, the holder of such July 2022 Common Warrants (together with the holder’s affiliates, and any other persons acting as a group together with the holder or any of the holder’s affiliates), would beneficially own in excess of 4.99% of the Company’s outstanding common stock (which may be increased or decreased, with 61 days prior written notice by the holder). Although the July 2022 Common Warrants have a tender offer provision, the July 2022 Common Warrants were determined to be equity-classified because they met the limited exception in the case of a change-in-control. Because the July 2022 Common Warrants are equity-classified, the placement agent fees and offering expenses will be accounted for as a reduction of additional paid in capital.

#### *COVID-19 Pandemic*

On March 11, 2020, the World Health Organization declared COVID-19 a pandemic. The global spread and impact of COVID-19 has created significant volatility, uncertainty and economic disruption. The extent of COVID-19’s effect on the Company’s operational and financial performance will depend on future developments, including the duration, spread and intensity of the pandemic (including any resurgences), the impact of variants of the virus that causes COVID-19, the wide distribution and public acceptance of COVID-19 vaccines, labor needs at the Company as well as in the supply chain, compliance with government or employer COVID-19 vaccine mandates and the resulting impact on available labor, and the level of social and economic restrictions imposed in the United States and abroad in an effort to curb the spread of the virus, all of which are uncertain and difficult to predict. As a result, it is not currently possible to ascertain the overall impact of COVID-19 on the Company’s business, results of operations, financial condition or liquidity. While the ultimate health and economic impact of COVID-19 continues to be highly uncertain, the Company does not currently expect an adverse impact on its business related to of COVID-19. Future events and effects related to the COVID-19 pandemic cannot be determined with precision and actual results could significantly differ from estimates or forecasts.

The follow up time for patient data and the statistical analysis for the Phase 2b Dupuytren’s Contracture clinical trial was delayed as a result of COVID-19, but such follow-up and statistical analysis are now completed and the Company announced the top-line data results from the Phase 2b trial on December 1, 2021 and the data was published on April 29, 2022 in a peer-reviewed journal. Additionally, COVID-19 has delayed the initiation of certain clinical trials and may delay the initiation of other clinical trials in the future or otherwise have a material adverse effect on our future operations.

## Significant Financial Statement Components

### *Research and Development*

To date, 180's research and development expenses have related primarily to discovery efforts and preclinical and clinical development of its three product platforms: fibrosis and anti-TNF; drugs which are derivatives of CBD, and  $\alpha 7nAChR$ . Research and development expenses consist primarily of costs associated with those three product platforms, which include:

- expenses incurred under agreements with 180's collaboration partners and third-party contract organizations, investigative clinical trial sites that conduct research and development activities on its behalf, and consultants;
- costs related to production of clinical materials, including fees paid to contract manufacturers;
- laboratory and vendor expenses related to the execution of preclinical and clinical trials;
- employee-related expenses, which include salaries, benefits and stock-based compensation; and
- facilities and other expenses, which include expenses for rent and maintenance of facilities, depreciation and amortization expense and other supplies.

We expense all research and development costs in the periods in which they are incurred. We accrue for costs incurred as services are provided by monitoring the status of each project and the invoices received from our external service providers. We adjust our accrual as actual costs become known. When contingent milestone payments are owed to third parties under research and development arrangements or license agreements, the milestone payment obligations are expensed when the milestone results are achieved.

Research and development activities are central to our business model. Product 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 that research and development expenses will increase over the next several years as clinical programs progress and as we seek to initiate clinical trials of additional product candidates. It is also expected that increased research and development expenses will be incurred as additional product candidates are selectively identified and developed. However, it is difficult to determine with certainty the duration and completion costs of current or future preclinical programs and clinical trials of product candidates.

The duration, costs and timing of clinical trials and development of product candidates will depend on a variety of factors that include, but are not limited to, the following:

- per patient trial costs;
- the number of patients that participate in the trials;
- the number of sites included in the trials;
- the countries in which the trials are conducted;
- the length of time required to enroll eligible patients;
- the number of doses that patients receive;
- the drop-out or discontinuation rates of patients;
- potential additional safety monitoring or other studies requested by regulatory agencies;
- the impact of COVID-19 on the length of our trials;
- the duration of patient follow-up; and
- the efficacy and safety profile of the product candidates.

In addition, the probability of success for each product candidate will depend on numerous factors, including competition, manufacturing capability and commercial viability. We will determine which programs to pursue and fund in response to the scientific and clinical success of each product candidate, as well as an assessment of each product candidate's commercial potential.

Because the product candidates are still in clinical and preclinical development and the outcome of these efforts is uncertain, we cannot estimate the actual amounts necessary to successfully complete the development and commercialization of product candidates or whether, or when, we may achieve profitability. Due to the early-stage nature of these programs, we do not track costs on a project-by-project basis. As these programs become more advanced, we intend to track the external and internal cost of each program.

#### ***General and Administrative***

General and administrative expenses consist primarily of salaries and other staff-related costs, including stock-based compensation for shares of common stock issued and options granted to founders, directors and personnel in executive, commercial, finance, accounting, legal, investor relations, facilities, business development and human resources functions and include vesting conditions.

Other significant general and administrative costs include costs relating to facilities and overhead costs, legal fees relating to corporate and patent matters, litigation, SEC filings, insurance, investor relations costs, fees for accounting and consulting services, and other general and administrative costs. General and administrative costs are expensed as incurred, and we accrue amounts for services provided by third parties related to the above expenses by monitoring the status of services provided and receiving estimates from our service providers and adjusting our accruals as actual costs become known.

It is expected that the general and administrative expenses will increase over the next several years to support our continued research and development activities, manufacturing activities, potential commercialization of our product candidates and the increased costs of operating as a public company. These increases are anticipated to include increased costs related to the hiring of additional personnel, developing commercial infrastructure, fees to outside consultants, lawyers and accountants, and increased costs associated with being a public company, as well as expenses related to services associated with maintaining compliance with Nasdaq listing rules and SEC requirements, insurance and investor relations costs.

#### ***Interest Expense***

Interest expense consists primarily of interest expense related to debt instruments.

#### ***Gain (Loss) on Extinguishment of Convertible Notes***

Gain (loss) on extinguishment of convertible notes represents the shortfall (excess) of the reacquisition cost of convertible notes as compared to their carrying value.

### *Change in Fair Value of Derivative Liabilities*

Change in fair value of derivative liabilities represents the non-cash change in fair value of derivative liabilities during the reporting period. Gains resulting from change in fair value of derivative liabilities during the three and nine months ended September 30, 2022, were driven by decreases in stock price during the periods, resulting in a lower fair value of the underlying liability.

### *Offering Costs Allocated to Warrant Liabilities*

Change in offering costs allocated to warrant liabilities represents placement agent fees and offering expenses which were allocated to the February 2021 PIPE Warrants and expensed immediately as they are liability classified.

### *Change in Fair Value of Accrued Issuable Equity*

Change in fair value of accrued issuable equity represents the non-cash change in fair value of accrued equity prior to its formal issuance.

