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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, DC 20549

FORM 10-Q

☒ **QUARTERLY REPORT UNDER SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the quarterly period ended November 30, 2023

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES ACT OF 1933**

For the transition period from _____ to _____

Commission File Number: 000-49908

CYTODYN INC.

(Exact name of registrant as specified in its charter)

Delaware	**83-1887078**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer or Identification No.)
1111 Main Street, Suite 660 **Vancouver, Washington**	**98660**
(Address of principal executive offices)	(Zip Code)

(360) 980-8524
(Registrant's telephone number, including area code)

Not applicable
(Former name, former address and former fiscal year, if changed since last report)

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

Title of Each Class	Trading Symbol(s)	Name of Each Exchange on Which Registered
None	**None**	**None**

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 (Section 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

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

Large Accelerated Filer	☐	Accelerated Filer	☐
Non-accelerated Filer	☒	Smaller Reporting Company	☒
		Emerging Growth Company	☐

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

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

On December 31, 2023, there were 979,527 thousand shares outstanding of the registrant's $0.001 par value common stock.

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PART I. Financial Information

Item 1. Consolidated Financial Statements

CytoDyn Inc.
Consolidated Balance Sheets
(Unaudited, in thousands, except par value)

	November 30, 2023	May 31, 2023
Assets		
Current assets:		
Cash	$ 147	$ 2,541
Restricted cash	6,577	6,507
Prepaid expenses	1,578	1,167
Prepaid service fees	538	590
Total current assets	8,840	10,805
Other non-current assets	400	487
Total assets	$ 9,240	$ 11,292
Liabilities and Stockholders' Deficit		
Current liabilities:		
Accounts payable	$ 62,328	$ 62,725
Accrued liabilities and compensation	9,150	6,669
Accrued interest on convertible notes	12,936	10,598
Accrued dividends on convertible preferred stock	6,049	5,308
Convertible notes payable, net	32,914	34,417
Derivative liability - equity instruments	33	79
Total current liabilities	123,410	119,796
Notes payable, net	—	714
Operating leases	211	283
Total liabilities	123,621	120,793
Commitments and Contingencies (Note 8)		
Stockholders' deficit:		
Preferred stock, $0.001 par value; 5,000 shares authorized:		
Series B convertible preferred stock, $0.001 par value; 400 authorized; 19 issued and outstanding at November 30, 2023 and May 31, 2023	—	—
Series C convertible preferred stock, $0.001 par value; 8 authorized; 6 issued and outstanding at November 30, 2023 and May 31, 2023	—	—
Series D convertible preferred stock, $0.001 par value; 12 authorized; 9 issued and outstanding at November 30, 2023 and May 31, 2023	—	—
Common stock, $0.001 par value; 1,750,000 shares authorized; 971,729 and 919,053 issued, and 971,286 and 918,610 outstanding at November 30, 2023 and May 31, 2023, respectively	971	919
Treasury stock, $0.001 par value; 443 shares at November 30, 2023 and May 31, 2023	—	—
Additional paid-in capital	747,472	731,270
Accumulated deficit	(862,824)	(841,690)
Total stockholders' deficit	(114,381)	(109,501)
Total liabilities and stockholders' deficit	$ 9,240	$ 11,292

See accompanying notes to consolidated financial statements.

CytoDyn Inc.
Consolidated Statements of Operations
(Unaudited, in thousands, except per share data)

	Three months ended November 30,		Six months ended November 30,	
	2023	2022	2023	2022
Operating expenses:				
General and administrative	$ 2,311	$ 5,043	$ 4,999	$ 11,376
Research and development	1,079	137	2,993	713
Amortization and depreciation	8	54	18	153
Inventory charge	—	17,929	—	20,633
Total operating expenses	3,398	23,163	8,010	32,875
Operating loss	(3,398)	(23,163)	(8,010)	(32,875)
Interest and other expenses:				
Interest on convertible notes	(1,164)	(1,159)	(2,361)	(2,305)
Amortization of discount on convertible notes	(142)	(580)	(542)	(1,156)
Amortization of debt issuance costs	(3)	(18)	(369)	(34)
Issuance costs for private placement of shares and warrants through placement agent (Note 5)	(906)	—	(906)	—
Loss on induced conversion	(636)	(638)	(2,640)	(638)
Finance charges	(891)	(937)	(1,803)	(1,877)
Loss on note extinguishment	(2,406)	—	(4,490)	—
Gain (loss) on derivatives	(17)	—	(13)	(8,601)
Total interest and other expenses	(6,165)	(3,332)	(13,124)	(14,611)
Loss before income taxes	(9,563)	(26,495)	(21,134)	(47,486)
Income tax benefit	—	—	—	—
Net loss	$ (9,563)	$ (26,495)	$ (21,134)	$ (47,486)
Basic and diluted:				
Weighted average common shares outstanding	958,988	813,373	941,191	800,545
Loss per share	$ (0.01)	$ (0.03)	$ (0.02)	$ (0.07)

See accompanying notes to consolidated financial statements.

CytoDyn Inc.
Consolidated Statement of Changes in Stockholders' Deficit
(Unaudited, in thousands)

	Preferred stock		Common stock		Treasury stock		Additional paid-in capital	Accumulated deficit	Total stockholders' deficit
	Shares	Amount	Shares	Amount	Shares	Amount			
Balance at May 31, 2023	34	$ —	919,053	$ 919	443	$ —	$ 731,270	$ (841,690)	$ (109,501)
Issuance of stock for convertible note repayment	—	—	8,661	8	—	—	1,492	—	1,500
Loss on induced conversion	—	—	—	—	—	—	2,004	—	2,004
Warrants issued in note offering	—	—	—	—	—	—	170	—	170
Stock issued for compensation	—	—	686	1	—	—	154	—	155
Warrant exercises	—	—	3,000	3	—	—	297	—	300
Dividends accrued on Series C and D convertible preferred stock	—	—	—	—	—	—	(373)	—	(373)
Reclassification of warrants from liability to equity classified	—	—	—	—	—	—	79	—	79
Stock-based compensation	—	—	—	—	—	—	348	—	348
Net loss	—	—	—	—	—	—	—	(11,571)	(11,571)
Balance at August 31, 2023	34	—	931,400	931	443	—	735,441	(853,261)	(116,889)
Issuance of stock for convertible note repayment	—	—	3,535	4	—	—	496	—	500
Loss on induced conversion	—	—	—	—	—	—	636	—	636
Warrants issued in note offering	—	—	—	—	—	—	10	—	10
Note conversion	—	—	14,339	14	—	—	4,379	—	4,393
Stock issued for compensation	—	—	559	1	—	—	97	—	98
Stock issued for private offering	—	—	21,453	21	—	—	6,307	—	6,328
Dividends accrued on Series C and D convertible preferred stock	—	—	—	—	—	—	(368)	—	(368)
Stock-based compensation	—	—	—	—	—	—	474	—	474
Net loss	—	—	—	—	—	—	—	(9,563)	(9,563)
Balance at November 30, 2023	34	$ —	971,286	$ 971	443	$ —	$ 747,472	$ (862,824)	$ (114,381)

	Preferred stock		Common stock		Treasury stock		Additional paid-in capital	Accumulated deficit	Total stockholders' deficit
	Shares	Amount	Shares	Amount	Shares	Amount			
Balance at May 31, 2022	35	$ —	720,028	$ 720	443	$ —	$ 671,013	$ (766,131)	$ (94,398)
Stock issued for compensation	—	—	879	1	—	—	344	—	345
Stock issued for private offerings	—	—	85,378	85	—	—	17,459	—	17,544
Issuance costs related to stock issued for private offerings	—	—	—	—	—	—	(6,289)	—	(6,289)
Conversion of Series C convertible preferred stock to common stock	(1)	—	1,136	1	—	—	(1)	—	—
Warrant exercises	—	—	657	1	—	—	263	—	264
Deemed dividend paid in common stock due to down round provision, recorded in additional paid-in capital	—	—	4,620	5	—	—	(5)	—	—
Accrued preferred stock dividends	—	—	—	—	—	—	(384)	—	(384)
Reclassification of warrants from liability to equity classified	—	—	—	—	—	—	8,601	—	8,601
Stock-based compensation	—	—	—	—	—	—	996	—	996
Reclassification of prior period preferred stock dividends	—	—	—	—	—	—	(4,265)	4,265	—
Net loss	—	—	—	—	—	—	—	(20,991)	(20,991)
Balance at August 31, 2022	34	—	812,698	813	443	—	687,732	(782,857)	(94,312)
Issuance of stock for convertible note repayment	—	—	1,822	2	—	—	498	—	500
Loss on induced conversion	—	—	—	—	—	—	638	—	638
Stock issued for compensation	—	—	765	—	—	—	310	—	310
Exercise of warrants, net of issuance costs	—	—	9,652	10	—	—	2,123	—	2,133
Make-whole shares related to private warrant exchange	—	—	23	—	—	—	—	—	—
Dividend paid in common stock upon conversion of Series C convertible preferred stock ($0.50 per share)	—	—	319	—	—	—	159	—	159
Dividends accrued on Series C and D convertible preferred stock	—	—	—	—	—	—	(369)	—	(369)
Stock-based compensation	—	—	—	—	—	—	1,467	—	1,467
Net loss	—	—	—	—	—	—	—	(26,495)	(26,495)
Balance at November 30, 2022	34	$ —	825,279	$ 825	443	$ —	$ 692,558	$ (809,352)	$ (115,969)

See accompanying notes to consolidated financial statements.

CytoDyn Inc.
Consolidated Statements of Cash Flows
(Unaudited, in thousands)

	Six months ended November 30,	
	2023	**2022**
Cash flows from operating activities:		
Net loss	$ (21,134)	$ (47,486)
Adjustments to reconcile net loss to net cash used in operating activities:		
Amortization and depreciation	18	153
Amortization of debt issuance costs	369	34
Issuance costs for private placement of shares and warrants through placement agent	906	—
Amortization of discount on convertible notes	542	1,156
Loss on derivatives	13	8,601
Loss on induced conversion	2,640	638
Loss on note extinguishment	4,490	—
Inventory charge	—	20,633
Stock-based compensation	1,075	3,118
Changes in operating assets and liabilities:		
(Increase) decrease in prepaid expenses and other assets	(290)	(303)
(Decrease) increase in accounts payable and accrued expenses	4,374	(2,024)
Net cash used in operating activities	(6,997)	(15,480)
Cash flows from investing activities:		
Net cash Provided by/used in investing activities	—	—
Cash flows from financing activities:		
Proceeds from warrant transactions, net of offering costs	—	2,133
Proceeds from sale of common stock and warrants, net of issuance costs	3,016	11,255
Proceeds from warrant exercises	300	264
Proceeds held in trust	—	200
Proceeds from convertible note and warrant issuances, net of issuance costs	1,357	—
Net cash provided by financing activities	4,673	13,852
Net change in cash and restricted cash	(2,324)	(1,628)
Cash and restricted cash at beginning of period	9,048	4,231
Cash and restricted cash at end of period	$ 6,724	$ 2,603
Cash and restricted cash consisted of the following:		
Cash	$ 147	$ 2,403
Restricted cash	6,577	200
Total cash and restricted cash	$ 6,724	$ 2,603
Supplemental disclosure:		
Cash paid for interest	$ 38	$ —
Non-cash investing and financing transactions:		
Derivative liability associated with warrants	$ 80	$ 8,601
Issuance of common stock for principal of convertible notes	$ 2,000	$ 500
Accrued dividends on Series C and D convertible preferred stock	$ 741	$ 753
Warrants issued to placement agent	$ 413	$ 159
Deemed dividend on common stock issued due to down round provision, recorded in additional paid-in capital	$ —	$ 5,294
Note conversion to common stock and warrants	$ 2,295	$ —

See accompanying notes to consolidated financial statements.

CYTODYN INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
AS OF NOVEMBER 30, 2023
(Unaudited)

Note 1. Organization

CytoDyn Inc. (together with its wholly owned subsidiaries, the "Company") was originally incorporated under the laws of Colorado on May 2, 2002, under the name RexRay Corporation and, effective August 27, 2015, reincorporated under the laws of Delaware. The Company is a clinical-stage biotechnology company focused on the clinical development of innovative treatments for multiple therapeutic indications based on its product candidate, leronlimab, a novel humanized monoclonal antibody targeting the C-C chemokine receptor type 5 ("CCR5").

The Company has been investigating leronlimab as a viral entry inhibitor for treatment of human immunodeficiency virus ("HIV"), believed to competitively bind to the N-terminus and second extracellular loop of the CCR5 receptor. For immunology, the CCR5 receptor is believed to be implicated in immune-mediated illnesses such as Metabolic dysfunction-associated steatohepatitis ("MASH"), replacement for the term nonalcoholic steatohepatitis ("NASH"). Leronlimab is being or has been studied in MASH, MASH-HIV, solid tumors in oncology, and other HIV indications where CCR5 is believed to play an integral role.

Note 2. Summary of Significant Accounting Policies

Basis of presentation

The unaudited interim consolidated financial statements include the accounts of CytoDyn Inc. and its wholly owned subsidiary, CytoDyn Operations Inc. All intercompany transactions and balances are eliminated in consolidation. The consolidated financial statements reflect all normal recurring adjustments which are, in the opinion of management, necessary for a fair statement of the results of operations for the interim financial statements. Certain information and footnote disclosures normally included in financial statements prepared in accordance with accounting principles generally accepted in the United States ("U.S. GAAP" or "GAAP") have been omitted in accordance with the rules and regulations of the United States Securities and Exchange Commission ("SEC"). The interim financial information and notes thereto should be read in conjunction with the Company's latest Annual Report on Form 10-K for the fiscal year ended May 31, 2023 (the "2023 Form 10-K"). The results of operations for the periods presented are not necessarily indicative of results to be expected for the entire fiscal year or for any other future annual or interim period.

Reclassifications

Certain prior year and prior quarter amounts shown in the accompanying consolidated financial statements have been reclassified to conform to the current period presentation. Such reclassifications did not have a material effect on the Company's previously reported financial position, results of operations, stockholders' deficit, or net cash provided by operating activities.

