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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, DC 20549

FORM 10-Q/A
(Amendment No. 1)

☒ **QUARTERLY REPORT UNDER SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the quarterly period ended August 31, 2022

☐ **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 September 30, 2022, there were 812,825,217 shares outstanding of the registrant's $0.001 par value common stock.

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EXPLANATORY NOTE

This Amendment No. 1 has been filed solely to complete the interactive data file generated as part of our Quarterly Report on Form 10-Q for the quarterly period ended August 31, 2022 filed on October 11, 2022 (the "Original Quarterly Report"), with a table presented in Note 6, *Equity Awards,* discussing Black-Scholes valuation assumptions, which was included in Item 1 of Part I of the Original Quarterly Report but which was omitted from the interactive data file generated on October 11, 2022. Other than the inclusion in this Amendment No. 1 of new certifications required by management (and related amendment to the exhibit index to reflect the addition of such certifications), this Amendment No. 1 speaks only as of the date of the Original Quarterly Report and does not modify or update any other disclosures contained in the Original Quarterly Report.

PART I. Financial Information

Item 1. Consolidated Financial Statements

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

	August 31, 2022	May 31, 2022
Assets		
Current assets:		
Cash	$ 4,676	$ 4,231
Prepaid expenses	4,143	5,198
Prepaid service fees	1,038	1,086
Total current assets	9,857	10,515
Inventories, net	17,929	17,929
Other non-current assets	608	741
Total assets	$ 28,394	$ 29,185
Liabilities and Stockholders' Deficit		
Current liabilities:		
Accounts payable	$ 68,991	$ 67,974
Accrued liabilities and compensation	5,014	8,995
Accrued interest on convertible notes	7,120	5,974
Accrued dividends on convertible preferred stock	4,361	3,977
Convertible notes payable, net	36,833	36,241
Total current liabilities	122,319	123,161
Operating leases	387	422
Total liabilities	122,706	123,583
Commitments and Contingencies (Note 9)		
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 August 31, 2022 and May 31, 2022, respectively	—	—
Series C convertible preferred stock, $0.001 par value; 8 authorized; 6 and 7 issued and outstanding at August 31, 2022 and May 31, 2022, respectively	—	—
Series D convertible preferred stock, $0.001 par value; 12 authorized; 9 issued and outstanding at August 31, 2022 and May 31, 2022, respectively	—	—
Common stock, $0.001 par value; 1,350,000 shares authorized; 812,698 and 720,028 issued, and 812,255 and 719,585 outstanding at August 31, 2022 and May 31, 2022, respectively	813	720
Treasury stock, $0.001 par value; 443 at August 31, 2022 and May 31, 2022	—	—
Additional paid-in capital	687,732	671,013
Accumulated deficit	(782,857)	(766,131)
Total stockholders' deficit	(94,312)	(94,398)
Total liabilities and stockholders' deficit	$ 28,394	$ 29,185

See accompanying notes to consolidated financial statements.

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

	Three months ended August 31,	
	2022	2021 (Restated) [1]
Revenue	$ —	$ 41
Cost of goods sold	—	1
Gross margin	—	40
Operating expenses:		
General and administrative	6,333	7,617
Research and development	576	12,020
Amortization and depreciation	99	276
Inventory charge	2,704	1,764
Total operating expenses	9,712	21,677
Operating loss	(9,712)	(21,637)
Interest and other expense:		
Interest on convertible notes	(1,146)	(1,686)
Amortization of discount on convertible notes	(576)	(952)
Amortization of debt issuance costs	(16)	(28)
Loss on induced conversion	—	(18,530)
Finance charges	(940)	(35)
Inducement interest expense	—	(528)
Legal settlement	—	(1,941)
Loss on derivatives	(8,601)	—
Total interest and other expense	(11,279)	(23,700)
Loss before income taxes	(20,991)	(45,337)
Income tax benefit	—	—
Net loss	$ (20,991)	$ (45,337)
Basic and diluted:		
Weighted average common shares outstanding	787,856	632,597
Loss per share	$ (0.03)	$ (0.07)

(1) See Note 2, *Summary of Significant Accounting Policies*.

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, 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 to additional paid-in capital of prior period preferred stock dividends previously charged to accumulated deficit	—	—	—	—	—	—	(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)

	Preferred stock		Common stock		Treasury stock		Additional paid-in capital (Restated) [1]	Accumulated deficit (Restated) [1]	Total stockholders' deficit (Restated) [1]
	Shares	Amount	Shares	Amount	Shares	Amount			
Balance at May 31, 2021	96	$ —	626,123	$ 626	443	$ —	$ 532,031	$ (553,675)	$ (21,018)
Issuance of stock for convertible note repayment	—	—	11,816	12	—	—	13,832	—	13,844
Loss on induced conversion	—	—	—	—	—	—	18,530	—	18,530
Issuance of legal settlement warrants	—	—	—	—	—	—	1,744	—	1,744
Stock option exercises	—	—	300	—	—	—	189	—	189
Stock issued for compensation and tendered for income tax	—	—	1,014	1	—	—	(1)	—	—
Stock issued for private offerings	—	—	2,872	3	—	—	2,869	—	2,872
Private warrant exchanges	—	—	1,327	1	—	—	774	—	775
Warrant exercises	—	—	668	1	—	—	502	—	503
Inducement interest expense related to private warrant exchanges	—	—	—	—	—	—	528	—	528
Accrued preferred stock dividends	—	—	—	—	—	—	—	(420)	(420)
Stock-based compensation	—	—	—	—	—	—	2,597	—	2,597
Net loss	—	—	—	—	—	—	—	(45,337)	(45,337)
Balance at August 31, 2021	96	$ —	644,120	$ 644	443	$ —	$ 573,595	$ (599,432)	$ (25,193)

(1) See Note 2, *Summary of Significant Accounting Policies*.

See accompanying notes to consolidated financial statements.

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

	Three months ended August 31,	
	2022	2021 (Restated) [1]
Cash flows from operating activities:		
Net loss	$ (20,991)	$ (45,337)
Adjustments to reconcile net loss to net cash used in operating activities:		
Amortization and depreciation	99	276
Amortization of debt issuance costs	16	28
Amortization of discount on convertible notes	576	952
Legal settlement	—	1,744
Loss on derivatives	8,601	—
Loss on induced conversion	—	18,530
Inducement interest expense and non-cash finance charges	—	528
Inventory charge	2,704	1,764
Stock-based compensation	1,341	2,597
Changes in operating assets and liabilities:		
Increase in prepaid expenses and other assets	(1,601)	(2,370)
Decrease in accounts payable and accrued expenses	(1,819)	(10,453)
Net cash used in operating activities	(11,074)	(31,741)
Cash flows from investing activities:		
Furniture and equipment purchases	—	(8)
Net cash used in investing activities	—	(8)
Cash flows from financing activities:		
Proceeds from warrant transactions, net of offering costs	—	775
Proceeds from sale of common stock and warrants, net of issuance costs	11,255	2,872
Proceeds from warrant exercises	264	503
Exercise of option to repurchase shares held in escrow	—	9
Proceeds from stock option exercises	—	189
Net cash provided by financing activities	11,519	4,348
Net change in cash and restricted cash	445	(27,401)
Cash beginning of period	4,231	33,943
Cash end of period	$ 4,676	$ 6,542
Cash and restricted cash consisted of the following:		
Cash	$ 4,676	$ 6,533
Restricted cash	—	9
Total cash and restricted cash	$ 4,676	$ 6,542
Supplemental disclosure:		
Cash paid for interest	$ —	$ 35
Non-cash investing and financing transactions:		
Issuance of common stock for principal and interest of convertible notes	$ —	$ 14,950
Accrued dividends on convertible Series C and D Preferred Stock	$ 384	$ 420
Deemed dividend on common stock issued due to down round provision, recorded in additional paid-in capital	$ 4,154	$ —

(1) See Note 2, *Summary of Significant Accounting Policies*.

See accompanying notes to consolidated financial statements.

CYTODYN INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
AS OF AUGUST 31, 2022
(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 (PRO 140), a novel humanized monoclonal antibody targeting the CCR5 receptor. The Company is studying leronlimab in human immunodeficiency virus ("HIV"), oncology, and non-alcoholic steatohepatitis ("NASH").

Leronlimab is being investigated as a viral entry inhibitor for 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 NASH. Leronlimab is being studied in NASH, oncology, and other therapeutic indications where CCR5 is believed to play an integral role.

The Company has pursued the regulatory approval of leronlimab in hopes that commercial sales will be obtained based on positive data from its Phase 2b/3 clinical trial for leronlimab as a combination therapy with highly active antiretroviral therapy ("HAART") for highly treatment-experienced HIV patients, as well as information gathered from meetings with the U.S. Food and Drug Administration ("FDA") related to its Biologic License Application ("BLA") for this indication. 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 HAART for highly treatment-experienced HIV patients. The FDA informed the Company that the BLA did not contain certain information and data needed to complete a substantive review and therefore, the FDA would not file the BLA. The deficiencies cited by the FDA included administrative deficiencies, omissions, corrections to data presentation and related analyses, and clarifications regarding the manufacturing processes. In November 2021, the Company resubmitted the non-clinical and chemistry, manufacturing, and controls ("CMC") sections of the BLA. As of March 2022, the FDA had commenced its review of the CMC section.

As described in Note 9, *Commitments and Contingencies - Legal Proceedings*, the Company is in dispute with its former contract research organization ("CRO"). In the context of the litigation, the Company obtained an order requiring the CRO to release the Company's clinical data related to the BLA and other clinical trials, which the CRO had been withholding. Further, the order granted the Company the right to perform an audit of the CRO's services.

Additionally, in March of 2022, the FDA placed the HIV program on a partial clinical hold, which may affect our ability to resubmit the BLA. The Company is in the process of evaluating the data, results of the audit, and implications of the partial clinical hold. The Company will update the feasibility of the resubmission of the clinical section of the BLA once it completes its evaluation.

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 subsidiaries, CytoDyn Operations Inc. and Advanced Genetic Technologies, Inc. ("AGTI"); AGTI is a dormant entity. 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. 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, 2022 (the "2022 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 material effect on the Company's previously reported financial position, results of operations, stockholders' deficit, or net cash provided by operating activities.

During the quarter ended August 31, 2022, the Company reclassified amounts recorded as accumulated dividends for Series C and D preferred stockholders from accumulated deficit to additional paid-in capital. These reclassifications were made to reflect the proper presentation for accrued dividends when an entity has accumulated deficit.

Revision and Restatement of Financial Statements

During the preparation of the quarterly financial statements as of and for the period ended November 30, 2021, the Company identified an error in how non-cash inducement interest expense was calculated in previous reporting periods dating back to fiscal year 2018. The error resulted in an understatement of non-cash inducement interest expense and additional paid-in capital. For details, refer to Note 2, *Summary of Significant Accounting Policies - Revision of Financial Statements* in the 2022 Form 10-K. Also during the preparation and audit of the annual financial statements as of and for the fiscal year ended May 31, 2022, the Company concluded that a material error was identified in how the Company was accounting for common stock issued to settle certain convertible note obligations dating back to fiscal year 2021. For details, refer to Note 14, *Restatement* in the 2022 Form 10-K. Neither of the errors had impact on operating loss, cash, net cash used in or provided by operating, financing, and investing activities, assets, liabilities, commitments and contingencies, total stockholders' deficit, number of shares issued and outstanding, basic and diluted weighted average common shares outstanding, and number of shares available for future issuance for any period presented, and are reflected in the accompanying statement of operations, changes in stockholders' deficit, and statement of cash flows.

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 $21.0 million for the three months ended August 31, 2022, and has an accumulated deficit of approximately $782.9 million as of August 31, 2022. These factors, among others, 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 continuation 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 for multiple indications and expects to incur significant research and development expenses in the future primarily related to its regulatory compliance and approval, and clinical trials. 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 generally accepted in the United States (U.S. 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 stock-based compensation, capitalization of pre-launch inventories, write-off for excess and obsolete inventories, research and development expenses, commitments and contingencies, and the assumptions used to value warrants and warrant modifications. Actual results could differ from these estimates.

Pre-launch Inventories

Pre-launch inventories are comprised of raw materials required to commercially produce leronlimab and substantially completed commercially produced leronlimab in anticipation of commercial sales of the product upon potential regulatory approval as a combination therapy for HIV patients in the United States. The Company's pre-launch inventories consist of (1) raw materials purchased for commercial production, (2) work-in-progress materials which consist of bulk drug substance, which is the manufactured drug stored in bulk storage, and (3) drug product, which is the manufactured drug in unlabeled vials. The consumption of raw materials during production is classified as work-in-progress until saleable. Once it is determined to be in saleable condition, following regulatory approval, inventory is classified as finished goods.