## CONSOLIDATED RESULTS OF OPERATIONS

*For the Three Months Ended September 30, 2022 Compared to the Three Months Ended September 30, 2021*

	For the Three Months Ended September 30,	
	2022	2021
<b>Operating Expenses:</b>		
Research and development	\$ 583,177	\$ 316,473
Research and development - related parties	53,347	298,879
General and administrative	3,418,628	3,519,605
General and administrative - related parties	-	82,519
Total Operating Expenses	4,055,152	4,217,476
Loss From Operations	(4,055,152)	(4,217,476)
<b>Other (Expenses) Income:</b>		
Gain on settlement of liabilities	-	472,677
Other income	-	12,308
Interest expense	(7,348)	(5,455)
Interest expense - related parties	(1,536)	(14,201)
Loss on impairment of goodwill	(18,872,850)	-
Change in fair value of derivative liabilities	1,449,908	22,043,391
Total Other (Expenses) Income, Net	(17,431,826)	22,508,720
<b>(Loss) Income Before Income Taxes</b>	<b>(21,486,978)</b>	<b>18,291,244</b>
Income tax benefit	-	5,612
<b>Net (Loss) Income</b>	<b>\$ (21,486,978)</b>	<b>\$ 18,296,856</b>

### Research and Development

We incurred research and development expenses of \$583,177 for the three months ended September 30, 2022, compared to \$316,473 for the three months ended September 30, 2021, representing an increase of \$266,704 or 84%. The increase includes an increase in salary expenses of \$140,000, an increase in research and development expenses of \$125,000 related to our agreements with Oxford University, and an increase in stock-based compensation expenses of approximately \$100,000, as well as an increase due to a reduction of a tax credit of \$220,000. These increases in expenses were offset by a decrease in contract expenses of \$365,000 related to the 2018 Yissum Agreement.

### Research and Development – Related Parties

We incurred research and development expenses – related parties of \$53,347 for the three months ended September 30, 2022, compared to \$298,879 for the three months ended September 30, 2021, representing a decrease of \$245,532, or 82%. The decrease is primarily attributable to a decrease in stock-based compensation expenses of \$980,000, offset by a prior year period reclassification of \$570,000, an increase in consulting expenses of \$85,000 and an increase due to the reduction of a tax credit of \$80,000.

## General and Administrative

We incurred general and administrative expenses of \$3,418,628 and \$3,519,605 for the three months ended September 30, 2022 and 2021, respectively, representing a decrease of \$100,977 or 3%. The decrease resulted from a decrease in settlement expenses of \$250,000, a decrease due to a reclass in the prior period between cost centers (from general and administrative to research and development – related parties) of \$630,000 and a decrease to gains/losses on foreign exchange of \$200,000 (see Note 3, Summary of Significant Accounting Policies, “Foreign Currency Translation”), offset by increases in stock-based compensation expenses, insurance expenses and salaries expenses of \$850,000, \$270,000 and \$65,000, respectively.

## General and Administrative – Related Parties

We incurred general and administrative expenses - related parties of \$0 and \$82,519 for the three months ended September 30, 2022 and 2021, respectively, representing a decrease of \$82,519, or 100%. The decrease is attributable to a change in cost center for consulting fees (from general and administrative to research and development) from the prior period of approximately \$42,000 and \$40,000 in bad debt expenses from the prior year.

## Other (Expenses) Income, Net

We incurred other (expenses), net of (\$17,431,826) during the three months ended September 30, 2022, as compared to other income, net of \$22,508,720 for the three months ended September 30, 2021, representing an increase in other expenses of \$39,940,546 or 177%. The increase was primarily attributable to the non-cash change in fair value of the Company’s derivative liabilities from the prior period of \$20,593,483 (see Note 6 – Derivative Liabilities), as well as the loss on impairment of goodwill of \$18,872,850 (see Note 3, Summary of Significant Accounting Policies, “Impairment of Long-Lived Assets and Goodwill”).

### *For the Nine Months Ended September 30, 2022 Compared to the Nine Months Ended September 30, 2021*

	For the Nine Months Ended September 30,	
	2022	2021
<b>Operating Expenses:</b>		
Research and development	\$ 1,688,474	\$ 689,172
Research and development - related parties	158,401	1,287,583
General and administrative	10,405,933	8,740,067
General and administrative - related parties	5,261	462,081
Total Operating Expenses	<u>12,258,069</u>	<u>11,178,948</u>
Loss From Operations	<u>(12,258,069)</u>	<u>(11,178,948)</u>
<b>Other Expenses:</b>		
Gain on settlement of liabilities	-	927,698
Other income	-	12,308
Interest expense	(22,117)	(130,634)
Interest income (expense) - related parties	1,495	(42,279)
Loss on extinguishment of convertible notes payable, net	-	(9,737)
Loss on impairment of goodwill	(18,872,850)	-
Change in fair value of derivative liabilities	14,167,560	(10,342,337)
Change in fair value of accrued issuable equity	-	(9,405)
Offering costs allocated to warrant liabilities	-	(604,118)
Total Other Expenses, Net	<u>(4,275,912)</u>	<u>(10,198,504)</u>
<b>Loss Before Income Taxes</b>	<u>(16,983,981)</u>	<u>(21,377,452)</u>
Income tax benefit	-	16,587
<b>Net Loss</b>	<u>\$ (16,983,981)</u>	<u>\$ (21,360,865)</u>

## Research and Development

We incurred research and development expenses of \$1,688,474 for the nine months ended September 30, 2022, compared to \$689,217 for the nine months ended September 30, 2021, representing an increase of \$999,257 or 145%. The increase includes a \$305,000 increase in consulting expenses for the Scientific Advisory Board, an increase in salaries expenses of \$520,000, an increase in research and development expenses of \$270,000 related to our agreements with Oxford University, a \$70,000 increase in Anti-TNF therapies expenses, and an increase in stock-based compensation expenses of approximately \$250,000, as well as a change due to various accruals from the prior year reversing for a net increase of \$700,000. These increases were offset by a decrease in contract expenses of \$1,000,000 related to the 2018 Yissum Agreement.

## Research and Development – Related Parties

We incurred research and development expenses – related parties of \$158,401 for the nine months ended September 30, 2022, compared to \$1,287,583 for the nine months ended September 30, 2021, representing a decrease of \$1,129,182, or 88%. The decrease is primarily attributable to a decrease in stock-based compensation expenses of \$925,000 as well as a decrease in consultancy expenses totaling \$440,000, offset by a decrease in the research and development tax credit for the period, which resulted in an increase of \$240,000.

## General and Administrative

We incurred general and administrative expenses of \$10,405,933 and \$8,740,067 for the nine months ended September 30, 2022 and 2021, respectively, representing an increase of \$1,665,866 or 19%. The increase is attributable to an increase in professional fees, primarily legal, of approximately \$1,800,000 and an increase in insurance expenses of \$825,000, offset by decreases in settlement expenses and Anti-TNF therapies expenses of \$270,000 and \$525,000, respectively, as well as a decrease to gains/losses on foreign exchange of \$185,000 (see Note 3, Summary of Significant Accounting Policies, “Foreign Currency Translation”).

## General and Administrative – Related Parties

We incurred general and administrative expenses - related parties of \$5,261 and \$462,081 for the nine months ended September 30, 2022 and 2021, respectively, representing a decrease of \$456,820, or 99%. The decrease is attributable to a decrease in consultancy expenses totaling \$125,000 and \$340,000 in bad debt expenses from the prior year.

## Other Expenses, Net

We incurred other expenses, net of \$4,725,912 during the nine months ended September 30, 2022, as compared to other expenses, net of \$10,198,504 for the nine months ended September 30, 2021, representing a decrease in other expenses of approximately \$5,472,592 or 54%. The decrease was primarily attributable to the non-cash change in fair value of the Company’s derivative liabilities from the prior period of \$24,509,897 (see Note 6 – Derivative Liabilities), which was offset by a loss on the impairment of goodwill in the amount of \$18,872,850 (see Note 3, Summary of Significant Accounting Policies, “Impairment of Long-Lived Assets and Goodwill”).

## **Liquidity and Capital Resources**

As of September 30, 2022 and December 31, 2021, we had cash balances of \$3,588,639 and \$8,244,508, respectively, and working capital (deficit) of \$1,789,844 and (\$8,498,193), respectively.

For the nine months ended September 30, 2022 and 2021, cash used in operating activities was \$9,200,830 and \$14,343,898, respectively. Our cash used in operations for the nine months ended September 30, 2022 was primarily attributable to our net loss of \$16,983,981, adjusted for non-cash expenses in the aggregate amount of \$7,050,633, as well as \$732,518 of net cash provided by changes in the levels of operating assets and liabilities. Our cash used in operations for the nine months ended September 30, 2021 was primarily attributable to our net loss of \$21,360,865, adjusted for non-cash expenses in the aggregate amount of \$14,424,088 as well as \$7,407,121 of net cash used to fund changes in the levels of operating assets and liabilities.

