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NORTHWEST BIOTHERAPEUTICS INC

FORM 10-Q

(Quarterly Report)

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

FORM 10-Q

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

For the quarterly period ended March 31, 2023

OR

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

For the transition period from _____ to _____

Commission File Number: 001-35737

NORTHWEST BIOTHERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

Delaware

94-3306718

(State or Other Jurisdiction of Incorporation or Organization)

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

4800 Montgomery Lane, Suite 800, Bethesda, MD 20814

(Address of principal executive offices) (Zip Code)

(240) 497-9024

(Registrant's telephone number)

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, 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

Accelerated filer

Non-accelerated filer

Smaller reporting company

Emerging growth company

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

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.

Title of each class	Trading Symbol	Name of each exchange on which registered
Common Stock, par value \$0.001 per share	NWBO	OTCQB

As of May 8, 2023, the total number of shares of common stock, par value \$0.001 per share, outstanding was 1,086,771,876.

NORTHWEST BIOTHERAPEUTICS, INC.
FORM 10-Q
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PART I - FINANCIAL INFORMATION

NORTHWEST BIOTHERAPEUTICS, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(in thousands, except share and per share amounts)

	March 31, 2023 (Unaudited)	December 31, 2022
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 6,191	\$ 6,965
Prepaid expenses and other current assets	3,300	2,460
Total current assets	<u>9,491</u>	<u>9,425</u>
Non-current assets:		
Property, plant and equipment, net	13,570	13,418
Construction in progress	3,321	2,028
Right-of-use asset, net	4,209	4,189
Indefinite-lived intangible asset	1,292	1,292
Goodwill	626	626
Other assets	362	345
Total non-current assets	<u>23,380</u>	<u>21,898</u>
TOTAL ASSETS	<u>\$ 32,871</u>	<u>\$ 31,323</u>
LIABILITIES, MEZZANINE EQUITY AND STOCKHOLDERS' DEFICIT		
Current liabilities:		
Accounts payable and accrued expenses	\$ 11,892	\$ 10,687
Accounts payable and accrued expenses to related parties and affiliates	8,744	6,955
Convertible notes, net	135	135
Notes payable, net	10,471	15,403
Contingent payable derivative liability	8,451	8,668
Warrant liability	1,445	80,559
Investor advances	2,616	2,566
Share liability	585	678
Lease liabilities	369	354
Total current liabilities	<u>44,708</u>	<u>126,005</u>
Non-current liabilities:		
Notes payable, net of current portion, net	16,019	5,991
Lease liabilities, net of current portion	4,370	4,370
Total non-current liabilities	<u>20,389</u>	<u>10,361</u>
Total liabilities	<u>65,097</u>	<u>136,366</u>
COMMITMENTS AND CONTINGENCIES (Note 12)		
Mezzanine equity:		
Series C Convertible Preferred Stock, 10,000,000 shares designated; 1.4 million and 1.4 million shares issued and outstanding as of March 31, 2023 and December 31, 2022, respectively; aggregate liquidation preference of \$22.1 million	23,752	23,060
Stockholders' deficit:		
Preferred stock (\$0.001 par value); 100,000,000 shares authorized as of March 31, 2023 and December 31, 2022, respectively	—	—
Common stock (\$0.001 par value); 1,700,000,000 shares authorized; 1,083.1 million and 1,068.4 million shares issued and outstanding as of March 31, 2023 and December 31, 2022, respectively	1,083	1,068
Additional paid-in capital	1,248,397	1,164,885
Stock subscription receivable	(79)	(79)
Accumulated deficit	(1,307,774)	(1,297,122)
Accumulated other comprehensive income	2,395	3,145
Total stockholders' deficit	<u>(55,978)</u>	<u>(128,103)</u>
TOTAL LIABILITIES, MEZZANINE EQUITY AND STOCKHOLDERS' DEFICIT	<u>\$ 32,871</u>	<u>\$ 31,323</u>

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

NORTHWEST BIOTHERAPEUTICS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(in thousands, except per share amounts)
(Unaudited)

	For the three months ended	
	March 31,	
	2023	2022
Revenues:		
Research and other	\$ 880	\$ 403
Total revenues	<u>880</u>	<u>403</u>
Operating costs and expenses:		
Research and development	6,861	4,820
General and administrative	6,983	7,869
Total operating costs and expenses	<u>13,844</u>	<u>12,689</u>
Loss from operations	(12,964)	(12,286)
Other income (expense):		
Change in fair value of derivative liabilities	3,880	540
Change in fair value of share liabilities	(52)	—
(Loss) gain from extinguishment of debt	(1,408)	410
Interest expense	(1,027)	(1,903)
Foreign currency transaction gain (loss)	919	(975)
Total other income (loss)	<u>2,312</u>	<u>(1,928)</u>
Net loss	(10,652)	(14,214)
Deemed dividend related to warrant modifications	(395)	—
Net loss attributable to common stockholders	<u>\$ (11,047)</u>	<u>\$ (14,214)</u>
Other comprehensive income (loss)		
Foreign currency translation adjustment	(750)	808
Total comprehensive loss	<u>\$ (11,797)</u>	<u>\$ (13,406)</u>
Net loss per share applicable to common stockholders		
Basic	<u>\$ (0.01)</u>	<u>\$ (0.01)</u>
Diluted	<u>\$ (0.01)</u>	<u>\$ (0.01)</u>
Weighted average shares used in computing basic loss per share	<u>1,074,902</u>	<u>959,251</u>
Weighted average shares used in computing diluted loss per share	<u>1,074,902</u>	<u>959,251</u>

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

NORTHWEST BIOTHERAPEUTICS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF STOCKHOLDERS' DEFICIT
(in thousands)
(Unaudited)

For the Three Months Ended March 31, 2023

	Mezzanine equity		Common Stock		Additional Paid-in Capital	Subscription Receivable	Accumulated Deficit	Accumulated Other Comprehensive Income	Total Stockholders' Deficit
	Series C Convertible Preferred Stock		Shares	Par value					
	Shares	Amount	Shares	Par value					
Balances at January 1, 2023	1,415	\$ 23,060	1,068,394	\$ 1,068	\$1,164,885	\$ (79)	\$ (1,297,122)	\$ 3,145	\$ (128,103)
Issuance of Series C convertible preferred stock for cash	148	2,385	—	—	—	—	—	—	—
Issuance of Series C convertible preferred stock in lieu of debt redemption	43	806	—	—	—	—	—	—	—
Series C convertible preferred stock conversion	(198)	(2,617)	4,946	5	2,612	—	—	—	2,617
Warrants exercised for cash	—	—	767	1	247	—	—	—	248
Cashless stock options exercise	—	—	710	1	(1)	—	—	—	—
Reclassification of warrant liabilities to stockholders' deficit	—	—	—	—	76,258	—	—	—	76,258
Issuance of common stock for conversion of debt and accrued interest	—	—	8,267	8	5,608	—	—	—	5,616
Stock-based compensation	8	118	—	—	918	—	—	—	918
Reclass earned but unissued milestone shares from equity to liability	—	—	—	—	(2,130)	—	—	—	(2,130)
Net loss	—	—	—	—	—	—	(10,652)	—	(10,652)
Warrants modification	—	—	—	—	395	—	—	—	395
Deemed dividend related to warrants modification	—	—	—	—	(395)	—	—	—	(395)
Cumulative translation adjustment	—	—	—	—	—	—	—	(750)	(750)
Balances at March 31, 2023	1,416	\$ 23,752	1,083,084	\$ 1,083	\$1,248,397	\$ (79)	\$ (1,307,774)	\$ 2,395	\$ (55,978)

For the three months ended March 31, 2022

	Common Stock		Additional Paid-in Capital	Subscription Receivable	Accumulated Deficit	Accumulated Other Comprehensive Income	Total Stockholders' Deficit
	Shares	Par value					
	Shares	Par value					
Balances at January 1, 2022	948,445	\$ 948	\$1,066,873	\$ (79)	\$ (1,192,090)	\$ 357	\$ (123,991)
Issuance of common stock for cash	4,553	5	3,359	—	—	—	3,364
Warrants exercised for cash	15,256	15	4,170	—	—	—	4,185
Reclassification of warrant liabilities related to warrants exercised for cash	—	—	7,715	—	—	—	7,715
Cashless warrants exercise	26	—	—	—	—	—	—
Reclassification of warrant liabilities related to cashless warrants exercise	—	—	4	—	—	—	4
Issuance of common stock conversion of debt and accrued interest	1,412	2	985	—	—	—	987
Stock-based compensation	5	—	617	—	—	—	617
Net loss	—	—	—	—	(14,214)	—	(14,214)
Cumulative translation adjustment	—	—	—	—	—	808	808
Balances at March 31, 2022	969,697	\$ 970	\$1,083,723	\$ (79)	\$ (1,206,304)	\$ 1,165	\$ (120,525)

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

NORTHWEST BIOTHERAPEUTICS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(in thousands)
(Unaudited)

