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

FORM 10-K

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

For the fiscal year ended May 31, 2025

or

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

For the transition period from _____ to _____

Commission file number 000-49908

CytoDyn Inc.
(Exact name of registrant as specified in its charter)

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

Registrant's Telephone Number, including area code: (360) 980-8524

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.**

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

Title of class
Common Stock, par value $0.001 per share

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☐ No ☒

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ☐ No ☒

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

Indicate by checkmark 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 has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☐

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

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

State the aggregate market value of the voting and non-voting common equity held by non-affiliates computed by reference to the price at which the common equity was last sold, or the average bid and ask price of such common equity, as of the last business day of the registrant's most recently completed second fiscal quarter: $134,520 thousand as of November 30, 2024.

As of June 30, 2025, the registrant had 1,251,534 thousand shares of common stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Document	**Parts Into Which Incorporated**
Portions of the Proxy Statement for the 2025 Annual Meeting of Stockholders	**Part III**

CYTODYN INC.
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FORWARD-LOOKING STATEMENTS

This annual report contains certain forward-looking statements that involve risks, uncertainties, and assumptions that are difficult to predict. Words and expressions reflecting optimism, satisfaction, or disappointment with current prospects, as well as words such as "believes," "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 risk factors identified in this annual report, including the matters set forth under the heading Risk Factors, 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 implement a successful operating strategy for the development of leronlimab and thereby create shareholder value, the ability to obtain regulatory approval of the Company's drug products for commercial sales, and the strength of the Company's leadership team. The Company's forward-looking statements are not guarantees of performance, and actual results could vary materially from those contained in or expressed by such statements due to risks and uncertainties, including: (i) the regulatory determinations of leronlimab's safety and effectiveness to treat the disease and conditions for which we are studying the product by the U.S. Food and Drug Administration (the "FDA") and, potentially, drug regulatory agencies in other countries; (ii) the Company's ability to raise additional capital to fund its operations; (iii) the Company's ability to meet its debt and other payment obligations; (iv) the Company's ability to recruit and retain key employees; (v) the Company's ability to enter into or maintain partnership or licensing arrangements with third parties; (vi) 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 applications for approval of the Company's drug product; (vii) the Company's ability to achieve approval of a marketable product; (viii) the design, implementation and conduct of clinical trials; (ix) the results of any such clinical trials, including the possibility of unfavorable clinical trial results; (x) the market for, and marketability of, any product that is approved; (xi) 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; (xii) regulatory initiatives, compliance with governmental regulations, and the regulatory approval process; (xiii) legal proceedings, investigations, or inquiries affecting the Company or its products; (xiv) general economic and business conditions; (xv) changes in domestic and foreign political and social conditions; (xvi) stockholder actions or proposals with regard to the Company, its management, or its Board of Directors; and (xvii) various other matters, many of which are beyond the Company's control.

We intend that all forward-looking statements made in this annual report on Form 10-K will be subject to the safe harbor protection of the federal securities laws pursuant to Section 27A of the Securities Act of 1933, as amended (the "Securities Act"), and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), to the extent applicable. Except as required by law, we do not undertake any responsibility to update these forward-looking statements to address events or circumstances that occur after the date of this annual 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.

PART I

Item 1. BUSINESS

Corporate History/Business Overview

CytoDyn Inc. (together with its wholly owned subsidiary, 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 (also referred to as PRO 140), a novel humanized monoclonal antibody targeting the C-C chemokine receptor type 5 ("CCR5"). The pre-clinical and early clinical development of PRO 140 was led by Progenics through 2011. The Company acquired the asset from Progenics in October 2012. In November 2018, the United States Adopted Names Council adopted "leronlimab" as the official nonproprietary name for PRO 140.

Our principal business office is located at 1111 Main Street, Suite 660, Vancouver, Washington 98660. Our website can be found at www.cytodyn.com. We make available on our website, free of charge, the proxy statements and reports on Forms 8-K, 10-K, and 10-Q that we file with the Securities and Exchange Commission ("SEC"), as soon as reasonably practicable after such materials are electronically filed with or furnished to the SEC. By making this and other references to the Company's website, we do not intend to incorporate by reference any information posted on our website into this Form 10-K. The website should not be considered part of this Form 10-K.

The consolidated financial statements included in this Form 10-K include the accounts of CytoDyn Inc. and its wholly owned subsidiary CytoDyn Operations Inc.

Business Overview

The Company is a clinical stage biotechnology company focused on the clinical development and potential commercialization of its product candidate, leronlimab, which is being studied for its potential in solid-tumor oncology.

Our current business strategy is to continue to pursue the clinical development of leronlimab, which may include the following:

1. Continue the Phase II trial of leronlimab in patients with relapsed/refractory micro-satellite stable colorectal cancer;
2. Conduct additional studies exploring leronlimab and its therapeutic potential in other solid-tumor oncology indications, including but not limited to metastatic Triple-Negative Breast Cancer; and
3. Continue our work researching and developing a new or modified long-acting version of leronlimab.

We may need significant additional funding to execute the above business strategy in full, which may include conducting a variety of additional pre-clinical studies and clinical trials, in furtherance of our efforts to obtain FDA approval to commercialize leronlimab. In addition to traditional fundraising, the Company will pursue non-dilutive financing opportunities, such as license agreements and co-development or strategic partnerships, to help implement its strategy.