Going concern

The accompanying consolidated financial statements have been prepared on a going concern basis, which contemplates the realization of assets and satisfaction of liabilities in the normal course of business. As presented in the accompanying consolidated financial statements, the Company had losses for all periods presented. The Company incurred a net loss of approximately $21.1 million for the six months ended November 30, 2023, and has an accumulated deficit of approximately $862.8 million as of November 30, 2023. These factors, among several others, including the various matters discussed in Note 8, *Commitments and Contingencies*, raise substantial doubt about the Company's ability to continue as a going concern. The consolidated financial statements do not include any adjustments relating to the recoverability of assets and classification of liabilities that might be necessary should the Company be unable to continue as a going concern.

The Company's continuance as a going concern is dependent upon its ability to obtain additional operating capital, complete the development of its product candidate, leronlimab, obtain approval to commercialize leronlimab from regulatory agencies, continue to outsource manufacturing of leronlimab, and ultimately achieve revenues and attain profitability. The Company plans to continue to engage in research and development activities related to leronlimab and a new or modified longer-acting therapeutic for multiple indications and expects to incur significant research and development expenses in the future, primarily related to its regulatory compliance, including seeking the lifting of the U.S Food and Drug Administration's (the "FDA") clinical hold with regard to the Company's HIV program, performing additional pre-clinical and clinical studies in various indications, and seeking regulatory approval for its product candidate for commercialization. These research and development activities are subject to significant risks and uncertainties. The Company intends to finance its future development activities and its working capital needs primarily from the sale of equity and debt securities, combined with additional funding from other sources. However, there can be no assurance that the Company will be successful in these endeavors.

Use of estimates

The preparation of the consolidated financial statements in accordance with accounting principles GAAP requires management to make estimates and judgments that affect the reported amounts of assets, liabilities, and the disclosure of contingent assets and liabilities at the date of consolidated financial statements, and the reported amounts of revenue and expenses during the reporting period. Estimates are assessed each period and updated to reflect current information, such as the status of our analysis of the results of our clinical trials and/or discussions with the FDA which could have an impact on the Company's significant accounting estimates and assumptions. The Company's estimates are based on historical experience and on various market and other relevant, appropriate assumptions. Significant estimates include, but are not limited to, those relating to capitalization and write-off of pre-launch inventories, charges for excess and obsolete inventories, research and development expenses, commitments and contingencies, stock-based compensation, and the assumptions used to value warrants and warrant modifications. Actual results could differ from these estimates.

Restricted cash

As of November 30, 2023, the Company had recorded approximately $6.6 million of restricted cash. The restricted cash is related to cash held as collateral in connection with a surety bond that was posted as required in the Amarex litigation and will remain as restricted cash until the litigation is resolved.

Recent Accounting Pronouncements

In July 2023, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") 2023-03, *"Presentation of Financial Statements (Topic 205), Income Statement - Reporting Comprehensive Income (Topic 220), Distinguishing Liabilities from Equity (Topic 480), Equity (Topic 505), and Compensation - Stock Compensation (Topic 718): Amendments to SEC Paragraphs Pursuant to SEC Staff Accounting Bulletin No. 120, SEC Staff Announcement at the March 24, 2022 EITF Meeting, and Staff Accounting Bulletin Topic 6.B, Accounting Series Release 280 - General Revision of Regulation S-X: Income or Loss Applicable to Common Stock"* ("ASU 2023-03"). This ASU amends various paragraphs in the accounting codification pursuant to the issuance of Commission Staff Bulletin ("SAB") number 120. ASU 2023-03 does not provide any new guidance and is immediately effective. ASU 2023-03 did not have a material impact on the consolidated financial statements.

In October 2023, the FASB issued ASU 2023-06, *Disclosure Improvements – Codification Amendments in Response to the SEC's Disclosure Update and Simplification Initiative.* The amendments clarify or improve disclosure and presentation requirements on various disclosure areas, including the statement of cash flows, earnings per share, debt, equity, and derivatives. The amendments will align the requirements in the FASB ASC with the SEC's regulations. The amendments in this ASU will be effective on the date the related disclosures are removed from Regulation S-X or Regulation S-K by the SEC, and will not be effective if the SEC has not removed the applicable disclosure requirement by June 30, 2027. Early adoption is prohibited. The Company is currently evaluating the impact of the amendments on its financial statement disclosures.

On December 14, 2023, the FASB issued ASU No. 2023-09, Improvements to Income Tax Disclosures, which requires disclosure of disaggregated income taxes paid, prescribes standard categories for the components of the effective tax rate reconciliation, and modifies other income tax-related disclosures. The ASU is effective for annual periods beginning after December 15, 2024 and allows for adoption on a prospective basis, with a retrospective option. The Company is currently evaluating the effect of this update on its consolidated financial statements and related disclosures.

Note 3. Accounts Payable and Accrued Liabilities and Compensation

As of November 30, 2023 and May 31, 2023, the accounts payable balance was approximately $62.3 million and $62.7 million, respectively, with two vendors accounting for 70% and 72% of the total balance of accounts payable at the respective dates.

The components of accrued liabilities and compensation are as follows (in thousands):

	November 30, 2023	May 31, 2023
Compensation and related expense	$ 228	$ 335
Legal fees and settlement	81	168
Clinical expense	346	187
Accrued inventory charges and expenses	7,023	4,978
License fees	1,330	862
Lease payable	142	139
Total accrued liabilities	$ 9,150	$ 6,669

Note 4. Convertible Instruments and Accrued Interest

Convertible preferred stock

The following table presents the number of potentially issuable shares of common stock should shares of preferred stock and amounts of undeclared and accrued preferred dividends be converted to common stock.

	November 30, 2023			May 31, 2023		
(in thousands except conversion rate)	**Series B**	**Series C**	**Series D**	**Series B**	**Series C**	**Series D**
Shares of preferred stock outstanding	19	6	9	19	6	9
Common stock conversion rate	10:1	2,000:1	1,250:1	10:1	2,000:1	1,250:1
Total shares of common stock if converted	190	12,670	10,565	190	12,670	10,565
Undeclared dividends	$ 17	$ -	$ -	$ 15	$ -	$ -
Accrued dividends	$ -	$ 2,818	$ 3,231	$ -	$ 2,500	$ 2,808
Total shares of common stock if dividends converted	34	5,636	6,462	30	5,000	5,616

Under the Company's Amended and Restated Certificate of Incorporation, as amended (the "Certificate of Incorporation"), dividends on its outstanding shares of Series B Convertible Preferred Stock (the "Series B preferred stock") may be paid in cash or shares of the Company's common stock at the option of the Company. Dividends on outstanding shares of Series C Convertible Preferred Stock (the "Series C preferred stock") and Series D Convertible Preferred Stock (the "Series D preferred stock") are payable in cash or shares of common stock at the election of the holder. The preferred stockholders have the right to dividends only when and if declared by the Company's Board of Directors. Under Section 170 of the Delaware General Corporation Law, the Company is permitted to pay dividends only out of capital surplus or, if none, out of net profits for the fiscal year in which the dividend is declared or net profits from the preceding fiscal year.

Series B preferred stock provides for a liquidation preference over the common shares of $5.00 per share, plus any accrued and unpaid dividends. In the event of liquidation, holders of Series C and Series D preferred stock will be entitled to receive, on a pari passu basis, and in preference of any payment or distribution to holders of the Series B preferred stock and common stock, an amount per share equal to $1,000 per share plus any accrued and unpaid dividends.

Convertible notes and accrued interest

	November 30, 2023				May 31, 2023			
(in thousands)	April 2, 2021 Note	April 23, 2021 Note	Short-term Notes	Total	April 2, 2021 Note	April 23, 2021 Note	Placement Agent Notes	Total
Convertible notes payable outstanding principal	$ 4,081	$ 29,369	$ 250	$ 33,700	$ 6,081	$ 29,369	$ 1,000	$ 36,450
Less: Unamortized debt discount and issuance costs	(102)	(607)	(77)	(786)	(211)	(822)	(286)	(1,319)
Convertible notes payable, net	3,979	28,762	173	32,914	5,870	28,547	714	35,131
Accrued interest on convertible notes	4,261	8,675	-	12,936	3,804	6,789	5	10,598
Outstanding convertible notes payable, net and accrued interest	$ 8,240	$ 37,437	$ 173	$ 45,850	$ 9,674	$ 35,336	$ 719	$ 45,729

Reconciliation of changes to the outstanding balance of convertible notes, including accrued interest, were as follows:

(in thousands)	April 2, 2021 Note	April 23, 2021 Note	Placement Agent Notes	Short-Term Notes	Total
Outstanding balance at May 31, 2023	$ 9,674	$ 35,336	$ 719	$ -	$ 45,729
Consideration received	-	-	975	169	1,144
Amortization of issuance discount and costs	109	215	583	4	911
Interest expense	457	1,886	18	-	2,361
Fair market value of shares and warrants exchanged for repayment	(2,640)	-	(4,379)	-	(7,019)
Difference between market value of common shares and reduction of principal	640	-	2,084	-	2,724
Outstanding balance at November 30, 2023	$ 8,240	$ 37,437	$ -	$ 173	$ 45,850

April 2, 2021 & April 23, 2021 Notes

Key terms of the outstanding convertible notes are as follows:

	November 30, 2023	
	April 2, 2021 Note	April 23, 2021 Note
Interest rate per annum	10 %	10 %
Conversion price per share upon five trading days' notice	$ 10.00	$ 10.00
Party that controls the conversion rights	Investor	Investor
Maturity date	April 5, 2025	April 23, 2025
Security interest	All Company assets excluding intellectual property	

In addition to standard anti-dilution adjustments, the conversion price of the April 2, 2021 Note and April 23, 2021 Note is subject to full-ratchet anti-dilution protection, pursuant to which the conversion price will be automatically reduced to equal the effective price per share in any new offering by the Company of equity securities that have registration rights, are registered, or become registered under the Securities Act of 1933, as amended (the "Securities Act"). The April 2, 2021 Note and April 23, 2021 Note provide for liquidated damages upon failure to deliver common stock within specified timeframes and require the Company to maintain a share reservation of 6.0 million shares of common stock for each Note.

During the six months ended November 30, 2023, in satisfaction of redemptions, the Company and the April 2, 2021 Noteholder entered into four exchange agreements, pursuant to which the April 2, 2021 Note was partitioned into new notes (the "Partitioned Notes") with an aggregate principal amount of $2.0 million, which was exchanged concurrently with the issuance of approximately 12.2 million shares of common stock. The outstanding balance of the

April 2, 2021 Note was reduced by the Partitioned Notes to a principal amount of $4.1 million. The Company accounted for the Partitioned Notes and exchange settlements as induced conversions, and, accordingly, recorded a non-cash loss on convertible debt induced conversion of $2.6 million for the six months ended November 30, 2023.

As of December 31, 2023, the holders of the April 2 and April 23 Notes waived all provisions in the convertible notes that, based on the occurrence of various events through that date, could have triggered the imposition of a default interest rate, a downward adjustment of the conversion price, or specified other provisions relating to default, breach or imposition of a penalty. Accordingly, the Company was not in default under the notes on December 31, 2023.

Please refer to Note 6, *Convertible Instruments and Accrued Interest*, in the Company's 2023 Form 10-K for additional information.

Placement Agent Notes

During the period April through June 2023, the Company entered into securities purchase agreements pursuant to which the Company issued secured promissory notes bearing interest at a rate of 6.0% and with an 18-month term to accredited investors through a placement agent ("Placement Agent Notes") for a total principal amount of $2.3 million, of which $1.3 million was sold in June 2023. The Placement Agent Notes were secured by the net cash recovery, if any, by the Company in its dispute with Amarex and provided the investors with a right to convert the unpaid principal and accrued but unpaid interest into shares of common stock upon the occurrence of an event of default. The Placement Agent Notes had maturity dates during the fiscal year ending May 31, 2025.

In connection with the sale in June 2023, the Company issued warrants to investors to purchase approximately 1.3 million shares of common stock with a three-year term and an exercise price of $0.50 per share. The net proceeds from the sale of the Placement Agent Notes in June of approximately $1.1 million reflect issuance costs of approximately $0.2 million. The Company also issued warrants to purchase approximately 0.4 million shares of common stock to the placement agent with a ten-year term and an exercise price of $0.26 per share, which the Company accounted for as additional issuance costs related to the sale of Placement Agent Notes in June 2023. The Company allocated the proceeds between the liability-classified Placement Agent Notes and the equity-classified warrants based on their relative fair values.

During June 2023, an amendment was entered into with the investors of the Placement Agent Notes, which stated that the principal amount and accrued but unpaid interest on the notes would be converted into shares of common stock and warrants as of the first closing of a subsequent private placement of common stock and warrants through a placement agent. The deemed purchase price of a unit of one share plus one warrant was fixed at 90% of the lower of the intraday volume weighted average price ("VWAP") on the date of the first closing and last closing of the private placement, while the exercise price of the warrants was set at $0.306 per share, compared to $0.50 per share in the original private placement.

In July 2023, the first closing of the subsequent private placement of common stock and warrants through a placement agent occurred. Therefore, the Placement Agent Notes were converted into units with the same pricing as the private placement described in Note 5, *Equity Awards and Warrants – Private placement of common stock and warrants through placement agent*. The $2.1 million difference in fair value between the shares and warrants and the principal amount of the Placement Agent Notes was accounted for as a loss on note extinguishment. See Note 5, *Equity Awards and Warrants – Liability-classified equity instruments* for additional information.