The Company capitalizes inventories procured or produced in preparation for product launches. Typically, capitalization of such inventory begins when the results of clinical trials have reached a status sufficient to support regulatory approval, uncertainties regarding ultimate regulatory approval have been significantly reduced, and the Company has determined it is probable that these capitalized costs will provide future economic benefit in excess of capitalized costs. The material factors considered by the Company in evaluating these uncertainties include the receipt and analysis of positive Phase 3 clinical trial results for the underlying product candidate, results from meetings with the relevant regulatory authorities prior to the filing of regulatory applications, and status of the Company's regulatory applications. The Company closely monitors the status of the product within the regulatory review and approval process, including all relevant communications with regulatory authorities. If the Company becomes aware of any specific material risks or contingencies other than the normal regulatory review and approval process or if there are any specific issues identified relating to safety, efficacy, manufacturing, marketing or labeling, it may make a determination that the related inventory no longer qualifies for capitalization.

The Company determines whether raw materials purchased for commercial production are usable for production based on the manufacturer's assigned expiration date. In evaluating whether raw materials included in the pre-launch inventories will be usable for production, the Company takes into account the shelf-life of raw materials at the time they are expected to be used in manufacturing. Any raw materials past expiration date at the time of the next manufacturing run are removed from inventory.

As one stage of the manufacturing process, the Company produces work-in-progress materials which consist of bulk drug substance, which is the manufactured drug stored in bulk storage. The initial shelf-life of bulk drug substance is established based on prior experience and periodically performed stability studies and is set at four years from the date of manufacturing. Bulk drug substance is subject to deep freeze storage, and stability studies are performed on a periodic basis in accordance with the established stability protocols. If drug substance meets suitability criteria beyond the initial shelf-life, its shelf-life may be extended based on prior experience and stability trend analysis, and during the extension period periodic stability testing is performed on the drug substance. Regardless of the number of stability studies performed, if drug substance continues to meet prespecified suitability parameters it may be used in manufacturing; if drug substance fails to meet suitability criteria beyond its assigned shelf-life at that time, it may no longer be used and is considered to be expired.

The Company utilizes resins, a reusable raw material, in its bulk drug manufacturing process. Shelf-life of a resin used in commercial manufacturing of biologics is determined by the number of cycles for which it has been validated to be used in a manufacturing process before it is considered unusable. Unpacked and unused resins have a manufacturer's expiration date by which resins are expected to start being used in the manufacturing process without loss of their properties. Prior to a new manufacturing campaign, and between manufacturing campaigns, the resins are removed from storage, and are treated and tested for suitability. Once resins are used in the manufacturing process, their shelf-life is measured by a validated predetermined number of manufacturing cycles they are usable for, conditional on appropriate storage solution under controlled environment between production campaigns, as well as by performing pre-production usability testing. Before a manufacturing campaign, each resin is tested for suitability. Regardless of the number of cycles, if a resin fails to meet prespecified suitability parameters it may not be used in manufacturing; likewise, even if the resin meets suitability criteria beyond the lifetime cycles, it may no longer be used. The cost of the resins used in a manufacturing campaign is allocated to the cost of the drug product in vials.

The Company values its inventory at the lower of cost or net realizable value using the average cost method. Inventory is evaluated for recoverability by considering the likelihood that revenue will be obtained from the future sale of the related inventory considering the status of the product within the regulatory approval process. The Company evaluates its inventory levels on a quarterly basis and writes down inventory that became obsolete, has a cost in excess of its expected net realizable value, or is in quantities in excess of expected requirements. In assessing the lower of cost or net realizable value for pre-launch inventory, the Company relies on independent analyses provided by third parties knowledgeable about the range of likely commercial prices comparable to current comparable commercial product. Quarterly, the Company also evaluates whether certain raw materials held in its inventory are expected to reach the end of their estimated shelf-lives based on passage of time, the number of manufacturing cycles they are used in and results of pre-production testing prior to the expected production date, or when resins used in the manufacturing process fail suitability tests. If any of such events occur, the Company may make a determination to record a charge if it is expected that such inventories will become obsolete prior to the expected production date.

Anticipated future sales, shelf lives, and expected approval date are considered when evaluating realizability of capitalized inventory. The shelf-life of a product is determined as part of the regulatory approval process; however, in assessing whether to capitalize pre-launch inventories, the Company considers the product stability data for all of the pre-approval inventory procured or produced to date to determine whether there is adequate shelf-life. When the remaining shelf-life of drug product inventory is less than 12 months, it is likely that it will not be accepted by potential customers. However, as inventories approach their shelf-life expiration, the Company may perform additional stability testing to determine if the inventory is still viable, which can result in an extension of its shelf-life and revaluation of the need for and the amount of the previously recorded reserves. Further, in addition to performing additional stability testing, certain raw materials inventory may be sold in its then current condition prior to reaching expiration. If the Company determines that it is not likely that shelf-life may be extended or the inventory cannot be sold prior to expiration, the Company may record a charge to bring inventory to its net realizable value.

For additional information about the Company's significant accounting policies, refer to Note 2, *Summary of Significant Accounting Policies,* in the 2022 Form 10-K.

Recently Adopted Accounting Pronouncements

In August 2020, the FASB issued ASU No. 2020-06, *Debt with Conversion and Other Options (Subtopic 470-20)* and *Derivatives and Hedging - Contracts in Entity's Own Equity (Subtopic 815-40)*, which simplifies the accounting for convertible instruments. The guidance removes certain accounting models that separate the embedded conversion features from the host contract for convertible instruments. Either a modified retrospective method of transition or a fully retrospective method of transition is permissible for the adoption of this standard. Update No. 2020-06 is effective for fiscal years beginning after December 15, 2021, including interim periods within those fiscal years. Early adoption is permitted no earlier than the fiscal year beginning after December 15, 2020. The Company adopted ASU No. 2020-06 as of June 1, 2022, using the modified retrospective method. The adoption of ASU No. 2020-06 had no impact on the Company's balance sheets, statements of operations, cash flows or financials statement disclosures.

In May 2021, the FASB issued ASU No. 2021-04, *Earnings Per Share (Topic 260), Debt—Modifications and Extinguishments (Subtopic 470-50), Compensation - Stock Compensation (Topic 718), and Derivatives and Hedging—Contracts in Entity's Own Equity (Subtopic 815-40): Issuer's Accounting for Certain Modifications or Exchanges of*

Freestanding Equity-Classified Written Call Options. ASU 2021-04 addresses the accounting for certain modifications or exchanges of freestanding equity-classified written call options (e.g., warrants). Entities should treat a modification of the terms or conditions, or an exchange of a freestanding equity-classified written call option that remains equity-classified after modification or exchange, as an exchange of the original instrument for a new instrument. Guidance should be applied prospectively after the date of initial application. ASU 2021-04 is effective for fiscal years beginning after December 15, 2021, and interim periods within those fiscal years, with early adoption permitted.

The Company adopted the new guidance prospectively as of June 1, 2022 and used the framework to record a modification to the exercise price of equity classified warrants during the three months ended August 31, 2022. The incremental value of modification to equity instruments as a result of a trigger of a down round provision was recorded as a deemed dividend in accordance with this guidance, resulting in an approximate $4.2 million charge to additional paid-in capital. The deemed dividend was included in the loss per share calculation; refer to Note 7*, Loss per Common Share*. Refer to Note 6*, Equity Awards and Warrants* for further information.

Note 3. Inventories, net

Inventories were as follows (in thousands):

	August 31, 2022	May 31, 2022
Raw materials	$ 16,264	$ 16,264
Work-in-progress	1,665	1,665
Total inventories, net	$ 17,929	$ 17,929

The table below summarizes inventory that had been capitalized and subsequently charged off for accounting purposes. Work-in-progress and finished drug product inventories continue to be physically maintained, can be used for clinical trials, and can be commercially sold if the shelf-lives can be extended as a result of the performance of on-going stability tests.

		Raw Materials				Work-in-progress		
(in thousands, Expiration period ending August 31,)	Remaining shelf-life (mos)	Specialized	Resins	Other	Total Raw Materials	Bulk drug product	Finished drug product	Total inventories
2023	0 to 12	$ 3,658	$ -	$ 1,421	$ 5,079	$ 1,824	$ -	$ 6,903
2024	13 to 24	682	16,264	1,590	18,536	1,665	-	20,201
2025	25 to 36	2,099	-	-	2,099	-	29,142	31,241
2026	37 to 48	3,435	-	-	3,435	-	32,344	35,779
Thereafter	49 or more	-	-	-	-	-	-	-
Inventories, gross		9,874	16,264	3,011	29,149	3,489	61,486	94,124
Inventory charge		(9,874)	-	(3,011)	(12,885)	(1,824)	(61,486)	(76,195)
Inventories, net		$ -	$ 16,264	$ -	$ 16,264	$ 1,665	$ -	$ 17,929

The Company determines whether raw materials purchased for commercial production are usable for production based on the manufacturer's assigned expiration date. In evaluating whether raw materials included in the pre-launch inventories will be usable for production, the Company takes into the account the shelf-life of raw materials at the time they are expected to be used in manufacturing. Any raw materials past expiration date at the time of the next manufacturing run are removed from inventory. Also, as one of the stages of the manufacturing process, the Company produces work-in-progress materials which consist of bulk drug substance, which is the manufactured drug stored in bulk storage. The initial shelf-life of bulk drug substance is established based on prior experience and periodically performed stability studies and is set at four years from the date of manufacturing. Bulk drug substance is subject to deep freeze storage, and stability studies performed on a periodic basis in accordance with the established stability protocols. If drug substance meets suitability criteria beyond the initial shelf-life, its shelf-life may be extended based on prior experience and stability trend analysis, and during the extension period periodic stability testing is performed on the drug substance. Regardless of the number of stability studies performed, if drug substance continues to meet prespecified suitability parameters it may be used in manufacturing; if drug substance fails to meet suitability criteria beyond its assigned shelf-life at that time, it may no longer be used and is considered to be expired. Further, the Company utilizes resins, a reusable raw material, in its bulk drug manufacturing process. Shelf-life of a resin used in commercial

manufacturing of biologics is determined by the number of cycles for which it has been validated to be used in a manufacturing process before it is considered unusable. Unpacked and unused resins have a manufacturer's expiration date by which resins are expected to start being used in the manufacturing process without loss of their properties. Prior to a new manufacturing campaign, and between manufacturing campaigns, the resins are removed from storage, treated and tested for suitability. Once resins are used in the manufacturing process, their shelf-life is measured by a validated predetermined number of manufacturing cycles they are usable for, conditional on appropriate storage solution under controlled environment between production campaigns, as well as by performing pre-production usability testing. Before a manufacturing campaign, each resin is tested for suitability. Regardless of the number of cycles, if a resin fails to meet prespecified suitability parameters it may not be used in manufacturing; likewise, even if the resin meets suitability criteria beyond the lifetime cycles, it may no longer be used. The cost of the resins used in a manufacturing campaign is allocated to the cost of the drug product in vials.

During the fourth quarter of fiscal 2022, the Company concluded that a significant portion of inventories no longer qualify for capitalization as pre-launch inventories due to expiration of shelf-life prior to expected commercial sales and the ability to obtain additional commercial product stability data until after shelf-life expiration. This is due to delays experienced from the originally anticipated BLA approval by the FDA. Although these inventories are no longer being capitalized as pre-launch inventories for US GAAP accounting purposes, the inventories written-off for accounting purposes continue to be physically maintained, can be used for clinical trials, and can be commercially sold if the shelf-lives are extended as the result of the performance of on-going stability testing of drug product. In the event the shelf-lives of these written-off inventories are extended, and the inventories are sold commercially, the Company will not recognize any costs of goods sold on the previously expensed inventories. The Company also concluded that, due to delays of future production, certain raw materials would expire prior to production and as such no longer qualify for capitalization. Specifically, the Company evaluated its raw materials, which consist of specialized raw materials, resins, and other, against the anticipated production date and determined that while the next production date was indeterminable as of May 31, 2022, specialized raw materials have remaining shelf-lives ranging from 2023 to 2026. Therefore, a reserve of $10.2 million for the entire remaining value of specialized and other raw materials was recorded as of May 31, 2022. The Company also concluded that approximately $29.1 million, composed of five batches of drug product, out of a total of nine manufactured, is likely to expire prior to the anticipated date the product may be approved for commercialization. Additionally, the Company anticipates that approximately $34.2 million of the drug product comprising the remaining four manufactured batches, with shelf-lives lasting into 2026, may expire prior to receiving approval for commercialization. The Company wrote-off the entire remaining balance of the drug product, in the amount of $63.3 million, as of May 31, 2022.