Recent Corporate Developments

On May 2, 2025, the Company entered into an employment agreement with Robert E. Hoffman under which he began serving as the Company's Chief Financial Officer effective as of May 15, 2025, as well as the Company's principal financial officer and principal accounting officer. Mr. Hoffman assumed the role from Mitchell Cohen, who had served as the Company's Interim Chief Financial Officer from February 1, 2024, until May 15, 2025.

Based on information provided by Marcum LLP ("Marcum"), the Company's then current independent registered public accounting firm, to the Company, the attest business of Marcum was acquired by CBIZ CPAs P.C. ("CBIZ") on November 1, 2024, and substantially all the partners and staff of Marcum that provided attestation services joined CBIZ as of that date. Marcum continued to serve as the Company's independent registered public accounting firm until May 14, 2025, when Marcum notified the Company by letter that Marcum was resigning as the Company's independent

registered public accounting firm as of that date. Also on May 14, 2025, with the approval of the Audit Committee of the Company's Board of Directors, CBIZ was engaged as the Company's independent registered public accounting firm for its fiscal year ended May 31, 2025.

Background: Leronlimab and Cancer

The CCR5 receptor is a protein located on the surface of various cells, including white blood cells and cancer cells. On white blood cells, it serves as a receptor for chemical attractants known as chemokines. Chemokines are key orchestrators of cell trafficking by directing immune cells to sites of inflammation. Chemokines are released at the site of an inflammatory reaction. These chemokines bind to the CCR5 receptor and facilitate the migration of T-cells to these sites, promoting further inflammation. Leronlimab is a humanized monoclonal antibody that binds to human CCR5 receptors with a unique mechanism of action. Preclinical research has shown that leronlimab blocks calcium channel signaling of the CCR5 receptor when present on the surface of cancer cells. It is believed that calcium channel signaling through the CCR5 receptor is a crucial component leading to the metastatic spread of cancer.

Among other potential benefits, leronlimab's mechanism of action has the potential to modulate the movement of T-cells to inflammatory sites, which could be beneficial by diminishing overactive inflammatory responses. Leronlimab is a unique monoclonal antibody that binds to the second extracellular loop and N-terminus of the CCR5 receptor, and, due to its selectivity and target-specificity, does not appear to activate the immune function of the CCR5 receptor through agonist activity. This apparent target specificity differentiates leronlimab from other CCR5 antagonists. Leronlimab is a competitive rather than allosteric inhibitor of the CCR5 receptor.

Research indicates that the CCR5 receptor works as a potential "GPS" system for cancer cells that promotes the spread of metastatic disease. Pre-clinical studies have shown that leronlimab blocks the calcium channel signaling of the CCR5 receptor and has the potential to disable this GPS system. CCR5 inhibition may disrupt signaling and ultimately diminish the spread of CCR5+ Circulating Tumor Cells ("CTCs"). Most current therapies are directed to the primary tumor rather than the tumor microenvironment, and/or the spread of cancer in the bloodstream. However, it is metastatic disease and not the primary tumor itself that is the cause of death in most cancer patients.

Research has shown that CCR5 expression is increased in a variety of solid tumors including breast, colon, prostate, and pancreatic cancer among others. Increased CCR5 expression has also been identified as an indicator of increased risk of progression in several cancers. Research has hypothesized that CCR5 may play a variety of roles in the progression of cancer. As already indicated, the CCR5 receptor on cancer cells appears to play a role in the migration and invasion of cancer cells into the bloodstream, which may lead to metastasis. Second, blocking the CCR5 receptor on immunosuppressive immune cells known as Regulatory T cells (Tregs) and Myeloid-derived suppressor cells (MDSCs) could unleash anti-tumor fighting immune cells into the tumor microenvironment. A third observation is that blocking the interaction of CCR5 with a chemokine known as RANTES (also known as CCL5) has a potentially synergistic effect with chemotherapy in causing DNA damage and promoting the death of cancer cells. Fourth, animal studies revealed a significant decrease in angiogenesis or new blood vessel formation following CCR5 inhibition with the administration of leronlimab. Such new blood vessel formation is critically important for the growth of tumors. And lastly, it is hypothesized that leronlimab exerts an effect on tissue macrophages in the tumor microenvironment to repolarize these cells into anti-tumor fighting cells.

Leronlimab and Colorectal Cancer ("CRC")

In August 2024, the Company completed a meeting with the U.S. Food and Drug Administration (FDA) to gain alignment on the rationale and proposed dosing for a Phase II study investigating the preliminary safety and activity of leronlimab in combination with trifluridine plus tipiracil (TAS-102) and bevacizumab in participants with CCR5+, microsatellite stable ("MSS"), relapsed or refractory metastatic colorectal cancer (mCRC).

In October 2024, the Company engaged Syneos Health as the contract research organization ("CRO") for its Phase II trial of leronlimab in patients with relapsed/refractory MSS mCRC. Syneos Health is a leading fully integrated biopharmaceutical solutions organization that supports customers in accelerating the delivery of life-saving therapies to market. Syneos Health leverages advanced data analytics and AI/ML capabilities to improve outcomes at every stage of the asset lifecycle, from clinical development to commercialization.