For the nine months ended September 30, 2022 and 2021, cash provided by financing activities was \$4,477,924 and \$23,862,871, respectively. Cash provided by financing activities during the nine months ended September 30, 2022 was due to proceeds from the sale of common stock, warrants and pre-funded warrants, net of issuance costs, in the amount of \$5,969,910, as well as repayments of loans payable in the amount of \$1,491,986. Cash provided by financing activities during the nine months ended September 30, 2021 was due to \$24,611,070 of net proceeds from our February 2021 private offering of common stock and warrants, partially offset by the repayment of loans and convertible debt in the aggregate amount of \$748,199.

Our product candidates may never achieve commercialization and we anticipate that we will continue to incur losses for the foreseeable future. We expect that our research and development expenses, general and administrative expenses, and capital expenditures will continue to increase. As a result, until such time, if ever, as we are able to generate substantial product revenue, we expect to finance our cash needs through a combination of equity offerings, debt financings or other capital sources, including potentially collaborations, licenses and other similar arrangements, which may not be available on favorable terms, if at all. The sale of additional equity or debt securities, if accomplished, may result in dilution to our then stockholders. Our primary uses of capital are, and we expect will continue to be, compensation and related expenses, third-party clinical research and development services, license payments or milestone obligations that may arise, laboratory and related supplies, clinical costs, potential manufacturing costs, legal and other regulatory expenses and general overhead costs.

Our material cash requirements and time periods of such requirements from known contractual and other obligations include milestone and royalty payments related to license agreements with Oxford University and Yissum Research Development Company of the Hebrew University of Jerusalem, Ltd., payments related to directors and officers (“D&O”) insurance, payments to consultants and payments related to outside consulting firms, such as legal counsel, auditors, accountants, etc. These cash requirements, in the aggregate, are expected to amount to approximately \$1,040,000 for the remainder of 2022 and \$33,800,000 for the years 2023 through 2026.

Further, our operating plans may change, and we may need additional funds to meet operational needs and capital requirements for clinical trials and other research and development activities. We currently have no credit facility or committed sources of capital. Because of the numerous risks and uncertainties associated with the development and commercialization of our product candidates, we are unable to estimate the amounts of increased capital outlays and operating expenditures associated with our current and anticipated product development programs.

Our condensed consolidated financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America (“U.S. GAAP”), which contemplate continuation of the Company as a going concern and the realization of assets and satisfaction of liabilities in the normal course of business. The carrying amounts of assets and liabilities presented in the condensed consolidated financial statements do not necessarily purport to represent realizable or settlement values. The condensed consolidated financial statements do not include any adjustment that might result from the outcome of this uncertainty.

## Recent Financing and Settlement Transactions

### *July 2022 Offering*

On July 17, 2022, the Company entered into a Securities Purchase Agreement with certain purchasers, pursuant to which the Company agreed to sell an aggregate of 3,500,000 shares of common stock, pre-funded warrants to purchase up to an aggregate of 2,632,076 shares of common stock (“July 2022 Pre-Funded Warrants”), and common stock warrants to purchase up to an aggregate of 6,132,076 shares of common stock (the “July 2022 Common Warrants”), at a combined purchase price of \$1.06 per share and warrant (the “July 2022 Offering”). Aggregate gross proceeds from the July 2022 Offering were \$6,499,737. The July 2022 Offering closed on July 20, 2022.

The July 2022 Pre-Funded Warrants have an exercise price equal to \$0.0001, are immediately exercisable and are subject to customary anti-dilution adjustments for stock splits or dividends or other similar transactions. The exercise price of the July 2022 Pre-Funded Warrants will not be subject to adjustment as a result of subsequent equity issuances at effective prices lower than the then-current exercise price. The July 2022 Pre-Funded Warrants are exercisable until they are exercised in full. The July 2022 Pre-Funded Warrants are subject to a provision prohibiting the exercise of such July 2022 Pre-Funded Warrants to the extent that, after giving effect to such exercise, the holder of such July 2022 Pre-Funded Warrants (together with the holder’s affiliates, and any other persons acting as a group together with the holder or any of the holder’s affiliates), would beneficially own in excess of 9.99% of the Company’s outstanding common stock (which may be increased or decreased, with 61 days prior written notice by the holder). Although the July 2022 Pre-Funded Warrants have a tender offer provision, the July 2022 Pre-Funded Warrants were determined to be equity-classified because they met the limited exception in the case of a change-in-control. Because the July 2022 Pre-Funded Warrants are equity-classified, the placement agent fees and offering expenses will be accounted for as a reduction of additional paid in capital.

The July 2022 Common Warrants have an exercise price equal to \$1.06 per share, are exercisable 6 months following the closing of the July 2022 Offering (the “Initial Exercise Date”) and are subject to customary anti-dilution adjustments for stock splits or dividends or other similar transactions. The exercise price of the July 2022 Common Warrants will not be subject to adjustment as a result of subsequent equity issuances at effective prices lower than the then-current exercise price. The July 2022 Common Warrants are exercisable for 5 years following the Initial Exercise Date. The July 2022 Common Warrants are subject to a provision prohibiting the exercise of such July 2022 Common Warrants to the extent that, after giving effect to such exercise, the holder of such July 2022 Common Warrants (together with the holder’s affiliates, and any other persons acting as a group together with the holder or any of the holder’s affiliates), would beneficially own in excess of 4.99% of the Company’s outstanding common stock (which may be increased or decreased, with 61 days prior written notice by the holder). Although the July 2022 Common Warrants have a tender offer provision, the July 2022 Common Warrants were determined to be equity-classified because they met the limited exception in the case of a change-in-control. Because the July 2022 Common Warrants are equity-classified, the placement agent fees and offering expenses will be accounted for as a reduction of additional paid in capital.

## Critical Accounting Policies and Estimates

The Company's condensed consolidated financial statements are prepared in accordance with accounting principles that are generally accepted in the United States. The preparation of these condensed consolidated financial statements requires management to make estimates and assumptions that affect the reported amounts of its assets, liabilities, revenue and expenses. The Company has identified certain policies and estimates as critical to its business operations and the understanding of its past or present results of operations related to (i) goodwill and (ii) intangible assets and in-process research and development. These policies and estimates are considered critical because they had a material impact, or they have the potential to have a material impact, on the Company's condensed consolidated financial statements and because they require management to make significant judgments, assumptions or estimates. The Company believes that the estimates, judgments and assumptions made when accounting for the items described below were reasonable, based on information available at the time they were made. However, actual results may differ from those estimates, and these differences may be material.

### *Goodwill/Intangible Assets and In-Process Research and Development ("IPR&D")*

The Company has a significant amount of goodwill, intangible assets and IPR&D assets that are assessed at least annually for impairment. Prior to the interim testing of goodwill for impairment, goodwill, intangible assets and IPR&D assets totaled \$46.7 million or 88% of the Company's total assets as of September 30, 2022, and totaled \$51.5 million, or 82% of the Company's total assets as of December 31, 2021. The impairment analyses of these assets are considered critical because of their significance to the Company. Intangible assets arising from business combinations or acquisitions, such as goodwill, patents and IPR&D assets are initially recorded at estimated fair value. Licensed patents are amortized over the remaining life of the patent. IPR&D assets are considered to be indefinite-lived until the completion or abandonment of the associated research and development projects. Our goodwill was derived from acquisitions where the purchase price exceeded the fair value of the net assets acquired. The Company is required to reassign goodwill to reporting units whenever reorganizations of the internal reporting structure change the composition of its reporting units. The Company identified one reporting unit which represents its sole operating segment.