During the first quarter of fiscal 2023, the Company reviewed purchase commitments made by its manufacturing partner, Samsung BioLogics Co., Ltd. ("Samsung"), under the master agreement between the Company and Samsung, and its vendors for specialized raw materials for which the Company made a prepayment in the amount of $2.7 million in the third quarter of fiscal 2022, which were recorded as other assets in the consolidated financial statements as of May 31, 2022. The Company and its manufacturing partner have been in discussions, among other things, about cancelling the commitments to the suppliers, which have been unsuccessful to date. These additional specialized raw materials are estimated to have shelf-lives ranging from 2023 to 2026. The entire amount was reserved for as of August 31, 2022.

During the fourth quarter of fiscal 2022, the Company completed its validation of the resins' properties based on the number of cycles they have been used for, and the remaining number of manufacturing cycles they may be used for; the Company did not identify any resins that failed suitability validation. As of August 31, 2022, the remaining life of resins remained unchanged, ranging between 37 and 62 cycles. The Company will continue to present its resins inventory based on the remaining shelf-lives until a new shelf-life is assigned based on the results of usability testing.

Note 4. Accounts Payable and Accrued Liabilities

As of August 31, 2022 and May 31, 2022, the accounts payable balance was approximately $69.0 million and $68.0 million, respectively, with two vendors accounting for 69% and 73% of the total balance of accounts payable at the respective dates.

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

	August 31, 2022	May 31, 2022
Compensation and related expense	$ 792	$ 1,522
Legal fees and settlement	1,017	2,006
Clinical expense	311	3,727
Unbilled inventory	2,218	1,392
License fees	541	150
Lease payable	135	134
Other liabilities	-	64
Total accrued liabilities	$ 5,014	$ 8,995

Note 5. 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.

	August 31, 2022			May 31, 2022		
(in thousands)	Series B	Series C	Series D	Series B	Series C	Series D
Shares of preferred stock	19	6	9	19	7	9
Total shares of common stock if converted	190	12,670	10,565	190	13,806	10,565
Undeclared dividends	$ 11	$ -	$ -	$ 10	$ -	$ -
Accrued dividends	$ -	$ 2,186	$ 2,175	$ -	$ 2,014	$ 1,963
Total shares of common stock if dividends converted	22	4,372	4,350	20	4,028	3,926

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 Convertible Preferred Stock

Each share of the Series B preferred stock is convertible into ten shares of the Company's common stock. Dividends are cumulative and payable to the Series B preferred stockholders when and as declared by the Company's Board of Directors (the "Board"). Dividends on the Series B preferred stock accumulate at the rate of $0.25 per share per annum, and may be paid, at the option of the Company at the time of conversion, either in cash or shares of the Company's common stock valued at $0.50 per share. The Series B preferred stock has liquidation preferences over the common shares at $5.00 per share, plus any accrued and unpaid dividends. Except as provided by law, the Series B preferred stockholders have no voting rights. The Company does not accrue dividends on Series B preferred stock until such dividends are declared.

Series C and Series D Convertible Preferred Stock

The Series C and Series D Certificates of Designation provide, among other things, that holders of Series C and Series D preferred stock shall be entitled to receive, when and as declared by the Board and out of any assets at the time legally available therefor, cumulative dividends at the rate of ten percent (10%) per share per annum of the stated value of the Series C and Series D preferred stock, which is $1,000 per share (the "Stated Value"). Dividends on the Series C and Series D preferred stock are cumulative, and will accrue and be compounded annually, whether or not declared and whether or not there are any profits, surplus or other funds or assets of the Company legally available therefor. Dividends on the Series C and Series D preferred stock may be paid in cash or shares of the Company's common stock at the option of the holder. Series C and Series D preferred stock does not have redemption rights. Each share of Series C and Series D preferred stock is convertible at the holder's option into shares of common stock, with Series C stockholders having conversion price of $0.50 per share, and Series D stockholders having conversion price of $0.80 per share, together with accrued and unpaid dividends payable, at the option of the holder, in cash or shares of common stock based on the conversion price. Given the obligation to settle all dividends, including those in arrears, in cash at the election of the preferred stockholder upon conversion, whether or not declared by the Company, the Company accrues dividends on Series C and D preferred stock as a liability in its consolidated financial statements.

In the event of liquidation, dissolution or winding up of the Company, the holders of Series D preferred stock will be entitled to receive, on a pari passu basis with the holders of the Series C preferred stock and in preference to any payment or distribution to holders of the Series B preferred stock and common stock, an amount per share equal to the Stated Value plus the amount of any accrued and unpaid dividends. If, at any time while the Series C and Series D preferred stock is outstanding, the Company effects any reorganization, merger or consolidation of the Company, sale of substantially all of its assets, or other specified transaction (each, as defined in the Series C and the Series D Certificates of Designation, a "Fundamental Transaction"), a holder of Series C and Series D preferred stock will have the right to receive any shares of the acquiring corporation or other consideration it would have been entitled to receive if it had been a holder of the number of shares of common stock then issuable upon conversion in full of the Series C and Series D preferred stock immediately prior to the Fundamental Transaction. Except as otherwise provided in the Series C and Series D Certificates of Designation or as otherwise required by law, the Series C and Series D preferred stock have no voting rights.

Convertible Notes and Accrued Interest

(in thousands)	August 31, 2022			May 31, 2022		
	April 2, 2021 Note	April 23, 2021 Note	Total	April 2, 2021 Note	April 23, 2021 Note	Total
Convertible notes payable outstanding principal	$ 9,819	$ 28,500	$ 38,319	$ 9,819	$ 28,500	$ 38,319
Less: Unamortized debt discount and issuance costs	(359)	(1,127)	(1,486)	(512)	(1,566)	(2,078)
Convertible notes payable, net	9,460	27,373	36,833	9,307	26,934	36,241
Accrued interest on convertible notes	2,920	4,200	7,120	2,599	3,375	5,974
Outstanding convertible notes payable, net and accrued interest	$ 12,380	$ 31,573	$ 43,953	$ 11,906	$ 30,309	$ 42,215

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

(in thousands)	April 2, 2021 Note	April 23, 2021 Note	Total
Outstanding balance at May 31, 2022	$ 11,906	$ 30,309	$ 42,215
Amortization of issuance discount and costs	153	439	592
Interest expense	321	825	1,146
Outstanding balance at August 31, 2022	$ 12,380	$ 31,573	$ 43,953

Long-term Convertible Note – April 2, 2021 Note

On April 2, 2021, the Company entered into a securities purchase agreement pursuant to which the Company issued a secured convertible promissory note with a two-year term in the initial principal amount of $28.5 million (the "April 2, 2021 Note"). The Company received consideration of $25.0 million, reflecting an original issue discount of $3.4 million and issuance costs of $0.1 million. Interest accrues at an annual rate of 10% on the outstanding balance, with the rate increasing to the lesser of 22% per annum or the maximum rate permitted by applicable law upon occurrence of an event of default. In addition, upon any event of default, the investor may accelerate the outstanding balance payable under the April 2, 2021 Note; upon such acceleration, the outstanding balance will increase automatically by 15%, 10% or 5%, depending on the nature of the event of default. The events of default are listed in Section 4 of the April 2, 2021 Note filed as Exhibit 4.1 to the Company's Current Report on Form 8-K filed on April 8, 2021. The April 2, 2021 Note is secured by all the assets of the Company, excluding the Company's intellectual property.

Pursuant to the terms of the April 2, 2021 Note, the Company must obtain the investor's consent before assuming additional debt with aggregate net proceeds to the Company of less than $50.0 million. In the event of any such approval, the outstanding principal balance of the April 2, 2021 Note will increase automatically by 5% upon the issuance of such additional debt. The investor may convert all or any part the outstanding balance of the April 2, 2021 note into shares of common stock at an initial conversion price of $10.00 per share upon five trading days' notice, subject to certain adjustments and volume and ownership limitations. In addition to standard anti-dilution adjustments, the conversion price of the April 2, 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 provides for liquidated damages upon failure to deliver common stock within specified timeframes and requires the Company to maintain a share reservation of 6.0 million shares of common stock. The investor may redeem any portion of the note, at any time beginning six months after the issue date upon three trading days' notice, subject to a maximum monthly redemption amount of $3.5 million. The April 2, 2021 Note requires the Company to satisfy its redemption obligations in cash within three trading days of the Company's receipt of such notice. The Company may prepay the outstanding balance of the note, in part or in full, plus a 15% premium, at any time upon 15 trading days' notice.

Pursuant to the terms of the April 2, 2021 Note, the Company is obligated, at the discretion of the noteholder, to reduce the outstanding balance by $7.5 million per month for five months. During fiscal 2022, in partial satisfaction of debt reduction amounts, the Company and the April 2, 2021 Note holder entered into exchange agreements, pursuant to

which the April 2, 2021 Note was partitioned into new notes (the "Partitioned Notes") with an aggregate principal amount of $18.7 million, which were exchanged concurrently with the issuance of approximately 25.3 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 $9.8 million. The Company accounted for the restructured partitioned notes and exchange settlements as induced conversion, and, accordingly, recorded an aggregate loss on convertible debt induced conversion of $18.8 million through May 31, 2022; none for the three months ended August 31, 2022 and 2021.

Long-term Convertible Note – April 23, 2021 Note

On April 23, 2021, the Company entered into a securities purchase agreement pursuant to which the Company issued a secured convertible promissory note with a two-year term to an institutional accredited investor affiliated with the holder of the April 2, 2021 Note in the initial principal amount of $28.5 million (the "April 23, 2021 Note"). The Company received consideration of $25.0 million, reflecting an original issue discount of $3.4 million and issuance costs of $0.1 million. Interest accrues at an annual rate of 10% on the outstanding balance of the April 23, 2021 Note, with the rate increasing to the lesser of 22% per annum or the maximum rate permitted by applicable law upon the occurrence of an event of default. In addition, upon any event of default, the investor may accelerate the outstanding balance payable under the April 23, 2021 Note; upon such acceleration, the outstanding balance will increase automatically by 15%, 10% or 5%, depending on the nature of the event of default. The events of default are listed in Section 4 of the April 23, 2021 Note filed as Exhibit 4.1 to the Company's Current Report on Form 8-K filed on April 29, 2021. The April 23, 2021 Note is secured by all the assets of the Company, excluding the Company's intellectual property.

Pursuant to the terms of the April 23, 2021 Note, the Company must obtain the investor's consent before assuming additional debt with aggregate net proceeds to the Company of less than $75.0 million. In the event of any such approval, the outstanding principal balance of the April 23, 2021 Note will increase automatically by 5% upon the issuance of such additional debt. The investor may convert all or any part of the outstanding balance into shares of common stock at an initial conversion price of $10.00 per share upon five trading days' notice, subject to certain adjustments and volume and ownership limitations specified in the April 23, 2021 Note. In addition to standard anti-dilution adjustments, the conversion price of the 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. The April 23, 2021 Note provides for liquidated damages upon failure to deliver common stock within specified timeframes and requires the Company to maintain a share reservation of 6.0 million shares of common stock. The investor may redeem any portion of the April 23, 2021 Note, at any time beginning six months after the issue date, upon three trading days' notice, subject to a maximum monthly redemption amount of $7.0 million. The April 23, 2021 Note requires the Company to satisfy its redemption obligations in cash within three trading days of the Company's receipt of such notice. The Company may prepay the outstanding balance of the April 23, 2021 Note, in part or in full, plus a 15% premium, at any time upon 15 trading days' notice.

The holders of the April 2 and April 23 Notes waived provisions in the notes that 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. The related events included the grant of registration rights to investors in specified private offerings, the issuance of warrants to purchase 30 million shares of common stock with registration rights to certain parties and potential incurrence of debt pursuant to a Surety Bond Backstop Agreement (the "Backstop Agreement"), and the grant of a security interest in the Company's intellectual property to certain parties to the Backstop Agreement. Refer to Note 6, *Equity Awards and Warrants*.

Note 6. Equity Awards

Approval of Increase in Authorized Common Stock

On August 31, 2022, the stockholders' of the Company, at a special stockholders' meeting approved a proposal to increase the total number of authorized shares of common stock from 1.0 billion shares to 1.35 billion shares.