In November 2024, the Company received clearance from the US Food and Drug Administration ("FDA") to commence its Phase II CRC trial. This milestone reflected the continued improvement in the Company's relationship with the FDA.

In December 2024, the Company announced that Dr. Ben Weinberg from Georgetown University and the MedStar Health Alliance had agreed to be the lead Principal Investigator for the CRC study. As requested by FDA, the first five patients enrolled in this study will receive 350 mg of leronlimab SQ once/week in combination with TAS-102 and Bevacizumab. After a preliminary safety review, subsequent patients will then be randomized to 350 or 700 mg of weekly leronlimab with the same background regimen. The Data and Safety Monitoring Board (DSMB) will perform a second safety review after the first 20 patients have completed at least 1 cycle of therapy. The DSMB could then recommend restricting further enrollment to a single dose level, should they identify a signal of superior activity in either one of the treatment arms.

In June 2025, the first patient was dosed in the Company's Phase II trial evaluating the efficacy of leronlimab in patients with relapsed/refractory MSS mCRC, and that patient enrollment and initiating additional clinical sites was underway through Syneos Health.

In July 2025, the Company announced encouraging historical clinical findings among patients with advanced mCRC, previously treated with leronlimab. The results indicated that three of five patients treated with leronlimab had at least a partial response, as measured by radiologic criteria, including one patient with a complete response who remains alive five years later. These final results, from patients treated under a prior compassionate use protocol, reiterate a favorable safety profile of leronlimab as well as its potential for clinical benefit in patients with mCRC. The results also support the rationale for the design and therapeutic potential of the Phase II CRC trial.

As of July 25, 2025, nine clinical sites had been approved to participate in the Phase II CRC trial, and two patients had received at least one dose in the trial. For additional information, the CRC trial protocol is posted on the NCI Clinical Trials website, and can be viewed here: https://clinicaltrials.gov/study/NCT06699836?cond=colorectal%20cancer&intr=leronlimab&rank=1

Leronlimab and Metastatic Triple-Negative Breast Cancer ("mTNBC")

In November 2018, the Company received FDA approval of its Investigational New Drug ("IND") submission and subsequently initiated a Phase 1b/2 clinical trial for mTNBC. In May 2019, the FDA granted Fast Track designation for leronlimab for use in combination with carboplatin to treat patients with CCR5+ positive mTNBC. The first patient in the trial was treated in September 2019. This Phase 1b/2 trial evaluated the feasibility of leronlimab in combination with carboplatin in patients with CCR5+ mTNBC. This trial eventually advanced from Phase 1b/2 to Phase 2. The Phase 2 trial was a single arm study to test the hypothesis that the combination of intravenous carboplatin and maximum tolerated dose of subcutaneous leronlimab will increase progression free survival. This study also evaluated the change in Circulating Tumor Cells as a potential prognostic marker for clinical efficacy. Leronlimab, in combination with carboplatin was well-tolerated at all three dose levels of 350mg, 525mg, and 700mg.

A compassionate use study was also commenced in 2019. This was a single-arm study of leronlimab combined with a treatment of Physician's Choice ("TPC") in patients with metastatic/locally advanced CCR5+ mTNBC. Leronlimab was administered subcutaneously as a weekly dose of 350 mg until disease progression or intolerable toxicity. Based on the Company's prior success in the Phase 1b/2 mTNBC trial with 350 mg dose, the Company was eventually able to transition the compassionate use patients to 525 mg dose. In this study, patients were evaluated for tumor response approximately every three months or according to the institution's standard practice by CT, PET/CT or MRI with contrast (per treating investigator's discretion) using the same method as at baseline.

During this same time period, the Company also conducted a compassionate use study in patients with a variety of CCR5+ solid tumors in a Phase 2 Basket Study. This was a single arm study of leronlimab in patients with CCR5+ locally advanced or metastatic solid tumors. Leronlimab was administered subcutaneously as a weekly dose of 350 mg and 525 mg until disease progression or intolerable toxicity. Subjects participating in this study were also allowed to receive/continue standard-of-care chemotherapy or radiotherapy. In this study, patients were evaluated for tumor response approximately every three months or according to the institution's standard practice by CT, PET/CT or MRI

with contrast using the same method as at baseline. Data analysis on the above studies was delayed due to the Company's subsequent dispute with its former CRO. Following the resolution of the Company's dispute with its former CRO in 2024, the Company was able to obtain and analyze the underlying data and follow-up records as to patients treated with leronlimab in the above studies.

In February and March 2025, the Company announced encouraging survival outcomes among a group of patients with mTNBC treated with leronlimab in the aforementioned 2019 trial(s). Although mTNBC patients typically have a poor prognosis, observed survival rates at 12, 24, 36, and 48 months after treatment with leronlimab compare favorably with reported life expectancy after treatment with currently approved therapies. In addition, the Company confirmed that a small group of patients who failed treatment after developing metastatic disease survived more than 48 months after receiving leronlimab, are alive today, and currently identify as having no evidence of ongoing disease.