Short-term Notes

During November 2023, the Company began issuing unsecured promissory notes bearing interest at a rate of 10% to accredited investors under a securities purchase agreement through a placement agent ("Short-term Notes"). Short-term Notes for a total principal amount of $0.3 million were issued in November 2023. The principal amount and accrued but unpaid interest on the notes will be converted into units consisting of shares of common stock and warrants as of the first closing of a subsequent private placement of common stock and warrants through a placement agent at a 20% discount to the price at which the units are sold in the private placement. The Short-term Notes' maturity date is June 7, 2024. The Company also agreed to issue warrants at the final closing of the sale of Short-term Notes to purchase one share of common stock for each dollar of principal amount of Short-term Notes sold. The warrants have a five-year term and an exercise price of $0.35 per share. The net proceeds from the sale of the Short-term Notes in November 2023 of $0.2 million reflect issuance costs of approximately $37.5 thousand. The Company allocated the proceeds between the liability-classified Short-term Notes and the equity-classified warrants based on their relative fair values.

The Company also agreed to issue warrants to purchase shares of common stock to the placement agent with a ten-year term, with the number of warrants and the exercise price of the warrants to be determined by the share price on the final closing date of the sale of Short-term Notes. The Company accounted for the warrants to be issued to the placement agent as additional issuance costs. See Note 5, *Equity Awards and Warrants – Liability-classified equity instruments* for additional information.

Note 5. Equity Awards and Warrants

Liability-classified equity instruments

During April and May 2023, the Company sold Placement Agent Notes through a placement agent. See Note 4, *Convertible Instruments and Accrued Interest – Placement Agent Notes*. The Company agreed to issue warrants to the placement agent as part of the issuance costs with an exercise price that was not determined until the final closing date. As the exercise price of the warrants was to be fixed based on the final terms of the offering, the Company accounted for the warrants as a liability-classified warrant beginning on the initial closing date until the final closing date. The value of the warrants at May 31, 2023, was recorded as a derivative liability on the balance sheet, and the change in the fair value of the warrants was recorded as a gain or loss on derivatives. On June 23, 2023, the final closing of the Placement Agent Notes occurred, and the fair value of the warrants became equity classified.

On July 31, 2023, the Placement Agent Notes were converted into units that had similar terms to units being offered in a private placement of shares and warrants through a placement agent. See *Private placement of common stock and warrants through placement agent* below. As the unit price was not determinable until the final closing date of the subsequent private placement, the units related to the conversion of the Placement Agent Notes were recorded as a liability and at fair value. On October 23, 2023, the private placement was concluded, which finalized the unit purchase price at $0.16, and the fair value of the units became equity-classified.

During November 2023, in connection with the issuance of the Short-term Notes as described in Note 4, *Convertible Instruments and Accrued Interest – Short-term Notes*, the Company agreed to issue warrants to the placement agent as part of the issuance costs, with the ultimate number of warrants and exercise price to be determined as of the final closing date of a private placement of common stock and warrants through a placement agent that commenced in December 2023. As the number of warrants and the exercise price of the warrants will be variable until the final closing date, the Company accounted for the warrants as a liability-classified warrant beginning on the initial closing date until the final closing date. The value of the warrants was recorded as a derivative liability on the balance sheet, and the change in the fair value of the warrants is recorded as a gain or loss on derivatives.

In accordance with the prescribed accounting guidance, the Company measured fair value of liability-classified equity instruments using fair value hierarchy which include:

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

Level 2. Observable inputs other than Level 1 prices, such as quoted prices for similar assets or liabilities, quoted prices in markets with insufficient volume or infrequent transactions (less active markets), or

model-derived valuations in which all significant inputs are observable or can be derived principally from or corroborated with observable market data for substantially the full term of the assets or liabilities. Level 2 inputs also include non-binding market consensus prices that can be corroborated with observable market data, as well as quoted prices that were adjusted for security-specific restrictions.

Level 3. Unobservable inputs to the valuation methodology are significant to the measurement of the fair value of assets or liabilities. These Level 3 inputs also include non-binding market consensus prices or non-binding broker quotes that the Company was unable to corroborate with observable market data.

The table below presents a reconciliation of the beginning and ending balances for liabilities measured at fair value as of May 31, 2023, and November 30, 2023:

(in thousands)		Derivative liability
Balance at May 31, 2023	$	79
Value upon notes converted to units in the private offering		4,379
Warrants classified as equity during quarter		(79)
Gain on derivative due to change in fair market value		(4)
Balance at August 31, 2023	$	4,375
Value upon liability-classified equity instruments reclassified to equity		(4,393)
Warrants classified as a liability during quarter		34
Loss on derivative due to change in fair market value		17
Balance at November 30, 2023	$	33

The Company used a Black-Scholes valuation model to estimate the value of the liability-classified warrants using assumptions presented in the table below. The Black-Scholes valuation model was used because management believes it reflects all the assumptions that market participants would likely consider in negotiating the transfer of the warrant. The Company's derivative liability is classified within Level 3.

	Placement Agent warrants at May 31, 2023	Note conversion warrants on conversion date	Placement Agent warrants at equity classification	Note conversion warrants at August 31, 2023	Note conversion warrants at equity classification	Placement Agent warrants at issuance	Placement Agent warrants at November 30, 2023
Fair value of underlying stock	$ 0.26	$ 0.21	$ 0.27	$ 0.21	$ 0.17	$ 0.18	$ 0.17
Risk free rate	3.64%	4.18%	3.74%	4.23%	4.81%	4.42%	4.37%
Expected term (in years)	10.00	5.00	10.00	5.00	5.00	10.00	10.00
Stock price volatility	97.90%	124.55%	97.45%	124.06%	124.70%	95.82%	95.82%
Expected dividend yield	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%

Equity Incentive Plan ("EIP")

As of November 30, 2023, the Company had one active stock-based equity plan, the *CytoDyn Inc. Amended and Restated 2012 Equity Incentive Plan* (the "EIP"). As of November 30, 2023 and May 31, 2023, the EIP covered a total of 56.3 million shares of common stock. The Board also made a determination to waive the "evergreen provision" that would have automatically increased the number of shares of common stock subject to the EIP by an amount equal to 1%

of the total outstanding shares on June 1, 2023. The EIP provides for awards of stock options to purchase shares of common stock, restricted and unrestricted shares of common stock, restricted stock units ("RSUs"), and performance share units ("PSUs").

The Company recognizes the compensation cost of employee and director services received in exchange for equity awards based on the grant date estimated fair value of the awards. The Company estimates the fair value of RSUs and PSUs using the value of the Company's stock on the date of grant. Share-based compensation cost is recognized over the period during which the employee or director is required to provide service in exchange for the award and, as forfeitures occur, the associated compensation cost recognized to date is reversed. For awards with performance-based payout conditions, the Company recognizes compensation cost based on the probability of achieving the performance conditions, with changes in expectations recognized as an adjustment to earnings in the period of change. Any recognized compensation cost is reversed if the conditions ultimately are not met.

Stock-based compensation for the three months ended November 30, 2023 and 2022 was $0.6 million and $1.8 million, respectively, and for the six months ended November 30, 2023 and 2022 was $1.1 million and $3.1 million, respectively. Stock-based compensation is recorded in general and administrative costs.

Stock options

Stock option activity is presented in the table below:

(in thousands, except per share data and years)	Number of shares	Weighted average exercise price	Weighted average remaining contractual life in years	Aggregate intrinsic value
Options outstanding at May 31, 2023	19,823	$ 0.99	7.87	$ —
Granted	500	$ 0.26		
Exercised	—	$ -		
Forfeited, expired, and cancelled	(692)	$ 1.45		
Options outstanding at November 30, 2023	19,631	$ 0.96	7.46	$ —
Options outstanding and exercisable at November 30, 2023	14,187	$ 1.12	6.93	$ —

During the six months ended November 30, 2023 and 2022, stock options for approximately 0.5 million shares and 12.4 million shares, respectively, were granted. The current year options vest when performance conditions are completed. Of the prior year options, 10.9 million options vest over four years, 1.1 million vested over one year, and 0.4 million vested immediately. The Company records compensation expense based on the Black-Scholes fair value per share of the awards on the grant date. The weighted average fair value per share was $0.23 and $0.34 for the six months ended November 30, 2023 and 2022, respectively.

RSUs and PSUs

The EIP provides for equity instruments, such as RSUs and PSUs, which grant the right to receive a specified number of shares over a specified period of time. RSUs and PSUs are service-based awards that vest according to the terms of the grant. PSUs have performance-based payout conditions.

The following table summarizes the Company's RSU and PSU activity:

(shares in thousands)	Number of RSUs and PSUs (1)	Weighted average grant date fair value	remaining contractual life in years
Unvested RSUs and PSUs at May 31, 2023	1,293	$ 0.58	0.81
RSUs and PSUs granted	—	—	
RSUs and PSUs forfeited	(1,293)	0.58	
RSUs and PSUs vested	—	—	
Unvested RSUs and PSUs at November 30, 2023	—	$ —	—

(1) The number of PSUs disclosed in this table are at the target level of 100%.

Issuance of shares to consultants and employees

The Board has approved the issuance under the EIP of shares of common stock to consultants as payment for services provided. During the six months ended November 30, 2023 and 2022, a total of 1,091,865 and 510,872 shares of common stock, respectively, were issued pursuant to the respective award agreements with the consultants.

In order to preserve cash resources, the Board has approved the issuance under the EIP of shares of common stock as severance payments to former employees. During the six months ended November 30, 2023 and 2022 a total of 153,027 and 460,095 shares of common stock, respectively, were issued as severance.

Private placement of common stock and warrants through placement agent

In July 2023, the Company commenced a private placement of units consisting of common stock and warrants to accredited investors through a placement agent. Each unit sold included a fixed combination of one share of common stock and one warrant to purchase one share of common stock. The purchase price per unit was $0.16, equal to 90% of the intraday VWAP of the common stock as of the last closing on September 27, 2023. From July through September 2023, the Company sold a total of approximately 21.5 million units for a total of approximately $3.0 million of proceeds, net of issuance costs. The Company classified the securities issued in the private placement as a liability until the final close, when it was reclassified as equity. As part of the offering, the Company issued approximately 21.5 million warrants to investors, with each such warrant having a five-year term and an exercise price of $0.50 per share. The warrants were immediately exercisable. In connection with the above, the Company paid the placement agent a total cash fee of approximately $0.4 million, equal to 12% of the gross proceeds of the offering, as well as a one-time fee for expenses of $5,000, and issued to the placement agent and its designees, a total of approximately 3.2 million warrants with an exercise price of $0.16 per share and a ten-year term, representing 15% of the total number of shares of common stock sold in the offering.

Based on contractual payment terms, the private placement transactions above are considered convertible debt instruments prior to final settlement, and the option to enter a final closing that would lower the purchase price is considered a share-settled redemption feature. Therefore, the approximately $0.9 million of cash and non-cash issuance costs associated with such issuances were capitalized and subsequently recognized through the statement of operations as interest expense on the final closing date. As the VWAP of the final closing was lower than the VWAP on the initial closing, the share-settled redemption feature was triggered, and the Company recorded a $2.4 non-cash million loss on note extinguishment.

In addition, approximately $2.3 million principal and interest of the Placement Agent Notes were converted into approximately 14.3 million units with the same terms as described above except for a warrant exercise price of $0.306. See Note 4, *Convertible Instruments and Accrued Interest – Placement Agent Notes*, and *Liability-classified equity instruments* above for additional information.

Warrants

Warrant activity is presented in the table below:

(in thousands, except for share data and years)	Number of shares	Weighted average exercise price	Weighted average remaining contractual life in years	Aggregate intrinsic value
Warrants outstanding at May 31, 2023	259,910	$ 0.37	4.57	$ 7,276
Granted	42,019	$ 0.40		
Exercised	(3,000)	$ 0.10		
Forfeited, expired, and cancelled	(5,603)	$ 0.75		
Warrants outstanding at November 30, 2023	293,326	$ 0.37	4.31	$ 2,902
Warrants outstanding and exercisable at November 30, 2023	293,326	$ 0.37	4.31	$ 2,902

Warrant exercises

During the six months ended November 30, 2023, the Company issued approximately 3.0 million shares of common stock in connection with the exercise of an equal number of warrants. The stated exercise price was $0.10 per share, which resulted in aggregate gross proceeds of approximately $0.3 million.

Note 6. Loss per Common Share

Basic loss per share is computed by dividing the net loss adjusted for preferred stock dividends by the weighted average number of common shares outstanding during the period. Diluted loss per share includes the weighted average common shares outstanding and potentially dilutive common stock equivalents. Because of the net losses for all periods presented, the basic and diluted weighted average shares outstanding are the same since including the additional shares would have an anti-dilutive effect on loss per share. The reconciliation of the numerators and denominators of the basic and diluted net loss per share computations are as follows:

(in thousands, except per share amounts)	Three months ended November 30,		Six months ended November 30,	
	2023	2022	2023	2022
Net loss	$ (9,563)	$ (26,495)	$ (21,134)	$ (47,486)
Less: Deemed dividends	—	(1,140)	—	(5,294)
Less: Accrued preferred stock dividends	(368)	(370)	(741)	(756)
Net loss applicable to common stockholders	$ (9,931)	$ (28,005)	$ (21,875)	$ (53,536)
Basic and diluted:				
Weighted average common shares outstanding	958,988	813,373	941,191	800,545
Loss per share	$ (0.01)	$ (0.03)	$ (0.02)	$ (0.07)

The table below shows the approximate number of shares of common stock issuable upon the exercise, vesting, or conversion of outstanding options, warrants, unvested RSUs and PSUs, convertible notes, and convertible preferred

stock (including undeclared dividends) that were not included in the computation of basic and diluted weighted average number of shares of common stock outstanding for the periods presented:

(in thousands)	Three and six months ended November 30,	
	2023	**2022**
Stock options, warrants, and unvested restricted stock units	312,956	204,273
Convertible notes	12,000	12,000
Convertible preferred stock	35,558	32,591

Note 7. Income Taxes

The Company calculates its quarterly taxes under the effective tax rate method based on applying an anticipated annual effective rate to its year-to-date income, except for discrete items. Income taxes for discrete items are computed and recorded in the period that the specific transaction occurs. The Company's net tax expense for the three and six months ended November 30, 2023 and 2022 was zero. The Company does not consider it more likely than not that the benefits from the net deferred tax assets will be realized; therefore, the Company maintains a full valuation allowance as of November 30, 2023 and May 31, 2023, thus creating a difference between the effective tax rate of 0% and the statutory rate of 21%.