From June 24, 2022 through August 31, 2022, the Company had insufficient authorized common stock to reserve for the shares underlying the Surety Backstop warrants and warrants issued to a placement agent in connection with the June 2022 offering (Refer to *Private Placement of Warrants under Surety Bond Backstop Agreement* and *Private Placement of Common Stock and Warrants through Placement Agent* sections below.) On August 31, 2022, the stockholders of the Company approved an increase to the Company's authorized common stock, after which sufficient shares were authorized, including those to cover the shares underlying the warrants. Given that the Company did not have a sufficient number of authorized shares for the two instruments at the time they were issued, the Company evaluated, and accounted for such warrants between June and August, as liability classified warrants consistent with ASC 815, *Derivatives and Hedging.*

In accordance with the prescribed accounting guidance, the Company measured fair value of liability classified warrants 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.

As of August 31, 2022, in accordance with ASC 815, *Derivatives and Hedging,* the Company reclassified the warrants to equity due to having a sufficient number of authorized shares upon receiving approval of an increase to the Company's authorized common stock. The Company recorded a loss on derivatives of approximately $8.6 million in the quarter ended August 31, 2022 due to change in fair market value of the liability classified warrants between June 24 and August 31, 2022. The table below presents a reconciliation of the beginning and ending balances for liabilities measured at fair value during the three months ended August 31, 2022, and the year ended May 31, 2022:

(in thousands)		**Liability Classified Warrants**
Balance at May 31, 2022	$	—
Classified as liability due to lack of shares availability at issuance		14,522
Classified as equity upon increase in availability		(23,123)
Loss on derivative due to change in fair market value		8,601
Balance at August 31, 2022	$	—

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.

	Initial Fair Market Value At Issuance			**Fair Market Value at August 31, 2022**		
	Backstop Warrant #1	Backstop Warrant #2	Placement Agent Warrants	Backstop Warrant #1	Backstop Warrant #2	Placement Agent Warrants
Fair value of underlying stock	$ 0.44	$ 0.42	$ 0.44	$ 0.52	$ 0.52	$ 0.52
Risk free rate	3.17%	3.06%	3.13%	3.34%	3.31%	3.16%
Expected term (in years)	4.65	5.00	10.00	4.46	4.88	9.82
Stock price volatility	110.20%	109.49%	95.99%	117.29%	113.59%	95.87%
Expected dividend yield	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%

Equity Incentive Plan

As of August 31, 2022, the Company had one active stock-based equity plan, the *CytoDyn Inc. Amended and Restated 2012 Equity Incentive Plan* (the "2012 Plan"), and one stock-based equity plan that is no longer active, but under which certain prior awards remain outstanding. As of May 31, 2022, the 2012 Plan covered a total of 34.3 million shares of common stock. As of May 31, 2022, the Board had released from reservation under the 2012 Plan a total of 22.0 million shares of common stock to permit their use for general purposes, leaving approximately 3.9 million shares available for future stock-based awards under the 2012 Plan. The Board also made a determination on May 31, 2022, to waive the "evergreen provision" that would have automatically increased the number of shares of common stock subject to the 2012 Plan by an amount equal to 1% of the total outstanding shares on that date. Following approval by the stockholders of the 350.0 million increase in authorized shares of common stock on August 31, 2022, the 22.0 million shares were restored for issuance under the 2012 Plan.

Stock Options, Equity Awards, Warrants, and Stock-Based Compensation

Stock option and warrants activity is presented in the table below:

(in thousands, except per share data)	Number of shares	Weighted average exercise price	Weighted average remaining contractual life in years	Aggregate intrinsic value
Options and warrants outstanding at May 31, 2022	90,705	$ 0.77	4.06	$ 352
Granted	104,104	$ 0.25		
Exercised	(863)	$ 0.49		
Forfeited, expired, and cancelled	(484)	$ 1.57		
Options and warrants outstanding at August 31, 2022	193,462	$ 0.48	4.36	$ 36,758
Options and warrants outstanding and exercisable at August 31, 2022	187,896	$ 0.45	4.24	$ 36,717

As of August 31, 2022, approximately 11.9 million outstanding stock options were vested, approximately 5.3 million outstanding stock options were unvested, and all outstanding warrants were exercisable.

In the three months ended August 31, 2022 and 2021, stock-based compensation expense, inclusive of stock issued for compensation, presented in general and administrative expense in the Company's consolidated statements of operations, totaled approximately $1.3 million and $2.6 million, respectively. For the three months ended August 31, 2022, approximately $5.3 million of stock-based compensation expense related to warrants issued under the Backstop Agreement, as amended, was recorded as a finance charge in the accompanying consolidated statement of operations; none in the three-month period ended August 31, 2021. Refer to *Private Placement of Warrants under Surety Bond Backstop Agreement* below for further information.

During the three months ended August 31, 2022, the Company granted stock options covering a total of approximately 0.2 million shares of common stock to employees with exercise prices ranging from $0.41 to $0.67 per share. The stock options vest over four years, have a ten-year term, and a grant date fair value between $0.33 and $0.54 per share. During the same period in the prior year, the Company also issued approximately 0.2 million shares of common stock in connection with the time-based vesting of restricted stock units ("RSUs") for which it recognized $0.1 million in stock-based compensation expense; there were no issuances of shares of common stock in connection with the exercise of stock options or in connection with the vesting of performance stock units ("PSUs") in the three months ended August 31, 2022.

Issuance of Shares to Former and Current Executives

During the fiscal year ended May 31, 2022, the employment of our CEO and General Counsel was terminated. Under the terms of their respective employment agreements, the Company was obligated to pay severance equal to 18 months of salary to our former CEO and 12 months of salary to our former General Counsel. As permitted by the

employment agreements, in March 2022, the Board authorized the severance payments to our former CEO and the remaining severance payments to our former General Counsel to be made through the issuance of shares of common stock.

During the three months ended August 31, 2022, the Company issued to our former General Counsel a total of 79,391 shares of common stock to satisfy in full its obligation under the terms of the employment agreement. During the same period, consistent with the terms of our former CEO's employment agreement, the Company also issued 88,983 shares of common stock in satisfaction of the severance amounts due for the months of June, July, and August 2022. The numbers of shares issued were based on the closing price of the common stock on the applicable date.

In order to preserve cash resources, in April 2022, the Board of Directors approved the issuance to then executive officers of shares of common stock with a value equal to 25 percent of salary in lieu of cash, net of payroll deductions and withholding taxes. During the three months ended August 31, 2022, a total of 235,676 shares of common stock were issued pursuant to this cash preservation program. The number of shares issued was based on the closing price of the common stock on each payroll date.

Private Placement of Warrants under Surety Bond Backstop Agreement

On February 14, 2022, the Company entered into the Backstop Agreement with an accredited investor in his individual capacity and as trustee of a revocable trust, as well as certain other related parties (collectively, the "Indemnitors"). Pursuant to the Backstop Agreement, the Indemnitors agreed to assist the Company in obtaining a surety bond (the "Surety Bond") for posting in connection with the Company's ongoing litigation with Amarex Clinical Research, LLC ("Amarex") by, among other things, agreeing to indemnify the issuer of the Surety Bond (the "Surety") with respect to the Company's obligations under the Surety Bond through August 13, 2022. As consideration for the Indemnitors' agreement to indemnify the Surety, the Company agreed (i) to issue to 4-Good Ventures LLC, an affiliate of the Indemnitors ("4-Good"), a warrant for the purchase of 15,000,000 shares of common stock as a backstop fee (the "Initial Warrant"), (ii) to issue to 4-Good a warrant for the purchase of an additional 15,000,000 shares, to be exercisable only if the Indemnitors were required to make any payment to the Surety (the "Make-Whole Warrant" and, together with the Initial Warrant, the "4-Good Warrants"), and (iii) if the Indemnitors are required to make a payment to the Surety, (A) within 90 days of such payment, to reimburse the Indemnitors for any amount paid to the Surety and (B) to pay to the Indemnitors an indemnification fee in an amount equal to 1.5 times the amount paid by the Indemnitors to the Surety. The payment obligations of the Company to the Indemnitors will bear interest at 10% per annum and are secured by substantially all of the patents held by the Company. The Company recognized a finance charge of approximately $6.6 million related to the warrant issuance for the year ended May 31, 2022.

Pursuant to an amendment to the Backstop Agreement executed on July 18, 2022 (the "Backstop Amendment"), among other matters: (i) the obligation of the Indemnitors to indemnify the Surety was extended from August 13, 2022 to November 15, 2022; (ii) each of the 4-Good Warrants has a five-year term from the date of issuance and an exercise price of $0.20 per share (reduced from $0.30 per share); (iii) the Make-Whole Warrant was amended to be fully exercisable immediately; (iv) the Indemnitors and 4-Good agreed to waive the requirement to reserve for issuance the shares subject to the Make-Whole Warrant pending stockholder approval of an increase in the authorized shares of common stock; and (v) upon the exercise in full of the 4-Good Warrants, the Company agreed to take reasonable steps to cause the Indemnitors to be released from their indemnity obligations by an amount equal to the exercise proceeds.

Private Placement of Common Stock and Warrants through Placement Agent

In April 2022, the Company initiated a private placement of common stock and warrants, completed in June 2022, to accredited investors through a placement agent. Between April and June 2022, the Company sold a total of approximately 85.4 million shares of common stock for a total of approximately $18.9 million of proceeds, net of issuance costs. Of these, approximately $7.7 million of proceeds, net of issuance costs, relating to approximately 34.6 million shares were remitted to the Company by May 31, 2022. Each unit sold included a fixed combination of one share of common stock and three-quarters of one warrant to purchase one share of common stock for a purchase price of $0.255 per unit. The Company issued approximately 64.0 million warrants to investors with each such warrant having a five-year term and an exercise price of 120% of the final unit price, or $0.306 per share, and are immediately exercisable. The Company paid the placement agent a total cash fee of approximately $2.8 million, equal to 13% of the gross proceeds of the offering, as well as a one-time fee for expenses of $50,000, and issued a total of approximately

19.4 million warrants with an exercise price of $0.255 per share and a ten-year term, representing 13% of the total number of shares, including shares subject to warrants sold in the offering, to the placement agent and its designees. The issuance of the warrants to the placement agent was subject to the approval by the Company's stockholders of an increase in authorized shares of common stock, which was approved on August 31, 2022.

Down Round Provision Issuance and Modification to Previous Private Offerings

During the three months ended August 31, 2022, common stock and warrants previously issued between February and April 2022 to accredited investors directly by the Company in a private placement became subject to a down round provision under the original purchase agreements requiring the Company to reduce the purchase price of common stock from the original price of $0.40 to $0.255 per share, to increase the percentage of the warrant coverage from 50% to 75% based on the revised amount of total shares issued, and to reduce the exercise price of the warrants from the original price of $0.40 to $0.255, the terms in the latest round of financing conducted by the Company through the placement agent as discussed above. As a result, an approximate additional 4.6 million shares of common stock and 5.5 million warrants were issued. The incremental fair value of the warrants were measured using the Black-Scholes pricing model, resulting in an approximately $4.2 million charge to additional paid-in capital which was accounted for as a deemed dividend.

Warrant Exercises

During the three months ended August 31, 2022, the Company issued approximately 0.5 million shares of common stock in connection with the exercise of an equal number of warrants. The stated exercise prices ranged from $0.45 to $0.75 per share, which resulted in aggregate gross proceeds of approximately $0.3 million. Additionally, during the three months ended August 31, 2022, the Company issued approximately 0.2 million shares of common stock in connection with the cashless exercise of approximately 0.3 million warrants with stated exercise prices ranging from $0.40 to $0.50 per share.

Note 7. 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 August 31,	
	2022	2021
		(Restated) [1]
Net loss	$ (20,991)	$ (45,337)
Less: Deemed dividends due to down round provision	(4,154)	—
Less: Accrued preferred stock dividends	(385)	(425)
Net loss applicable to common stockholders	$ (25,530)	$ (45,762)
Basic and diluted:		
Weighted average common shares outstanding	787,856	632,597
Loss per share	$ (0.03)	$ (0.07)

(1) See Note 2, *Summary of Significant Accounting Policies*.

The table below shows the approximate number of shares of common stock issuable upon the exercise, vesting or conversion of outstanding options, warrants, unvested restricted stock units (including those subject to performance conditions), 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 months ended August 31, 2022	2021
Stock options, warrants, and unvested restricted stock units	193,609	60,141
Convertible notes	12,000	12,000
Convertible preferred stock	32,170	33,858

Note 8. 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 months ended August 31, 2022 and 2021 was zero. The Company does not consider it more likely than not that the benefits from the net deferred taxes will be realized; therefore the Company maintains a full valuation allowance as of August 31, 2022 and May 31, 2022 thus creating a difference between the effective tax rate of 0% and the statutory rate of 21%.