The Company is required to assess goodwill/intangible assets and IPR&D assets at least annually, or more frequently, if an event occurs or circumstances change that indicates it is more likely than not the fair value of the Company's reporting unit was less than its carrying value. In assessing goodwill/intangible assets and IPR&D assets for impairment, the Company may first assess qualitative factors to determine whether it is more likely than not that the fair value of its reporting unit is less than its carrying value. For December 31, 2021, the Company elected to bypass the qualitative analysis and proceeded directly to the two-step test.

The first step of the goodwill/intangible assets and IPR&D assets impairment test used to identify potential impairment compares the fair value of the reporting unit with its carrying amount, including goodwill/intangible assets and IPR&D assets. The Company determined the fair market value of its single reporting unit as of December 31, 2021 to be its market capitalization of \$132,760,680, which represents \$3.90 per share (the market close price on December 31, 2021) multiplied by 34,021,200 shares (consisting of 34,035,925 shares of common stock plus 5,275 special voting shares which are exchangeable into common stock for no additional consideration) on December 31, 2021. The carrying amount of the reporting unit as of December 31, 2021 was \$39,322,695 (total assets of \$62.7 million less total liabilities of \$23.4 million).

Since the fair value of the Company (\$132,760,680) exceeded the carrying value of the Company (\$39,322,695) as of December 31, 2021, and the carrying value of the Company is greater than zero, management concluded the goodwill/intangible assets and IPR&D assets of the reporting unit were not impaired.

During the quarter, the market value of the Company's single reporting unit had significantly declined (see Note 3 – Summary of Significant Accounting Policies). As of September 30, 2022, the market value of the Company's publicly traded stock was \$0.67 per share; the Company determined the fair market value of its single reporting unit as of that date to be \$26,102,105, which represents the value per share multiplied by 39,251,286 shares (consisting of 39,246,011 shares of common stock outstanding as of September 30, 2022 plus 5,275 special voting shares which are exchangeable into common stock for no additional consideration). The carrying amount of the reporting unit as of September 30, 2022 was \$44,974,955 (total assets of \$53.2 million less total liabilities of \$8.2 million). As of this measurement date, the carrying value exceeded the fair market value by \$18,872,850, and management believed that the goodwill of the reporting unit was impaired by this amount. To recognize the impairment of goodwill, the Company recorded a loss (which appears as an expense on the income statement) for \$18,872,850, which reduced the goodwill of its CBR and 180T subsidiaries by \$11,264,612 and \$7,608,238, respectively.

The Company will continue to perform goodwill/intangible assets and IPR&D assets impairment testing on an annual basis, or as needed if there are changes to the composition of its reporting unit. As of September 30, 2022, there have been no changes to the composition of the reporting unit.

## *Derivative Liabilities*

The Company evaluates its debt and equity issuances to determine if those contracts or embedded components of those contracts qualify as derivatives requiring separate recognition in the Company's financial statements. As of September 30, 2022 and December 31, 2021, derivative liabilities totaled \$1.1 million and \$15.2 million, or 13% and 65%, respectively, of the Company's total liabilities. The analyses of these liabilities are considered critical because of their significance to the Company. Entities must consider whether to classify contracts that may be settled in its own stock, such as warrants, as equity of the entity or as an asset or liability. If an event that is not within the entity's control could require net cash settlement, then the contract should be classified as an asset or a liability rather than as equity.

The result of this accounting treatment is that the fair value of the embedded derivative is marked-to-market at each balance sheet date and recorded as a liability and the change in fair value is recorded in other (expense) income, net in the consolidated statements of operations. In circumstances where there are multiple embedded instruments that are required to be bifurcated, the bifurcated derivative instruments are accounted for as a single, compound derivative instrument. The classification of derivative instruments, including whether such instruments should be recorded as liabilities or as equity, is reassessed at the end of each reporting period. Equity instruments that are initially classified as equity that become subject to reclassification are reclassified to liability at the fair value of the instrument on the reclassification date. Derivative instrument liabilities are classified in the balance sheet as current or non-current based on whether or not net-cash settlement of the derivative instrument is expected within twelve months of the balance sheet date.

If the embedded conversion options do not require bifurcation, the Company then evaluates for the existence of a beneficial conversion feature by comparing the fair value of the Company's underlying stock as of the commitment date to the effective conversion price of the instrument (the intrinsic value).

The Company has computed the fair value of warrants, options, convertible notes and convertible preferred stock issued using the Monte-Carlo and Black-Scholes option pricing models. The expected term used for warrants, convertible notes and convertible preferred stock are the contractual life and the expected term used for options issued is the estimated period of time that options granted are expected to be outstanding. The Company utilizes the "simplified" method to develop an estimate of the expected term of "plain vanilla" option grants. The Company is utilizing an expected volatility figure based on a review of the historical volatilities, over a period of time, equivalent to the expected life of the instrument being valued, of similarly positioned public companies within its industry. The risk-free interest rate was determined from the implied yields from U.S. Treasury zero-coupon bonds with a remaining term consistent with the expected term of the instrument being valued.

The Company evaluated the terms of its AGP Warrants (see Note 6 – Derivative Liabilities) when they were originally earned and determined that the AGP Warrants should initially be liability-classified at their fair value at issuance with subsequent remeasurement (mark-to-market) at period ends. As of September 30, 2022, the Company has concluded that its warrants should remain liability-classified as of that date due to the presence of the tender offer provision combined with the existence of the exchangeable shares that have voting rights consistent with common stockholders.

### **Recently Issued Accounting Pronouncements**

See Note 3 – Summary of Significant Accounting Policies of our consolidated financial statements included within our 2021 Annual Report on Form 10-K for a summary of recently issued accounting pronouncements.

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

Pursuant to Item 305(e) of Regulation S-K (§ 229.305(e)), the Company is not required to provide the information required by this Item as it is a "smaller reporting company," as defined by Rule 229.10(f)(1).

## Item 4. Controls and Procedures.

### Evaluation of Disclosure Controls and Procedures

We have established and maintain a system of disclosure controls and procedures that are designed to provide reasonable assurance that information required to be disclosed in our reports filed with the SEC pursuant to the Exchange Act, is recorded, processed, summarized and reported within the time periods specified in the rules and forms of the Commission and that such information is accumulated and communicated to our management, including our Chief Executive Officer (CEO) (principal executive officer) and Chief Financial Officer (CFO) (principal accounting/financial officer), as appropriate, to allow timely decisions regarding required disclosures.

The Company's management evaluated, with the participation of our principal executive officer and principal financial and accounting officer, the effectiveness of our disclosure controls and procedures as defined in Rules 13a-15(e) and 15d-15(e) of the Exchange Act, as of the end of the period covered by this Report.

In designing and evaluating our disclosure controls and procedures, management recognizes that any disclosure controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives. In addition, the design of disclosure controls and procedures must reflect the fact that there are resource constraints and that management is required to apply its judgment in evaluating the benefits of possible controls and procedures relative to their costs.

Based on their evaluation, our principal executive officer and principal financial and accounting officer concluded that, as of September 30, 2022, our disclosure controls and procedures were not effective to provide assurance at a reasonable level that the information we are required to disclose in reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in SEC rules and forms, and that such information is accumulated and communicated to our management, including our principal executive officer and principal financial and accounting officer, as appropriate, to allow timely decisions regarding required disclosures as of September 30, 2022.

Management's evaluation was based on the following material weaknesses in our internal control over financial reporting which existed as of December 31, 2021, and which continue to exist, as discussed in the Company's Annual Report on Form 10-K:

- *Financial Reporting Systems*: The Company did not maintain a fully integrated financial consolidation and reporting system throughout the period and as a result, extensive manual analysis, reconciliation and adjustments were required in order to produce financial statements for external reporting purposes.
- *Ineffective controls*: Ineffective review controls over period end financial disclosure and reporting processes related to stock-based compensation and payroll expense classification.