In May 2025, the Company announced new data suggesting a novel mechanism of action of leronlimab for the treatment of solid tumors. The Company analyzed data from its prior clinical trials of patients with mTNBC and found that leronlimab treatment correlated with increased expression of an immune cell protein or "checkpoint inhibitor" known as programmed death-ligand 1 ("PD-L1") on patient's circulating tumor cells ("CTCs"). The results indicated that 15 of 17 (88%) of patients who received a weekly dose of 525 mg or higher experienced a significant increase in PD-L1 expression on their CTCs over a 30-to-90-day period after starting leronlimab. Increasing expression of PD-L1 can be likened to turning "cold" tumors "hot", elevating PD-L1 levels to the level necessary for patients to potentially derive benefit from further treatment with a class of drugs known as immune checkpoint inhibitors ("ICIs"). The Company also confirmed that all five patients (100%) who demonstrated a significant increase in PD-L1 expression after receiving leronlimab and received treatment with any ICI remain alive today.

The Company is currently in the process of resuming its clinical development in mTNBC, with the intention to prospectively confirm the retrospective observations in mTNBC outlined above. In early 2025, the Company announced several preclinical studies in TNBC intended to identify treatment strategies to optimize the design of a future Phase II study, and to further examine the apparent mechanism behind the observed increase in survival as compared to existing treatment paths. In the interim, ongoing discussions with KOLs are being conducted towards initiating a study in patients with mTNBC on an abbreviated timeline.

Leronlimab and Glioblastoma Multiforme ("GBM")

In December 2023, the Company entered into a partnership with Albert Einstein College of Medicine and Montefiore Medical Center, located in New York. The Company provided leronlimab to support two pre-clinical studies evaluating the efficacy of leronlimab independently and in combination with temozolomide in treating glioblastoma multiforme, also known as grade IV astrocytoma ("GBM") in infected humanized mice. The study evaluated three groups of humanized mice: one control group, one group that will receive only leronlimab, and another group that will receive a combination of leronlimab and temozolomide. The primary objective of this study was to evaluate the effect of leronlimab on the primary tumor growth and occurrence of metastases on CCR5+ and CCR5- cells in humanized mice. Unfortunately, the unexpectedly aggressive behavior of the Glioblastoma cell lines used for these studies rendered interpretation of these preclinical results difficult. However, given the encouraging results described above in patients with mTNBC, the Company is moving forward with an investigator-initiated pilot study in a group of patients with recurrent GBM at two US academic medical centers.

Pre-Clinical Development of Long-Acting CCR5 Antagonist

The Company has an active and ongoing joint development agreement with a third-party company with generative AI drug discovery and development tools in an effort to develop one or more longer-acting molecules. The Company believes this collaboration will result in the expedited development of a modified, longer-acting therapeutic, and could lead to greater acceptance by patients due to the requirement for less frequent injections. The services provided by the third party may yield extended intellectual property protection, thereby increasing the value of the Company's patent portfolio. If successful, such a modified therapeutic would require less frequent injections for patients on drug, furthering the convenience and overall marketability of the product. Working with a company with established AI-capabilities allows for a robust development path for this modified, longer-acting therapeutic for the Company. This joint development initiative remains in progress at this time and the Company will provide further updates when appropriate.

Patents, Proprietary Technology and Data Exclusivity

Protection of the Company's intellectual property rights is important to our business. We may file patent applications in the U.S., Canada, China, Japan, European countries that are party to the European Patent Convention, and other countries on a selective basis, to protect inventions we consider to be important to the development of our business.

Generally, patents issued in the U.S. are effective for 20 years from the earliest asserted filing date. A U.S. patent, to be selected by us upon receipt of FDA regulatory approval, may be subject to up to a five-year patent term extension in certain instances. While the duration of foreign patents varies in accordance with the provisions of applicable local law, most countries provide for a patent term of 20 years measured from the application filing date and some may also allow for patent term extension to compensate for regulatory approval delay.

We pursue opportunities for seeking new meaningful patent protection on an ongoing basis. Absent patent protection, others may attempt to make and use the leronlimab antibody for uses not covered by later patent filings, such as attempts to produce and sell the leronlimab antibody as a research reagent and/or as a component for use in diagnostics. However, the formulation composition patent protection remains viable, and third parties face additional regulatory hurdles together with the Company's various method patents with respect to any contemplated attempts to commercialize leronlimab for therapeutic indications. We currently anticipate, absent patent term extension, that patent protection relating to the leronlimab antibody itself started to expire in 2023, the leronlimab concentrated protein formulation will start to expire in 2031, certain methods of using leronlimab for treatment of HIV will start to expire on or before 2035, certain methods of using leronlimab for cancer indications if granted will start to expire in 2040, certain methods of using leronlimab for treatment of COVID-19 will start to expire in 2040, certain methods of using leronlimab for treatment of MASH if granted will start to expire in 2043, and certain newly developed methods of using leronlimab for cancer indications if granted will start to expire in 2046.

Patents do not enable us to preclude competitors from commercializing drugs in direct competition with our products that are not covered by granted and enforceable patent claims. Consequently, patents may not provide us with any meaningful competitive advantage. Refer to Item 1A, *Risk Factors,* for the related risks. We may also rely on data exclusivity, trade secrets, and proprietary know-how to develop and attempt to achieve a competitive position with our product candidates. We require our employees, consultants, and partners who have access to our proprietary information to sign confidentiality agreements to protect our intellectual property.