	For the three months ended March 31,	
	2023	2022
Cash Flows from Operating Activities:		
Net loss	\$ (10,652)	\$ (14,214)
Reconciliation of net loss to net cash used in operating activities:		
Depreciation and amortization	335	100
Amortization of debt discount	552	809
Change in fair value of derivatives	(3,880)	(540)
Change in fair value of share liability	52	—
Loss (gain) from extinguishment of debt	1,408	(410)
Amortization of operating lease right-of-use asset	67	60
Stock-based compensation for services	933	617
Subtotal of non-cash charges	(533)	636
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(709)	(199)
Other non-current assets	(16)	679
Accounts payable and accrued expenses	975	795
Related party accounts payable and accrued expenses	(341)	(694)
Lease liabilities	37	30
Net cash used in operating activities	(11,239)	(12,967)
Cash Flows from Investing Activities:		
Purchase of equipment and construction in progress	(1,333)	(58)
Net cash used in investing activities	(1,333)	(58)
Cash Flows from Financing Activities:		
Proceeds from issuance of Series C convertible preferred stock	2,385	—
Proceeds from issuance of common stock	—	3,140
Proceeds from exercise of warrants	248	4,185
Proceeds from investor advance	50	—
Proceeds from issuance of notes payable, net	10,000	600
Repayment of notes payable	(101)	(4,005)
Net cash provided by financing activities	12,582	3,920
Effect of exchange rate changes on cash and cash equivalents	(784)	899
Net decrease in cash and cash equivalents	(774)	(8,206)
Cash and cash equivalents, beginning of the period	6,965	15,169
Cash and cash equivalents, end of the period	\$ 6,191	\$ 6,963
Supplemental disclosure of cash flow information		
Interest payments on notes payable	\$ (30)	\$ (702)

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

NORTHWEST BIOTHERAPEUTICS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(in thousands)
(Unaudited)

	For the three months ended	
	March 31,	
	2023	2022
Supplemental schedule of non-cash investing and financing activities:		
Cashless warrants and stock options exercise	\$ 1	\$ —
Reclassification of warrant liabilities related to warrants exercised for cash	\$ —	\$ 7,715
Reclassification of warrant liabilities to stockholders' deficit	\$ 76,258	\$ —
Reclassification of warrant liabilities related to cashless warrants exercise	\$ —	\$ 4
Reclass earned but unissued milestone shares from equity to liability	\$ 2,130	\$ —
Issuance of common stock for conversion of debt and accrued interest	\$ 5,616	\$ 987
Issuance of Series C convertible preferred stock in lieu of debt redemption	\$ 806	\$ —
Series C convertible preferred stock conversion	\$ 2,617	\$ —
Capital expenditures included in accounts payable	\$ 1,013	\$ 86
Capital expenditures included in accounts payable and accrued expenses to related parties and affiliates	\$ —	\$ 11
Reclassification between shares payable and equity	\$ —	\$ 250
Deemed dividend related to warrant modification	\$ 395	\$ —

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

**NORTHWEST BIOTHERAPEUTICS, INC.
NOTES TO CONDENSED CONSOLIDATED STATEMENTS**

1. Organization and Description of Business

Northwest Biotherapeutics, Inc. and its wholly owned subsidiaries Flaskworks, Aracaris Ltd, Aracaris Capital, Ltd, Northwest Biotherapeutics B.V., and NW Bio GmbH (collectively, the “Company”, “we”, “us” and “our”) were organized to discover and develop innovative immunotherapies for cancer. The Company has developed DCVax® platform technologies for both operable and inoperable solid tumor cancers. The Company has wholly owned subsidiaries in Boston, the U.K., the Netherlands and Germany. On August 28, 2020, the Company acquired Flaskworks, LLC (“Flaskworks”), a company that has developed a system designed to close and automate the manufacturing of cell therapy products such as DCVax®.

The Company relies upon contract manufacturers for production of its DCVax products, research and development services, distribution and logistics, and related services, in compliance with the Company’s specifications and the applicable regulatory requirements.

The Company has completed a Phase 3 clinical trial of its DCVax®-L product for glioblastoma brain cancer, has publicly reported the results in a peer reviewed publication in a medical journal as well as at a medical conference, and is working on prerequisites and preparations for filing an application for regulatory approval of the product.

2. Financial Condition, Going Concern and Management Plans

The Company has incurred annual net operating losses since its inception. The Company had a net loss of \$10.7 million for the three months ended March 31, 2023. The Company used approximately \$11.2 million of cash in its operating activities during the three months ended March 31, 2023.

The Company does not expect to generate material revenue in the near future from the sale of products and is subject to all of the risks and uncertainties that are typically faced by biotechnology companies that devote substantially all of their efforts to research and development (“R&D”) and clinical trials and do not yet have commercial products. The Company expects to continue incurring annual losses for the foreseeable future. The Company’s existing liquidity is not sufficient to fund its operations, anticipated capital expenditures, working capital and other financing requirements until the Company reaches significant revenues. Until that time, the Company will need to obtain additional equity and/or debt financing, especially if the Company experiences downturns in its business that are more severe or longer than anticipated, or if the Company experiences significant increases in expense levels resulting from being a publicly-traded company or from expansion of operations. If the Company attempts to obtain additional equity or debt financing, the Company cannot assume that such financing will be available to the Company on favorable terms, or at all.

Because of recurring operating losses and operating cash flow deficits, there is substantial doubt about the Company’s ability to continue as a going concern for at least one year from the date of this filing. The consolidated financial statements have been prepared assuming that the Company will continue as a going concern, however, they do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets, or the amounts and classification of liabilities that may result from the outcome of this uncertainty.

3. Summary of Significant Accounting Policies

Basis of Presentation

The accompanying unaudited condensed consolidated interim financial statements include the accounts of the Company and its subsidiaries. All intercompany balances and transactions have been eliminated. Certain immaterial reclassifications have been made to prior period amounts to conform to the current period presentation.

NORTHWEST BIOTHERAPEUTICS, INC.
NOTES TO CONDENSED CONSOLIDATED STATEMENTS

The accompanying unaudited condensed consolidated financial statements of the Company have been prepared in accordance with the accounting principles generally accepted in the United States of America (“U.S. GAAP”) for interim financial information and pursuant to the instructions to Form 10-Q and Article 8 of Regulation S-X of the Securities and Exchange Commission (“SEC”) and on the same basis as the Company uses to prepare its annual audited consolidated financial statements. The condensed consolidated balance sheet as of March 31, 2023, condensed consolidated statements of operations and comprehensive loss for the three months ended March 31, 2023 and 2022, condensed consolidated statement of stockholders’ deficit for the three months ended March 31, 2023 and 2022, and the condensed consolidated statements of cash flows for the three months ended March 31, 2023 and 2022 are unaudited, but include all adjustments, consisting only of normal recurring adjustments, which the Company considers necessary for a fair presentation of the financial position, operating results and cash flows for the periods presented. The results for the three months ended March 31, 2023 are not necessarily indicative of results to be expected for the year ending December 31, 2023 or for any future interim period. The condensed consolidated balance sheet at December 31, 2022 has been derived from audited financial statements; however, it does not include all of the information and notes required by U.S. GAAP for complete financial statements. The accompanying unaudited condensed consolidated financial statements should be read in conjunction with the consolidated financial statements for the year ended December 31, 2022 and notes thereto included in the Company’s annual report on Form 10-K (the “2022 Annual Report”), which was filed with the SEC on February 28, 2023.

Use of Estimates

In preparing condensed consolidated financial statements in conformity with U.S. GAAP, management is required to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements, as well as the reported amounts of expenses during the reporting period. Due to inherent uncertainty involved in making estimates, actual results reported in future periods may be affected by changes in these estimates.

On an ongoing basis, the Company evaluates its estimates and judgments, including valuing equity securities in share-based payment arrangements, estimating the fair value of financial instruments recorded as derivative liabilities, useful lives of depreciable assets, and whether impairment charges may apply. The Company bases its estimates on historical experience and on various other assumptions that it believes to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities and the reported amounts of revenues and expenses that are not readily apparent from other sources. Actual results could differ from those estimates, particularly given the significant social and economic disruptions and uncertainties associated with the ongoing coronavirus pandemic (“COVID-19”) and the COVID-19 control responses.

Significant Accounting Policies

There have been no material changes in the Company’s significant accounting policies from those previously disclosed in the 2022 Annual Report other than those discussed below.

Sequencing

The Company adopted a sequencing policy under ASC 815-40-35 to determine if reclassification of contracts from equity to liabilities is necessary pursuant to ASC 815 due to the Company’s inability to demonstrate it has sufficient authorized shares. Certain contracts were classified as liabilities as the result of the instruments containing a potentially indeterminable number of shares and, most recently, due to the Company entering into agreements providing for the potential issuance of more shares than authorized. While temporary suspensions are in place to keep the potential exercises beneath the number authorized, certain instruments are classified as liabilities, after allocating available authorized shares on the basis of the earliest grant date of potentially dilutive instruments. Pursuant to ASC 815, issuance of stock-based awards to the Company’s employees, nonemployees or directors are not subject to the sequencing policy.

On January 9, 2023, the Company filed a Certificate of Amendment of its Seventh Amended and Restated Certificate of Incorporation (the “Certificate of Amendment”) with the Secretary of the State of Delaware, which effected an increase in the Company’s authorized shares of common stock, from 1.2 billion to 1.7 billion, par value \$0.001 per share. As a result of this increase in authorized shares, the liability-classified warrants were reclassified to equity. Approximately 141 million warrants, with a value of approximately \$76.3 million, to purchase shares of the Company’s common stock were reclassified from liabilities to equity on January 9, 2023. The remaining balance of \$1.4 million in warrant liability as of March 31, 2023 was related to certain conditional rights to independently purchase shares from the Company in a future raise of capital (the “Piggy-back Rights”).