A material weakness is a control deficiency or combination of control deficiencies, that results in more than a remote likelihood that a material misstatement of the annual or interim financial statements will not be prevented or detected on a timely basis. As a company with limited accounting resources, a significant amount of management's time and attention has been and will be diverted from our business to ensure compliance with these regulatory requirements.

Our management plans to establish procedures to monitor and evaluate the effectiveness of our internal controls over financial reporting on an ongoing basis and are committed to taking further action and implementing necessary enhancements or improvements. Management expects to complete its assessment of the design and operating effectiveness of its internal controls over financial reporting during the second half of 2022. Projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

#### **Remediation Plan**

Management continues to take steps to develop and enhance its internal controls over financial reporting, including:

- Retaining the same accounting personnel throughout all reporting periods in 2022 to establish continuity of processes and implement sustainable improvements and efficiencies in the financial reporting and consolidation tools and procedures.
- Considering opportunities for improving the consolidations and financial statement processes, including exploring migrating to an automated consolidations application which integrates with the existing general ledger program to streamline the consolidations and reporting processes and enhance efficiency and accuracy.
- As part of the systems review and potential migration, our plan is to:
  - Strengthen the chart of accounts to provide required roll ups;
  - Review current mapping and implement new procedures to enhance the controls on future changes; and
  - Automate reporting and calculations whenever possible.
- To the extent manual processes, schedules and/or adjustments exist as part of, or following implementation, management reviews must include additional high-level steps such as mapping considerations to financial reporting and detailed reviews of annual schedules to ensure the completeness and appropriate classification of expenses in the financial disclosure and reporting process.

#### **Inherent Limitations on Effectiveness of Controls and Procedures**

In designing and evaluating our disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within the Company have been detected. The design of any system of controls also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions. Over time, controls may become inadequate because of changes in conditions, or the degree of compliance with the policies or procedures may deteriorate. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected.

#### **Changes in Internal Control over Financial Reporting**

There have been no changes in our internal control over financial reporting that occurred during the three months ended September 30, 2022 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

## PART II - OTHER INFORMATION

### Item 1. Legal Proceedings.

From time to time, we may be a party to litigation that arises in the ordinary course of our business. The impact and outcome of litigation, if any, is subject to inherent uncertainties, and an adverse result in these or other matters may arise from time to time that may harm our business. We believe the ultimate resolution of any such current proceeding will not have a material adverse effect on our continued financial position, results of operations or cash flows.

Such current litigation or other legal proceedings are described in, and incorporated by reference in, this “Item 1. Legal Proceedings” of this Form 10-Q from, “Part I – Item 1. Financial Statements” in the Notes to Condensed Consolidated Financial Statements in “Note 8 – Commitments and Contingences”, under the heading Legal Matters. The Company believes that the resolution of currently pending matters will not individually or in the aggregate have a material adverse effect on our financial condition or results of operations. However, assessment of the current litigation or other legal claims could change in light of the discovery of facts not presently known to the Company or by judges, juries or other finders of fact, which are not in accord with management’s evaluation of the possible liability or outcome of such litigation or claims.

Additionally, the outcome of litigation is inherently uncertain. If one or more legal matters were resolved against the Company in a reporting period for amounts in excess of management’s expectations, the Company’s financial condition and operating results for that reporting period could be materially adversely affected.

### Item 1A. Risk Factors.

There have been no material changes from the risk factors previously disclosed in Part I, Item 1A of the Company’s Annual Report on Form 10-K for the year ended December 31, 2021, as filed with the Commission on March 31, 2022, under the heading “Risk Factors”, which risk factors are incorporated by reference herein, except as described below, and investors should review the risks provided in the Form 10-K and below prior to making an investment in the Company. The business, financial condition and operating results of the Company can be affected by a number of factors, whether currently known or unknown, including but not limited to those described in the Form 10-K for the year ended December 31, 2021, under “Risk Factors”, and below, any one or more of which could, directly or indirectly, cause the Company’s actual financial condition and operating results to vary materially from past, or from anticipated future, financial condition and operating results. Any of these factors, in whole or in part, could materially and adversely affect the Company’s business, financial condition, operating results and stock price.

#### Risks Related to Our Business Operations

##### *Our goodwill and intangible assets are subject to impairment risks.*

The Company assesses the potential impairment of indefinite-lived intangible assets and goodwill at least annually and otherwise when there is evidence that events or changes in circumstances indicate that an impairment condition may exist. Many of the factors used in assessing fair value are outside the control of management, and it is reasonably likely that assumptions and estimates will change in future periods. These changes could result in future impairments. Events and circumstances that the Company considers important which could trigger impairment include the following:

- Significant underperformance relative to historical or projected future operating results;
- Significant changes in the Company’s strategy for its overall business or use of acquired assets;
- Significant negative industry or economic trends;
- Significant decline in the Company’s stock price for a sustained period;
- Decreased market capitalization relative to net book value;
- Unanticipated technological change or competitive activities;
- Change in consumer demand;
- Loss of key personnel; and
- Acts by governments and courts.

When there is indication that the carrying value of intangible assets may not be recoverable based upon the existence of one or more of the above indicators, an impairment loss is recognized if the carrying amount of the asset exceeds its fair value. When there is an indication of impairment of goodwill, an impairment loss is recognized to the extent that the carrying amount of the goodwill exceeds its implied fair value.

It is possible that changes in circumstances, existing at that time or at other times in the future, or in the numerous variables associated with the assumptions and estimates made by the Company in assessing the appropriate valuation of its indefinite-lived intangible assets or goodwill, could in the future require the Company to record impairment charges, which would adversely affect future reported results of operations and stockholders' equity, although such charges would not affect our cash flow.

As discussed in the risk factor below, we had material impairment charges to our goodwill during the three months ended September 30, 2022.

***We have in the past, and may in the future, impair long-lived assets and/or goodwill.***

The Company reviews long-lived assets and certain identifiable assets for impairment whenever circumstances and situations change such that there is an indication that the carrying amounts may not be recovered. An impairment exists when the carrying value of the long-lived asset is not recoverable and exceeds its estimated fair value. Goodwill represents the difference between the purchase price and the fair value of assets and liabilities acquired in a business combination. The Company reviews goodwill yearly, or more frequently whenever circumstances and situations change such that there is an indication that the carrying amounts may not be recovered, for impairment by initially considering qualitative factors to determine whether it is more likely than not that the fair value of a reporting unit is less than its carrying amount, including goodwill, as a basis for determining whether it is necessary to perform a quantitative analysis. If it is determined that it is more likely than not that the fair value of reporting unit is less than its carrying amount, a quantitative analysis is performed to identify goodwill impairment. Beginning in the second quarter of 2022, the market value of the Company's single reporting unit began to decline and as such, the Company elected to conduct a quantitative analysis of goodwill to assess for impairment. As of September 30, 2022, the market value of the Company's publicly traded stock was \$0.67 per share; the Company determined the fair market value of its single reporting unit as of that date to be \$26,102,105, which represents the value per share multiplied by 39,251,286 shares (consisting of 39,246,011 shares of common stock outstanding as of September 30, 2022 plus 5,275 special voting shares which are exchangeable into common stock for no additional consideration). The carrying amount of the reporting unit as of September 30, 2022 was \$44,974,955 (total assets of \$53.2 million less total liabilities of \$8.2 million). As of this measurement date, the carrying value exceeded the fair market value by \$18,872,850 and as such, management determined that the goodwill of the reporting unit was impaired by this amount. To recognize the goodwill impairment, the Company recorded a loss on goodwill impairment (which appears as an expense on the income statement) for \$18,872,850, which reduced the goodwill of its CBR and 180T subsidiaries by \$11,264,612 and \$7,608,238, respectively.