Separate from and in addition to the patent rights noted above, we expect that leronlimab will be subject to market and data exclusivity period, during which period no other applications referencing leronlimab will be approved by FDA. Accordingly, this period of regulatory exclusivity is expected to provide a term of protection against competing products shown to be biosimilar or interchangeable with leronlimab. Similar data exclusivity or data protection periods may be provided in other countries. We note that data exclusivity is not an extension of patent rights, and it does not prevent the introduction of generic versions of the innovative drug during the data exclusivity period, as long as the marketing approval of the generic version does not use or rely upon the innovator's test data.

Patents and data exclusivity are different concepts, protect different subject matter, arise from different efforts, and have different legal effects over different time periods. Information with respect to our current patent portfolio as of July 25, 2025 is as follows:

	Number of Patents			Number of Patent Applications	
	U.S.	International	Expiration Dates[1]	U.S.	International
Leronlimab (PRO 140) product candidate[2]	3	13	2024-2032	3	1
Methods of treatment by indication (e.g., HIV-1; COVID-19; GvHD); MASH[2]	2	—	2036-2040	3	8
Methods of treatment - Cancer	—	1		5	18

(1) Patent term extensions and pending patent applications may extend periods of patent protection.
(2) Leronlimab (PRO 140) patents and applications relate to the antibody and formulations.

Research, development and commercialization of a biopharmaceutical product often requires choosing between alternative development and optimization routes at various stages in the development process. Preferred routes depend upon availability of financial resources and may also be affected by subsequent discoveries, test results and other factors, and therefore cannot be identified with certainty. There are numerous third-party patents in fields in which we work, and we may need to obtain licenses under patents of others to pursue a preferred development route of one or more of our product candidates. The need to obtain a license would decrease the ultimate value and profitability of an affected product. If we cannot negotiate such a license, we might have to pursue a less desirable development route or terminate the program altogether.

Government Regulation

The research, development, testing, manufacture, quality control, packaging, labeling, storage, record-keeping, distribution, import, export, promotion, advertising, marketing, sale, and reimbursement of pharmaceutical products is extensively regulated by governmental authorities in the United States and other countries. The processes for obtaining regulatory approvals in the United States and in foreign countries and jurisdictions, along with compliance with applicable statutes and regulations and other requirements, both pre-approval and post-approval, require the expenditure of substantial time and financial resources. The regulatory requirements applicable to product development, approval, and marketing are subject to change, and regulations and administrative guidance often are revised or reinterpreted by the agencies in ways that may have a significant impact on our business.

Licensure and Regulation of Biological Products in the United States

In the United States, the FDA regulates human drugs under the Federal Food, Drug, and Cosmetic Act, or the FDCA, and in the case of biological products, also under the Public Health Service Act, or the PHSA, and their implementing regulations. The failure to comply with the applicable U.S. requirements may result in FDA refusal to approve any pending applications or delays in development and may subject an applicant to administrative or judicial sanctions, such as issuance of warning letters, or the imposition of fines, civil penalties, product recalls, product seizures, total or partial suspension of production or distribution, and injunctions and/or civil or criminal prosecution brought by the FDA and the U.S. Department of Justice or other governmental entities.

The FDA must approve product candidates for therapeutic indications before they may be marketed in the United States. For biological products, such as our product candidate, leronlimab, the FDA must approve a BLA. An applicant seeking approval to market and distribute a new biologic in the United States generally must satisfactorily complete each of the following steps:

- completion of pre-clinical laboratory tests, animal studies, and formulation studies according to good laboratory practices, or GLP, regulations, or other applicable regulations;
- submission to the FDA of an IND, which must become effective before human clinical trials may begin and must be updated when certain changes are made;
- approval by an independent institutional review board (“IRB”), or ethics committee representing each clinical trial site before each clinical trial may be initiated;
- performance of adequate and well-controlled human clinical trials in accordance with applicable IND regulations, good clinical practices, or GCPs, and other clinical-trial related regulations to evaluate the safety and efficacy of the investigational product for each proposed indication;
- preparation and submission to the FDA of a BLA requesting marketing approval for one or more proposed indications, including payment of application user fees;
- review of the BLA by an FDA advisory committee, where applicable;
- satisfactory completion of one or more FDA inspections of the manufacturing facility or facilities at which the biologic is produced to assess compliance with cGMP requirements to assure that the facilities, methods and controls are adequate to preserve the product’s identity, strength, quality and purity;
- satisfactory completion of any FDA audits of clinical trial sites to assure compliance with GCPs and the integrity of the clinical data submitted in support of the BLA; and

- FDA review and approval of the BLA, which may be subject to additional post-approval requirements, including the potential requirement to implement a REMS, and any post-approval studies required by the FDA.

Pre-clinical Studies

Before an applicant begins testing a product candidate with potential therapeutic value in humans, the product candidate enters the pre-clinical testing stage. Pre-clinical tests include laboratory evaluations of product chemistry, formulation, and stability, as well as other studies to evaluate, among other things, the toxicity of the product candidate. The conduct of the pre-clinical tests and formulation of the compounds for testing must comply with federal regulations and requirements, including GLP regulations and standards. The results of the pre-clinical tests, together with manufacturing information and analytical data, are submitted to the FDA as part of an IND. Some long-term pre-clinical testing, such as animal tests of reproductive adverse events and carcinogenicity, and long-term toxicity studies, may continue after the IND is submitted.