Note 8. Commitments and Contingencies

Commitments with Samsung BioLogics Co., Ltd. ("Samsung")

In April 2019, the Company entered into several agreements with Samsung, pursuant to which Samsung agreed to perform technology transfer, process validation, manufacturing, pre-approval inspection, and supply services for the commercial supply of leronlimab bulk drug substance. In 2020, the Company entered into an additional agreement, pursuant to which Samsung agreed to perform technology transfer, process validation, vial filling, and storage services for clinical, pre-approval inspection, and commercial supply of leronlimab drug product. Under the agreements, Samsung is obligated to procure necessary raw materials for the Company and manufacture a specified minimum number of batches, and the Company is required to provide a rolling three-year forecast of future estimated manufacturing requirements to Samsung that are binding.

On January 6, 2022, Samsung provided written notice to the Company alleging that the Company had materially breached the parties' Master Services and Project Specific Agreements (the "Samsung Agreements") for failure to pay $13.5 million due on December 31, 2021. An additional $22.8 million became due under the agreements on January 31, 2022.

On November 21, 2023, Samsung informed the Company of Samsung's intent to terminate the Samsung Agreements, effective January 5, 2024. As of the date of this filing, the parties remain in communication about the outstanding issues under the agreements and potential options moving forward with Samsung. Under the Samsung Agreements, Samsung may be entitled to terminate its services if the parties cannot agree on the past-due balance. The Company currently holds sufficient leronlimab to conduct its prospective clinical trial(s) in the short term. Management continues to be in contact with Samsung regarding potential approaches to resolve these issues. Samsung paused manufacturing for all unfulfilled commitments not needed by the Company starting in January 2022. Accordingly, the Company has not recorded any accruals associated with the unfulfilled commitments as of November 30, 2023. In the event negotiations are unsuccessful, the Company may have to accrue a liability related to the unfulfilled commitments.

As of November 30, 2023, the Company had past due balances of approximately $32.0 million due to Samsung, which were included in accounts payable.

As of November 30, 2023, the future commitments pursuant to these agreements were estimated as follows (in thousands):

Fiscal Year	Amount
2024 (6 months remaining)	$ 156,388
2025	76,400
2026 and thereafter	—
Total	$ 232,788

Operating lease commitments

We lease our principal office location in Vancouver, Washington (the "Vancouver Lease"). The Vancouver Lease expires on April 30, 2026. Consistent with the guidance in ASC 842, Leases, we have recorded this lease in our consolidated balance sheet as an operating lease. For the purpose of determining the right of use asset and associated lease liability, we determined that the renewal of the Vancouver lease was not reasonably probable. The lease does not include any restrictions or covenants requiring special treatment under ASC 842, Leases. Operating lease costs for the three months ended November 30, 2023 and 2022 were $32.0 thousand and $46.4 thousand, respectively, and for the six months ended November 30, 2023 and 2022 were approximately $0.1 million and $0.1 million, respectively. Operating lease right-of-use assets are included in other non-current assets and the current portion of operating lease liabilities are included in accrued liabilities and compensation on the consolidated balance sheets. The long-term operating lease liabilities are presented separately as operating lease on the consolidated balance sheets. The following table summarizes the operating lease balances:

(in thousands)	November 30, 2023	May 31, 2023
Assets		
Right-of-use asset	$ 332	$ 400
Liabilities		
Current operating lease liability	$ 142	$ 139
Non-current operating lease liability	211	283
Total operating lease liability	$ 353	$ 422

The minimum (base rental) lease payments are expected to be as follows as of November 30, 2023 (in thousands):

Fiscal Year	Amount
2024 (6 months remaining)	$ 91
2025	185
2026	169
Thereafter	—
Total operating lease payments	445
Less: imputed interest	(92)
Present value of operating lease liabilities	$ 353

Supplemental information related to operating leases was as follows:

	November 30, 2023
Weighted average remaining lease term	2.4 years
Weighted average discount rate	10.0 %

Distribution and licensing commitments

Refer to Note 10, *Commitments and Contingencies*, in the 2023 Form 10-K for additional information.

Legal proceedings

As of November 30, 2023, the Company did not record any accruals related to the outcomes of the legal matters described below. It may not be possible to determine the outcome of these proceedings, including the defense and other litigation-related costs and expenses that may be incurred by the Company, as the outcomes of legal proceedings are inherently uncertain. Therefore, it is possible that the ultimate outcome of any proceeding, if in excess of a recognized accrual, if any, could be material to the Company's consolidated financial statements.

Securities Class Action Lawsuits

On March 17, 2021, a stockholder filed a putative class-action lawsuit (the "March 17, 2021 lawsuit") in the U.S. District Court for the Western District of Washington against the Company and certain former officers. The complaint generally alleges the defendants made false and misleading statements regarding the viability of leronlimab as a potential treatment for COVID-19. On April 9, 2021, a second stockholder filed a similar putative class action lawsuit in the same court, which the plaintiff voluntarily dismissed without prejudice on July 23, 2021. On August 9, 2021, the court appointed lead plaintiffs for the March 17, 2021 lawsuit. On December 21, 2021, lead plaintiffs filed an amended complaint, which is brought on behalf of an alleged class of those who purchased the Company's common stock between March 27, 2020 and May 17, 2021. The amended complaint generally alleges that the defendants violated Sections 10(b) and/or 20(a) of the Securities Exchange Act of 1934 and Rule 10b-5 promulgated thereunder by making purportedly false or misleading statements concerning, among other things, the safety and efficacy of leronlimab as a potential treatment for COVID-19, the Company's CD10 and CD12 clinical trials, and its HIV Biologic License Application ("BLA"). The amended complaint also alleges that the individual defendants violated Section 20A of the Exchange Act by selling shares of the Company's common stock purportedly while in possession of material nonpublic information. The amended complaint seeks, among other relief, a ruling that the case may proceed as a class action and unspecified damages and attorneys' fees and costs. On February 25, 2022, the defendants filed a motion to dismiss the amended complaint. On June 24, 2022, lead plaintiffs filed a second amended complaint. The second amended complaint is brought on behalf of an alleged class of those who purchased the Company's common stock between March 27, 2020 and March 30, 2022, makes similar allegations, names the same defendants, and asserts the same claims as the prior complaint, adds a claim for alleged violation of Section 10(b) of the Exchange Act and Rule 10b-5(a) and (c) promulgated thereunder, and seeks the same relief as the prior complaint. All defendants have filed motions to dismiss the second amended complaint in whole or in part. The Company and the individual defendants deny all allegations of wrongdoing in the complaint and intend to vigorously defend the matter. Since this case is in an early stage where the number of plaintiffs is not known, and the claims do not specify an amount of damages, the Company is unable to predict the ultimate outcome of the lawsuit and cannot reasonably estimate the potential loss or range of loss the Company may incur.

2021 Shareholder Derivative Lawsuits

On June 4, 2021, a stockholder filed a purported derivative lawsuit against certain of the Company's former officers and directors, and the Company as a nominal defendant, in the U.S. District Court for the Western District of Washington. Two additional shareholder derivative lawsuits were filed against the same defendants in the same court on June 25, 2021 and August 18, 2021, respectively. The court has consolidated these three lawsuits for all purposes ("Consolidated Derivative Suit"). On January 20, 2022, the plaintiffs filed a consolidated complaint. The consolidated complaint generally alleges that the director defendants breached their fiduciary duties by allowing the Company to make false and misleading statements regarding, among other things, the safety and efficacy of leronlimab as a potential treatment for COVID-19, the Company's CD10 and CD12 clinical trials and its HIV BLA, and by failing to maintain an adequate system of oversight and controls. The consolidated complaint also asserts claims against one or more individual defendants for waste of corporate assets, unjust enrichment, contribution for alleged violations of the federal securities laws, and for breach of fiduciary duty arising from alleged insider trading. The consolidated complaint seeks declaratory and equitable relief, an unspecified amount of damages, and attorneys' fees and costs. The Company and the individual

defendants deny all allegations of wrongdoing in the complaints and intend to vigorously defend the litigation. In light of the fact that the Consolidated Derivative Suit is in an early stage and the claims do not specify an amount of damages, the Company cannot predict the ultimate outcome of the Consolidated Derivative Suit and cannot reasonably estimate the potential loss or range of loss the Company may incur.

Securities and Exchange Commission and Department of Justice Investigations

The Company has received subpoenas from the SEC and the United States Department of Justice ("DOJ") requesting documents and information concerning, among other matters, leronlimab, the Company's public statements regarding the use of leronlimab as a potential treatment for COVID-19, HIV, and triple-negative breast cancer, related communications with the FDA, investors, and others, litigation involving former employees, the Company's retention of investor relations consultants, and trading in the Company's securities. Certain former Company executives and directors have received subpoenas concerning similar issues and have been interviewed by the DOJ and SEC, including the Company's former CEO, Nader Z. Pourhassan.

On January 24, 2022, Mr. Pourhassan was terminated and removed from the Board of Directors and has had no role at the Company since. On December 20, 2022, the DOJ announced the unsealing of a criminal indictment charging both Mr. Pourhassan, and Kazem Kazempour, CEO of Amarex, a subsidiary of NSF International, Inc., and which had formerly served as the Company's contract research organization ("CRO"). Mr. Pourhassan was charged with one count of conspiracy, four counts of securities fraud, three counts of wire fraud, and three counts of insider trading. Mr. Kazempour was charged with one count of conspiracy, three counts of securities fraud, two counts of wire fraud, and one count of making a false statement. That same day, the SEC announced charges against both Mr. Pourhassan and Mr. Kazempour for alleged violations of federal securities laws.

The Company is committed to cooperating fully with the DOJ and SEC investigations, which are ongoing, and which the Company's counsel frequently engages with them on. Further, the Company has made voluminous productions of information and made witnesses available for voluntary interviews. The Company will continue to comply with the requests of the SEC and DOJ. The Company cannot predict the ultimate outcome of the DOJ and SEC investigations or the case against Mr. Pourhassan, nor can it predict whether any other governmental authorities will initiate separate investigations or litigation. The investigations and any related legal and administrative proceedings could include a wide variety of outcomes, including the institution of administrative, civil injunctive, or criminal proceedings involving the Company and/or former executives and/or former directors in addition to Mr. Pourhassan, the imposition of fines and other penalties, remedies and/or sanctions, modifications to business practices and compliance programs, and/or referral to other governmental agencies for other appropriate actions. It is not possible to accurately predict at this time when matters relating to the investigations will be completed, the final outcome of the investigations, what additional actions, if any, may be taken by the DOJ or SEC or by other governmental agencies, or the effect that such actions may have on our business, prospects, operating results, and financial condition, which could be material.

The DOJ and SEC investigations, including any matters identified in the investigations and indictments, could also result in (1) third-party claims against the Company, which may include the assertion of claims for monetary damages, including but not limited to interest, fees, and expenses, (2) damage to the Company's business or reputation, (3) loss of, or adverse effect on, cash flow, assets, results of operations, business, prospects, profits, or business value, including the possibility of certain of the Company's existing contracts being cancelled, (4) adverse consequences on the Company's ability to obtain or continue financing for current or future projects, and/or (5) claims by directors, officers, employees, affiliates, advisors, attorneys, agents, debt holders or other interest holders, or constituents of the Company or its subsidiaries, any of which could have a material adverse effect on the Company's business, prospects, operating results, and financial condition. Further, to the extent that these investigations and any resulting third-party claims yield adverse results over time, such results could jeopardize the Company's operations, exhaust its cash reserves, and could cause stockholders to lose their entire investment.

Amarex Dispute

On October 4, 2021, the Company filed a complaint for declaratory and injunctive relief and a motion for a preliminary injunction against NSF International, Inc. and its subsidiary Amarex, the Company's former CRO. Over the

past eight years, Amarex provided clinical trial management services to the Company and managed numerous clinical studies of the Company's drug product candidate, leronlimab. On December 16, 2021, the U.S. District Court for the District of Maryland issued a preliminary injunction requiring Amarex to provide the Company with access to all of its materials in the possession of Amarex. The court also granted CytoDyn the right to conduct an audit of Amarex's work for CytoDyn. That case has been administratively closed. The Company simultaneously filed a demand for arbitration with the American Arbitration Association. In response, Amarex filed a counterclaim alleging that CytoDyn has failed to pay certain invoices due under the contract between the parties.

On July 10, 2023, the Company filed a Statement of Particulars and requested a final hearing date be set in the proceeding against Amarex. The Statement of Particulars alleges that Amarex failed to perform services to an acceptable professional standard and failed to perform certain services required by the parties' agreements. Further, the Statement of Particulars alleges that Amarex billed the Company for services it did not perform. The Company contends that, due to Amarex's failures, it has suffered avoidable delays in obtaining regulatory approval of leronlimab and has paid for services not performed, among other damages. As the formal arbitration process is still at an early stage, the Company cannot predict the ultimate outcome of the lawsuit and cannot reasonably estimate the potential loss or range of loss that the Company may incur.

Following a formal scheduling request by the Company, the final arbitration hearing was recently ordered to commence on August 19, 2024, and the parties are now in the discovery phase of the litigation.

Note 9. Subsequent Events

Issuance of Short-term Notes

In December 2023, the Company entered into securities purchase agreements pursuant to which the Company issued Short-term Notes with a six-month term to accredited investors in the aggregate principal amount of approximately $0.8 million through a placement agent. The Company also issued warrants to purchase approximately 0.8 million shares of common stock with a five-year term and an exercise price of $0.35 as part of the debt issuance. The Company also issued warrants to purchase approximately 0.4 million shares of common stock to the placement agent with a ten-year term. The exercise price for the warrants issued to the placement agent was determined to be $0.35 per share, based on the intraday VWAP of the Company's stock on December 7, 2023. The net proceeds of approximately $0.7 million reflect issuance costs of approximately $0.1 million.