NORTHWEST BIOTHERAPEUTICS, INC.
NOTES TO CONDENSED CONSOLIDATED STATEMENTS

Modification of Equity Classified Warrants

A change in the terms or conditions of a warrant is accounted for as a modification. For a warrant modification accounted for under ASC 815, the effect of a modification shall be measured as the difference between the fair value of the modified warrant and the fair value of the original warrant immediately before its terms are modified, with each measured on the modification date. The accounting for incremental fair value of the modified warrants over the original warrants is based on the specific facts and circumstances related to the modification. When a modification is directly attributable to an equity offering, the incremental change in fair value of the warrants is accounted for as an equity issuance cost. When a modification is directly attributable to a debt offering, the incremental change in fair value of the warrants is accounted for as a debt discount or debt issuance cost. For all other modifications, the incremental change in fair value is recognized as a deemed dividend.

Recently Issued Accounting Standards Not Yet Adopted

Fair Value Measurement of Equity Securities Subject to Contractual Sale Restrictions

In June 2022, the FASB issued ASU 2022-03, ASC Subtopic 820 “Fair Value Measurement of Equity Securities Subject to Contractual Sale Restrictions”. The FASB is issuing this Update (1) to clarify the guidance in Topic 820, Fair Value Measurement, when measuring the fair value of an equity security subject to contractual restrictions that prohibit the sale of an equity security, (2) to amend a related illustrative example, and (3) to introduce new disclosure requirements for equity securities subject to contractual sale restrictions that are measured at fair value in accordance with Topic 820.

For public business entities, the amendments in this Update are effective for fiscal years beginning after December 15, 2023, and interim periods within those fiscal years. Early adoption is permitted for both interim and annual financial statements that have not yet been issued or made available for issuance.

The Company is still evaluating the impact of this pronouncement on the consolidated financial statements.

4. Fair Value Measurements

In accordance with ASC 820 (Fair Value Measurements and Disclosures), the Company uses various inputs to measure the fair value of liabilities related to certain outstanding warrants, certain embedded conversion features associated with convertible debt and the contingent payable to Cognate BioServices on a recurring basis to determine the fair value of these liabilities. ASC 820 establishes a hierarchy categorizing inputs into three levels used to measure and disclose fair value. The hierarchy gives the highest priority to quoted prices available in active markets and the lowest priority to unobservable inputs. An explanation of each level in the hierarchy is described below:

Level 1 - Unadjusted quoted prices in active markets for identical instruments that are accessible by the Company on the measurement date.

Level 2 - Quoted prices in markets that are not active or inputs which are either directly or indirectly observable.

Level 3 - Unobservable inputs for the instrument requiring the development of assumptions by the Company.

NORTHWEST BIOTHERAPEUTICS, INC.
NOTES TO CONDENSED CONSOLIDATED STATEMENTS

The following table classifies the Company’s liabilities measured at fair value on a recurring basis into the fair value hierarchy as of March 31, 2023 and December 31, 2022 (in thousands):

	Fair value measured at March 31, 2023			
	Fair value at March 31, 2023	Quoted prices in active markets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)
Warrant liability	\$ 1,445	\$ —	\$ —	\$ 1,445
Contingent payable derivative liability	8,451	—	—	8,451
Share liability	585	—	—	585
Total fair value	<u>\$ 10,481</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 10,481</u>

	Fair value measured at December 31, 2022			
	Fair value at December 31, 2022	Quoted prices in active markets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)
Warrant liability	\$ 80,559	\$ —	\$ —	\$ 80,559
Embedded redemption option	807	—	—	807
Contingent payable derivative liability	8,668	—	—	8,668
Share liability	678	—	—	678
Total fair value	<u>\$ 90,712</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 90,712</u>

There were no transfers between Level 1, 2 or 3 during the three-month period ended March 31, 2023.

The following table presents changes in Level 3 liabilities measured at fair value for the three-month period ended March 31, 2023. Both observable and unobservable inputs were used to determine the fair value of positions that the Company has classified within the Level 3 category. Unrealized gains and losses associated with liabilities within the Level 3 category include changes in fair value that were attributable to both observable (e.g., changes in market interest rates) and unobservable (e.g., changes in unobservable long- dated volatilities) inputs (in thousands).

	Warrant Liability	Embedded Redemption Option	Contingent Payable Derivative Liability	Share Liability	Total
Balance - January 1, 2023	\$ 80,559	\$ 807	\$ 8,668	\$ 678	\$ 90,712
Additional share liability	—	—	—	538	538
Redemption of share liability	—	—	—	(683)	(683)
Reclassification of warrant liabilities	(76,258)	—	—	—	(76,258)
Change in fair value	(2,856)	(807)	(217)	52	(3,828)
Balance - March 31, 2023	\$ 1,445	\$ —	\$ 8,451	\$ 585	\$ 10,481

(1) The remaining balance of \$1.4 million in warrant liability as of March 31, 2023 was related to certain conditional rights to independently purchase shares from the Company in a future raise of capital (the “Piggy-back Rights”). The Company accounted for the Piggy-back Rights as a freestanding financial instrument, which was classified as a liability at fair value on the Condensed Consolidated Balance Sheet.

On January 9, 2023, the Company reclassified the fair value of the warrant liability of \$76.3 million into the additional paid-in capital. The change in fair value of the common stock warrant liability of \$2.3 million between December 31, 2022 and January 9, 2023 is reflected in “Change in fair value of derivative liabilities” in the accompanying condensed consolidated statements of comprehensive loss for the three months ended March 31, 2023.

NORTHWEST BIOTHERAPEUTICS, INC.
NOTES TO CONDENSED CONSOLIDATED STATEMENTS

A summary of the weighted average (in aggregate) significant unobservable inputs (Level 3 inputs) used in measuring the Company's warrant liabilities and embedded conversion feature that are categorized within Level 3 of the fair value hierarchy as of January 9, 2023 (the reclassification date), March 31, 2023 and December 31, 2022 is as follows:

	As of January 9, 2023		As of March 31, 2023	
	Warrant Liability	0.31	Share Liability	Contingent Payable Derivative Liability
Strike price	\$	0.31	\$ 0.63 *	\$ 0.63 *
Contractual term (years)		1.5	0.04	1.3
Volatility (annual)		87 %	114 %	73 %
Risk-free rate		4.3 %	2.2 %	4.9 %
Dividend yield (per share)		0 %	0 %	0 %

	As of December 31, 2022		
	Warrant Liability	Share Liability	Contingent Payable Derivative Liability
Strike price	\$ 0.31	\$ 0.78 *	\$ 0.78 *
Contractual term (years)	1.5	0.1	0.6
Volatility (annual)	86 %	76 %	77 %
Risk-free rate	4.3 %	2.0 %	4.8 %
Dividend yield (per share)	0 %	0 %	0 %

* The strike price assumes the current stock price as of March 31, 2023 and December 31, 2022.

The key unobservable inputs for Piggy-back rights that was included in the warrant liability as of March 31, 2023 and December 31, 2022 was the assumption of the estimated remaining life which was based on the estimate of next qualified financing.

5. Stock-based Compensation

The following table summarizes total stock-based compensation expense for the three months ended March 31, 2023 and 2022 (in thousands).

	For the three months ended March 31,	
	2023	2022
Research and development	\$ 296	\$ 510
Research and development - related party	—	—
Milestones achieved ⁽¹⁾	520	—
Future milestones ⁽²⁾	100	—
General and administrative	17	107
Total stock-based compensation expense	\$ 933	\$ 617

The related party amounts were for milestone incentives that either were earned or are deemed probable to be achieved in the future and become issuable at that time (as detailed below in Restricted Stock Awards).

- (1) During the quarter ended March 31, 2023, the Company recognized the remaining \$0.5 million stock-based compensation related to the achieved milestone (obtaining a commercial manufacturing license from the MHRA) and accrued for 3.0 million shares that will become issuable for this milestone. The Company has previously recognized \$1.6 million stock-based compensation as of December 31, 2022.
- (2) This is related to a one-time milestone (drafting key portions of the application for product approval) that is anticipated to be achieved and earned in the future. The Company recognized and expensed (but did not issue shares for) the pro-rata portion of the remaining potential milestone stock awards during the quarter ended March 31, 2023, of \$0.1 million.

NORTHWEST BIOTHERAPEUTICS, INC.
NOTES TO CONDENSED CONSOLIDATED STATEMENTS

The total unrecognized compensation cost was approximately \$0.8 million as of March 31, 2023 and will be recognized over the next 1.3 years.

Stock Options

The following table summarizes stock option activity for the Company's option plans during the three months ended March 31, 2023 (amount in thousands, except per share number):

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (in years)	Total Intrinsic Value
Outstanding as of January 1, 2023	301,263	\$ 0.34	7.0	\$ 135,225
Cashless exercised	(1,325)	0.33	—	—
Outstanding as of March 31, 2023	299,938	\$ 0.34	6.8	\$ 90,543
Options vested ⁽¹⁾	281,009	\$ 0.33	6.8	\$ 85,618

(1) An aggregate 153 million stock options held by Ms. Linda Powers, the Company's Chief Executive Officer, and Mr. Leslie Goldman, the Company's Senior Vice President, are subject to an agreement (the "Blocker Letter Agreement") under which they cannot exercise any options or warrants except upon at least 61 days' prior notice.