Note 9. Commitments and Contingencies

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

In April 2019, the Company entered into an agreement with Samsung, pursuant to which Samsung will perform technology transfer, process validation, manufacturing, pre-approval inspection and supply services for the commercial supply of leronlimab bulk drug substance effective through calendar year 2027. In 2020, the Company entered into an additional agreement, pursuant to which Samsung will perform technology transfer, process validation, vial filling and storage services for clinical, pre-approval inspection, and commercial supply of leronlimab drug product. 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 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. Under the agreements, Samsung may be entitled to terminate its services if the parties cannot reach an agreement as to the past due balance. Management is in ongoing discussions with Samsung regarding potential approaches to resolve these issues, including proposals by both parties of a revised schedule of payments over an extended period of time, and proposals by the Company of satisfaction of a portion of the Company's payment obligations in equity securities of the Company and postponing or cancelling the manufacturing of additional drug provided for in the agreements. As of August 31, 2022, the Company had past due balances of approximately $35.7 million due to Samsung which were included in accounts payable. As of August 31, 2022, the future commitments pursuant to these agreements were estimated as follows (in thousands):

Fiscal Year	Amount
2023 (9 months remaining)	$ 34,638
2024	121,750
2025	76,400
2026 and thereafter	—
Total	$ 232,788

Operating Lease Commitments

We lease our principal office location in Vancouver, Washington. 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*. During the three months ended August 31, 2022 and 2021, we recognized approximately $46.0 thousand and $48.9 thousand of operating lease costs. 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)	August 31, 2022	May 31, 2022
Assets		
Right-of-use asset	$ 502	$ 536
Liabilities		
Current operating lease liability	$ 135	$ 134
Non-current operating lease liability	387	422
Total operating lease liability	$ 522	$ 556

The minimum (base rental) lease payments are expected to be as follows as of August 31, 2022 (in thousands):

Fiscal Year	Amount
2023 (9 months remaining)	$ 133
2024	182
2025	185
2026	169
Total operating lease payments	669
Less: imputed interest	(147)
Present value of operating lease liabilities	$ 522

Supplemental information related to operating leases was as follows:

	August 31, 2022
Weighted average remaining lease term	3.6 years
Weighted average discount rate	10.0 %

Distribution and Licensing Commitments

Refer to Note 10, *Commitments and Contingencies*, in the 2022 Form 10-K for information.

Legal Proceedings

As of August 31, 2022, the Company did not record any legal accruals related to the outcomes of the 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 Lawsuit

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 current and 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 Company and certain current and former officers 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 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. 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 current and former officers, certain current and former Board members, 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 United States Securities and Exchange Commission ("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 Company executives have received subpoenas concerning similar issues and may be interviewed by the DOJ or SEC in the future. The SEC informed the Company that its inquiry should not be construed as an indication that any violations of law have occurred or that the SEC has any negative opinion of any person, entity or security The Company is cooperating fully with these non-public, fact-finding investigations, and as of the date of this filing, the Company is unable to predict the ultimate outcome and cannot reasonably estimate the potential possible loss or range of loss, if any.

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 Clinical Research LLC ("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. The arbitration demand 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 demand 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. Amarex has counterclaimed alleging that CytoDyn has failed to pay invoices due under the contract between the parties. In light of the fact that this dispute is in 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.

Note 10. Subsequent Events

Issuance of Shares to Former CEO

During the fiscal year ended May 31, 2022, the employment of our CEO was terminated. Under the terms of the employment agreement, the Company was obligated to pay severance equal to 18 months of salary. As permitted by the employment agreement, in March 2022, the Board authorized the severance payments to be made through the issuance of shares of common stock. During September and October, the Company issued a total of 80,816 shares of common stock in satisfaction of the severance amounts due during September 2022. The numbers of shares issued were based on the closing price of the common stock on the applicable dates.

In September 2022, the Company appointed to its Scientific Advisory Board ("SAB"): Dr. Jordan Lake to assist with trial design for HIV/NASH and identifying collaborative opportunities, Dr. Stefan Glück to assist with identifying partners, trial design, identifying collaborations, and opportunities in oncology, and Dr. Nueto Ueno to assist with trial design and identifying opportunities for collaboration in oncology. The Company issued 50,000 options for shares of common stock to each SAB member in consideration for their annual service on the SAB.

On September 6, 2022, the Board's Compensation Committee approved, under the Company's 2012 Plan, grants of fully vested nonqualified stock options to purchase shares of common stock to three of the Company's nonemployee directors for their service during the fiscal year ended May 31, 2022, as follows: Tanya Durkee Urbach, 112,500 shares; Lishomwa Ndhlovu, 112,500 shares; and Karen J. Brunke, 37,500 shares. The Compensation Committee also approved, under the 2012 Plan, grants of nonqualified stock options to purchase shares of common stock to the Company's four nonemployee directors as of September 6, 2022, for service during the fiscal year ending May 31, 2023, as follows; each of Ms. Urbach, Dr. Brunke, and Dr. Ndhlovu, 247,111 shares, of which 25% were fully vested on the grant date and the balance will vest in nine equal monthly installments beginning on October 1, 2022, subject to continuous service (as defined in the 2012 Plan) through the applicable vesting date; and Ryan Dunlap, 185,333 shares, vesting in nine equal monthly installments beginning on October 1, 2022, subject to continuous service through the applicable vesting date. Dr. Ndhlovu was also granted a fully vested nonqualified stock option to purchase 50,000 shares of common stock for

service on the Company's Scientific Advisory Board beginning in July 2021. All of the stock options have an exercise price of $0.50 per share and a 10-year term.

On September 20, 2022, the Board's Compensation Committee approved the grant of equity awards under the Company's 2012 Plan to its President in accordance with the terms of his employment agreement as follows: (i) nonqualified stock options to purchase 1,575,557 shares of common stock at an exercise price of $0.58 per share, with 25% of the options vesting on July 9, 2023, and the balance in 36 equal monthly installments thereafter, subject to continuous service through the applicable vesting date; (ii) RSUs relating to 646,552 shares of common stock vesting in four equal annual installments beginning July 9, 2023, also subject to continuous service through the applicable vesting date; and (iii) PSUs relating to 646,552 shares of common stock, with vesting subject to the attainment of performance goals approved by the Compensation Committee.

Also on September 20, 2022, the Compensation Committee approved the grant of nonqualified stock options under the 2012 Plan to the Company's CFO to purchase 630,222 shares of common stock at an exercise price of $0.58 per share, with 25% of the options vesting on January 24, 2023, and the balance in 36 equal monthly installments thereafter, subject to continuous service through the applicable vesting date, as additional compensation for his service as interim President from January 24, 2022, through July 9, 2022.

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 this quarterly report, and those set forth in Item 1A. *Risk Factors* in our 2022 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 holds imposed by the U.S. Food and Drug Administration (the "FDA") and information regarding future operations, future capital expenditures and future net cash flows. 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 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 Biologic License Application ("BLA") resubmission or other 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 the Company's clinical trials; the results of the Company's 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; legal proceedings, investigations or inquiries affecting the Company or its products; general economic and business conditions; changes in foreign, political, and social conditions; 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 take into account 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 Annual Report on Form 10-K (the "2022 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 biotechnology company focused on the clinical development and potential commercialization of its product candidate, leronlimab, which is being studied for the treatment of HIV infection, NASH, and solid tumors in oncology. Our current business strategy is to seek the removal of the partial and full clinical holds imposed by the US FDA in March 2022, evaluate the feasibility of the resubmission of the clinical section of the BLA for leronlimab as a

combination therapy for highly treatment-experienced HIV patients, and to seek to further develop for leronlimab in NASH, NASH-HIV, and solid tumors in oncology.

As further discussed in Part I, Item 1, Note 2, *Summary of Significant Accounting Policies - Inventories,* Note 3, *Inventories, net*, and Note 9, *Commitments and Contingencies,* the Company capitalized procured or produced pre-launch inventories in preparation for product launches. The Company considers anticipated future sales, shelf-lives, and expected approval date when evaluating realizability of prelaunch inventories. The shelf-life of a product is determined as part of the regulatory approval process; however, in assessing whether to capitalize pre-launch inventory, the Company considers the stability data of all inventories. As inventories approach their shelf-life expiration, the Company may perform additional stability testing to determine if the inventory is still viable, which may result in an extension of its shelf-life. Further, in addition to performing additional stability testing, certain raw materials inventory may be sold in its then current condition prior to reaching expiration. In determining whether pre-approval inventory remains salable, the Company considers a number of factors, including potential delays in obtaining regulatory approval, the introduction of competing products that may negatively impact the demand for our product, the likelihood that physicians would be willing to prescribe leronlimab to their patients, and whether the target patient population would be willing to try leronlimab as a new therapy.

First Quarter Overview

HIV BLA and Clinical Developments

The remaining BLA section to be completed and submitted remains in the clinical section as of the date of this report. The Company is in a dispute with its former contract research organization ("CRO"); the Company obtained an order requiring the CRO to release the Company's clinical data related to the BLA and other clinical trials, which the CRO had been withholding, thereby preventing the Company from completing necessary clinical data submissions to the FDA. The order granted the Company access to the data and the right to perform an audit of the CRO's services. In March 2022, the FDA notified the Company that it had placed a partial clinical hold on the Company's HIV program; the Company was not enrolling any new patients in the trials placed on hold. The partial clinical hold on the HIV program impacted patients enrolled in HIV extension trials. The affected patients have been transitioned to other available therapeutics. No clinical studies can be initiated or resumed until the partial clinical hold is resolved, which may affect our ability to resubmit the BLA. The Company's efforts are focused on activities that will allow us to resolve the partial clinical hold and potentially resume the BLA resubmission process. The Company will update the feasibility of the resubmission of the clinical section of the BLA once it completes its evaluation of the clinical data, results of the CRO audit, and the timelines of the clinical holds.

NASH Clinical Developments

Non-alcoholic steatohepatitis (NASH) is a chronic liver disease characterized by the presence of hepatic inflammation and cell. Patients with advanced fibrosis due to NASH are at significantly higher risk of liver‑related mortality. There is currently no approved drug for NASH. Liver disease is one of the leading causes of non-AIDS-related death in HIV patients. The Company is identifying the next steps in clinical development to continue the investigation of leronlimab in the NASH indication and HIV patients with NASH.

In NASH, liver homeostasis is impaired due to an accumulation of toxic lipids which can activate both Kupffer cells (KCs) and tissue-resident macrophages resulting in the production of fibrogenic cytokines and chemoattractant chemokines such as transforming growth factor-beta (TGF-β) and monocyte chemoattractant protein-1 (MCP-1). Not only do these cytokines/chemokines promote transdifferentiation of hepatic stellate cells (HSCs) into myofibroblasts (the primary source for fibrillary collagens), but they also amplify the immune response by recruiting additional cells into the damaged area. Recruitment of extra-hepatic inflammatory cells to the site of hepatic injury is typically mediated by interactions between cytokines/chemokines and their receptors. It has also been shown that patients with NASH also have high levels of C-C chemokine receptor 5 (CCR5) and the associated ligand, CCL5, thus demonstrating a potential role of CCR5 and its ligands in liver fibrosis.

The potential for leronlimab in the treatment of NASH was demonstrated in a pre-clinical model of fatty liver disease. Immunodeficient, NOD-SCID Gamma (NSG) mice were fed a high fat, NASH-inducing diet, transplanted with

human stem cells to repopulate the deficient immune system, and treated with leronlimab. Sixteen (16) male NOD.Cg-*Prkdcscid Il2rgtm1Wjl/SzJ*, commonly known as the NOD *scid* IL-2 receptor gamma knockout mice (NSG) were first humanized by intravenous inoculation with normal human umbilical cord blood cells (105). After 5 weeks on normal mouse chow, mice were successfully humanized, demonstrating >25% human CD45 cells in peripheral blood. Mice were switched to high fat (52%) high cholesterol (1.25%) diet (FPC diet: fructose, palmitate, cholesterol, trans-fat; Envigo-Teklad TD.160785). Leronlimab and control antibody (normal human IgG, Sigma) were administered i.p. at a dose of 2mg i.p. twice weekly, n=8 mice/group. The results showed that leronlimab inhibited fatty liver development, a key characteristic of early-stage NASH, such that treatment of humanized NSG mice with leronlimab caused a three fold reduction in hepatic steatosis compared to control in an animal model of high fructose, high palmitate, high cholesterol diet.