The principal and accrued interest on the Short-term Notes were converted into units based on a price of $0.14 per unit, which represented 80% of the unit pricing in the offering described above. Units for a total of approximately 7.2 million shares of common stock and additional fully exercisable warrants to purchase a total of approximately 7.2 million shares of common stock at a price of $0.35 per share were issued to the investors in connection with the conversion.

Private placement of common stock and warrants through placement agent

In December 2023, the Company commenced a private placement of units consisting of common stock and warrants to accredited investors through a placement agent. Each unit sold included a fixed combination of one share of common stock and one warrant to purchase one share of common stock. Each unit has a purchase price of $0.17, which was equal to 90% of the closing price of the common stock on December 29, 2023. During December 2023, the Company sold a total of approximately 10.3 million units for a total of approximately $1.5 million of proceeds, net of issuance costs. The Company classified the securities issued in the private placement through the placement agent as a liability until the final issuance date. As part of the offering, the Company will issue approximately 10.3 million warrants to investors, with each such warrant having a five-year term and an exercise price of $0.35 per share. The warrants were immediately exercisable. In connection with the above, the Company paid the placement agent a total cash fee of approximately $0.2 million, equal to 13% of the gross proceeds of the offering, as well as a one-time fee for expenses of $5.0 thousand, and will issue a total of approximately 1.5 million warrants with an exercise price of $0.17 per share and a ten-year term, representing 15% of the total number of common stock sold in the offering, to the placement agent and its designees.

Induced note conversions

During December 2023, in satisfaction of redemptions, the Company and the April 2, 2021 Noteholder entered into exchange agreements, pursuant to which a portion of the April 2, 2021 Note was partitioned into new notes with an aggregate principal amount of approximately $1.3 million, which were exchanged concurrently with the issuance of approximately 8.3 million shares of common stock.

Stock option cancellations and issuances

On January 3, 2024, the Board's Compensation Committee approved the grant of nonqualified stock options to purchase a total of 10,750,779 shares of common stock under the EIP with an exercise price of $0.21 per share. The grants covered a total of (i) 4,000,000 options granted to the Company's five directors; (ii) 2,980,222 options granted to two of the Company's executive officers; and (iii) 3,770,557 options granted to non-executive employees of the Company. The Compensation Committee also approved the cancellation of a total of 4,060,779 outstanding options with exercise prices ranging from $0.41 to $5.57 per share held by executive officers and non-executive employees, with an equal number of options with the same vesting schedules and expiration dates as the cancelled options issued as replacement options as part of the January 3, 2024 option grants. The remaining 6,690,000 options have a ten-year term, with the options granted to directors vesting through May 31, 2024, and those granted to officers and employees vesting through May 31, 2027.

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

Certain information included in this quarterly report on Form 10-Q contains, or incorporates by reference, forward-looking statements within the meaning of Section 21E of the Exchange Act. Words and expressions reflecting optimism, satisfaction or disappointment with current prospects, as well as words such as "believes," "hopes," "intends," "estimates," "expects," "projects," "plans," "anticipates" and variations thereof, or the use of future tense, identify forward-looking statements, but their absence does not mean that a statement is not forward-looking.

Our forward-looking statements are not guarantees of performance, and actual results could vary materially from those contained in or expressed by such statements. In evaluating all such statements, we urge you to specifically consider various risks identified in Part II, Item 1A and elsewhere in this quarterly report, and those set forth in Item 1A. *Risk Factors* in our Annual Report on Form 10-K for the fiscal year ended May 31, 2023 (the "2023 Form 10-K"), any of which could cause actual results to differ materially from those indicated by our forward-looking statements. Our forward-looking statements reflect our current views with respect to future events and are based on currently available financial, economic, scientific, and competitive data and information about current business plans. Forward-looking statements include, among others, statements about leronlimab, its ability to have positive health outcomes, the Company's ability to resolve the clinical hold imposed by the FDA in December 2023, and information regarding future operations and clinical studies and trials, future operating and capital expenditures, and future availability of capital. You should not place undue reliance on our forward-looking statements, which are subject to risks and uncertainties relating to, among other things: the regulatory determinations of leronlimab's safety and effectiveness by the FDA and various drug regulatory agencies in other countries; the Company's ability to raise additional capital to fund its operations; the Company's ability to meet its debt and other payment obligations; the Company's ability to enter into or maintain partnership or licensing arrangements with third parties; the Company's ability to recruit and retain key employees; the timely and sufficient development, through internal resources or third-party consultants, of analyses of the data generated from the Company's clinical trials required by the FDA or other regulatory agencies in connection with the Company's regulatory submissions or applications for approval of the Company's drug product; the Company's ability to achieve approval of a marketable product; the design, implementation and conduct of clinical trials; the results of any such clinical trials, including the possibility of unfavorable clinical trial results; the market for, and marketability of, any product that is approved; the existence or development of vaccines, drugs, or other treatments that are viewed by medical professionals or patients as superior to the Company's products; regulatory initiatives, compliance with governmental regulations and the regulatory approval process; the Company's ability to resolve its disputes with Amarex and Samsung; other legal proceedings, investigations or inquiries affecting the Company or its products; stockholder actions or proposals with regard to the Company, its management, or its Board of Directors; and various other matters, many of which are beyond the Company's control. Should one or more of these risks or uncertainties develop, or should underlying assumptions prove to be incorrect, actual results may vary materially and adversely from those anticipated, believed, estimated, or otherwise indicated by our forward-looking statements. Except as required by law, we do not undertake any responsibility to update these forward-looking statements to address events or circumstances that occur after the date of this quarterly report. Additionally, we do not undertake any responsibility to update you on the occurrence of any unanticipated events that may cause actual results to differ from those expressed or implied by these forward-looking statements.

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our 2023 Form 10-K, and the other sections of this Form 10-Q, including our consolidated financial statements and related notes set forth in Part I, Item 1. This discussion and analysis contain forward-looking statements, including information about possible or assumed results of our financial condition, operations, plans, objectives and performance that involve risks, uncertainties and assumptions. The actual results may differ materially from those anticipated and set forth in such forward-looking statements.

Overview

The Company is a clinical stage biotechnology company focused on the clinical development and potential commercialization of its product candidate, leronlimab, which is being studied for MASH, MASH-HIV, solid tumors in oncology, and other HIV indications. The Company's focus is on implementing a therapeutic development and commercialization pathway for leronlimab through an approach that is opportunistic and minimizes the amount of

Company capital needed for the creation of value by identifying strategies that are time- and cost-effective and support the creation of non-dilutive financing opportunities, such as license agreements and co-development or strategic partnerships. Our current business strategy is to seek the removal of the clinical hold imposed by the FDA in December 2023, and proceed towards conducting a Phase II study evaluating the effects of leronlimab on chronic immune activation and inflammation in cisgender men and women and transgender women living with HIV; pursuing research and development of longer-acting molecules, including for the treatment and/or prevention of HIV; evaluating whether to conduct a combination pre-clinical study or monotherapy Phase 2b/3 clinical trial in MASH; evaluating opportunities for pre-clinical studies in solid tumors in oncology and publishing data from previously conducted studies; and resolving legal, regulatory, and financial matters.

Second Quarter Overview

HIV program and clinical hold developments

In March 2022, the FDA notified the Company that it had placed a partial clinical hold on the Company's HIV program. The FDA's hold letter requested that the Company provide the agency with an aggregate analysis of cardiovascular events across all leronlimab clinical programs, a Safety Surveillance Plan, an aggregate safety data analysis, an updated Investigator's Brochure, annual reports, a benefit-risk assessment, and a general investigational plan. In November 2023, the Company submitted a response to the FDA's clinical hold letter addressing comments received through previous incomplete response communications and an informal meeting with the agency primarily related to the benefit-risk assessment for the intended HIV population and the proposed new HIV clinical trial protocol. The Company held a series of advisory board meetings with key opinion leaders in the HIV space to further inform responses to the FDA's comments with regard to the benefit-risk analysis and an appropriate population of patients for a future clinical trial in HIV who could benefit from leronlimab given the current competitive landscape. The FDA notified the Company in early December 2023 that the partial clinical hold on the HIV program had been lifted.

At the same time, the FDA notified the Company that it had issued a new full clinical hold related to the newly proposed clinical trial protocol the Company submitted in November 2023, alongside its complete response to the partial clinical hold. The FDA's new hold and comments relate to the design of the trial, particularly with regard to the measurement of endpoints, control arms, dose selection, and study-stopping rules. The newly proposed HIV clinical trial is a Phase II study evaluating the effects of leronlimab on chronic immune activation and inflammation in cisgender men and women and transgender women living with HIV. Chronic immune activation and inflammation are a complicated and critical unmet need which can cause strokes, heart attacks, and other vascular events, and remains the leading cause of death in people with HIV. The Company is currently diligently working to resolve the FDA's comments associated with its newly proposed clinical trial protocol and expects to submit a revised protocol incorporating the FDA's guidance by the end of January 2024.

Long-acting CCR5 antagonist developments

In March 2023, the Company entered into a joint development agreement with a third-party generative artificial intelligence ("AI") drug discovery and development company to develop one or more longer-acting molecules. The Company believes working with a partner with AI capabilities will result in the expedited development of a modified, longer-acting therapeutic, and could lead to greater acceptance by patients due to the requirement for less frequent injections. The services provided by the third party may yield extended intellectual property protection, thereby increasing the value of the Company's patent portfolio. In December 2023, the Company received various iterations of potential long-acting therapeutics, on which the Company will be performing assays to determine the suitability and feasibility of the long-acting therapeutic candidates for further development.

MASH program developments

The Company is currently evaluating whether to perform a combination therapy pre-clinical study in MASH that could generate valuable data leading to potential non-dilutive financing opportunities and would be significantly less

capital-intensive than a human clinical trial. The Company has also developed a Phase 2b/3 clinical trial protocol for a future MASH monotherapy clinical trial.

Cancer program developments

In December 2023, the Company entered into a partnership with Albert Einstein College of Medicine and Montefiore Medical Center, located in New York. The Company will be providing leronlimab to support a pre-clinical study evaluating the efficacy of leronlimab independently and in combination with temozolomide in treating glioblastoma multiforme, also known as grade IV astrocytoma ("GBM") in infected humanized mice. The study will involve three groups of humanized mice: one control group, one group that will receive only leronlimab, and another group that will receive a combination of leronlimab and temozolomide. The primary objective of this study is to evaluate the effect of leronlimab on the primary tumor growth and occurrence of metastases on CCR5+ and CCR5- cells in humanized mice. Upon completion of the study, the academic institutions will provide the Company with a research report outlining the study results, and they will have the right to publish and present the study results. GBM is the most common type of primary malignant brain tumor and is aggressive and fast-growing. This study is expected to take place in the 2024 calendar year.

The Company continues to identify the next steps in the clinical development of leronlimab and is exploring potential business opportunities to continue the investigation of leronlimab for solid tumors in oncology based on data generated to date by the Company.

Corporate developments

On September 19, 2023, the Company received notice from the Company's then current independent registered public accounting firm, Macias Gini & O'Connell LLP ("MGO"), that MGO declined to stand for re-election as the Company's fiscal year 2024 registered public accounting firm. The Company's Audit Committee had considered, but had not formally taken action regarding, a change in the Company's independent registered public accounting firm prior to September 19, 2023. On October 6, 2023, the Audit Committee engaged BF Borgers CPA PC and appointed the firm as the Company's independent registered public accounting firm for the Company's fiscal year ending May 31, 2024.

On November 9, 2023, at the Company's annual meeting, our stockholders voted in favor of an amendment to the Company's Certificate of Incorporation to provide for an increase in the total number of shares of common stock authorized for issuance from 1,350,000,000 shares to 1,750,000,000 shares. Additionally, stockholders voted in favor of the reelection of existing directors and on an advisory basis in favor of named executive officer compensation.

On November 17, 2023, the Company appointed Jacob Lalezari, M.D., as interim CEO. Dr. Lalezari is responsible for leading the Company's corporate and product development, with a focus on short-term clinical development and related fundraising. Antonio Migliarese, who had been serving as interim president since May 2023, in addition to CFO, resumed his previous role as CFO.

On November 21, 2023, Samsung informed the Company of Samsung's intent to terminate, effective January 5, 2024, the Master Services Agreement (the "Agreement") entered into between Samsung and the Company in April 2019. As of the date of this filing, the parties remain in communication about the outstanding issues under the Agreement and potential options moving forward. The Agreement provides for Samsung to perform non-exclusive services relating to technology transfer, process validation, manufacturing, pre-approval inspection, vial filling, and supply and storage services for leronlimab bulk drug substance and drug product. Samsung paused manufacturing for all unfulfilled commitments under the Agreement in January 2022. The Company currently holds sufficient leronlimab to conduct its prospective clinical trial(s) in the short term. As of the date of this filing, the Company continues its efforts to resolve outstanding issues under the Agreement with Samsung.

During the quarter ended November 30, 2023, the Company concluded a private offering through a placement agent for a total net proceeds of approximately $3.0 million, including approximately $0.4 million during the quarter. Additionally, the Company commenced a sale of unsecured promissory notes during the quarter resulting in net proceeds

of approximately $0.2 million. Subsequent to November 30, 2023, the Company continued the sale of unsecured promissory notes and commenced a private offering through a placement agent, resulting in aggregate net proceeds of approximately $0.7 million and $1.5 million, respectively.

Results of Operations

Fluctuations in operating results

The Company's operating results may fluctuate significantly depending on the outcomes, number and timing of pre-clinical and clinical studies, patient enrollment and/or completion rates in the studies, and their related effect on research and development expenses, regulatory and compliance activities, activities related to seeking removal of the clinical hold and FDA approval of our drug product, general and administrative expenses, professional fees, and legal and regulatory proceedings and related consequences. We require a significant amount of capital to continue to operate; therefore, we regularly conduct financing offerings to raise capital, which may result in various forms of non-cash interest expense or other expenses. Additionally, we periodically seek to negotiate settlement of debt payment obligations in exchange for equity securities of the Company and enter into warrant exchanges or modifications that may result in non-cash charges. Our ability to continue to fund operations will depend on our ability to raise additional funds. See the *Liquidity and Capital Resources* and *Going Concern* sections in this Item 2 of Part I and Part II, Item 1A Risk Factors included in this quarterly report and Item 1A. *Risk Factors* in our 2023 Form 10-K.