A continued period of low trading prices of our common stock may force us to incur further material impairments of our reporting units, which could have a material effect on the value of our assets and cause the value of our securities to decline in value. An impairment recognized in one period may not be reversed in a subsequent period even if the value of our common stock increases in the future. We have in the past and could in the future incur additional impairments of long-lived assets and/or goodwill which may be material.

***Our operations are subject to risks associated with ongoing and potential future global conflicts.***

Currently, there is an ongoing conflict involving Russia and Ukraine and the war between the two countries continues to evolve as military activity proceeds and additional sanctions are imposed. The war is increasingly affecting economic and global financial markets and exacerbating ongoing economic challenges, including issues such as rising inflation and global supply-chain disruption. While we do not believe this conflict currently has a material impact on our financial accounting and reporting, the degree to which we will be affected in the future largely depends on the nature and duration of uncertain and unpredictable events, and our business could be impacted. Furthermore, future global conflicts or wars could create further economic challenges, including, but not limited to, increases in inflation and further global supply-chain disruption. Consequently, the ongoing Russia/Ukraine conflict and/or other future global conflicts could result in an increase in operating expenses and/or a decrease in any future revenue and could further have a material adverse effect on our results of operations and cash flow.

***We have identified material weaknesses in our disclosure controls and procedures and internal control over financial reporting. If not remediated, our failure to establish and maintain effective disclosure controls and procedures and internal control over financial reporting could result in material misstatements in our financial statements and a failure to meet our reporting and financial obligations, each of which could have a material adverse effect on our financial condition and the trading price of our securities.***

Maintaining effective internal control over financial reporting and effective disclosure controls and procedures are necessary for us to produce reliable financial statements. As reported in our Annual Report on Form 10-K for the year ended December 31, 2021, we have determined that our internal control over financial reporting was not effective and as described in this Quarterly Report on Form 10-Q, our management has determined that, as of September 30, 2022, our disclosure controls and procedures were not effective to provide assurance at a reasonable level that the information we are required to disclose in reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in SEC rules and forms, and that such information is accumulated and communicated to our management, including our principal executive officer and principal financial and accounting officer, as appropriate, to allow timely decisions regarding required disclosures. Such internal control over financial reporting has not been effective since December 31, 2019 and such disclosure controls and procedures have not been effective since December 31, 2021.

Our internal control of financial reporting was deemed not effective as of December 31, 2021, because the following material weaknesses existed as of December 31, 2021:

- The Company did not maintain a fully integrated financial consolidation and reporting system throughout the period and as a result, extensive manual analysis, reconciliation and adjustments were required in order to produce financial statements for external reporting purposes; and
- The Company had ineffective review controls over period end financial disclosure and reporting processes related to stock-based compensation and payroll expense classification.

A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of the Company's annual or interim financial statements will not be prevented or detected on a timely basis. Accordingly, a material weakness increases the risk that the financial information we report contains material errors. A control deficiency exists when the design or operation of a control does not allow management or employees, in the normal course of performing their assigned functions, to prevent or detect misstatements on a timely basis.

Maintaining effective disclosure controls and procedures and effective internal control over financial reporting are necessary for us to produce reliable financial statements and the Company is committed to remediating its material weaknesses in such controls as promptly as possible. However, there can be no assurance as to when these material weaknesses will be remediated or that additional material weaknesses will not arise in the future. Any failure to remediate the material weaknesses, or the development of new material weaknesses in our internal control over financial reporting, could result in material misstatements in our financial statements and cause us to fail to meet our reporting and financial obligations on a timely and accurate basis. If our financial statements are not accurate, investors may not have a complete understanding of our operations or may lose confidence in our reported financial information. Likewise, if our financial statements are not filed on a timely basis as required by the SEC and NASDAQ, we could face severe consequences from those authorities. In any of these cases, it could result in a material adverse effect on our business, on our financial condition or have a negative effect on the trading price of our common stock and warrants. Further, if we fail to remedy this deficiency (or any other future deficiencies) or maintain the adequacy of our disclosure controls and procedures and our internal controls, we could be subject to regulatory scrutiny, civil or criminal penalties or shareholder litigation against us or our management.

We can give no assurance that the measures we have taken and plan to take in the future will remediate the material weakness identified or that any additional material weaknesses or restatements of our financial statements will not arise in the future due to a failure to implement and maintain adequate internal control over financial reporting or circumvention of those controls.

Further, in the future, if we cannot conclude that we have effective internal control over our financial reporting, or if our independent registered public accounting firm is unable to provide an unqualified opinion regarding the effectiveness of our internal control over financial reporting (to the extent we may be required in the future), investors could lose confidence in the reliability of our financial statements, which could lead to a decline in our stock price. Failure to comply with reporting requirements could also subject us to sanctions and/or investigations by the SEC or NASDAQ, as applicable, or other regulatory authorities.

In addition, even if we are successful in strengthening our controls and procedures, those controls and procedures may not be adequate to prevent or identify irregularities or facilitate the fair presentation of our financial statements or our periodic reports filed with the SEC. This may require us to restate prior financial statements.

***Global economic conditions could materially adversely affect the Company's business, results of operations, financial condition and growth.***

Adverse macroeconomic conditions, including inflation, slower growth or recession, new or increased tariffs, changes to fiscal and monetary policy, tighter credit, higher interest rates, high unemployment and currency fluctuations could materially adversely affect the Company operations, expenses, access to capital and the market for the Company's planned future products. In addition, consumer confidence and spending could be adversely affected in response to financial market volatility, negative financial news, conditions in the real estate and mortgage markets, declines in income or asset values, changes to fuel and other energy costs, labor and healthcare costs and other economic factors.

In addition, uncertainty about, or a decline in, global or regional economic conditions could have a significant impact on the Company's funding sources, suppliers and partners. Potential effects include financial instability; inability to obtain credit to finance operations and purchases of the Company's future planned products; and insolvency.

A downturn in the economic environment could also lead to limitations on the Company's ability to issue new debt; reduced liquidity; and declines in the fair value of the Company's financial instruments. These and other economic factors could materially adversely affect the Company's business, results of operations, financial condition and growth.

***Our industry and the broader US economy have experienced higher than expected inflationary pressures in the first three quarters of 2022, related to continued supply chain disruptions, labor shortages and geopolitical instability. Should these conditions persist our business, future results of operations and cash flows could be materially and adversely affected.***

The first three quarters of 2022 have seen significant increases in the costs of certain materials, products and shipping costs, as a result of availability constraints, supply chain disruption, increased demand, labor shortages associated with a fully employed US labor force, high inflation and other factors. Supply and demand fundamentals have been further aggravated by disruptions in global energy supply caused by multiple geopolitical events, including the ongoing conflict between Russia and Ukraine. Service, materials and shipping costs have also increased accordingly with general supply chain and inflation issues seen throughout the United States leading to increased operating costs. Recent supply chain constraints and inflationary pressures may adversely impact our operating costs and may negatively impact our future product costs, consulting costs and expenses which could have a material adverse effect on our business, financial condition, results of operations and cash flows.

***Economic uncertainty may affect our access to capital and/or increase the costs of such capital.***

Global economic conditions continue to be volatile and uncertain due to, among other things, consumer confidence in future economic conditions, fears of recession and trade wars, the price of energy, fluctuating interest rates, the availability and cost of consumer credit, the availability and timing of government stimulus programs, levels of unemployment, increased inflation, tax rates, and the war between Ukraine and Russia which began in February 2022. These conditions remain unpredictable and create uncertainties about our ability to raise capital in the future. In the event required capital becomes unavailable in the future, or more costly, it could have a material adverse effect on our business, future results of operations, and financial condition.