Restricted Stock Awards

During April 2022, the Company's Board approved, and the Company entered into a Statement of Work #6 (the "SOW 6") with Advent BioServices, a related party of the Company, for five workstreams that are prerequisites for an application for regulatory approval of DCVax-L, for three required licenses for the Sawston facility, and for drafting of key portions of the application for approval. The SOW provides for baseline costs and for milestone incentives for successful completion of each of the workstreams, for the completion and submission of each application for product approval, and for obtaining regulatory approval of each of the three Sawston licenses. The milestone incentives will be a combination of cash and stock and are not paid until they are achieved. On September 26, 2022, the Company amended the SOW6 (the "Amended SOW6") to (1) extend the service period through September 30, 2023, and (2) clarify the assessment and application of the milestones, and (3) add a sixth workstream. (The potential cost for all unearned stock awards for milestones not yet achieved was re-measured on the modification date and will be further re-measured until the date the milestone award is achieved and the stock awards are earned.) If all of the 10 one-time milestones are achieved (i.e., for all six workstreams that are prerequisites for an application for product approval, for obtaining all three licenses required for the Sawston facility, and for the completion of key portions of the application for product approval), the aggregate stock-based compensation under the Amended SOW 6 will be 13.5 million shares (including the shares already earned and issued for the milestones already achieved) for an aggregate fair value of \$10.1 million.

As of December 31, 2022, seven milestones were completed, including five of the workstreams, and the regulatory approvals of two licenses required for the Sawston facility. An eighth milestone was partly completed and the stock component of that milestone was earned, but the cash portion of that eighth milestone was not yet earned.

During the three months ended March 31, 2023, the eighth milestone workstream for Mechanism of Action and the milestone for obtaining the commercial manufacturing license from the MHRA were completed. For this license milestone, the Company recognized the remaining \$0.5 million in expense in the condensed consolidated statements of operations and comprehensive loss and accrued for 3.0 million shares that will become issuable.

For the remaining one-time milestone that is anticipated to be achieved and earned in the future, the Company recognized and expensed (but did not issue) the pro-rata portion of the remaining potential milestone stock awards during the three months ended March 31, 2023, of \$0.1 million.

NORTHWEST BIOTHERAPEUTICS, INC.
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Other Service Agreement

On March 16, 2023, the Company issued 8,000 shares of Series C convertible preferred stock to an unrelated vendor who provided professional services for the Company. The fair value of the Series C convertible preferred stock on the issuance date was approximately \$0.1 million, which will be expensed over a four-month service period. During the three months ended March 31, 2023, the Company recognized approximately \$15,000 as part of general and administrative expenses.

6. Property, Plant and Equipment

Property, plant and equipment consist of the following at March 31, 2023 and December 31, 2022 (in thousands):

	March 31, 2023	December 31, 2022	Estimated Useful Life
Leasehold improvements	\$ 13,213	\$ 13,070	Lesser of lease term or estimated useful life
Office furniture and equipment	445	300	3-5 years
Computer and manufacturing equipment and software	2,454	2,238	3-5 years
Land in the United Kingdom	84	82	NA
	<u>16,196</u>	<u>15,690</u>	NA
Less: accumulated depreciation	(2,626)	(2,272)	
Total property, plant and equipment, net	<u>\$ 13,570</u>	<u>\$ 13,418</u>	
Construction in progress	<u>\$ 3,321</u>	<u>\$ 2,028</u>	

Depreciation expense was approximately \$0.3 million and \$0.1 million for the three months ended March 31, 2023, and 2022, respectively.

NORTHWEST BIOTHERAPEUTICS, INC.
NOTES TO CONDENSED CONSOLIDATED STATEMENTS

7. Notes Payable

The following two tables summarize outstanding debt as of March 31, 2023 and December 31, 2022, respectively (amount in thousands):

	Maturity Date	Stated Interest Rate	Conversion Price	Face Value	Remaining Debt Discount	Carrying Value
Short term convertible notes payable						
6% unsecured	Due	6 %	\$ 3.09	\$ 135	\$ —	\$ 135
				135	—	135
Short term notes payable						
8% unsecured	Various	8 %	N/A	10,610	(859)	9,751
9% unsecured	Various	9 %	N/A	157	—	157
12% unsecured	On Demand	12 %	N/A	563	—	563
				11,330	(859)	10,471
Long term notes payable						
8% unsecured	7/26/2024	8 %	N/A	16,510	(1,326)	15,184
6% secured	3/25/2025	6 %	N/A	835	—	835
				17,345	(1,326)	16,019
Ending balance as of March 31, 2023				\$ 28,810	\$ (2,185)	\$26,625

	Maturity Date	Stated Interest Rate	Conversion Price	Face Value	Remaining Debt Discount	Embedded Redemption Option	Carrying Value
Short term convertible notes payable							
6% unsecured	Due	6 %	\$ 3.09	\$ 135	\$ —	\$ —	\$ 135
				135	—	—	135
Short term notes payable							
8% unsecured	Various	8 %	N/A	14,540	(1,300)	807	14,047
9% unsecured	Various	9 %	N/A	793	—	—	793
12% unsecured	On Demand	12 %	N/A	563	—	—	563
				15,896	(1,300)	807	15,403
Long term notes payable							
8% unsecured	7/26/2024	8 %	N/A	5,505	(432)	—	5,073
6% secured	3/25/2025	6 %	N/A	918	—	—	918
				6,423	(432)	—	5,991
Ending balance as of December 31, 2022				\$ 22,454	\$ (1,732)	\$ 807	\$21,529

On March 2, 2023, the Company entered into a Commercial Loan Agreement (the “Commercial Loan”) with a commercial lender for an aggregate principal amount of \$11.0 million. The Commercial Loan bears interest at 8% per annum with a 22-month term. There are no principal repayments during the first eight months of the term. The Commercial Loan is amortized in 14 installments starting on November 2, 2023. The Commercial Loan carries an original issue discount of \$1.0 million.

During the three months ended March 31, 2023, the Company issued approximately 8.3 million shares of common stock with a fair value of \$5.6 million to certain lenders in lieu of cash payments of \$4.1 million of debt, including \$0.2 million of accrued interest. In addition, pursuant to exchange agreements executed with various holders, the Company is required to potentially issue additional common stock (the “Share liability”) if the stock price is less than the price defined in the exchange agreement as of the true-up date. During the three months ended March 31, 2023, the Company extinguished Share liabilities of \$0.7 million and recognized an additional \$0.5 million in Share liabilities. The Company recognized an approximately \$1.3 million debt extinguishment loss during the three months ended March 31, 2023 from the debt redemption.

During the three months ended March 31, 2023, the Company recognized \$0.8 million change in fair value of embedded redemption option as this embedded feature had de minimis value based on the remaining life of the note and the next qualified financing.

NORTHWEST BIOTHERAPEUTICS, INC.
NOTES TO CONDENSED CONSOLIDATED STATEMENTS

During the three months ended March 31, 2023, the Company issued approximately 43,000 shares of Series C preferred stock with a fair value of \$0.8 million to certain lenders in lieu of cash payments of \$0.7 million in debt, including \$0.1 million of accrued interest. The Company recognized an approximately \$0.1 million debt extinguishment loss.

For the three months ended March 31, 2023 and 2022, interest expense related to notes payable totaled approximately \$0.5 million and \$1.1 million including amortization of debt discounts totaling \$0.6 million and \$0.8 million, respectively.

8. Net Loss per Share Applicable to Common Stockholders

Basic loss per common share is computed by dividing net loss by the weighted average number of common shares outstanding during the reporting period. Diluted loss per common share would be computed similar to basic loss per common share except that it reflects the potential dilution that could occur if dilutive securities or other obligations to issue common stock were exercised or converted into common stock. Because of the net loss from operations for each period, inclusion of such securities in the computation of loss per share would be anti-dilutive and thus they are excluded. Potentially dilutive weighted average common shares include common stock potentially issuable under the Company's convertible notes and preferred stock, warrants and vested and unvested stock options.

The following securities were not included in the diluted net loss per share calculation because their effect was anti-dilutive as of the periods presented (in thousands):

	For the three months ended	
	March 31,	
	2023	2022
Series C convertible preferred stock	35,412	—
Common stock options	299,938	304,867
Common stock warrants	140,244	208,705
Convertible notes and accrued interest	79	76
Potentially dilutive securities	475,673	513,648

9. Related Party Transactions

The Company had three operational programs with Advent: (a) an ongoing manufacturing program at the GMP facility in London, (b) an ongoing development and manufacturing program at the Sawston GMP facility, and (c) a one-time program for specialized work, organized into 10 sets of one-time milestones, for the following:

- Qualifying for and obtaining 3 required licenses for the Sawston facility: a license from the Human Tissue Authority to collect and process human cells and tissues, a license from the MHRA for manufacturing for clinical trials and compassionate use cases, and a license from the MHRA for commercial manufacturing.
- 6 workstreams relating to product matters required for an application for regulatory approval of DCVax-L, including Comparability, Stability, Potency, Product Profile, Mechanism of Action and Fill/Finish.
- Drafting of key portions of the application for product approval itself.

Each of the three operational programs is covered by a separate contract. The ongoing manufacturing in the London facility is covered by a Manufacturing Services Agreement ("MSA") entered into on May 14, 2018. The development and manufacturing program at the Sawston facility is covered by an Ancillary Services Agreement entered into on November 18, 2019. The specialized work associated with the 10 one-time milestones is covered by an SOW 6 entered into under the Ancillary Services Agreement as of April 1, 2022 and amended on September 26, 2022.