The IND and IRB Processes

An IND is an exemption from the premarket approval requirements of the FDCA allowing an unapproved product candidate to be shipped in interstate commerce for use in an investigational clinical trial. An IND must be in effect prior to interstate shipment and administration of any product candidate that is not the subject of an approved NDA or BLA. When submitting an IND to the FDA, applicants must submit a protocol for each planned clinical trial, and any subsequent protocol amendments must be submitted to the FDA as part of the IND. The FDA requires a 30-day waiting period after the filing of each IND before clinical trials may begin. This waiting period is designed to allow the FDA to review the IND to determine whether human research subjects will be exposed to unreasonable health risks. At any time during this 30-day period, the FDA may raise concerns or questions about the conduct of the trials as outlined in the IND and impose a clinical hold or partial clinical hold. In this case, the IND sponsor and the FDA must resolve any outstanding concerns before clinical trials can begin.

At any time after the IND goes into effect, the FDA may also place a clinical hold or partial clinical hold on the IND or on any clinical trial that has commenced under the IND. A clinical hold is an order issued by the FDA to the sponsor to delay a proposed clinical investigation or to suspend an ongoing investigation. A partial clinical hold is a delay or suspension of only part of the clinical work requested under the IND. For example, a partial clinical hold might state that a specific protocol or part of a protocol may not proceed, while other parts of a protocol or other protocols may do so. No more than 30 days after the imposition of a clinical hold or partial clinical hold, the FDA will provide the sponsor with a written explanation of the basis for the hold. Following the issuance of a clinical hold or partial clinical hold, a clinical investigation may only resume once the FDA has notified the sponsor that the investigation may proceed. The FDA will base that determination on information provided by the sponsor correcting the deficiencies previously cited or otherwise satisfying the FDA that the investigation can proceed or recommence.

For each foreign clinical study, a sponsor may choose, but is not required, to conduct it under an IND. When a foreign clinical study is conducted under an IND, all IND requirements must be met unless waived by the FDA. When a foreign clinical study is not conducted under an IND, the sponsor must ensure that the study complies with certain regulatory requirements of the FDA to use the study as support for an IND or application for marketing approval. Specifically, the studies must be conducted in accordance with GCP, including undergoing review and receiving approval by an independent ethics committee, or IEC, and seeking and receiving informed consent from subjects. The GCP requirements in the final rule encompass both ethical and data integrity standards for clinical studies. The FDA's regulations are intended to help ensure the protection of human subjects enrolled in non-IND foreign clinical studies, as well as the quality and integrity of the resulting data.

In addition to the foregoing IND requirements, an IRB must review and approve the plan for any clinical trial before it commences at each institution participating in the clinical trial, and the IRB must conduct continuing review and reapprove the study at least annually. The IRB, which must operate in compliance with FDA regulations, must review and approve, among other things, the study protocol and informed consent information to be provided to study subjects. An IRB can suspend or terminate approval of a clinical trial at its institution, or an institution it represents, if the clinical trial is not being conducted in accordance with the IRB's requirements or if the product candidate has been associated with unexpected serious harm to patients.

Additionally, some trials are overseen by an independent group of qualified experts organized by the trial sponsor, known as a data safety monitoring board, or DSMB. This group provides authorization as to whether a trial may move forward at designated checkpoints based on review of available data from the study, to which only the DSMB maintains access. Suspension or termination of development during any phase of a clinical trial can occur if the DSMB determines that the participants or patients are being exposed to an unacceptable health risk. A sponsor may suspend or terminate development for other reasons, including evolving business objectives and/or a competitive climate.

Expanded Access

Expanded access, sometimes called "compassionate use," is the use of investigational new drug products outside of clinical trials to treat patients with serious or immediately life-threatening diseases or conditions when there are no comparable or satisfactory alternative treatment options. The rules and regulations related to expanded access are intended to improve access to investigational drugs for patients who may benefit from investigational therapies. FDA regulations allow access to investigational drugs under an IND by the company or the treating physician for treatment purposes on a case-by-case basis for: individual patients (single-patient IND applications for treatment in emergency settings and non-emergency settings); intermediate-size patient populations; and larger populations for use of the drug under a treatment protocol or Treatment IND Application. FDA's regulations also provide for emergency procedures if there is a situation that requires the patient to be treated before a written submission can be made.

When considering an IND application for expanded access to an investigational product with the purpose of treating a patient or a group of patients, the sponsor and treating physicians or investigators will determine suitability when all of the following criteria apply: patient(s) have a serious or immediately life-threatening disease or condition, and there is no comparable or satisfactory alternative therapy to diagnose, monitor, or treat the disease or condition; the potential patient benefit justifies the potential risks of the treatment and the potential risks are not unreasonable in the context or condition to be treated; and the expanded use of the investigational drug for the requested treatment will not interfere with the initiation, conduct, or completion of clinical investigations that could support marketing approval of the product or otherwise compromise the potential development of the product.