The results of operations were as follows for the periods presented:

	Three months ended November 30,		Change		Six months ended November 30,		Change	
(in thousands, except for per share data)	2023	2022	$	%	2023	2022	$	%
Operating expenses:								
General and administrative	$ 2,311	$ 5,043	$ (2,732)	(54)%	$ 4,999	$ 11,376	$ (6,377)	(56)%
Research and development	1,079	137	942	688	2,993	713	2,280	320
Amortization and depreciation	8	54	(46)	(85)	18	153	(135)	(88)
Inventory charge	—	17,929	(17,929)	(100)	—	20,633	(20,633)	(100)
Total operating expenses	3,398	23,163	(19,765)	(85)	8,010	32,875	(24,865)	(76)
Operating loss	(3,398)	(23,163)	19,765	85	(8,010)	(32,875)	24,865	76
Interest and other expenses:								
Interest on convertible notes	(1,164)	(1,159)	(5)	(0)	(2,361)	(2,305)	(56)	(2)
Amortization of discount on convertible notes	(142)	(580)	438	76	(542)	(1,156)	614	53
Amortization of debt issuance costs	(3)	(18)	15	83	(369)	(34)	(335)	(985)
Issuance costs for private placement of shares and warrants through placement agent	(906)	—	(906)	(100)	(906)	—	(906)	(100)
Loss on induced conversion	(636)	(638)	2	0	(2,640)	(638)	(2,002)	(314)
Finance charges	(891)	(937)	46	5	(1,803)	(1,877)	74	4
Loss on note extinguishment	(2,406)	—	(2,406)	(100)	(4,490)	—	(4,490)	(100)
Gain (loss) on derivatives	(17)	—	(17)	(100)	(13)	(8,601)	8,588	100
Total interest and other expenses	(6,165)	(3,332)	(2,833)	(85)	(13,124)	(14,611)	1,487	10
Loss before income taxes	(9,563)	(26,495)	16,932	64	(21,134)	(47,486)	26,352	55
Income tax benefit	—	—	—	—	—	—	—	—
Net loss	$ (9,563)	$ (26,495)	$ 16,932	64 %	$ (21,134)	$ (47,486)	$ 26,352	55 %
Basic and diluted:								
Weighted average common shares outstanding	958,988	813,373	145,615	18	941,191	800,545	140,646	18
Loss per share	$ (0.01)	$ (0.03)	$ 0.02	67 %	$ (0.02)	$ (0.07)	$ 0.05	71 %

General and administrative ("G&A") expenses

G&A expenses consisted of the following:

	Three months ended November 30,		Change		Six months ended November 30,		Change	
(in thousands)	2023	2022	$	%	2023	2022	$	%
Salaries, benefits, and other compensation	$ 461	$ 979	$ (518)	(53)%	$ 1,103	$ 2,257	$ (1,154)	(51)%
Stock-based compensation	572	1,777	(1,205)	(68)	1,075	3,118	(2,043)	(66)
Legal fees	476	1,044	(568)	(54)	793	2,497	(1,704)	(68)
Insurance	521	687	(166)	(24)	937	1,371	(434)	(32)
Other	281	556	(275)	(49)	1,091	2,133	(1,042)	(49)
Total general and administrative	$ 2,311	$ 5,043	$ (2,732)	(54)%	$ 4,999	$ 11,376	$ (6,377)	(56)%

The decreases in G&A expenses for the three- and six-month periods ended November 30, 2023, compared to the same periods in the prior year, were primarily due to a reduction in legal fees, other, stock-based compensation, and salaries, benefits, and other compensation. The decreases in legal fees were primarily due to decreased legal fees related to the SEC and DOJ investigations, offset by a decrease in the amount of fees covered by the Company's insurance carrier(s) and increased fees related to the Amarex litigation. Additionally, for the three-month period ending November 30, 2023, legal fees were further decreased due to a reduction in fees related to regulatory and corporate related matters. The decreases in other expenses were primarily the result of a reduction in auditor and audit-related fees. The decreases in stock-based compensation and salaries, benefits, and other compensation were primarily related to headcount reductions as an effort by the Company to preserve cash and align resources with necessary corporate priorities.

Research and development ("R&D") expenses

R&D expenses consisted of the following:

	Three months ended November 30,		Change		Six months ended November 30,		Change	
(in thousands)	2023	2022	$	%	2023[1]	2022	$	%
Clinical	$ 277	$ (712)	$ 989	(139)%	$ 1,528	$ (631)	$ 2,159	(342)%
Non-clinical	237	(22)	259	(1,177)	488	26	462	1,777
CMC	319	707	(388)	(55)	488	920	(432)	(47)
License and patent fees	246	164	82	50	489	398	91	23
Total research and development	$ 1,079	$ 137	$ 942	688 %	$ 2,993	$ 713	$ 2,280	320 %

(1) Certain prior year amounts have been reclassified from CMC to Clinical and Non-clinical for consistency with the current quarter presentation. These reclassifications have no effect on the reported results of operations.

The increases in R&D expenses in the three- and six-month periods ended November 30, 2023, compared to the same periods in the prior year, were primarily related to a credit balance in prior year clinical expense related to credits received related to the Brazilian COVID-19 trials offset by decreases in costs related to activities focused on addressing the HIV program partial clinical hold and studies completed, paused, or closed in the prior year. Additionally for the six-month period ended November 30, 2023, clinical expenses were further increased by close-out costs incurred related to the Brazilian COVID-19 trials. The increase in non-clinical expenses was primarily driven by activities related to the discovery and development of a long-acting modified therapeutic. The decrease in CMC expenses was primarily driven by the reduction in necessary stability testing of previously manufactured leronlimab.

The future trend of our R&D expenses is dependent on the timing of FDA clearance of the current clinical hold and any future clinical trials, our decision-making and timing of which indications on which to focus our future efforts toward the development and study of leronlimab, which may include pre-clinical and clinical studies for MASH, MASH-HIV, oncology, and other HIV related indications, as well as efforts to develop a long-acting new or modified therapeutic, and the timing and outcomes of such efforts, and the timing of the final close-out of closed studies.

Inventory charge

The decrease in the inventory charge for the three- and six-month periods ended November 30, 2023, compared to the same periods in the prior year was attributable to the full inventory write-off in the prior year due to the pre-launch inventories no longer qualifying for inventory capitalization due to the withdrawal of the Company's BLA submission to the FDA. See Note 3, *Inventories, net*, in the 2023 Form 10-K for additional information.

Interest and other expense

Interest and other expense consisted of the following:

	Three months ended November 30,		Change		Six months ended November 30,		Change	
(in thousands)	2023	2022	$	%	2023	2022	$	%
Interest on convertible notes payable	$ (1,164)	$ (1,159)	$ (5)	(0) %	$ (2,361)	$ (2,305)	$ (56)	2 %
Amortization of discount on convertible notes	(142)	(580)	438	76	(542)	(1,156)	614	(53)
Amortization of debt issuance costs	(3)	(18)	15	83	(369)	(34)	(335)	985
Issuance costs for private placement of shares and warrants through placement agent	(906)	—	(906)	(100)	(906)	—	(906)	(100)
Loss on induced conversion	(636)	(638)	2	0	(2,640)	(638)	(2,002)	314
Finance charges	(891)	(937)	46	5	(1,803)	(1,877)	74	(4)
Loss on note extinguishment	(2,406)	—	(2,406)	(100)	(4,490)	—	(4,490)	(100)
Gain (loss) on derivatives	(17)	—	(17)	(100)	(13)	(8,601)	8,588	(100)
Total interest and other expenses	$ (6,165)	$ (3,332)	$ (2,833)	85 %	$ (13,124)	$ (14,611)	$ 1,487	(10)%

The increase in interest and other expenses for the three-month period ended November 30, 2023, compared with the same period in the prior year, was primarily due to the increase in loss on note extinguishment that resulted from the Company finalizing a private placement at a lower price than the initial closing price, as described above.

The decrease in interest and other expenses for the six-month period ended November 30, 2023, compared to the same period in the prior year, was primarily due to a decrease in non-cash loss on derivatives, offset by increases in loss on note extinguishment and loss on induced conversion. The decrease in loss on derivatives is due to fewer liability-classified warrants in the current six-month period compared to the same period in the prior year. The increase in loss on induced conversions resulted from the Company settling a larger balance of the outstanding convertible debt with common stock during the current six-month period compared to the prior period. The increase in loss on note extinguishment resulted from the Company retiring outstanding convertible debt by converting notes outstanding to common stock and warrants and due to the final closing price of the private placement being lower than the initial closing price, which resulted in a loss on note extinguishment during the current six-month period.

Liquidity and Capital Resources

As of November 30, 2023, we had a total of approximately $0.1 million in cash and $6.6 million in restricted cash and approximately $123.4 million in short-term liabilities. We expect to continue to incur operating losses and require a significant amount of capital in the future as we continue to develop and seek approval to commercialize leronlimab. We cannot be certain, however, that future funding will be available to us when needed on terms that are acceptable to us, or at all. We sell securities and incur debt when the terms of such arrangements are deemed acceptable to both parties under then current circumstances and as necessary to fund our current and projected cash needs. As of December 31, 2023, we have approximately 371.0 million shares of common stock available for issuance in new financing transactions.

Since inception, the Company has financed its activities principally from the public and private sale of equity securities as well as with proceeds from issuance of convertible notes and related party notes payable. The Company intends to finance its future operating activities and its working capital needs largely from the sale of equity and debt securities. The sale of equity and convertible debt securities to raise additional capital is likely to result in dilution to

stockholders and those securities may have rights senior to those of common shares. If the Company raises funds through the issuance of additional preferred stock, convertible debt securities or other debt or equity financing, the related transaction documents could contain covenants restricting its operations.

During the 2021 fiscal year, the Company entered into long-term convertible notes that are secured by all of our assets (excluding our intellectual property), and include certain restrictive provisions, including limitations on incurring additional indebtedness and future dilutive issuances of securities, any of which could impair our ability to raise additional capital on acceptable terms.

Future third-party funding arrangements may also require the Company to relinquish valuable rights. Additional capital, if available, may not be available on reasonable or non-dilutive terms.

Cash

The Company's cash and restricted cash position of approximately $0.1 million and $6.6 million, respectively, as of November 30, 2023, decreased by approximately $2.4 million and increased by approximately $0.1 million, respectively, when compared to the balance of $2.5 million and $6.5 million, respectively, as of May 31, 2023. This decrease was primarily the result of approximately $7.0 million in cash used in our operating activities, offset by approximately $4.7 million in cash provided by financing activities during the six months ended November 30, 2023. Refer to Item 1, Note 2, *Summary of Significant Accounting Policies – Going Concern*, and the *Going Concern* discussion below for information regarding concerns about the Company's ability to continue to fund its operations and satisfy its payment obligations and commitments. A summary of cash flows and changes between the periods presented is as follows:

(in thousands)	Six months ended November 30, 2023	Six months ended November 30, 2022	Change $
Net cash (used in) provided by:			
Net cash used in operating activities	$ (6,997)	$ (15,480)	$ 8,483
Net cash provided by/ used in investing activities	$ —	$ —	$ —
Net cash provided by financing activities	$ 4,673	$ 13,852	$ (9,179)

Cash used in operating activities

Net cash used in operating activities totaled approximately $7.0 million during the six months ended November 30, 2023, representing an improvement of approximately $8.5 million compared to the six months ended November 30, 2022. The decrease in the net amount of cash used was due primarily to a decrease in our net loss, primarily attributable to decreased G&A expense, and working capital fluctuations, all of which are highly variable. Refer to *General and Administrative Expenses* section for further discussion.

Cash provided by financing activities

Net cash provided by financing activities totaled approximately $4.7 million during the six months ended November 30, 2023, a decrease of approximately $9.2 million compared to the six months ended November 30, 2022. The decrease in net cash provided was primarily the result of raising less funds from private placements of common stock and warrants, partially offset by an increase in funds from the issuance of convertible notes.

Pre-launch inventories

The Company previously capitalized pre-launch inventories which were subsequently charged-off in October of 2022 for GAAP accounting purposes due to no longer qualifying for pre-launch inventory capitalization. Work-in-progress and finished drug product inventories continue to be physically maintained, can be used for clinical trials, and can be sold commercially upon regulatory approval if the shelf-lives can be extended as a result of the performance of on-going stability tests. Raw materials continued to be maintained so that they can be used in the future if needed.

The table below summarizes previously capitalized pre-launch inventories that were subsequently charged-off for GAAP accounting purposes due to no longer qualifying for pre-launch inventory capitalization due to the withdrawal of the Company's BLA in October 2022 and estimated expiration based on remaining shelf life.

		Raw Materials				Work-in-progress		
(in thousands, Expiration period ending November 30,)	**Remaining shelf-life (mos)**	**Specialized**	**Resins**	**Other**	**Total Raw Materials**	**Bulk drug product**	**Finished drug product**	**Total inventories**
2023	None	$ 4,764	$ 16,264	$ —	$ 21,028	$ —	$ —	$ 21,028
2024	1 to 12	2,511	—	1,589	4,100	1,661	29,142	34,903
2025	13 to 24	189	—	—	189	—	32,343	32,532
2026	25 to 36	2,115	—	—	2,115	—	—	2,115
Thereafter	37 or more	—	—	—	—	—	—	—
Inventories, gross		9,579	16,264	1,589	27,432	1,661	61,485	90,578
Inventory charge		(9,579)	(16,264)	(1,589)	(27,432)	(1,661)	(61,485)	(90,578)
Inventories, net		$ —	$ —	$ —	$ —	$ —	$ —	$ —

For additional information, refer to Note 3, *Inventories, net*, in the 2023 Form 10-K.