The Ancillary Services Agreement establishes a structure under which the Company and Advent negotiate and agree upon the scope and terms for Statements of Work ("SOWs") for facility development activities and compassionate use program activities. After an SOW is agreed and approved by the Company, Advent will proceed with, or continue, the applicable services and will invoice the Company pursuant to the SOW. Since both the facility development and the compassionate use program involve pioneering and

NORTHWEST BIOTHERAPEUTICS, INC.
NOTES TO CONDENSED CONSOLIDATED STATEMENTS

uncertainties in most aspects, the invoicing under the Ancillary Services Agreement is on the basis of costs incurred plus fifteen percent. The SOWs may involve ongoing activities or specialized one-time projects and related one-time milestone payments. The current term of the Ancillary Services Agreement ends in July 2023.

SOW 6 provides for ongoing baseline costs for manufacturing at the Sawston facility and one-time milestone incentives for (a) regulatory approval of each of the 3 licenses required for the Sawston facility, (b) successful completion of each of the 6 workstreams and (c) completion of drafting key portions of an application for product approval. The milestone incentives are a combination of cash and stock, and are not paid until the milestone is achieved and earned.

During the three months ended March 31, 2023, the Company paid an aggregate of \$1.0 million in cash, which was related to two milestones that were completed and fully expensed but unpaid as of December 31, 2022, and accrued for 3.0 million shares that will become issuable for completion of the milestone (obtaining a commercial manufacturing license from the MHRA). The fair value of the 3.0 million shares was approximate \$2.1 million, of which \$0.5 million was recognized during the three months ended March 31, 2023 and \$1.6 million had already been recognized in 2022. During the three months ended March 31, 2023, the Company also expensed (but did not pay) an aggregate of \$0.5 million related to completed cash milestone payments; the Company also expensed (but did not pay) an aggregate of \$0.2 million related to future cash milestone payments that the Company anticipates will be achieved and earned, and \$0.1 million related to fair value of future shares milestone payments that the Company anticipates will be achieved and earned over the course of the contract period.

The following table summarizes total research and development costs from Advent for the three months ended March 31, 2023 and 2022, respectively (in thousands).

	For the three months ended	
	March 31,	
	2023	2022
Advent BioServices		
Manufacturing cost in London	\$ 1,643	\$ 1,404
Manufacturing cost at Sawston facility	1,712	1,425
SOW 6 one-time milestones - Shares		
Expensed but unpaid (milestone complete) ⁽¹⁾	520	—
Expensed but unpaid, not yet due (milestone not yet complete) ⁽²⁾	100	—
SOW 6 one-time milestones - Cash		
Expensed and due, but unpaid (milestone complete) ⁽³⁾	550	—
Expensed but unpaid, not yet due (milestone not yet complete) ⁽²⁾	150	—
Total	\$ 4,675	\$ 2,829

(1) This covers the one-time milestone for obtaining a commercial manufacturing license for the Sawston facility. The milestone was achieved and the shares will become issuable following final Board approval. The shares were not issued as of March 31, 2023.

(2) This covers the one-time milestone for drafting key portions of the application for product approval.

(3) This covers two one-time milestones: Mechanism of Action and obtaining a commercial manufacturing license from the MHRA.

Advent BioServices Sublease Agreement

On December 31, 2021, the Company entered into a Sub-lease Agreement (the "Agreement") with Advent. The Agreement permits use by Advent of a portion of the space in the Sawston facility, which is leased by the Company under a separate head lease with a different counterparty (Huawei) that commenced on December 14, 2018. The Company subleased approximately 14,459 square feet of the 88,000 square foot building interior space, plus corresponding exterior support space and parking. The lease payments amount under the Agreement are two times the £5.75 rate per square foot (approximately \$7.11 per square foot based on exchange rate as of March 31, 2023) payable under the head lease, but subject to a cap of \$10 per square foot. Accordingly, the monthly lease payments under the Sublease are based on \$145,000 annually for 2022. The total lease payments paid by the Company to Huawei for the facility, exterior spaces and parking under the head lease are 500,000 pounds (approximately \$618,000) per year. The term of the Agreement shall end on the same date as the head lease term ends.

NORTHWEST BIOTHERAPEUTICS, INC.
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During the three months ended March 31, 2023, the Company recognized sub-lease income of \$36,000.

Related Party Accounts Payable

As of March 31, 2023, there was approximately \$0.4 million of unpaid board compensation to one of our Directors that was included in the accounts payable to related party on the condensed consolidated balance sheets.

As of March 31, 2023, there were outstanding unpaid accounts payable and accrued expenses owed to Advent as summarized in the following table (in thousands). *These unpaid amounts are part of the Related Party expenses reported in the above section.*

	March 31, 2023	December 31, 2022
Advent BioServices - amount invoiced but unpaid	\$ 1,765	\$ 1,844
Advent BioServices - amount accrued but unpaid ⁽¹⁾	6,566	4,736
Total payable and accrued, but unpaid to Advent BioServices	\$ 8,331	\$ 6,580

(1) This includes \$2.1 million which is not payable in cash but represents the value of 3 million shares that will become issuable to Advent, following final Board approval, for achievement of the one-time milestone for obtaining a commercial manufacturing license for the Sawston facility. Such shares were not issued as of March 31, 2023, and the total value, previously recognized as stock compensation expense, was reclassified from Additional Paid-in-Capital to Accounts payable and accrued expenses to related parties and affiliates.

10. Preferred Stock

Series C Convertible Preferred Stock

During the three months ended March 31, 2023, the Company entered into various Subscription Agreements (the "Series C Subscription Agreements") with certain investors (the "Series C Investors"). Pursuant to the Series C Subscription Agreements, the Company issued the Series C Investors an aggregate of 0.1 million shares of the Company's Series C convertible preferred stock, par value \$0.001 per share (the "Series C Shares"), at a weighted purchase price of \$16.11 per share for proceeds of approximately \$2.4 million.

During the three months ended March 31, 2023, the Company issued approximately 43,000 Series C Shares with a fair value of \$0.8 million to certain lenders in lieu of cash payments of \$0.7 million in debt, including \$0.1 million accrued interest. The Company recognized an approximately \$0.1 million debt extinguishment loss.

During the three months ended March 31, 2023, approximately 0.2 million Series C Shares with a book value of \$2.6 million were converted into 4.9 million common shares at a ratio of 1:25.

The Company determined that the Series C Shares contain contingent redemption provisions allowing redemption by the holder upon certain defined events ("deemed liquidation events"). As the event that may trigger the redemption of the Series C Shares is not solely within the Company's control, the Series C Shares are classified as mezzanine equity (temporary equity) in the Company's condensed consolidated balance sheets.

11. Stockholders' Deficit

Common Stock

On January 9, 2023, the Company filed a Certificate of Amendment of its Seventh Amended and Restated Certificate of Incorporation (the "Certificate of Amendment") with the Secretary of the State of Delaware, which effected an increase in the Company's authorized shares of common stock, from 1.2 billion to 1.7 billion, par value \$0.001 per share.

During the three months ended March 31, 2023, the Company received \$0.2 million from the exercise of warrants with an exercise price between \$0.22 and \$0.85. The Company issued approximately 0.8 million shares of common stock upon these warrant exercises.

NORTHWEST BIOTHERAPEUTICS, INC.
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During the three months ended March 31, 2023, certain options holders elected to exercise some of their options pursuant to cashless exercise formulas. The Company issued approximately 0.7 million shares of common stock upon exercise of 1.3 million options at exercise prices between \$0.25 and \$0.35.

During the three months ended March 31, 2023, the Company issued approximately 8.3 million shares of common stock to certain lenders in lieu of cash payments on \$4.1 million of outstanding debt, including \$0.2 million interest (see Note 7).

Stock Purchase Warrants

The following is a summary of warrant activity for the three months ended March 31, 2023 (dollars in thousands, except per share data):

	Number of Warrants	Weighted Average Exercise Price	Remaining Contractual Term
Outstanding as of January 1, 2023	141,048	\$ 0.31	1.46
Warrants exercised for cash	(767)	0.32	—
Warrants expired and cancellations	(38)	0.34	—
Outstanding as of March 31, 2023	140,243	\$ 0.31	1.42

The options and warrants held by Ms. Powers and Mr. Goldman are subject to an ongoing suspension on a rolling basis pursuant to the Blocker Letter Agreement.

At March 31, 2023, of the approximately 140 million total outstanding warrants listed above, approximately 97 million warrants were under the Blocker Letter Agreement or suspension agreements.

Warrant Modifications

Between January 10 and March 31, 2023, the Company amended multiple warrants whereby the maturity dates of certain warrants were extended for an additional approximately 3 months. The value of these modifications were calculated using the Black-Scholes-Merton option pricing model based on the following weighted average assumptions.

	Post-modification	Pre-modification
Exercise price	\$ 0.27	\$ 0.27
Expected term (in years)	2.1	1.9
Volatility	74 %	95 %
Risk-free interest rate	4.3 %	4.2 %
Dividend yield	0 %	0 %

The incremental fair value attributable to the modified awards compared to the original awards immediately prior to the modification was calculated at \$0.4 million and was treated as a deemed dividend and is reflected as “Deemed dividend related to warrant modifications” in the accompanying condensed consolidated statement of operations and comprehensive loss.