***We may not receive any amounts under our pre-merger directors and officers insurance policy in connection with certain litigation matters.***

On June 29, 2022, AmTrust International Underwriters DAC ("AmTrust"), which was the premerger directors and officers insurance policy underwriter for KBL, filed a declaratory relief action against the Company in the U.S. District Court for the Northern District of California (the "Declaratory Relief Action") seeking declaration of AmTrust's obligations under the directors and officers insurance policy. In the Declaratory Relief Action, AmTrust is claiming that as a result of the merger, the Company is no longer the insured under the subject insurance policy, notwithstanding the fact that the fees which the Company seeks to recover from AmTrust relate to matters occurring prior to the merger. On September 20, 2022, the Company filed its Answer and Counterclaims against AmTrust for bad faith breach of AmTrust's insurance coverage obligations to the Company under the subject directors and officers insurance policy, and seeking damages of at least \$2 million in compensatory damages, together with applicable punitive damages. In addition, the Company brought a Third-Party Complaint against its excess insurance carrier, Freedom Specialty Insurance Company ("Freedom") seeking declaratory relief that Freedom will also be required to honor its policy coverage as soon as the amount of AmTrust's insurance coverage obligations to the Company have been exhausted. On October 25, 2022, AmTrust filed its Answer to the Company's Counterclaims; however, Freedom's response to the Third-Party Complaint is not yet due. As of September 30, 2022, the Company has recorded an insurance claims receivable of \$1,836,940, which it believes is the net recoverable amount advanced to former directors and officers of the Company as of September 30, 2022. While the Company believes it has a strong case against AmTrust, there can be no assurance that the Company will prevail in this action. In the event that the Company does not prevail in the action, it will not receive the estimated \$1,836,940 net recoverable amount, which may have a material adverse effect on our cash flows, results of operations, and balance sheet. Additionally, any funds spent towards the lawsuit may be lost which could also have a material adverse effect on our results of operations. The occurrence of any of the above could have a material adverse effect on the trading value of our securities.

## Risks Related to our Common Stock and Warrants

*We face significant penalties and damages in the event registration statements we have previously filed to register certain securities sold in our prior offerings are subsequently suspended or terminated.*

Pursuant to certain prior private offerings of securities, we entered into registration rights agreements which required us to file certain registration statements to register the resale of the privately sold shares and certain securities issuable upon exercise/conversion thereof, and to maintain the effectiveness of such registration statements for certain periods of time. To date, all such required registration statements have been declared effective by the SEC. However, in the event the registration statements are subsequently suspended or terminated, or we otherwise fail to meet certain requirements set forth in the registration right agreements, we could be required to pay significant penalties which could adversely affect our cash flow and cause the value of our securities to decline in value.

*We are not currently in compliance with the continued listing standards of NASDAQ and may not be able to comply with NASDAQ's continued listing standards in the future.*

Our common stock and warrants trade on The NASDAQ Capital Market under the symbols "ATNF" and "ATNFW," respectively. Notwithstanding such listing, there can be no assurance any broker will be interested in trading our securities. Therefore, it may be difficult to sell our securities publicly. There is also no guarantee that we will be able to maintain our listings on The NASDAQ Capital Market for any period of time by perpetually satisfying NASDAQ's continued listing requirements. We are not currently in compliance with NASDAQ's continued listing standards and our failure to continue to meet these requirements may result in our securities being delisted from NASDAQ.

On September 30, 2022, we received written notice (the "Notification Letter") from the Listing Qualifications Department of The NASDAQ Stock Market LLC ("NASDAQ") notifying the Company that it is not in compliance with the minimum bid price requirements set forth in NASDAQ Listing Rule 5550(a)(2) for continued listing on The NASDAQ Capital Market. NASDAQ Listing Rule 5550(a)(2) requires listed securities to maintain a minimum bid price of \$1.00 per share, and Listing Rule 5810(c)(3) (A) provides that a failure to meet the minimum bid price requirement exists if the deficiency continues for a period of thirty (30) consecutive business days. Based on the closing bid price of the Company's common stock for the thirty (30) consecutive business days from August 18, 2022 to September 29, 2022, the Company no longer meets the minimum bid price requirement. The Notification Letter states that the Company has 180 calendar days or until March 29, 2023, to regain compliance with NASDAQ Listing Rule 5550(a)(2). To regain compliance, the bid price of the Company's common stock must have a closing bid price of at least \$1.00 per share for a minimum of 10 consecutive business days. If the Company does not regain compliance by March 29, 2023, an additional 180 days may be granted to regain compliance, so long as the Company meets The NASDAQ Capital Market initial listing criteria (except for the bid price requirement) and notifies NASDAQ in writing of its intention to cure the deficiency during the second compliance period by effecting a reverse stock split, if necessary. If the Company does not qualify for the second compliance period or fails to regain compliance during the second 180-day period, the Company's common stock will be subject to delisting, at which point the Company would have an opportunity to appeal the delisting determination to a Hearings Panel. The Company intends to monitor the closing bid price of its common stock and may, if appropriate, consider implementing available options to regain compliance with the minimum bid price requirement under the NASDAQ Listing Rules. The Company plans to seek shareholder approval to authorize a range of a reverse stock split to be implemented and approved at the discretion of the Company's Board of Directors.

In addition to the minimum price requirement described above, other conditions required for continued listing on The NASDAQ Capital Market include requiring that we maintain at least \$2.5 million in stockholders' equity, \$35 million of market value of listed securities, or \$500,000 in net income over the prior two years or two of the prior three years, and having a majority of independent directors. Our stockholders' equity may not remain above NASDAQ's \$2.5 million minimum, our market value of listed securities may not remain above \$35,000,000, we may not generate over \$500,000 of yearly net income, and we may not be able to maintain independent directors. Furthermore, we are required to maintain a majority of independent directors and at least three members on our audit committee.

If we fail to comply with NASDAQ rules and requirements (including curing the minimum bid price deficiency discussed above), our stock may be delisted. In addition, even if we demonstrate compliance with the requirements above, we will have to continue to meet other objective and subjective listing requirements to continue to be listed on The NASDAQ Capital Market. Delisting from The NASDAQ Capital Market could make trading our common stock and/or warrants more difficult for investors, potentially leading to declines in our share price and liquidity. Without a NASDAQ Capital Market listing, stockholders may have a difficult time getting a quote for the sale or purchase of our stock, the sale or purchase of our stock would likely be made more difficult and the trading volume and liquidity of our stock could decline. Delisting from The NASDAQ Capital Market could also result in negative publicity and could also make it more difficult for us to raise additional capital. The absence of such a listing may adversely affect the acceptance of our common stock and/or warrants as currency or the value accorded by other parties. Further, if we are delisted, we would also incur additional costs under state blue sky laws in connection with any sales of our securities. These requirements could severely limit the market liquidity of our common stock and/or warrants and the ability of our stockholders to sell our common stock and/or warrants in the secondary market. If our common stock and/or warrants are delisted by NASDAQ, our common stock and/or warrants may be eligible to trade on an over-the-counter quotation system, such as the OTCQB Market, where an investor may find it more difficult to sell our stock or obtain accurate quotations as to the market value of our common stock and/or warrants. In the event our common stock and/or warrants are delisted from The NASDAQ Capital Market, we may not be able to list our common stock and/or warrants on another national securities exchange or obtain quotation on an over-the counter quotation system.

***Provisions of the pre-funded warrants and common warrants granted in July 2022 could discourage an acquisition of us by a third party.***

Certain provisions of the pre-funded warrants and common warrants granted by us in July 2022 could make it more difficult or expensive for a third party to acquire us. The pre-funded warrants and common warrants granted by us in July 2022 prohibit us from engaging in certain transactions constituting “fundamental transactions” unless, among other things, the surviving entity assumes our obligations under the pre-funded warrants and common warrants. Further, the common warrants granted by us in July 2022 provide that, in the event of certain transactions constituting “fundamental transactions,” with some exception, holders of such warrants will have the right, at their option, to require us to repurchase such common stock warrants at a price described in such warrants. These and other provisions of the pre-funded warrants and common warrants offered by this prospectus could prevent or deter a third party from acquiring us even where the acquisition could be beneficial to stockholders.