There is no obligation for a sponsor to make its drug products available for expanded access; however, as required by the 21st Century Cures Act, or Cures Act, passed in 2016, a sponsor must make its policy regarding how it evaluates and responds to expanded access requests public and readily available. Sponsors are required to make such policies publicly available upon the earlier of initiation of a Phase 2 or Phase 3 study; or 15 days after the investigational drug or biologic receives designation as a breakthrough therapy, fast track product, or regenerative medicine advanced therapy.

In addition, on May 30, 2018, the Right to Try Act was signed into law. The law, among other things, provides a federal framework for certain patients to access certain investigational new products that have completed a Phase 1 clinical trial and that are undergoing investigation for FDA approval. Under certain circumstances, eligible patients can seek treatment without enrolling in clinical trials and without obtaining FDA permission under the FDA expanded access program. There is no obligation for a manufacturer to make its products available to eligible patients as a result of the Right to Try Act, but the manufacturer must develop an internal policy and respond to patient requests according to that policy.

Human Clinical Trials in Support of an NDA or BLA

Clinical trials involve the administration of the investigational product candidate to human subjects under the supervision of a qualified investigator in accordance with GCP requirements which include, among other things, the requirement that all research subjects provide their informed consent in writing before they participate in any clinical trial. Clinical trials are conducted under written clinical trial protocols detailing, among other things, the objectives of the study, inclusion and exclusion criteria, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated.

Human clinical trials are typically conducted in three sequential phases, but the phases may overlap or be combined. Additional studies may also be required after approval. As described in FDA's regulations at 21 CFR 312.21, the three phases are as follows:

Phase 1 includes the initial introduction of an investigational new drug into humans. Phase 1 studies are typically closely monitored and may be conducted in patients or normal volunteer subjects. These studies are designed to determine the metabolism and pharmacologic actions of the drug in humans, the side effects associated with increasing

doses, and, if possible, to gain early evidence on effectiveness. During Phase 1, sufficient information about the drug's pharmacokinetics and pharmacological effects should be obtained to permit the design of well-controlled, scientifically valid, Phase 2 studies. The total number of subjects and patients included in Phase 1 studies varies with the drug but is generally in the range of 20 to 80. Phase 1 studies also include studies of drug metabolism, structure-activity relationships, and mechanism of action in humans, as well as studies in which investigational drugs are used as research tools to explore biological phenomena or disease processes.

Phase 2 includes the controlled clinical studies conducted to evaluate the effectiveness of the drug for a particular indication or indications in patients with the disease or condition under study and to determine the common short-term side effects and risks associated with the drug. Phase 2 studies are typically well controlled, closely monitored, and conducted in a relatively small number of patients, usually involving no more than several hundred subjects.

Phase 3 studies are expanded controlled and uncontrolled trials. They are performed after preliminary evidence suggesting effectiveness of the drug has been obtained and are intended to gather the additional information about effectiveness and safety that is needed to evaluate the overall benefit-risk relationship of the drug and to provide an adequate basis for physician labeling. Phase 3 studies usually include from several hundred to several thousand subjects.

In some cases, the FDA may approve an NDA or BLA for a product candidate but require the sponsor to conduct additional clinical trials to further assess the product candidate's safety and effectiveness after approval. Such post-approval trials are typically referred to as Phase 4 clinical trials. These trials are used to gain additional experience from the treatment of a larger number of patients in the intended treatment group and to further verify and describe clinical benefit in the case of products approved under FDA's accelerated approval regulations. Failure to exhibit due diligence regarding conducting Phase 4 clinical trials could result in withdrawal of FDA approval for products.

Progress reports detailing the results of clinical trials must be submitted annually to the FDA. In addition, IND safety reports must be submitted to the FDA for any of the following: serious and unexpected suspected adverse reactions; findings from other studies or animal or in vitro testing that suggest a significant risk in humans exposed to the product; and any clinically important increase in the occurrence of a serious suspected adverse reaction over that listed in the protocol or investigator brochure. Expedited reporting is required for unexpected fatal or life-threatening suspected adverse reactions. Phase 1, Phase 2, and Phase 3 clinical trials may not be completed successfully within any specified period, or at all. The FDA will typically inspect one or more clinical sites to assure compliance with GCP and the integrity of the clinical data submitted.

Expedited Programs for Serious Conditions

The FDA is authorized to expedite the development and review of new therapeutic products to address unmet need in the treatment of a serious or life-threatening condition. A product development program may qualify for one or more of FDA's expedited programs for serious conditions: fast track designation, breakthrough therapy designation, accelerated approval, and priority review designation.

Any product candidate submitted to the FDA for marketing, including under a Fast Track program, may be eligible for other types of FDA programs intended to expedite development and review, such as breakthrough therapy designation, priority review, and accelerated approval.