The Company has reported clinical data from patients with NASH from the CDI-NASH-01 trial which was designed as a multi-center Phase 2a study and was subsequently converted into an exploratory study to evaluate the dose, efficacy, and safety of leronlimab at 350 mg and 700 mg, versus placebo. The study also included an expansive biomarker program designed to inform future clinical trials and to more fully understand leronlimab's mechanism of action within the NASH setting. CDI-NASH-01 was run in two parts, Part 1 of the study was to assess the efficacy of leronlimab 700 mg (n=22) in improving NAFLD/NASH measures in adult patients diagnosed with NASH compared to placebo (n=28). Part 2 was subsequently added to assess leronlimab 350 mg in improving NAFLD/NASH measures in adult patients diagnosed with NASH (n=22). In Part 1 of the study, eligible subjects were randomized 1:1 to one of the two study arms to receive either leronlimab 700mg (Group A), or placebo (Group B), given once per week (±1day) at the study site for up to 13 weeks during the treatment period (with up to 60 participants). In Part 2 of the study, eligible subjects enrolled to receive leronlimab 350 mg open-label given once per week (±1day) at the study site for up to 13 weeks during the treatment period (with up to 28 participants). The primary efficacy objective was percent change from baseline in hepatic fat fraction, as assessed by magnetic resonance imaging-derived proton density fat fraction (MRI-PDFF) at week 14. The secondary efficacy objective was absolute change from baseline in fibro-inflammatory activity in the liver as assessed by MRI-corrected T1 imaging (MRI-cT1) at week 14. MRI-cT1 is obtained by multiparametric magnetic resonance imaging of the liver and is a quantitative metric for assessing a composite of liver inflammation and fibrosis, expressed in milliseconds (msec). MRI-PDFF is being studied as an imaging surrogate endpoint for the fat density in the liver. MRI-cT1 is being studied as an imaging surrogate endpoint for hepatic fibro-inflammation. This is a critical unmet need in the NASH space, as many agents have been unable to show reductions in fibro-inflammation despite reductions in hepatic steatosis.

All analyses performed were exploratory. Treatment with leronlimab was well tolerated in both Part 1 and Part 2 compared to placebo. In Part 1 of the study, leronlimab 700 mg did not reduce mean change in PDFF and cT1 from baseline to week 14 vs. placebo. In Part 2, leronlimab 350 mg reduced mean change in PDFF and cT1 from baseline to week 14 vs. the placebo group from Part 1, despite increased degree of baseline fibro-inflammation. In the combined group of patients with moderate (≥ 875 msec) and severe (≥ 950 msec) cT1 values at baseline, leronlimab 350 mg reduced cT1 from baseline to week 14 vs. placebo. Based on post hoc CCR5 haplotype analysis of a small subgroup (n=5), we are considering further investigation of the 700mg dose of leronlimab for specific haplotypes.

Cancer Clinical Developments

The Company is identifying the next steps in clinical development 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.

Summary of TNBC Data

To assess the impact of leronlimab treatment on mTNBC patients, we pooled the data from 3 studies: CD07_TNBC Phase 1b/2, CD07_TNBC_Compassionate Use, and CD-09 Basket. The study population for pooled efficacy analysis was a total of 28 subjects (10 subjects from the Phase 1b/2 study, 16 subjects from the Compassionate Use Study, and 2 subjects were from the Basket Study).

To explore the impact of leronlimab in the mTNBC patients' disease progression, investigator assessed Progression Free Survival (PFS) was analyzed in the 28 subjects. There was a total of 19 subjects dosed between 525 mg and 700 mg (4 subjects increased dose from 350 mg to 525 mg and were included in the higher dose cohort). The median PFS

(mPFS) for the 525 mg – 700 mg cohort was 6.2 months (95% CI 2.6 months - 7.5 months). There were 9 subjects dosed at 350 mg, mPFS was 2.2 months (95% CI 0.7 months - 12+ months). There was a meaningful PFS advantage at the higher doses when compared with the lower, 350 mg dose cohort.

Furthermore, the preliminary results of the leronlimab studies also showed similarity in the PFS outcomes of mTNBC patients treated with leronlimab + carboplatin compared to overall leronlimab treated population. Of the 28 subjects enrolled, 13 subjects received leronlimab + carboplatin treatment. The mPFS for leronlimab + carboplatin population was 3.9 months (95% CI 2.3 months - 6.0 months).

The subgroup analysis of PFS based on the individual subjects in each study were also reviewed. The mPFS for Phase 1b/2 study was 3.9 months (95% CI 2.3 months – 6.2 months), mPFS for the Compassionate Use study was 3.3 months (95% CI 1.3 months – 7.5 months), and mPFS for the Basket Study was 2.8 months (95% CI N/A).

Combined, the overall mPFS for all 28 patients treated with leronlimab in the population of mTNBC patients regardless of dosage, conjunction therapy type, brain or bone metastases that have failed more than one line of previous therapy was 4.1 months (95% CI 2.5 months – 7.0 months). The mean PFS was 3.7 ± 2.93 standard deviation (SD).

To explore the impact of leronlimab in the mTNBC patients' disease progression, Overall Survival (OS) was analyzed in the same 28 subjects. The median OS (mOS) for leronlimab + carboplatin population was 12+ months (95% CI 5.4 months - 12+ months).

The mOS for the 350 mg cohort was 4.6 months (95% CI 1.1 months -12+ months). The mOS for the 525-700 mg cohort was 12+ months (95% CI 5.5 months – 12+ months).

The overall median OS for leronlimab treated population of mTNBC patients regardless of brain or bone metastases that have failed more than one line of previous therapy was 6.5 months (95% CI 5.0 months – 12+ months). The mean value for OS was 5.5 ±4.31 standard deviation (SD).

COVID-19 Clinical Developments

The Company has made the business decision to currently discontinue its investigation of leronlimab for the COVID-19 indications due to challenges in clinical enrollment in the severe/critical COVID-19 population, and the unclear path for regulatory approval of COVID-19 post-acute sequelae SARS-CoV-2 infection (PASC).

Corporate Developments

In June 2022, the Company concluded a private placement of common stock and warrants through a placement agent, selling approximately 50.7 million additional shares of common stock for gross proceeds of $12.9 million and net proceeds of $11.3 million. Refer to Note 6, *Equity Awards and Warrants - Private Placement of Common Stock and Warrants through Placement Agent* for details.

Effective July 9, 2022, Cyrus Arman, Ph.D. was appointed President, and Antonio Migliarese ceased his role as interim President. Dr. Arman previously held positions with a number of biotechnology companies, most recently serving as Chief Business Officer of Nimble Therapeutics, Inc., a company focused on engineering peptides. Prior to Nimble he was Vice President of Corporate Development and Strategy of NEUVOGEN, Inc., an 30mmune-oncology company, developing therapeutic whole cell cancer vaccines, from 2019 until 2021. Beginning in 2017, he served as co-founder and managing partner of BioVega Capital, LLC, a life sciences hedge fund. From 2014 through 2019, he served in a variety of strategy roles at Amgen (NASDAQ: AMGN), a leading independent biotechnology company, including as Director of Corporate Strategy and Global Director and Head of Competitive Intelligence and Strategy. Prior to Amgen he was a Principal at Deallus Consulting, a global lifesciences competitive strategy consulting firm. He received an M.S. degree in biomedical engineering and a Ph.D. in neuroscience from the University of Southern California and an M.B.A from the UCLA Anderson School of Management.

On August 24, 2022, Ryan Dunlap was appointed to the Company Board of Directors and was subsequently appointed chair of the Audit Committee. Mr. Dunlap has over 25 years' experience in accounting, finance and operations leadership, developing significant expertise in strategy setting, improving operational efficiency and effectiveness, fundraising and investor relations, financial reporting and compliance, and risk management. Mr. Dunlap currently serves as the CFO of Gurobi Optimization, a private, equity backed software company offering customers decision intelligence solutions utilizing mathematical optimization, where he started in October 2019. Prior to that, he spent 7

years as a CFO in the biotech and life science industries, including at MolecularMD (now ICON Specialty Labs), a growth equity-backed molecular diagnostics company, and Galena Biopharma, a publicly-traded oncology drug development company. Earlier in his career, Mr. Dunlap held various financial and operational leadership roles in large, multinational organizations, and spent 11 years with public accounting firms such as PwC, KPMG, and Moss Adams, where he provided business assurance and advisory services to both public and private companies predominately in the software, technology, and life sciences industries. Mr. Dunlap earned a B.S. degree in Accounting from the University of Oregon and is an active licensed CPA in the state of Oregon.

On August 31, 2022, the Company's stockholders approved a proposal to increase the total number of authorized shares of common stock from 1.0 billion shares to 1.35 billion shares at a special stockholders' meeting.

Results of Operations

Fluctuations in Operating Results

The Company's operating results may fluctuate significantly depending on the outcomes of clinical trials, patient enrollment and/or completion rates in clinical trials, entering into new clinical trial protocols, and their related effect on research and development expenses, regulatory and compliance activities, activities related to the HIV BLA, general and administrative expenses, professional fees, and legal proceedings and the related outcomes. We require a significant amount of capital to continue to operate; therefore, we regularly conduct offerings to raise capital, which can create various forms of non-cash interest expense or other expenses. Additionally, we periodically negotiate settlement of debt payment obligations in exchange for equity securities of the Company and enter into warrant exchanges or modifications that may create non-cash charges. Our ability to continue to fund operations will depend on our ability to raise additional capital. Refer to *Risk Factors*, *Liquidity and Capital Resources*, and *Going Concern* sections included in this quarterly report.

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

(in thousands, except for per share data)	Three months ended August 31,		Change	
	2022	2021 (Restated) [1]	$	%
Revenue	$ —	$ 41	$ (41)	(100)
Cost of goods sold	—	1	(1)	(100)
Gross margin	—	40	(40)	(100)
Operating expenses:				
General and administrative	6,333	7,617	(1,284)	(17)
Research and development	576	12,020	(11,444)	(95)
Amortization and depreciation	99	276	(177)	(64)
Inventory charge	2,704	1,764	940	53
Total operating expenses	9,712	21,677	(11,965)	(55)
Operating loss	(9,712)	(21,637)	11,925	55
Interest and other expense:				
Interest on convertible notes	(1,146)	(1,686)	540	32
Amortization of discount on convertible notes	(576)	(952)	376	39
Amortization of debt issuance costs	(16)	(28)	12	43
Loss on induced conversion	—	(18,530)	18,530	100
Finance charges	(940)	(35)	(905)	(2,586)
Inducement interest expense	—	(528)	528	100
Legal settlement	—	(1,941)	1,941	100
Loss on derivatives	(8,601)	—	(8,601)	(100)
Total interest and other expense	(11,279)	(23,700)	12,421	52
Loss before income taxes	(20,991)	(45,337)	24,346	54
Income tax benefit	—	—	—	—
Net loss	(20,991)	(45,337)	24,346	54
Basic and diluted:				
Weighted average common shares outstanding	787,856	632,597	$ 155,259	25
Loss per share	$ (0.03)	$ (0.07)	0.04	55

(1) See Note 2, *Summary of Significant Accounting Policies*.

Product revenue, Cost of goods sold ("COGS") and Gross margin

We had no revenue in the three months ended August 31, 2022 as compared to approximately $41.0 thousand in the comparable period of the previous year. Revenue was related to the fulfillment of orders under a Compassionate Special Permit ("CSP") in the Philippines for the treatment of COVID-19 patients. Sales were made under the April 2021 exclusive supply and distribution agreement granting Chiral the right to distribute and sell up to 200,000 vials of leronlimab through April 15, 2022. At the time of the sales, FDA approval had not yet been received for leronlimab and the product sold was previously expensed as research and development expense due to its being manufactured prior to the commencement of the manufacturing of commercial grade pre-launch inventories. Therefore, COGS consists only of the costs of packaging and shipping of the vials, including related customs and duties.

General and administrative expenses

General and administrative expenses consisted of the following:

	Three months ended August 31,		Change	
(in thousands)	2022	2021	$	%
Salaries, benefits, and other compensation	$ 1,278	$ 385	$ 893	232
Stock-based compensation	1,341	2,597	(1,256)	(48)
Legal fees	1,453	2,351	(898)	(38)
Other	2,261	2,284	(23)	(1)
Total general and administrative	$ 6,333	$ 7,617	$ (1,284)	(17)

General and administrative expenses decreased approximately $1.3 million, or 17%, for the three months ended August 31, 2022, compared to the same period in the prior year primarily due to a reduction in stock-based compensation expense and legal fees, offset by an increase in salaries, benefits, and other compensation. The decrease in stock-based compensation expense was the result of fewer equity awards granted during the three months ended August 31, 2022. Legal fees decreased due to legal expenses paid by the Company's insurance carrier. The increase in salaries, benefits, and other compensation was the result of a reclassification in the three-months ended August 31, 2021 of approximately $1.6 million of previously accrued incentive compensation to stock-based compensation due to the compensation being issued in shares of common stock.