12. Commitments and Contingencies

Operating Lease- Lessee Arrangements

The Company has operating leases for corporate offices in the U.S. and U.K., and for manufacturing facilities in the U.K. Leases with an initial term of 12 months or less are not recorded in the balance sheet. The Company has elected the practical expedient to account for each separate lease component of a contract and its associated non-lease components as a single lease component, thus causing all fixed payments to be capitalized. The Company also elected the package of practical expedients permitted within the new standard, which among other things, allows the Company to carry forward historical lease classification. The lease renewal options have not been included in the calculation of the lease liabilities and right-of-use (“ROU”) assets as the Company has not yet determined whether to exercise the options. Variable lease payment amounts that cannot be determined at the commencement of the lease such as increases in lease payments based on changes in index rates or usage, are not included in the ROU assets or liabilities. These are expensed as incurred and recorded as variable lease expense.

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At March 31, 2023, the Company had operating lease liabilities of approximately \$4.7 million for both the 20-year lease of the building for the manufacturing facility in Sawston, U.K., and the current office lease in the U.S. and ROU assets of approximately \$4.2 million for the Sawston lease and U.S. office lease are included in the condensed consolidated balance sheet.

The following summarizes quantitative information about the Company's operating leases (amount in thousands):

	For the three months ended March 31, 2023		
	U.K	U.S	Total
Lease cost			
Operating lease cost	\$ 144	\$ 65	\$ 209
Short-term lease cost	23	—	23
Variable lease cost	—	4	4
Sub-lease income	(36)	—	(36)
Total	\$ 131	\$ 69	\$ 200
Other information			
Operating cash flows from operating leases	\$ (152)	\$ (73)	\$ (225)
Weighted-average remaining lease term - operating leases	8.4	1.1	
Weighted-average discount rate - operating leases	12 %	12 %	

	For the three months ended March 31, 2022		
	U.K	U.S	Total
Lease cost			
Operating lease cost	\$ 87	\$ 65	\$ 152
Short-term lease cost	13	—	13
Variable lease cost	—	10	10
Total	(36)	—	(36)
	\$ 64	\$ 75	\$ 138
Other information			
Operating cash flows from operating leases	\$ (168)	\$ (71)	\$ (239)
Weighted-average remaining lease term - operating leases	8.9	1.6	
Weighted-average discount rate - operating leases	12 %	12 %	

The Company recorded lease costs as a component of general and administrative expense during the three months ended March 31, 2023 and 2022, respectively.

Maturities of our operating leases, excluding short-term leases and sublease agreement, are as follows:

Nine months ended December 31, 2023	\$ 688
Year ended December 31, 2024	823
Year ended December 31, 2025	618
Year ended December 31, 2026	618
Year ended December 31, 2027	618
Thereafter	6,783
Total	10,148
Less present value discount	(5,409)
Operating lease liabilities included in the Condensed Consolidated Balance Sheet at March 31, 2023	\$ 4,739

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Maturities of our operating leases under the sublease agreement, are as follows:

Nine months ended December 31, 2023	\$ 109
Year ended December 31, 2024	145
Year ended December 31, 2025	145
Year ended December 31, 2026	145
Thereafter	1,740
Total	<u>\$ 2,284</u>

Advent BioServices Services Agreement

The Company had three operational programs with Advent: (a) an ongoing manufacturing program at the existing GMP facility in London, (b) an ongoing development and manufacturing program at the Sawston facility, and (c) a one-time program for specialized work, organized into 10 sets of one-time milestones, for the following:

- Qualifying for and obtaining 3 required licenses for the Sawston facility: a license from the Human Tissue Authority to collect and process human cells and tissues, a license from the MHRA for manufacturing for clinical trials and compassionate use cases, and a license from the MHRA for commercial manufacturing.
- 6 workstreams relating to product matters required for an application for regulatory approval of DCVax-L, including Comparability, Stability, Potency, Product Profile, Mechanism of Action and Fill/Finish.
- Drafting of key portions of the application for product approval itself.

On May 14, 2018, the Company entered into a DCVax®-L Manufacturing and Services Agreement (“MSA”) with Advent BioServices, a related party which was formerly part of Cognate BioServices and was spun off separately as part of an institutional financing of Cognate. The MSA provides for manufacturing of DCVax-L products at an existing facility in London. The MSA is structured in the same manner as the Company’s prior agreements with Cognate BioServices. The MSA provides for certain payments for achievement of milestones and, as was the case under the prior agreement with Cognate BioServices, the Company is required to pay certain fees for dedicated production capacity reserved exclusively for DCVax production and pay for manufacturing of DCVax-L products for a certain minimum number of patients, whether or not the Company fully utilizes the dedicated capacity and number of patients. The MSA remains in force until five years after the first commercial sales of DCVax-L products pursuant to a marketing authorization, accelerated approval or other commercial approval, unless cancelled. Either party may terminate the MSA on twelve months’ notice, to allow for transition arrangements by both parties. During the notice period services would still be provided. Minimum required payments for this notice period are anticipated to total approximately £4.4 million (\$5.5 million).

On November 8, 2019, the Company and Advent entered into an Ancillary Services Agreement with an 8-month Term for U.K. Facility Development Activities and Compassionate Use Program Activities. The Ancillary Services Agreement establishes a structure under which Advent develops Statements of Work (“SOWs”) for the U.K. Facility Development Activities and Compassionate Use Program Activities and delivers those SOWs to the Company for review and approval. After an SOW is approved by the Company, Advent will proceed with, or continue, the applicable services and will invoice the Company pursuant to the SOW. Since both the U.K. Facility Development and the Compassionate Use Program involve pioneering and uncertainties in most aspects, the invoicing under the Ancillary Services Agreement is on the basis of costs incurred plus fifteen percent. The Agreement also provides for Statements of Work (SOWs) with operational milestones and related payments. The Ancillary Services Agreement had an original term of eight months, which ended in July 2020. The Company and Advent have entered into a series of modifications which have expanded the scope of work and milestones to be achieved and extended the term to September 2023.

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The Company entered into SOW 6 with Advent, which was incorporated into the Ancillary Services Agreement on April 1, 2022 and amended it on September 26, 2022. The amended SOW 6 provides for six workstreams that are prerequisites for an application for regulatory approval of DCVax-L, for drafting of key portions of the application, and for obtaining three required licenses for the Sawston facility. The SOW provides for baseline costs and provides for milestone incentives for completion of each of the six workstreams, for obtaining regulatory approval of each of the three Sawston licenses, and for the completion of the key portions of an application for product approval. The milestone incentives involve a combination of cash and stock and are not paid until they are achieved and earned, as described in Note 9.

German Tax Matter

The German tax authorities have audited our wholly owned subsidiary, NW Bio GmbH, for 2013-2015 and assessed additional tax against the subsidiary. NW Bio GmbH submitted substantial documentation to refute certain aspects of the assessments and the German tax authorities agreed in principle with the Company's proposed revised approach and settlement offer. A final settlement bill was received from the German Tax Authority confirming that only a portion of the original bill was owed, €277,000 (approximately \$329,000), for corporate taxes, interest, and reduced penalty for the period under audit, which the Company paid on September 2, 2021. The Company also received and paid the final settlement bill from the local authority for trade taxes for the audit period in the amount of €231,000 (approximately \$251,000). On November 4, 2021, the Company received a letter from the local tax authorities asking for additional late fees of €513,000 (now approximately \$558,000) on reimbursable withholding taxes that had been waived during the settlement process. On December 8, 2021, the Company appealed the assessment of additional late fees. Additionally, the Company requested that NW Bio GmbH be deregistered from the trade register, as it no longer had current operations. The deregistration was granted effective December 31, 2021. Between January 2022 and July 2022, the Company received tax bills for the corporate and trade taxes for the 2016-2020 tax years that totaled approximately €222,000 (approximately \$241,000). On July 27, 2022, the Company was informed that the German Tax Authorities were prepared to waive €135,000 (approximately \$147,000) of the penalties. The Company offered to pay this reduced penalty if an extended payment plan was approved. A response was received dated November 14, 2022 indicating that the tax authority would not be able to grant a further deferral of payment of these penalties. In a letter dated December 27, 2022, the Leipzig tax authority sent letters to the former and current managing directors of NW Bio GmbH giving 30 days to respond to a tax liability questionnaire. Based on the responses to the liability questionnaires the tax authorities have currently not directed any further measures against former and current managing directors of NW Bio GmbH with respect to tax liability proceedings. The Company currently has accrued for the current amounts owed for these penalties of €377,000 (approximately \$410,000) as well as for all unpaid taxes as of March 31, 2023. Based on the Company's current operating state in Germany and the negotiations, the Company believes, based on its evaluation under ASC 740, that the resolution of these tax matters will not likely result in a net material charge to the Company.

13. Subsequent Events

In April 2023, approximately 45,000 Series C Shares with a book value of \$0.7 million were converted into 1.1 million common shares in accordance with their terms at a ratio of 1:25.

On April 19, 2023, the Company issued approximately 2.6 million shares of common stock to certain lender in lieu of cash payments on \$1.3 million of outstanding debt, including \$0.1 million interest.

On May 8, 2023, the Company received a \$3.0 million prepayment for the purchase of securities for which the terms are in the process of being finalized.

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

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our unaudited condensed consolidated financial statements and the notes to those statements included with this report. In addition to historical information, this report contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended (the "Securities Act"), and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). Such forward-looking statements are subject to certain risks and uncertainties that could cause actual results to differ materially from those projected. The words "believe," "expect," "intend," "anticipate," and similar expressions are used to identify forward-looking statements, but some forward-looking statements are expressed differently. Many factors could affect our actual results, including those factors described under "Risk Factors" in our Form 10-K for the year ended December 31, 2022 and in Part II Item 1A of this report. These factors, among others, could cause results to differ materially from those presently anticipated by us. You should not place undue reliance on these forward-looking statements.