Convertible debt

April 2, 2021 Convertible Note

On April 2, 2021, we issued a convertible note with a principal amount of $28.5 million resulting in net cash proceeds of $25.0 million, after $3.4 million of debt discount and $0.1 million of offering costs. The note accrues interest daily at a rate of 10% per annum, contains a stated conversion price of $10.00 per share, and matures in April 2025. The April 2, 2021 Note required monthly debt reduction payments of $7.5 million for the six months beginning in May 2021, which could also be satisfied by payments on other notes held by the noteholder or its affiliates. Beginning six months after the issuance date, the noteholder may request monthly redemptions of up to $3.5 million. As of November 30, 2023, the outstanding balance of the April 2, 2021 Note, including accrued interest, was approximately $8.3 million.

April 23, 2021 Convertible Note

On April 23, 2021, we issued a convertible note with a principal amount of $28.5 million resulting in net cash proceeds of $25.0 million, after $3.4 million of debt discount and $0.1 million of offering costs. The note accrues interest daily at a rate of 10% per annum, contains a stated conversion price of $10.00 per share, and matures in April 2025. Beginning six months after the issuance date, the noteholder may request monthly redemptions of up to $7.0 million. As of November 30, 2023, the outstanding balance of the April 23, 2021 Note, including accrued interest, was approximately $38.0 million.

Short-term Notes

During November 2023, the Company entered into a securities purchase agreement pursuant to which the Company began issuing unsecured promissory notes bearing interest at a rate of 10% and with a maturity date of June 7, 2024, to accredited investors through a placement agent. The Short-term Notes will be converted into units consisting of shares of common stock and warrants as of the first closing of a subsequent private placement of common stock and warrants through a placement agent. As of November 30, 2023, the outstanding balance of the Short-term Notes, including accrued interest, was approximately $0.3 million.

Common stock

We have 1,750.0 million authorized shares of common stock. The table below summarizes intended uses of common stock.

(in millions)	As of November 30, 2023
Issuable upon:	
Warrants exercise	293.3
Convertible preferred stock and undeclared dividends conversion	35.6
Outstanding stock options exercise	19.6
Reserved for issuance pursuant to future stock-based awards under equity incentive plan	20.1
Reserved and issuable upon conversion of outstanding convertible notes	12.0
Reserved for private placement of warrants through a placement agent	0.5
Total shares reserved for future uses	381.1
Common stock outstanding	970.8

As of November 30, 2023, we had approximately 398.1 million unreserved authorized shares of common stock available for issuance. Our ability to continue to fund our operations depends on our ability to raise capital. The funding necessary for our operations may not be available on acceptable terms, or at all. If we deplete our cash reserves, we may be forced to file for bankruptcy protection, discontinue operations, or liquidate our assets.

Off-Balance Sheet Arrangements

As of November 30, 2023, we did not have any off-balance sheet arrangements that have, or are reasonably likely to have, a material effect on our current or future financial condition, results of operations, liquidity, capital expenditures or capital resources.

Contractual Obligations

Refer to Note 3, *Accounts Payable and Accrued Liabilities and Compensation*, Note 4, *Convertible Instruments and Accrued Interest*, and Note 8*, Commitments and Contingencies* included in Part I, Item 1 of this Form 10-Q, and Notes 6 and 10 in Part II, Item 8 in the 2023 Form 10-K.

Legal Proceedings

The Company is a party to various legal proceedings described in Part I, Item 1, Note 8, *Commitments and Contingencies – Legal Proceedings* of this Form 10-Q. We are unable to predict the outcome of these proceedings, including the defense and other litigation-related costs and expenses that may be incurred by the Company, as the outcomes of legal proceedings are inherently uncertain. Therefore, it is possible that the ultimate outcome of any proceeding, if in excess of a recognized accrual, if any, could be material to the Company's consolidated financial statements. As of November 30, 2023, the Company had not recorded any accruals related to the outcomes of the legal matters discussed in this Form 10-Q.

Regulatory Matters

Voluntary Withdrawal of HIV BLA Submission

In July 2020, the Company received a Refusal to File letter from the FDA regarding its BLA submission for leronlimab as a combination therapy with highly active antiretroviral therapy for highly treatment-experienced HIV patients. In October 2022, the Company voluntarily withdrew its BLA submission due to management's conclusion that a severe risk of the BLA not receiving approval by the FDA existed due to the Company's former CRO's inadequate process and performance around the monitoring and oversight of the clinical data. For additional information see Part I, Item 1, Note 8, *Commitments and Contingencies – Legal Proceedings*.

FDA HIV and COVID-19 clinical hold letters

In March 2022, the FDA placed a partial clinical hold on the Company's HIV program and a full clinical hold on its COVID-19 program in the United States. The Company was not enrolling any new patients in the trials placed on hold in the United States. Under the full clinical hold on the COVID-19 program, no new clinical studies may be initiated for the COVID-19 indication until the clinical hold is resolved. The Company has made a business decision not to pursue the use of leronlimab in COVID-19 patients, has no plans for further trials under the COVID-19 indication and has withdrawn the investigational new drug ("IND") for COVID-19. Should the opportunity arise, the Company may explore potential non-dilutive clinical development options.

During the third quarter ended February 28, 2023, the Company submitted the documents requested by the FDA in its March 2022 clinical hold letter. Subsequently, the FDA responded through written communication to the Company, requesting additional information and clarification regarding an item that was previously submitted, the benefit-risk assessment for the HIV population, and made a supplemental request that the Company submit an IND amendment containing the proposed general investigational plan for the coming year, appropriate protocols, and any additional information supporting the proposed investigation under the HIV program IND.

In March 2023, the Company responded to and submitted to the FDA the additional information and clarifications requested for the items previously requested. The FDA responded with further written communication requesting information relating to the benefit-risk assessment, as well as requesting the submission of a new protocol for the HIV indication. At the end of March 2023, the Company and the FDA held an informal meeting in which the FDA addressed certain clarifying questions with respect to the clinical hold submission and further information requests made by the FDA. In November 2023, the Company submitted a response to the FDA's clinical hold letter addressing comments received through previous incomplete response communications and an informal meeting with the agency primarily related to the benefit-risk assessment for the intended HIV population and the proposed new HIV clinical trial protocol. The Company held a series of advisory board meetings with key opinion leaders ("KOL") in the HIV space to further inform responses to the FDA's comments with regard to the benefit-risk analysis and an appropriate population of patients for a future clinical trial in HIV who could benefit from leronlimab given the current competitive landscape.

In early December 2023, the FDA notified the Company that the partial clinical hold on the HIV program had been lifted. At the same time, the FDA notified the Company that it had issued a new full clinical hold as it relates to the newly proposed clinical trial protocol submitted alongside the Company's complete response to the partial clinical hold. The FDA's new hold and comments relate to the design of the trial in particular with regard to the measurement of endpoints, controls arms, dose selection, and study-stopping rules. The newly proposed HIV clinical trial is a Phase II study evaluating the effects of 24 weeks of leronlimab on chronic immune activation and inflammation in cisgender men and women and transgender women living with HIV. Chronic immune activation and inflammation is a complicated and critical unmet need which causes strokes, heart attacks, and other vascular events and remains the leading cause of death in people with HIV. The Company is currently diligently working on resolving the FDA's comments associated with its newly proposed clinical trial protocol and expects to submit responses alongside a revised protocol incorporating the FDA's guidance by the end of January 2024.

Going Concern

The accompanying consolidated financial statements have been prepared on a going concern basis, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. As presented in the accompanying consolidated financial statements, the Company had losses for all periods presented. The Company incurred a net loss of approximately $21.1 million in the three months ended November 30, 2023, and has an accumulated deficit of approximately $862.8 million as of November 30, 2023. These factors, among several others, including the various matters discussed in Note 8, *Commitments and Contingencies*, raise substantial doubt about our ability to continue as a going concern. The consolidated financial statements do not include any adjustments relating to the recoverability and classification of assets and liabilities that might be necessary should the Company be unable to continue as a going concern.

The Company's continuance as a going concern is dependent upon its ability to obtain additional operating capital, complete the development of its product candidate, leronlimab, obtain approval to commercialize leronlimab from regulatory agencies, continue to outsource manufacturing of leronlimab, and ultimately achieve revenues and attain profitability. The Company plans to continue to engage in research and development activities related to leronlimab and a new or modified longer-acting therapeutic for multiple indications and expects to incur significant research and development expenses in the future, primarily related to its regulatory compliance, including seeking the lifting of the FDA's clinical hold related to the Company's recently submitted protocol, performing additional clinical trials, and seeking regulatory approval of its product candidate for commercialization. These research and development activities are subject to significant risks and uncertainties. The Company intends to finance its future development activities and its working capital needs primarily from the sale of equity and debt securities, combined with additional funding from other sources. However, there can be no assurance that the Company will be successful in these endeavors. See also *Liquidity and Capital Resources* above.

New Accounting Pronouncements

Refer to Part I, Note 2, *Summary of Significant Accounting Policies* – Recent Accounting Pronouncements in this Form 10-Q for the discussion.

Critical Accounting Policies and Estimates

This discussion and analysis of the Company's financial condition and results of operations is based on our consolidated financial statements, which have been prepared in accordance with GAAP. The preparation of our financial statements and related disclosures requires management to make estimates and judgments that affect the reported amounts of assets, liabilities, and the disclosure of contingent assets and liabilities at the date of the consolidated financial statements, and the reported amounts of revenue and expenses during the reporting period. The Company's critical accounting policies are described under the heading *Management's Discussion and Analysis of Financial Condition and Results of Operations — Critical Accounting Policies and Estimates* in our 2023 Form 10-K.

Item 3. Quantitative and Qualitative Disclosures about Market Risk

There have been no material changes from the information previously reported in Part II, Item 7A of the 2023 Form 10-K.

Item 4. Controls and Procedures

We maintain disclosure controls and procedures that are designed to provide reasonable assurance that information required to be disclosed in the reports that we file or submit under the Exchange Act, is (1) recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and (2) accumulated and communicated to our management, including our Principal Executive Officer and Chief Financial Officer, as appropriate to allow timely decisions regarding required disclosure.

Our management, with the participation of our Principal Executive Officer and Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures as of November 30, 2023 (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act). Our management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives, and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Our Principal Executive Officer and Chief Financial Officer concluded, based upon the evaluation described above, that as of November 30, 2023, our disclosure controls and procedures were effective at the reasonable assurance level.

During the quarter ended November 30, 2023, there have been no changes in our internal control over financial reporting, as such term is defined in Rules 13a-15(f) and 15(d)-15(f) promulgated under the Exchange Act, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II – Other Information

Item 1. Legal Proceedings

For a description of pending material legal proceedings, please see Note 8, *Commitments and Contingencies–Legal Proceedings*, of the Notes to Consolidated Financial Statements included in Part I, Item 1 of this Form 10-Q.

Item 1A. Risk Factors

We are subject to various risks, including risk factors identified in our 2023 Form 10-K. You should carefully consider those risk factors in addition to the risk factors set forth below and other information in this Form 10-Q.

Our cash reserves are extremely low, requiring that we obtain substantial additional financing to satisfy our current payment obligations and to fund our operations, which continues to be difficult in light of the low trading price of our common stock.

As of December 31, 2023, we had an unrestricted cash balance of approximately $0.5 million and a reserved cash balance of approximately $6.6 million. We must continue to raise substantial additional funds in the near term to meet our payment obligations and fund our operations. Additional funding may not be available on acceptable terms or at all. In addition, as of December 31, 2023, we had approximately 371.0 million shares of common stock unreserved for other purposes and available for issuance in new financing transactions. We will need to use some of the additional authorized shares (or funds raised through the sale of such shares) to satisfy a portion of our outstanding accounts payable and accrued liabilities, which totaled approximately $ 71.5 million on November 30, 2023. If we are not able to raise additional funds on a timely basis, we may be forced to delay, reduce the scope of, or eliminate one or more of our planned operating activities, including continuing to seek removal of the clinical hold placed on us by the FDA in December 2023, analyzing clinical trial data for purposes of responding to FDA requirements, and preparing additional regulatory submissions, developing additional clinical trials for indications we plan to pursue, regulatory and compliance activities, and legal defense activities. Any delay or inability to pursue our planned activities likely will adversely affect our business, financial condition, and stock price. The continued low trading price of our common stock (with a closing price of $0.20 per share on January 5, 2024) presents a significant challenge to our ability to raise additional funds. If we deplete our cash reserves, we may have to discontinue our operations and liquidate our assets.

The class-action litigation filed against us could harm our business, and existing insurance coverage may not be sufficient to cover all related costs and damages.

The securities class action lawsuits filed against the Company in March 2021 have exhausted certain coverage allowances under the Company's D&O insurance applicable to the relevant time period. This litigation, whether or not successful, may require us to incur substantial costs, which could harm our business and financial condition. During the course of litigation, negative public announcements regarding the results of hearings, motions, or other interim proceedings or developments may occur, which could have a further negative effect on the market price of our common stock. Refer to Note 8, *Commitments and Contingencies – Securities Class Action Lawsuits* for further information.

Our Principal Executive Officer is currently serving in an interim role. The loss, temporary loss, or transition of members of our senior management team or any other key employees may adversely affect our business.

During the past 24 months, we have experienced significant turnover among our senior executives, and currently have only three executive officers. Dr. Jacob Lalezari, the Company's current Principal Executive Officer, was appointed as the Company's interim CEO, effective November 17, 2023. The Board's search for a new President and/or Chief Executive Officer remains in progress. If we are successful in recruiting one or more individuals to executive positions, the complexity inherent in integrating a new key member of the senior management team with existing senior management may limit the effectiveness of any such successor or otherwise adversely affect our business. Leadership

transitions and any disruptions that result are inherently difficult to manage and may cause uncertainty or a disruption to our business or increase the likelihood of turnover of other key officers and employees. Further, we may incur significant expenses related to any executive transition costs. Finding suitable replacements for senior management and other key employees can be difficult, and there is no assurance we will be successful in attracting or retaining qualified personnel.

Our success depends significantly on the individual and collective contributions of our senior management team and key employees. The individual and collective efforts of these employees are important as we continue our efforts to develop leronlimab. The loss of the services of a member of our senior management team or the inability to hire and retain experienced management personnel likely would have a material adverse effect on our business and operations.