***Our outstanding options and warrants may adversely affect the trading price of our securities.***

As of September 30, 2022, we had (i) outstanding stock options to purchase an aggregate of 3.3 million shares of common stock at a weighted average exercise price of \$4.23 per share; (ii) outstanding pre-funded warrants to purchase 1.1 million shares of common stock at an exercise price of \$0.0001 per share; and (iii) outstanding warrants to purchase 17.3 million shares of common stock at a weighted average exercise price of \$3.30 per share. For the life of the options and warrants, the holders have the opportunity to profit from a rise in the market price of our common stock without assuming the risk of ownership. The issuance of shares upon the exercise of outstanding securities will also dilute the ownership interests of our existing stockholders.

The availability of these shares for public resale, as well as any actual resales of these shares, could adversely affect the trading price of our common stock. We cannot predict the size of future issuances of our common stock pursuant to the exercise of outstanding options or warrants or conversion of other securities, or the effect, if any, that future issuances and sales of shares of our common stock may have on the market price of our common stock. Sales or distributions of substantial amounts of our common stock (including shares issued in connection with an acquisition), or the perception that such sales could occur, may cause the market price of our common stock to decline.

In addition, the common stock issuable upon exercise/conversion of outstanding convertible securities may represent overhang that may also adversely affect the market price of our common stock. Overhang occurs when there is a greater supply of a company's stock in the market than there is demand for that stock. When this happens the price of our stock will decrease, and any additional shares which stockholders attempt to sell in the market will only further decrease the share price. If the share volume of our common stock cannot absorb shares sold by holders of our outstanding convertible securities, then the value of our common stock will likely decrease.

*A significant number of our shares of common stock are eligible for sale and their sale or potential sale may depress the market price of our common stock.*

Sales of a significant number of shares of our common stock in the public market could harm the market price of our common stock. Most of our common stock is available for resale in the public market, and if sold would increase the supply of our common stock, thereby causing a decrease in its price. Some or all of our shares of common stock may be offered from time to time in the open market pursuant to effective registration statements and/or compliance with Rule 144, which sales could have a depressive effect on the market for our shares of common stock. Subject to certain restrictions, a person who has held restricted shares for a period of six months may generally sell common stock into the market. The sale of a significant portion of such shares when such shares are eligible for public sale may cause the value of our common stock to decline in value.

*Future sales and issuances of our common stock or rights to purchase common stock, could result in additional dilution to our stockholders and could cause the price of our common stock to decline.*

We may issue additional common stock, convertible securities, or other equity in the future. We also issue common stock to our employees, directors, and other service providers pursuant to our equity incentive plans. Such issuances could be dilutive to investors and could cause the price of our common stock to decline. New investors in such issuances could also receive rights senior to those of current stockholders.

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

### *Recent Sales of Unregistered Securities*

There have been no sales of unregistered securities during the quarter ended September 30, 2022, and for the period from October 1, 2022, to the filing date of this report.

\* \* \* \* \*

## Purchases of Equity Securities by the Issuer and Affiliated Purchasers

None.

## Item 3. Defaults upon Senior Securities.

None.

## Item 4. Mine Safety Disclosures.

Not applicable.

## Item 5. Other Information.

None.

## Item 6. Exhibits.

Exhibit No.	Description	Filed/ Furnished Herewith	Form	File No.	Exhibit	Filing Date
1.1	<a href="#">Placement Agent Agreement dated July 17, 2022, between 180 Life Sciences Corp. and A.G.P./Alliance Global Partners</a>		8-K	001-38105	1.1	7/19/22
4.1	<a href="#">Form of Pre-Funded Warrant</a>		8-K	001-38105	4.1	7/19/22
4.2	<a href="#">Form of Common Warrant</a>		8-K	001-38105	4.2	7/19/22
10.1***	<a href="#">180 Life Sciences Corp. 2022 Omnibus Incentive Plan</a>		8-K	001-38105	10.1	6/14/22
10.2+	<a href="#">Securities Purchase Agreement dated July 17, 2022, by and between 180 Life Sciences Corp. and the Purchaser</a>		8-K	001-38105	10.1	7/19/22
10.3***	<a href="#">Form of Lock-Up Agreement (July 2022 Offering)</a>		8-K	001-38105	10.2	7/19/22
31.1*	<a href="#">Certification of Principal Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act</a>	X				
31.2*	<a href="#">Certification of Principal Accounting Officer pursuant to Section 302 of the Sarbanes-Oxley Act</a>	X				
32.1**	<a href="#">Certification of Principal Executive Officer Pursuant to Section 906 of the Sarbanes-Oxley Act</a>	X				
32.2**	<a href="#">Certification of Principal Accounting Officer Pursuant to Section 906 of the Sarbanes-Oxley Act</a>	X				
101.INS*	Inline XBRL Instance Document - the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document	X				
101.SCH*	Inline XBRL Taxonomy Extension Schema	X				
101.CAL*	Inline XBRL Taxonomy Calculation Linkbase	X				
101.DEF*	Inline XBRL Definition Linkbase Document	X				
101.LAB*	Inline XBRL Taxonomy Label Linkbase	X				
101.PRE*	Inline XBRL Definition Linkbase Document	X				
104*	Inline XBRL for the cover page of this Quarterly Report on Form 10-K, included in the Exhibit 101 Inline XBRL Document Set	X				

\* Filed herewith.

\*\* Furnished herewith.

\*\*\* Indicates management contract or compensatory plan or arrangement.

+ Pursuant to Item 601(a)(5) of Regulation S-K, schedules have been omitted and will be furnished on a supplemental basis to the Securities and Exchange Commission upon request.

## 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.

### 180 LIFE SCIENCES CORP.

Date: November 10, 2022

By: /s/ James N. Woody, M.D., Ph.D.  
James N. Woody, M.D., Ph.D.,  
Chief Executive Officer  
(Principal Executive Officer)

Date: November 10, 2022

By: /s/ Ozan Pamir  
Ozan Pamir  
Interim Chief Financial Officer  
(Principal Financial and Accounting Officer)

## CERTIFICATION

I, James N. Woody, certify that:

1. I have reviewed this quarterly report on Form 10-Q of 180 Life Sciences Corp.;
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(s) 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(s) 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.

By: /s/ James N. Woody

James N. Woody  
Chief Executive Officer  
(Principal Executive Officer)  
Date: November 10, 2022

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## CERTIFICATION

I, Ozan Pamir, certify that:

1. I have reviewed this quarterly report on Form 10-Q of 180 Life Sciences Corp.;
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(s) 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(s) 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.

By: /s/ Ozan Pamir

Ozan Pamir  
Interim Chief Financial Officer  
(Principal Financial Officer and Principal Accounting Officer)  
Date: November 10, 2022

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**180 LIFE SCIENCES CORP.**  
**CERTIFICATION PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

I, James N. Woody, certify, as of the date hereof, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge, the Quarterly Report of 180 Life Sciences Corp. on Form 10-Q for the quarterly period ended September 30, 2022, (i) fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and (ii) that the information contained in such Form 10-Q fairly presents in all material respects the financial condition and results of operations of 180 Life Sciences Corp. at the dates and for the periods indicated.

By: /s/ James N. Woody

James N. Woody

Chief Executive Officer

(Principal Executive Officer)

Date: November 10, 2022

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**180 LIFE SCIENCES CORP.**  
**CERTIFICATION PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

I, Ozan Pamir, certify, as of the date hereof, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge, the Quarterly Report of 180 Life Sciences Corp. on Form 10-Q for the quarterly period ended September 30, 2022, (i) fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and (ii) that the information contained in such Form 10-Q fairly presents in all material respects the financial condition and results of operations of 180 Life Sciences Corp. at the dates and for the periods indicated.

By: */s/ Ozan Pamir*

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Ozan Pamir

Interim Chief Financial Officer

(Principal Financial Officer and Principal Accounting Officer)

Date: November 10, 2022

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