Overview

We are a biotechnology company focused on developing personalized immune therapies for cancer. We have developed a platform technology, DCVax®, which uses activated dendritic cells to mobilize a patient's own immune system to attack their cancer.

Our lead product, DCVax®-L, is designed to treat solid tumor cancers in which the tumor can be surgically removed. We have completed a 331-patient international Phase III trial of DCVax-L for glioblastoma brain cancer (GBM). As previously reported, the data collection and confirmation process was conducted by the independent contract research organization (CRO) who managed the trial and by other independent service firms, and the data were analyzed by independent statisticians.

On May 10, 2022, top line data from the Phase III trial of DCVax-L were presented in a scientific conference at the New York Academy of Sciences by one of the investigators in the trial. The presentation was made available publicly on a third-party site. On November 17, 2022, the Phase III trial results were reported in a peer reviewed publication in JAMA Oncology, a top scientific and medical journal.

The Company is now working on preparations for an application for regulatory approval of DCVax-L. The Company is working with teams of specialized consultants on pre-requisites for the application, and on portions of the application package itself. One of the pre-requisites - obtaining regulatory approval of a Pediatric Investigation Plan (PIP) - was completed during 2022 on an accelerated basis, including regulatory approval to use the same trial design with external controls as was used in the Company's Phase 3 trial.

Additionally, substantial progress was made with the CRO and specialized consultants on preparing the Trial Master File to be inspection-ready for regulators.

Post-COVID difficulties continue to impact the Company's programs and operations, due to backlogs in the supply chain, at clinical trial sites, and at regulators. The supply chain backlogs include service firms and also vendors and suppliers of a wide variety of items, ranging from major equipment to particular reagents required for the manufacturing process. Shortages of certain key materials and supplies have also occurred. The clinical trial site backlogs involve delays for various clinical trial follow-up matters, such as queries and additional documentation. With regulators, committee processes and regulatory processes were focused on COVID matters during the pandemic, and a substantial backlog of non-COVID matters accumulated. The Company is hopeful that the various backlog circumstances will improve in 2023.

In the future, we plan to conduct clinical trials of DCVax-L for other types of solid tumor cancers, beyond brain cancer, when resources permit. Our second product, DCVax®-Direct, is designed to treat inoperable solid tumors. A 40-patient Phase I trial has been completed and included treatment of a diverse range of more than a dozen types of cancers. We plan to work on preparations for Phase II trials of DCVax-Direct as resources permit.

Critical Accounting Policies and Estimates

Our discussion and analysis of our financial condition and results of operations are based on our financial statements, which have been prepared in accordance with U.S. GAAP. The preparation of these financial statements requires us to make estimates and judgments that affect our reported amounts of assets, liabilities, revenues and expenses.

On an ongoing basis, we evaluate our estimates and judgments, including those related to derivative liabilities, accrued expenses and stock-based compensation. We based 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 and the reported amounts of revenues and expenses that are not readily apparent from other sources. Actual results could differ from those estimates, particularly given the significant social and economic disruptions and uncertainties associated with the ongoing coronavirus pandemic (“COVID-19”) and the COVID-19 control responses.

Our critical accounting policies and significant estimates are detailed in our Annual Report on Form 10-K for the year ended December 31, 2022. Our critical accounting policies and significant estimates have not changed substantially from those previously disclosed in our Annual Report on Form 10-K for the year ended December 31, 2022 other than those included below.

Sequencing

The Company adopted a sequencing policy under ASC 815-40-35 to determine if reclassification of contracts from equity to liabilities is necessary pursuant to ASC 815 due to the Company’s inability to demonstrate if it has sufficient authorized shares. Certain contracts were classified as liabilities as a result of the instruments containing a potentially indeterminable number of shares and, most recently, due to the Company entering into agreements providing for the potential issuance of more shares than authorized. While temporary agreements are in place to keep the potential exercises beneath the number authorized, certain instruments are classified as liabilities, after allocating available authorized shares on the basis of the earliest grant date of potentially dilutive instruments. Pursuant to ASC 815, issuance of stock-based awards to the Company’s employees, nonemployees or directors are not subject to the sequencing policy.

On January 9, 2023, the Company filed a Certificate of Amendment of its Seventh Amended and Restated Certificate of Incorporation (the “Certificate of Amendment”) with the Secretary of the State of Delaware, which effected an increase in the Company’s authorized shares of common stock, from 1.2 billion to 1.7 billion, par value \$0.001 per share. As a result of this increase in authorized shares, the liability-classified warrants were reclassified to equity. Approximately 141 million warrants to purchase shares of the Company’s common stock were classified as liabilities through January 8, 2023.

Modification of Equity Classified Warrants

A change in the terms or conditions of a warrant is accounted for as a modification. For a warrant modification accounted for under ASC 815, the effect of a modification shall be measured as the difference between the fair value of the modified warrant over and the fair value of the original warrant immediately before its terms are modified, with each measured on the modification date. The accounting for any incremental fair value of the modified warrants over the original warrants is based on the specific facts and circumstances related to the modification. When a modification is directly attributable to an equity offering, the incremental change in fair value of the warrants is accounted for as an equity issuance cost. When a modification is directly attributable to a debt financing, the incremental change in fair value of the warrants is accounted for as a debt discount or debt issuance cost. For all other modifications, the incremental change in fair value is recognized as a deemed dividend.

Results of Operations

Operating costs:

Our operating costs and expenses consist primarily of research and development (R&D) expenses. R&D expenses include clinical trial expenses, and additional costs related to completion of a trial, including substantial one-time expenses such as final site visits, query resolutions, additional data collection and documentation, and related matters. There are also increased costs after completion of a Phase III trial, such as statistical analyses, document collection and quality control checking of the documents, and preparations for an application for product approval.

In addition to clinical trial and post-trial costs, our operating costs may include ongoing work relating to our DCVax products, including R&D, product characterization, manufacturing process development, quality control process development, and related matters. Additional substantial costs relate to the development and expansion of manufacturing capacity.

Our operating costs also include the costs of preparations for the launch of new or expanded clinical trial programs, such as our planned Phase II clinical trials. The preparation costs include payments to regulatory consultants, lawyers, statisticians, sites and others, evaluation of potential investigators, the clinical trial sites and the CROs managing the trials and other service providers, and expenses related to institutional approvals, clinical trial agreements (business contracts with sites), training of medical and other site personnel, trial supplies and other.

Our operating costs also include legal and accounting costs in operating the Company.

The foregoing operating costs include the costs for Flaskworks' ongoing operations and intellectual property filings, and the operations of our subsidiaries in the U.K., the Netherlands and Germany.

Research and development:

R&D expenses include costs for substantial external scientific personnel, technical and regulatory advisers, and others, costs of laboratory supplies used in our internal research and development projects, travel, regulatory compliance, and expenditures for preclinical and clinical trial operation and management when we are actively engaged in clinical trials.

Because we are a pre-revenue company, we do not allocate R&D costs on a project basis. We adopted this policy, in part, due to the unreasonable cost burden associated with accounting at such a level of detail and our limited number of financial and personnel resources.

General and administrative:

General and administrative expenses include personnel related salary and benefit expenses, cost of facilities, insurance, travel, legal services, property and equipment and amortization of stock options and warrants.

Three Months Ended March 31, 2023 and 2022

We recognized a net loss of \$10.7 million and \$14.2 million for the three months ended March 31, 2023 and 2022, respectively.

Research and Development Expense

For the three months ended March 31, 2023 and 2022, research and development expense was \$6.9 million and \$4.8 million, respectively. The increase in R&D expense in 2023 was related in part to one-time milestone activities under the SOW 6 with Advent BioServices, and in part to increased activities by expert consultants. During the three months ended March 31, 2023, we accrued for 3.0 million shares that will become issuable for completion of a milestone (obtaining a commercial manufacturing license from the MHRA). The fair value of the 3.0 million shares was approximately \$2.1 million, of which \$0.5 million was recognized during the three months ended March 31, 2023 and \$1.6 million had already been recognized in 2022. During the three months ended March 31, 2023, the Company also expensed (but did not pay) an aggregate of \$0.5 million related to completed milestones; the Company also expensed (but did not pay) an aggregate of \$0.2 million related to future milestone payments and \$0.1 million related to fair value of future shares milestone payments that the Company anticipates will be achieved and earned.

General and Administrative Expense

For the three months ended March 31, 2023 and 2022, general and administrative expenses was \$7.0 million and \$7.9 million, respectively. The decrease in 2023 was mainly related to a decrease of \$0.6 million in legal and professional expense and a decrease of \$0.1 million in stock-based compensation.

Change in Fair Value of Derivatives

We recognized a non-cash gain of \$3.9 million and \$0.5 million for the three months ended March 31, 2023 and 2022, respectively. The non-cash gain was primarily due to the decrease of our stock price. Our closing stock prices as of March 31, 2023 and December 31, 2022 were as follows:

	March 31, 2023		December 31, 2022
\$	0.63	\$	0.78

Debt Extinguishment

During the three months ended March 31, 2023, we issued approximately 8.3 million shares of common stock with a fair value of \$5.6 million to certain lenders in lieu of cash payments of \$4.1 million of debt, including \$0.2 million accrued interest. In addition, pursuant to exchange agreements executed with various holders, the Company is required to potentially issue additional common stock (the "Share liability") if the stock price is less than the price defined in the exchange agreement as of the true-up date. During the three months ended March 31, 2023, we extinguished Share liabilities of \$0.7 million and recognized an additional \$0.5 million of Share liabilities. We recognized an approximately \$1.3 million debt extinguishment loss during the three months ended March 31, 2023 from the debt redemption.