We have been notified by Samsung of Samsung's intent to terminate the Company's agreements for manufacturing of our drug product and related services.

Beginning in fiscal 2022, we have received communications from Samsung regarding alleged breaches of our agreements with Samsung relating to past due balances. The Company has been pursuing negotiations with Samsung regarding potential approaches to resolve the issues short of litigation.

On November 21, 2023, Samsung informed the Company of Samsung's intent to terminate the agreements with the Company, effective January 5, 2024. As of the date of this filing, the parties remain in communication about the outstanding issues under the agreements and potential options moving forward. There can be no assurance that we will be able to address the issues raised by Samsung or avoid being found in breach of our agreements with Samsung. Failure to resolve the issues may ultimately result in termination of our agreements with Samsung, which could jeopardize our ability to properly store our inventories of drug product and manufacture additional drug product when needed.

Refer to Note 8, *Commitments and Contingencies – Commitments with Samsung BioLogics Co., Ltd. ("Samsung")* for further information.

If we are unable to obtain all required regulatory approvals for leronlimab, we will not be able to commercialize our primary product candidate, which would materially and adversely affect our business, financial condition, and stock price.

The FDA notified the Company at the beginning of December 2023 that: (i) the FDA's "partial hold" imposed in March 2022 had been lifted; and (ii) a new "full hold" had been applied related to the clinical trial protocol the Company submitted in November 2023 alongside the Company's complete response to the partial clinical hold. The Company currently anticipates that it will be able to submit a revised protocol to the FDA in January 2024, and will remain on clinical hold until the FDA clears the protocol.

Clinical testing is expensive, difficult to design and implement, may take many years to complete, and its outcome is uncertain. The research, testing, manufacturing, labeling, packaging, storage, approval, sale, marketing, advertising and promotion, pricing, export, import, and distribution of drug products are subject to extensive regulation by the FDA and other regulatory authorities in the United States and other countries, with regulations differing from country to country. We are not permitted to market a drug candidate as prescription pharmaceutical products in the United States until we receive approval from the FDA, or in foreign markets until we receive the requisite approval from comparable regulatory authorities in foreign countries. In the United States, the FDA generally requires the completion of clinical trials of each drug to establish its safety and efficacy, and extensive pharmaceutical development to ensure its quality before approval. Regulatory authorities in other jurisdictions impose similar requirements. Of the large number of drugs in development, only a small percentage are approved for commercialization. Receipt of necessary regulatory approval for the use of leronlimab for one or more indications is subject to a number of risks which include, among others:

- the FDA or comparable foreign regulatory authorities or institutional review boards ("IRBs") may disagree with the future design or implementation of our clinical trials,
- we may not be able to provide acceptable evidence of the safety and efficacy of our drug candidate,
- the results of our clinical trials may not be satisfactory or may not meet the level of statistical or clinical significance required by the FDA or foreign regulatory authorities for marketing approval,

- patients in our clinical trials may suffer adverse effects for reasons that may or may not be related to our drug candidate,
- the data collected from clinical trials may not be sufficient to support the submission of an application for marketing approval in the United States or elsewhere,
- the FDA or foreign regulatory authorities may not approve the manufacturing processes or facilities of third-party manufacturers with which we contract for clinical and commercial supplies, and
- the approval policies or regulations of the FDA or foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval.

We cannot guarantee that regulators will agree with our assessment of the results of our past or future clinical trials or that such trials will be considered by regulators to have shown safety or efficacy of our product candidate. In particular, there remains no guarantee that the FDA will lift the clinical hold on our recently submitted protocol. The FDA has substantial discretion in the approval process and may refuse to accept any application or may require additional clinical trials or pre-clinical or other studies. Additionally, we have limited experience in filing the applications necessary to gain regulatory approvals and expect to continue to rely on consultants and our CROs to assist us in this process. Securing FDA approval requires the submission of pre-clinical, clinical, and/or pharmacokinetic data, information about product manufacturing processes and inspection of facilities, and supporting information for each therapeutic indication to establish a product candidate's safety and efficacy for each indication. Our drug candidate may prove to have undesirable or unintended side effects, toxicities, or other characteristics that may preclude us from obtaining regulatory approval or prevent or limit commercial use with respect to one or all intended indications. Failure to obtain regulatory approval for leronlimab will prevent us from commercializing it as a prescription product, and our ability to generate revenue will be seriously impaired.

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

Private Placements of Common Stock and Warrants through Placement Agent

In October 2023, the Company ended a private placement to accredited investors of units through a placement agent that commenced in July 2023. Each unit consisted of one share of common stock and one warrant to purchase one share of common stock. The purchase price per unit was equal to 90% of the lower of (i) the intraday VWAP of the common stock as of the first closing on July 31, 2023, and (ii) the intraday VWAP on the date of the final closing on September 27, 2023. As the VWAP on September 27, 2023, was lower than the VWAP on July 31, 2023, the purchase price per unit decreased from $0.20 per unit to $0.16 per unit. The number of units sold in the offering therefore increased from 16.9 million units to 21.5 million units, and from 11.5 million units to 14.3 million units related to the conversion of the Placement Agent Notes. See Note 5 to the consolidated financial statements included in Part I, Item 1 of this Form 10-Q for additional information.

The warrants issued to investors in the offering are fully exercisable and have a five-year term and an exercise price of $0.50 per share. Other than as described above, the terms of the warrants are substantially similar to the form of warrant filed as Exhibit 4.1 to the Company's Current Report on Form 8-K filed with the SEC on September 7, 2021.

The warrants issued to investors for the Placement Agent Notes conversion are fully exercisable and have a five-year term and an exercise price of $0.306 per share. Other than as described above, the terms of the warrants are substantially similar to the form of warrant filed as Exhibit 4.1 to the Company's Current Report on Form 8-K filed with the SEC on September 7, 2021.

The Company agreed to pay a cash fee to the placement agent in the offering equal to 12% of the gross proceeds received from qualified investors. The Company also agreed to issue to the placement agent or its designees warrants equal in number to 15% of the total number of shares of common stock sold to qualified investors in the offering. Accordingly, the Company issued warrants to purchase a total of 3.2 million shares of common stock with a 10-year term and an exercise price of $0.16 per share to the placement agent or its designees.

The Company has agreed to use commercially reasonable efforts to prepare and file with the SEC, and cause the SEC to declare effective, a registration statement under the Securities Act of 1933, as amended (the "Securities Act") covering the resale of the shares and shares covered by warrants to purchase shares of common stock issued in the above offering.

In December 2023, the Company commenced a new private placement to accredited investors of units through a placement agent. Each unit consisted of one share of common stock and one warrant to purchase one share of common stock. The purchase price per unit will be equal to 90% of the lower of (i) the intraday volume weighted average price ("VWAP") of the common stock as of the first closing on December 29, 2023, and (ii) the intraday VWAP on the date of the final closing, which has not yet occurred. As of January 16, 2024, the Company had received binding subscription agreements to purchase an estimated total of approximately 10.3 million units at a total purchase price of approximately $1.8 million, based on a price of $0.17 per unit.

The warrants to be issued to investors in the offering will be fully exercisable and will have a five-year term and an exercise price of $0.35 per share. The warrants will be exercisable in full when issued. Other than as described above, the terms of the warrants will be substantially similar to the form of warrant filed as Exhibit 4.1 to the Company's Current Report on Form 8-K filed with the SEC on September 7, 2021.

As a fee to the placement agent in the offering, the Company has agreed to pay a cash fee equal to 13% of the gross proceeds received from qualified investors. The Company has also agreed to issue to the placement agent or its designees warrants with a 10-year term to purchase 15% of the total number of shares of common stock sold to qualified investors in the offering.

The Company has agreed to use commercially reasonable efforts to prepare and file with the SEC, and cause the SEC to declare effective, a registration statement under the Securities Act covering the resale of the shares and shares covered by warrants to purchase shares of common stock issued in the private placements described above.

The Company relied on the exemption provided by Section 4(a)(2) of the Securities Act and Rule 506 of Regulation D thereunder in the sale and issuance of shares and warrants in the foregoing offerings.

Issuances of Shares in Convertible Note Exchange Transactions

In December 2023, the Company and the holder of its April 2, 2021 Note, in partial satisfaction of the holder's redemption rights, entered into exchange agreements pursuant to which the original note was partitioned and new notes were issued, resulting in an aggregate principal reduction of $1.3 million. The new note was exchanged concurrently with issuance of a total of approximately 8.3 million shares of common stock. The Company relied on the exemption provided by Section 3(a)(9) of the Securities Act in connection with the exchange transactions.

Sale of Short-term Notes and Warrants and Shares to be Issued upon Conversion or Exercise

During November and December 2023, the Company issued unsecured promissory notes with a 6-month term to accredited investors in an aggregate principal amount of approximately $1.0 million through a placement agent (the "Short-term Notes"). The Short-term Notes provide for accrual of interest at an annual rate of 10% and are unsecured. As part of the sale, the Company issued fully exercisable warrants to purchase an aggregate of approximately 1.0 million shares of common stock with a five-year term and an exercise price of $0.35 per share. The Company also issued fully exercisable warrants to purchase approximately 0.4 million shares of common stock to the placement agent with a ten-year term and an exercise price of $0.35 per share and paid a total cash fee of approximately $0.1 million.

Other than as described above, the terms of the warrants issued in the foregoing offering of Short-term Notes are substantially similar to the form of warrant filed as Exhibit 4.1 to the Company's Current Report on Form 8-K filed with the SEC on September 7, 2021.

The principal and accrued interest on the Short-term Notes were converted into and will equal 80% the unit pricing of the offering described above, representing a total of approximately 7.2 million shares of common stock based on a price of $0.14 per unit. Additional fully exercisable warrants to purchase a total of approximately 7.2 million shares of common stock at a price of $0.35 per share were issued to the investors in connection with the conversion.

The Company has agreed to use commercially reasonable efforts to prepare and file with the SEC, and cause the SEC to declare effective, a registration statement under the Securities Act covering the resale of shares covered by warrants to purchase shares of common stock issued in the offering and upon conversion of the Short-term Notes described above.

The Company relied on the exemption provided by Section 4(a)(2) of the Securities Act and Rule 506 of Regulation D thereunder in connection with the foregoing offering of Short-term Notes and warrants and shares of common stock to be issued upon the conversion of the Short-term Notes as described above.

Item 6. Exhibits

(a) Exhibits:

Exhibit No	Description	Filed Herewith	Incorporated by Reference		
			Form	Exhibit No.	Filing Date
31.1	Rule 13a-14(a) Certification by Principal Executive Officer of the Registrant.	X			
31.2	Rule 13a-14(a) Certification by Chief Financial Officer of the Registrant.	X			
32	Certification of Principal Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350.*	X			
101.INS	Inline XBRL Instance Document.	X			
101.SCH	Inline XBRL Taxonomy Extension Schema Document.	X			
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document.	X			
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document.	X			
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document.	X			
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document.	X			
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101).	X			

*Furnished, not filed.

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.

CYTODYN INC.
(Registrant)

Dated: January 16, 2024

/s/ Jacob Lalezari
Jacob Lalezari
Interim Chief Executive Officer
(Principal Executive Officer)

Dated: January 16, 2024

/s/ Antonio Migliarese
Antonio Migliarese
Chief Financial Officer
(Principal Financial and Accounting Officer)

Exhibit 31.1

Certification of Principal Executive Officer

I, Jacob Lalezari, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of CytoDyn Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the Registrant as of, and for, the periods presented in this report;
4. I am responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the Registrant and have:
    a. designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the Registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this quarterly report is being prepared;
    b. designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
    c. evaluated the effectiveness of the Registrant's disclosure controls and procedures and presented in this quarterly report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report, based on such evaluation; and
    d. disclosed in this report any change in the Registrant's internal control over financial reporting that occurred during the registrant's most-recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the Registrant's internal control over financial reporting; and
5. I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the Registrant's auditors and the audit committee of the Registrant's board of directors (or persons performing the equivalent functions):
    a. all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the Registrant's ability to record, process, summarize and report financial information; and
    b. any fraud, whether or not material, that involves management or other employees who have a significant role in the Registrant's internal control over financial reporting.

Date: January 16, 2024

/s/ Jacob Lalezari
Jacob Lalezari
Interim Chief Executive Officer

Exhibit 31.2

Certification of Chief Financial Officer

I, Antonio Migliarese, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of CytoDyn Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the Registrant as of, and for, the periods presented in this report;
4. The Registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the Registrant and have:
    a. designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the Registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this quarterly report is being prepared;
    b. designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
    c. evaluated the effectiveness of the Registrant's disclosure controls and procedures and presented in this quarterly report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report, based on such evaluation; and
    d. disclosed in this report any change in the Registrant's internal control over financial reporting that occurred during the registrant's most-recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the Registrant's internal control over financial reporting; and
5. The Registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the Registrant's auditors and the audit committee of the Registrant's board of directors (or persons performing the equivalent functions):
    a. all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the Registrant's ability to record, process, summarize and report financial information; and
    b. any fraud, whether or not material, that involves management or other employees who have a significant role in the Registrant's internal control over financial reporting.

Date: January 16, 2024

/s/ Antonio Migliarese
Antonio Migliarese
Chief Financial Officer

Exhibit 32

CERTIFICATION PURSUANT TO

18 U.S.C. SECTION 1350

In connection with the Quarterly Report of CytoDyn Inc. (the "Company") on Form 10-Q for the fiscal quarter ended November 30, 2023, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned certify, pursuant to 18 U.S.C. Section 1350, that:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ Jacob Lalezari	/s/ Antonio Migliarese
JJacob Lalezari	Antonio Migliarese
Interim Chief Executive Officer	Chief Financial Officer
Date: January 16, 2024	Date: January 16, 2024

A signed original of this written statement required by Section 906 has been provided to CytoDyn Inc. and will be retained by CytoDyn Inc. and furnished to the Securities and Exchange Commission or its staff upon request.