Research and development expenses

Research and development expenses consisted of the following:

	Three months ended August 31,		Change	
(in thousands)	2022	2021	$	%
Clinical	$ 20	$ 9,227	$ (9,207)	(100)
CMC	323	2,559	(2,236)	(87)
License and patent fees	233	234	(1)	(0)
Total research and development	$ 576	$ 12,020	$ (11,444)	(95)

For the three months ended August 31, 2022, research and development expenses decreased approximately $11.4 million, or 95%, compared to the same period last year, primarily due to lower clinical trial expenses as a result of clinical trials related to US COVID-19, oncology, and NASH having been completed that were active in the same period last year; the pausing of the Brazilian COVID-19 trials; and the closing of HIV extension studies in March 2022 due to clinical holds placed on the Company by the FDA. The future trend of such expenses is dependent on the timing of FDA clearance from the clinical holds, the future clinical development of leronlimab in the treatment of HIV, NASH, NASH-HIV and oncology, the outcome of pre-clinical studies for additional cancer indications, the outcome or cessation of the Brazilian COVID-19 trials, and the feasibility of the resubmission of the clinical section of the BLA. The decrease in CMC-related expenses from the same period last year was the result of the Company having concluded the majority of its CMC manufacturing and HIV BLA related activities in the prior year.

Amortization and depreciation expenses

Amortization and depreciation expense totaled approximately $0.1 million for the three months ended August 31, 2022, a decrease of approximately $0.2 million, or 64% from the same period in the prior year. The decrease was

attributable to the intangible write-off of a proprietary algorithm intangible asset during the fiscal year ended May 31, 2021 and the ProstaGene noncompete intangible asset becoming fully amortized as of November 30, 2021, resulting in decreased amortization expense of intangibles.

Interest and other expense

Interest and other expense consisted of the following:

(in thousands)	Three months ended August 31, 2022	2021 (Restated) [1]	Change $	Change %
Interest on convertible notes payable	$ 1,146	$ 1,686	$ (540)	(32)
Amortization of discount on convertible notes	576	952	(376)	(39)
Amortization of debt issuance costs	16	28	(12)	(43)
Loss on induced conversion	—	18,530	(18,530)	(100)
Finance charges	940	35	905	2,586
Inducement interest expense	—	528	(528)	(100)
Legal settlement	—	1,941	(1,941)	(100)
Loss on derivatives	8,601	—	8,601	100
Total interest and other expense	$ 11,279	$ 23,700	$ (12,421)	(52)

See Note 2, *Summary of Significant Accounting Policies*.

For the three months ended August 31, 2022, interest and other expenses decreased approximately $12.4 million, or 52%, compared to the same period last year. The decrease was primarily due to a decrease in loss on induced conversion and legal settlement offset by an increase in loss on derivatives. The decrease in non-cash loss on induced conversions resulted from the Company not issuing any common stock to settle any outstanding convertible debt during the current period as compared to the same period last year (refer to Part II, Item 8, Note 14, *Restatement* in the 2022 Form 10-K). The decrease in legal settlement expense was the result of the Company having no legal settlements during the three months ended August 31, 2022. The increase in loss on derivatives was attributable to the change in the fair value of liability classified warrants related to the Surety Bond Backstop Agreement and placement agent warrants issued in connection with a recent offering. These warrants became equity classified upon the stockholders' approval of an increase in authorized shares on August 31, 2022.

Liquidity and Capital Resources

As of August 31, 2022, we had a total of approximately $4.7 million in cash and approximately $122.3 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. Despite the Company's negative working capital position, vendor relations remain relatively accommodative, and we do not currently anticipate significant delays in our business initiatives schedule due to liquidity constraints. 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 agreements are deemed favorable to both parties under then current circumstances and as necessary to fund our current and projected cash needs.

Cash

The Company's cash position of approximately $4.7 million as of August 31, 2022, increased by approximately $0.5 million, when compared to the balance of $4.2 million as of May 31, 2022. This increase was primarily the result of approximately $11.5 million in cash provided by financing activities offset by approximately $11.1 million in cash used in our operating activities during the three months ended August 31, 2022. Refer to Item 1, Note 2, *Summary of Significant Accounting Policies – Going Concern*, and the *Going Concern* discussion below for information regarding the Company's ability to continue to fund its operations and satisfy its payment obligations and commitments. Summary of cash flows and changes between the periods presented is as follows:

(in thousands)	Three months ended August 31, 2022	2021	Change $
Net cash (used in) provided by:			
Net cash used in operating activities	$ (11,074)	$ (31,741)	$ 20,667
Net cash used in investing activities	$ —	$ (8)	$ 8
Net cash provided by financing activities	$ 11,519	$ 4,348	$ 7,171

Cash used in operating activities

Net cash used in operating activities totaled approximately $11.1 million during the three months ended August 31, 2022, representing an improvement of approximately $20.7 million compared to the three months ended August 31, 2021. The decrease in the net amount of cash used was due primarily to a decrease in our net loss, attributable to decreased G&A expense, R&D expense, and non-cash interest and other expense, and working capital fluctuations, all of which are highly variable. Refer to *General and Administrative, Research and Development*, and *Interest and Other Expense* sections for the discussion.

Cash used in investing activities

Net cash used in investing activities for the three months ended August 31, 2022 when compared to the same period in the prior year did not change significantly.

Cash provided by financing activities

Net cash provided by financing activities totaled approximately $11.5 million, an increase of approximately $7.2 million compared to the three months ended August 31, 2021. The increase in net amount of cash provided was the result of receiving approximately $11.3 million through the private placement of common stock and warrants through a placement agent and approximately $0.2 million through the exercise of warrants (Refer to Note 6, *Equity Awards and Stock-Based Compensation)*.

Pre-launch inventories

During the fourth fiscal quarter of 2022, the Company concluded that a significant portion of inventories no longer qualify for capitalization as pre-launch inventories due to expiration of shelf-life prior to expected commercial sales and the ability to obtain additional commercial product stability data until after shelf-life expiration. This is due to delays experienced from the originally anticipated BLA approval date from the FDA. Although these inventories are no longer being capitalized as pre-launch inventories for US GAAP accounting purposes, the inventories written-off for accounting purposes continue to be physically maintained, can be used for clinical trials, and can be commercially sold if the shelf-lives are extended as the result of the performance of on-going continued stability testing of drug product. In the event the shelf-lives of these written-off inventories are extended, and the inventories are sold commercially, the Company will not recognize any costs of goods sold on the previously expensed inventories. The Company also concluded that, due to delays of future production, certain raw materials would expire prior to production and as such no longer qualify for capitalization. Specifically, the Company evaluated its raw materials, which consist of specialized raw materials, resins, and other, against the anticipated production date and determined that while the next production date is indeterminable as of May 31, 2022, specialized raw materials have remaining shelf-lives ranging from 2023 to 2026. Therefore, a reserve of $10.2 million for the entire remaining value of specialized and other raw materials was recorded as of May 31, 2022. The Company also concluded that approximately $29.1 million, composed of five batches of drug product, out of total of nine manufactured, is likely to expire prior to the anticipated date the product may be approved for commercialization. Additionally, the Company anticipates that approximately $34.2 million of the drug product comprising the remaining four manufactured batches, with shelf-lives lasting into 2026, may expire prior to receiving approval for commercialization. The Company wrote-off the entire remaining balance of the drug product, in the amount of $63.3 million, as of May 31, 2022.

During the first quarter of fiscal 2023, the Company reviewed purchase commitments made by its manufacturing partner, Samsung BioLogics Co., Ltd. (“Samsung”), under the master agreement between the Company and Samsung, and its vendors for specialized raw materials for which the Company made a prepayment in the amount of $2.7 million in the third quarter of fiscal 2022, which were recorded as other assets in the consolidated financial statements as of May 31, 2022. The Company and its manufacturing partner have been in discussions, among other things, about cancelling the commitments to the suppliers, which have been unsuccessful to date. These additional specialized raw materials are estimated to have shelf-lives ranging from 2023 to 2026. The entire amount was reserved for as of August 31, 2022.

During the fourth fiscal quarter of 2022, the Company completed its validation of the resins’ properties based on the number of cycles they have been used for, and the remaining number of manufacturing cycles they may be used for; the

Company did not identify any resins that failed suitability validation. As of August 31, 2022, the remaining life of resins remained unchanged, ranging between 37 and 62 cycles. The Company will continue to present its resins inventory based on the remaining shelf-lives until a new shelf-life is assigned based on the results of usability testing.

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 2023. 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 August 31, 2022, the outstanding balance of the April 2, 2021 Note, including accrued interest, was approximately $12.4 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 2023. Beginning six months after the issuance date, the noteholder may request monthly redemptions of up to $7.0 million. As of August 31, 2022, the outstanding balance of the April 23, 2021 Note, including accrued interest, was approximately $31.6 million.

Common stock

We have 1,350.0 million authorized shares of common stock. The table below summarizes intended uses of common stock.

(in millions)	As of August 31, 2022
Issuable upon:	
Warrants exercise	176.2
Convertible preferred stock and undeclared dividends conversion	32.2
Outstanding stock options exercise or vesting of outstanding RSUs	17.4
Reserved for issuance pursuant to future stock-based awards under equity incentive plan	26.1
Reserved and issuable upon conversion of outstanding convertible notes	12.0
Total shares reserved for future uses	263.8
Common stock outstanding	812.3

As of August 31, 2022, we had approximately 273.9 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 have to discontinue our operations and liquidate our assets, in extreme cases, we could be forced to file for bankruptcy protection, discontinue operations or liquidate assets.

Off-Balance Sheet Arrangements

As of August 31, 2022, 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 4, *Accounts Payable and Accrued Liabilities*, Note 5, *Convertible Instruments and Accrued Interest*, and Note 9*, Commitments and Contingencies* included in Part I, Item 1 of this Form 10-Q, and in Item 7 in the 2022 Form 10-K.

Legal Proceedings

The Company is a party to various legal proceedings described in Part I, Item 1, Note 9, *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 August 31, 2022, the Company did not record any legal accruals related to the outcomes of the matters discussed in this Form 10-Q.

Regulatory Matters

FDA Refusal to File Letter re 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 HAART for highly treatment-experienced HIV patients. The FDA informed the Company the BLA did not contain certain information and data needed to complete a substantive review and therefore, the FDA would not file the BLA. The deficiencies cited by FDA included administrative deficiencies, omissions, corrections to data presentation and related analyses, and clarifications regarding the manufacturing processes. In November 2021, the Company resubmitted the non-clinical and CMC sections of the BLA and is currently reevaluating the clinical section. As of March 2022, the FDA had commenced its review of the CMC section. Additionally, in March 2022 the FDA placed the HIV program on a partial clinical hold, which may affect our ability to resubmit the BLA. The Company is in dispute with its former contract research organization ("CRO"), as described in Note 9, *Commitments and Contingencies – Legal Proceedings* in this Form 10-Q. The Company previously obtained a court order requiring the CRO to release the Company's clinical data related to the BLA and other clinical trials, which the CRO had been withholding. Further, the order granted the Company the right to perform an audit of the CRO's services. The Company is in the process of evaluating the data, results of the audit, and implications of the partial clinical hold. The Company will update the feasibility of the resubmission of the clinical section of the BLA once it completes its evaluation.

FDA Warning Letter re COVID-19 Misbranding of Investigational Drug

In January 2022, the Company received a Warning Letter from the United States FDA alleging that its former CEO had made references in a video interview to COVID-19 and leronlimab in a promotional context to the effect that leronlimab, an investigational new drug, is safe and effective for the purpose for which it is being investigated or otherwise promoted the drug. The FDA warned the Company that leronlimab has not been approved or authorized by the FDA, its safety and effectiveness has not yet been established, and that the related clinical trial data was mischaracterized in the video. The FDA further alleged the video misbranded leronlimab under section 502(f)(1) of the FD&C Act and in violation of section 301(a) of the FD&C Act, as the claims in the video made representations in a promotional context regarding the safety and efficacy of an investigational new drug that has not been approved or authorized by the FDA. This matter was resolved with the FDA on September 26, 2022.

FDA HIV Partial Clinical Hold and COVID-19 Full Clinical Hold Letters

In March 2022, the United States 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 until the clinical hold is resolved. As discussed above, the Company has made a business decision not to

currently pursue the use of leronlimab in COVID-19 patients and has no plans for further trials under the COVID-19 indication. CytoDyn is working closely with the FDA to resolve the partial clinical hold as soon as possible. As of the date of this filing, the Company has submitted the updated Investigator Brochure to the FDA in connection with the lifting of the clinical hold. The Company is in the process of completing additionally requested materials and will submit them as soon as possible.