During the three months ended March 31, 2023, we issued approximately 43,000 shares of Series C preferred stock at fair value of \$0.8 million to certain lenders in lieu of cash payments of \$0.7 million debt, including \$0.1 million accrued interest. We recognized an approximately \$0.1 million debt extinguishment loss.

Interest Expense

During the three months ended and March 31, 2023 and 2022, we recorded interest expense of \$1.0 million and \$1.9 million, respectively. The decrease in interest expense in 2023 was mainly related to a decrease of outstanding debt as a result of the redemption of approximate \$18.1 million debt in 2022.

Foreign currency transaction gain (loss)

During the three months ended and March 31, 2023 and 2022, we recognized foreign currency transaction gain of \$0.9 million and loss of \$1.0 million, respectively. The gain during the three months ended March 31, 2023 was due to the weakening of the U.S. dollar relative to the British pound sterling, while the loss during the three months ended March 31, 2022 was due to the strengthening of the U.S. dollar relative to the British pound sterling.

Liquidity and Capital Resources

We have experienced recurring losses from operations since inception. We have not yet established an ongoing source of revenues and must cover our operating expenses through debt and equity financings to allow us to continue as a going concern. Our ability to continue as a going concern depends on the ability to obtain adequate capital to fund operating losses until we generate adequate cash flows from operations to fund our operating costs and obligations. If we are unable to obtain adequate capital, we could be forced to cease operations.

We depend upon our ability, and will continue to attempt, to secure equity and/or debt financing. We cannot be certain that additional funding will be available on acceptable terms, or at all. Our management determined that there was substantial doubt about our ability to continue as a going concern for at least one year after the annual consolidated financial statements were issued, and management's concerns about our ability to continue as a going concern within the year following this report persist.

Cash Flow

Operating Activities

During the three months ended March 31, 2023 and 2022, net cash outflows from operations were approximately \$11.2 million and \$13.0 million, respectively. The decrease in cash used in operating activities was primarily attributable to a decrease of \$0.8 million in payments to external service providers and a decrease of \$0.7 million interest payments to note holders.

Investing Activities

We spent approximately \$1.3 million and \$58,000 in cash for the purchase of additional equipment and our build out in Sawston, UK during the three months ended March 31, 2023 and 2022, respectively.

Financing Activities

We received approximately \$2.4 million of cash from issuance of 0.1 million shares of Series C convertible preferred stock during the three months ended March 31, 2023.

During the three months ended March 31, 2023, we received approximately \$10.0 million in cash proceeds from the issuance of a loan to a commercial lender, and during the three months ended March 31, 2022, we received approximately \$0.6 million in cash proceeds from the issuance of multiple loans to individual lenders.

We received approximately \$0.2 million and \$4.2 million of cash from the exercise of warrants during the three months ended March 31, 2023 and 2022, respectively.

We received approximately \$3.1 million of cash from issuance of 4.5 million shares of common stock during the three months ended March 31, 2022.

We made aggregate debt payments of \$0.1 million and \$4.0 million during the three months ended March 31, 2023 and 2022, respectively.

Other factors affecting our ongoing funding requirements include the number of staff we employ, the number of sites, number of patients and amount of activity in our clinical trial programs, the costs of further product and process development work relating to our DCVax products, the costs of preparations for Phase II trials, the costs of expansion of manufacturing, and unanticipated developments. The extent of resources available to us will determine which programs can move forward and at what pace.

Off-Balance Sheet Arrangements

Since our inception, we have not engaged in any off-balance sheet arrangements, as defined in the rules and regulations of the SEC.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

Market risk represents the risk of loss that may result from the change in value of financial instruments due to fluctuations in its market price. Market risk is inherent in all financial instruments. Market risk may be exacerbated in times of trading illiquidity when market participants refrain from transacting in normal quantities and/or at normal bid-offer spreads. Our exposure to market risk is directly related to derivatives, debt and equity linked instruments related to our financing activities.

Our assets and liabilities are overwhelmingly denominated in U.S. dollars. We do not use foreign currency contracts or other derivative instruments to manage changes in currency rates. We do not now, nor do we plan to, use derivative financial instruments for speculative or trading purposes. However, these circumstances might change.

The primary quantifiable market risk associated with our financial instruments is sensitivity to changes in interest rates. Interest rate risk represents the potential loss from adverse changes in market interest rates. We use an interest rate sensitivity simulation to assess our interest rate risk exposure. For purposes of presenting the possible earnings effect of a hypothetical, adverse change in interest rates over the 12-month period from our reporting date, we assume that all interest rate sensitive financial instruments will be impacted by a hypothetical, immediate 100 basis point increase in interest rates as of the beginning of the period. The sensitivity is based upon the hypothetical assumption that all relevant types of interest rates that affect our results would increase instantaneously, simultaneously and to the same degree. We do not believe that our cash and equivalents have significant risk of default or illiquidity.

The sensitivity analyses of the interest rate sensitive financial instruments are hypothetical and should be used with caution. Changes in fair value based on a 1% or 2% variation in an estimate generally cannot be extrapolated because the relationship of the change in the estimate to the change in fair value may not be linear. Also, the effect of a variation in a particular estimate on the fair value of financial instruments is calculated independent of changes in any other estimate; in practice, changes in one factor may result in changes in another factor, which might magnify or counteract the sensitivities. In addition, the sensitivity analyses do not consider any action that we may take to mitigate the impact of any adverse changes in the key estimates.

Based on our analysis, as of March 31, 2023, the effect of a 100+/- basis point change in interest rates on the value of our financial instruments and the resultant effect on our net loss are considered immaterial.

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

Under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, we conducted an evaluation as of March 31, 2023, of the design and operation of our disclosure controls and procedures, as such terms are defined in Exchange Act Rules 13a-15(e) and 15d-15(e). Based on this evaluation, management concluded that, as of such date, our disclosure controls and procedures are effective to ensure that information required to be disclosed by us in our Exchange Act reports is recorded, processed, summarized, and reported within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate to allow timely decisions regarding required disclosure.

Changes in Internal Control over Financial Reporting

No change in internal control over financial reporting occurred during the most recent quarter with respect to our operations, which materially affected, or is reasonable likely to materially affect, our internal controls over financial reporting.

Part II - Other Information

Item 1. Legal Proceedings

On December 1, 2022, we filed a Complaint in the United States District Court for the Southern District of New York against certain market makers. The Complaint alleges that the defendants engaged in manipulation of the Company's stock, in violation of the Securities Exchange Act of 1934 and common law fraud, over a period of years. On March 20, 2023, the defendants filed a Motion to Dismiss the Complaint. On April 10, 2020 we filed an Amended Complaint against Canaccord Genuity LLC, Citadel Securities LLC, G1 Execution Services LLC, GTS Securities LLC, Instinet LLC, Lime Trading Corp., and Virtu Americas LLC (*Northwest Biotherapeutics Inc. v. Canaccord, et al.*, No. 1:22-cv-10185-GHW-GWG). The Company plans to pursue this case vigorously.

In February and March, three stockholders filed in the Delaware Court of Chancery three similar derivative lawsuits against the Company and certain of its directors and officers, including J. Cofer Black, Marnix L. Bosch, Alton L. Boynton, Leslie J. Goldman, Jerry Jasinowski, Navid Malik, and Linda F. Powers (the "Individual Defendants"), alleging the Individual Defendants (i) breached their fiduciary duties, and (ii) were unjustly enriched by director and officer compensation awarded to the Individual Defendants—notwithstanding the fact that approximately 90% of shareholders voted to approve of the Company's executive compensation (the same compensation that these three stockholders are seeking to challenge) through its Say on Pay vote, and the director awards are subject to shareholder approval. On March 31, 2022, the Delaware Court of Chancery consolidated these actions into a single action under the caption *In re Northwest Biotherapeutics, Inc. Stockholder Litigation* (the "Derivative Action").

The Company believes these cases are baseless and is vigorously contesting the Derivative Action. On February 22, 2023, the Company filed a Motion to Dismiss the case. The parties fully briefed the motion in April 2023 and oral argument on the motion is scheduled for September 2023.

Item 1A. Risk Factors

Applicable risk factors are set forth in the Company's report on Form 10-K for 2022.

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

None.

Item 3. Defaults Upon Senior Securities

Not Applicable.

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information

Not Applicable

Item 6. Exhibits

31.1	Certification of President (Principal Executive Officer and Principal Financial and Accounting Officer), Pursuant to Exchange Act Rules 13a-14(a) and 15d-14(a), as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1	Certification of President, Chief Executive Officer and Principal Financial and Accounting Officer Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS	Inline XBRL Instance Document.
101.SCH	Inline XBRL Schema Document.
101.CAL	Inline XBRL Calculation Linkbase Document.
101.DEF	Inline XBRL Definition Linkbase Document.
101.LAB	Inline XBRL Label Linkbase Document.
101.PRE	Inline XBRL Presentation Linkbase Document.
104	The cover page from the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2023, formatted in Inline XBRL (included as Exhibit 101).

* Filed herewith

** Furnished herewith

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

NORTHWEST BIOTHERAPEUTICS, INC

Dated: May 10, 2023

By: /s/ Linda F. Powers

Name: Linda F. Powers

Title: President and Chief Executive Officer

Principal Executive Officer

Principal Financial and Accounting Officer