Under the full clinical hold on the COVID-19 program, no new clinical studies may be initiated until the clinical hold is resolved. The Company is not currently conducting any COVID-19 trials in the United States, and the Company has made the business decision to discontinue its investigation of leronlimab for COVID-19.

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 $21.0 million in the three months ended August 31, 2022 and has an accumulated deficit of approximately $782.9 million as of August 31, 2022. These factors, among several others, 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 has operated at a loss since inception. The Company's continuation as a going concern is dependent upon its ability to obtain a significant amount of additional operating capital, to continue to fund operations and pay its liabilities and commitments, its research into multiple indications for and development of its product candidate, to obtain FDA approval of its product candidate for use in treating one or more indications, to outsource manufacturing of its product, and ultimately to attain profitability. We intend to seek additional funding through equity or debt offerings, licensing agreements, supply and distribution agreements, and strategic alliances to implement our business plan. There are no assurances, however, that we will be successful in these endeavors. If we are not able to raise capital on a timely basis on favorable terms, if at all, we may need to significantly change or scale back operations, including our efforts related to the BLA and other development and commercialization initiatives or to adequately fund legal proceedings, all of which individually or in combination could materially impede our ability to achieve profitability. The Company's failure to raise additional capital could also affect our relationships with key vendors, including Samsung, disrupting our ability to timely execute our business plan. In extreme cases, the Company could be forced to file for bankruptcy protection, discontinue operations or liquidate assets.

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 fiscal 2021, 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. During fiscal 2022, in exchange for warrants, the Company entered into a backstop arrangement, as amended, with an accredited investor whereby the Company pledged its patents and the investor agreed to indemnify the issuer of the surety bond in the Amarex dispute with respect to the Company's obligations under the surety bond. 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.

New Accounting Pronouncements

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

Critical Accounting Policies and Estimates

Pre-launch inventories

We capitalize inventories procured or produced in preparation for product launches sufficient to support estimated initial market demand. Typically, capitalization of such inventory begins when the results of clinical trials have reached a status sufficient to support regulatory approval, uncertainties regarding ultimate regulatory approval have been significantly reduced and we have determined that it is probable that these capitalized costs will provide some future economic benefit in excess of capitalized costs. The material factors considered by the Company in evaluating these uncertainties include the receipt and analysis of positive Phase 3 clinical trial results for the underlying product candidate, results from meetings with the relevant regulatory authorities prior to the filing of regulatory applications, and the compilation of the regulatory application. We closely monitor the status of the product within the regulatory review and approval process, including all relevant communication with regulatory authorities. If we are aware of any specific material risks or contingencies other than the normal regulatory review and approval process or if there are any specific issues identified relating to safety, efficacy, manufacturing, marketing or labeling, the related inventory may no longer qualify for capitalization.

We value inventory at the lower of cost or net realizable value using the average cost method. Inventories currently consist of raw materials, bulk drug substance, and drug product in unlabeled vials to be used for commercialization of the Company's biologic, leronlimab, which is in the regulatory approval process. Inventory purchased in preparation for product launches is evaluated for recoverability by considering the likelihood that revenue will be obtained from the future sale of the related inventory, in light of the status of the product within the regulatory approval process. The Company evaluates its inventory levels on a quarterly basis and writes down inventory that has become obsolete or has a cost in excess of its expected net realizable value, and inventory quantities in excess of expected requirements. In assessing the lower of cost or net realizable value to pre-launch inventory, the Company relies on independent analysis provided by third parties knowledgeable of the range of likely commercial prices comparable to current comparable commercial product.

For inventories capitalized prior to FDA marketing approval in preparation of product launch, anticipated future sales, shelf-lives, and expected approval date are considered when evaluating realizability of pre-launch inventories. The shelf-life of a product is determined as part of the regulatory approval process; however, in assessing whether to capitalize pre-launch inventory the Company considers the stability data of all inventories. As inventories approach their shelf-life expiration, the Company may perform additional stability testing to determine if the inventory is still viable, which can result in an extension of its shelf-life. Further, in addition to performing additional stability testing, certain raw materials inventory may be sold in its then current condition prior to reaching expiration. We also consider potential delays associated with regulatory approval in determining whether preapproval inventory remains salable. In determining whether pre-approval inventory remains salable, the Company considers a number of factors ranging from potential delays associated with regulatory approval, whether the introduction of a competing product could negatively impact the demand for our product and affect the realizability of our inventories, whether physicians would be willing to prescribe leronlimab to their patients, or if the target patient population would be willing to try leronlimab as a new therapy.

Although the Company may conclude that certain inventories no longer qualify for capitalization as pre-launch inventories due to expiration of shelf-life prior to expected commercial sales and the ability to obtain additional commercial product stability data until after shelf-life expiration, and are therefore written-off for accounting purposes, we may continue to physically maintain them and may use them for clinical trials, or may sell them if the shelf-lives can be extended as a result of the performance of on-going continued stability testing of drug product. In the event the shelf-lives of these written-off inventories are extended, and the inventories are sold commercially, the Company will not recognize any costs of goods sold on the previously expensed inventories.

Stock-based compensation

We use the Black-Scholes option pricing model to estimate the fair value of stock options on the date of grant utilizing certain assumptions that require judgments and estimates. These assumptions include estimates for stock price volatility, expected term and risk-free interest rates in determining the fair value of the stock options. The risk-free interest rate assumption is based on observed interest rates appropriate for the expected term of the equity award. The expected volatility is based on the historical volatility of the Company's common stock at monthly intervals. The computation of the expected option term is based on the "simplified method," as the options issued by the Company are considered "plain vanilla" options. In accordance with ASC 718, *Compensation - Stock Compensation*, the Company has elected to recognize the effect of forfeitures as they are incurred, and as such does not estimate future unvested forfeitures for all periods presented. Quarterly expense is reduced during the period when grants are forfeited, such that the full expense is recorded at the time of grant and only reduced when the grant is forfeited.

We at times issue restricted common stock and/or restricted stock units to executives or third parties as compensation for services rendered. Such awards are valued at fair market value on the effective date of the Company's obligation. From time to time, we also issue stock options and warrants to consultants as compensation for services. Costs for these transactions are measured at the fair value of the consideration received or the fair value of the equity instruments issued, whichever is more readily measurable.

Contingent liabilities

We have significant license and contingent milestone and royalty liabilities. We estimate the likelihood of paying these contingent liabilities periodically based on the progress of our clinical trials, BLA approval status, and status of commercialization. We are also party to various legal proceedings. We recognize accruals for such proceedings to the extent a loss is determined to be both probable and reasonably estimable. The best estimate of a loss within a possible range is accrued; however, if no estimate in the range is more probable than another, then the minimum amount in the range is accrued. If it is determined that a material loss is not probable but reasonably possible it is disclosed and if the loss or range of loss can be estimated, the possible loss is also disclosed. It is not possible to determine the ultimate 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, and the outcomes could differ significantly from recognized accruals. 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. We periodically reassess these matters when additional information becomes available and adjust our estimates and assumptions when facts and circumstances indicate the need for any changes. Refer to Part I, Item 1, Note 9, *Commitments and Contingencies* of this Form 10-Q for additional information.

Item 3. Quantitative and Qualitative Disclosures about Market Risk

There have been no material changes from the information previously reported under Part II, Item 7A of the 2022 Form 10-K.

Item 4. Controls and Procedures

During the quarter ended August 31, 2022, 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. Our President and Chief Financial Officer concluded that our disclosure controls and procedures were not effective at the reasonable assurance level as of August 31, 2022 due to the unremediated material weakness in internal control over financial reporting described below.

We maintain controls and procedures that are designed to provide reasonable assurance that information required to be disclosed in our reports filed under the Securities Exchange Act of 1934, as amended ("the Exchange Act"), is accurately recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission's rules and that such information is accumulated and communicated to our management,

including our President and Chief Financial Officer, to allow for timely decisions regarding required disclosure. In designing and evaluating the disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives, and management is required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

As previously disclosed in Item 9A of the 2022 Form 10-K, during the fiscal year ended May 31, 2022, the Company identified an error that resulted in revisions to additional paid-in capital and non-cash inducement interest expense beginning in fiscal year 2018 through the three months ended August 31, 2021. Additionally, the Company also identified a material error in how the Company accounted for common stock issued to settle certain convertible note obligations dating back to fiscal year 2021. The error resulted in an understatement of the previously reported non-cash loss on induced conversion and additional paid-in capital. Therefore, management reached the following conclusions as of May 31, 2022.

- Management concluded that the failure to identify errors related to evaluation of complex accounting issues for which alternative accounting treatments exist constitutes a material weakness in the Company's internal control over financial reporting. This material weakness is deemed to be caused by lack of review of equity transactions to allow for consideration of alternative accounting treatments, and an insufficient number of finance reporting and accounting personnel with the knowledge, experience, or training appropriate in light of the Company's financial reporting requirements.

- The Company failed to perform an adequate risk assessment, did not adequately design, and did not fully document information technology (IT) general controls in the areas of user access, program change management, operations over certain IT systems that support the Company's financial reporting processes, including controls to respond to the Complementary User Entity Controls assumed in the design and implementation of third-party service organizations controls. We concluded that in the aggregate, these failures constitute a material weakness in the Company's internal control over financial reporting.

A "material weakness" is a deficiency, or combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of the Company's annual or interim financial statement will not be prevented or detected on a timely basis. Our independent registered public accounting firm, Macias Gini & O'Connell LLP, who audited the consolidated financial statements included in the 2022 Form 10-K, issued an adverse opinion on the effectiveness of the Company's internal control over financial reporting.

In connection with the identification of the material weaknesses in our internal control over financial reporting, we continue to evaluate, design and implement controls and procedures to address this weakness. We have entered into consulting arrangements for external resources and have hired additional personnel with accounting skills to strengthen internal control over financial reporting, specifically in the areas of technical accounting and financial reporting. We also plan to perform a risk assessment of our internal controls related to information technology systems, and plan to design and place in operation controls tailored to address risks that we deem to be relevant to our Company. Further, we plan to document all of our control activities in this area, including controls to respond to the Complementary User Entity Controls assumed in the design and implementation of third-party service organizations. A material weakness in internal control over financial reporting is a matter that may require some period of time to correct.

PART II – Other Information

Item 1. Legal Proceedings

There have been no material changes from the information previously reported in the 2022 Form 10-K.

Item 1A. Risk Factors

We are subject to various risks, including risk factors identified in our 2022 Form 10-K. You should carefully consider these risk factors in addition to the risk factor below and other information in this Form 10-Q.

Our cash reserves are extremely low, requiring that we raise 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.

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 September 30, 2022, despite the approval by our stockholders of an additional 350.0 million authorized shares of common stock on August 31, 2022, we had only approximately 273.9 million shares of common stock available for issuance in new financing transactions. We may also need to use some of the additional authorized shares (or funds raised through the sale of such shares) to satisfy our outstanding accounts payable and accrued liabilities. 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 seeking removal of clinical holds placed on us by the FDA, the potential resubmission of our BLA application, analysis of clinical trial data for purposes of responding to FDA requirements and preparing additional regulatory submissions, additional clinical trials for indications we plan to pursue, regulatory and compliance activities, and legal defense activities. Any such 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 $0.40 per share on October 6, 2022) 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.

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

During September and October 2022, the Company issued a total of 80,816 shares of common stock in satisfaction of a total of $40,205 in severance payments due in September 2022 to our former CEO. The numbers of shares issued were based on the closing price of the common stock on the applicable dates. The Company relied on the exemption from registration afforded by Section 4(a)(2) of the Securities Act in connection with the issuance of the shares.

Item 6. Exhibits

(a) Exhibits:

Exhibit No	Description	Filed Herewith	Incorporated by Reference		
			Form	Exhibit No.	Filing Date
3.1	Amended and Restated Certificate of Incorporation, as amended August 31, 2022.		10-Q	3.1	October 11, 2022
31.1	Rule 13a-14(a) Certification by President of Registrant.	X			
31.2	Rule 13a-14(a) Certification by CFO of the Registrant.	X			
32	Certification of Chief 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: October 13, 2022

/s/ Cyrus Arman
Cyrus Arman
President
(Principal Executive Officer)

Dated: October 13, 2022

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

Exhibit 31.1

Certification of Chief Executive Officer

I, Cyrus Arman, 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: October 13, 2022

/s/ Cyrus Arman
Cyrus Arman, Ph.D.
President

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: October 13, 2022

/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 August 31, 2022, 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/ Cyrus Arman	/s/ Antonio Migliarese
Cyrus Arman, Ph.D. President Date: October 13, 2022	Antonio Migliarese Chief Financial Officer Date: October 13, 2022

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.