- *Fast Track Designation.* The sponsor of a product candidate may request the FDA to designate the product for a specific indication as a Fast Track product concurrent with or after the filing of the IND. Candidate products are eligible for Fast Track designation if they are intended to treat a serious or life-threatening condition and nonclinical or clinical data demonstrate the potential to address unmet medical needs for the condition. Fast Track designation applies to the combination of the product candidate and the specific indication for which it is being studied. In addition to other benefits, such as the ability to have greater interactions with the FDA, the FDA may initiate review of sections of a Fast Track application before the application is complete, a process known as rolling review.
- *Breakthrough therapy designation.* To qualify for the breakthrough therapy designation, product candidates must be intended to treat a serious or life-threatening disease or condition and preliminary clinical evidence must indicate that such product candidates may demonstrate substantial improvement on one or more clinically significant endpoints over existing therapies. Features of breakthrough therapy designation include intensive

guidance on an efficient development program, intensive involvement of senior managers and experienced staff on a proactive, collaborative and cross-disciplinary review, and rolling review.

- *Priority review.* A product candidate is eligible for priority review if it treats a serious condition and, if approved, it would be a significant improvement in the safety or effectiveness of the treatment, diagnosis or prevention compared to marketed products. In addition, specific statutory provisions provide for priority review for various types of applications. FDA aims to complete its review of priority review applications within six months as opposed to 10 months for standard review.
- *Accelerated approval*. FDA may grant accelerated approval to a product that treats a serious condition, generally provides a meaningful advantage over available therapies, and has an effect on a surrogate endpoint that is reasonably likely to predict a clinical benefit, or on an intermediate clinical endpoint that can be measured earlier than irreversible morbidity or mortality, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity and prevalence of the condition and the availability or lack of alternative treatments. As a condition of approval, the FDA may require that a sponsor of a drug or biological product candidate receiving accelerated approval perform adequate and well controlled post-marketing clinical trials. In addition, the FDA currently requires, as a condition for accelerated approval, pre-submission of promotional materials.

None of these expedited programs change the standards for approval but they may help expedite the development or approval process of product candidates.

Emergency Use Authorizations

The FDA has the authority to permit the use of unapproved medical products following a determination of a public health emergency ("PHE") by the Secretary of Health and Human Services (the "Secretary") and a declaration by the Secretary that circumstances exist justifying the authorization of emergency use of types of medical products to respond to the PHE. Once the Secretary has made the requisite determination and declaration, the FDA may issue Emergency Use Authorizations, or EUAs, for specific unapproved medical products if the following statutory criteria have been met: (1) the pathogen that is the subject of the PHE can cause a serious or life-threatening condition; (2) based on the totality of the scientific evidence available, it is reasonable to believe that (i) the product may be effective in preventing or treating such condition, and (ii) the known and potential benefits of the product outweigh the known and potential risks; and (3) there is no adequate, approved, and available alternative to the product.

If an EUA is granted, it generally will remain in effect until the Secretary's declaration that circumstances exist justifying the authorization of emergency use of the type of products at issue or the product is approved under one of FDA's traditional approval pathways. The EUA also may be revoked or revised for other reasons, including a finding that the criteria for its issuance are no longer met or other circumstances make a revision or revocation appropriate to protect public health or safety.

Review and Approval of BLAs

Assuming successful completion of the required clinical testing, the results of the pre-clinical studies and clinical trials, along with information relating to the product's chemistry, manufacturing, and controls and proposed labeling, are submitted to the FDA as part of a BLA requesting approval to market the product for one or more indications. Data may come from company-sponsored clinical trials intended to test the safety and efficacy of a product's use or from a number of alternative sources, including studies initiated by investigators. To support marketing approval, the data submitted must be sufficient in quality and quantity to establish the safety, potency, and purity of the investigational product to the satisfaction of the FDA. The fee required for the submission of an NDA or BLA under the Prescription Drug User Fee Act, or PDUFA, is substantial (for example, for FY2024 the application fee is approximately $4.0 million), and the sponsor of an approved BLA is also subject to an annual program fee, approximately $0.4 million per program. These fees are typically adjusted annually, but exemptions and waivers may be available under certain circumstances.

The FDA conducts a preliminary review of all BLAs within 60 days of receipt and informs the sponsor by the 74th day after the FDA's receipt of the submission whether an application is sufficiently complete to permit substantive review. If the FDA determines that a BLA does not satisfy this standard, it will issue a Refuse to File, or RTF, determination to the applicant. Typically, an RTF for a BLA will be based on administrative incompleteness, such as

clear omission of information or sections of required information; scientific incompleteness, such as omission of critical data, information, or analyses needed to evaluate safety, purity, and potency or provide adequate directions for use; or inadequate content, presentation, or organization of information such that substantive and meaningful review is precluded. The FDA may request additional information rather than accept a BLA for filing. In this event, the application must be resubmitted with the additional information. The resubmitted application is also subject to review before the FDA accepts it for filing.

After the submission is accepted for filing, the FDA begins an in-depth substantive review of the application. Under the goals and policies agreed to by the FDA under PDUFA, the FDA aims to review and act on 90 percent of standard submissions within ten months of the filing date and 90 percent of priority review submissions within six months of the filing date. The review process may be extended by the FDA for three additional months to consider new information or, in the case of a clarification provided by the applicant, to address an outstanding deficiency identified by the FDA following the original submission. Despite these review goals, it is not uncommon for FDA review of a BLA to extend beyond the PDUFA goal date.

Before approving a BLA, the FDA will typically conduct a pre-approval inspection of the manufacturing facilities for the new product to determine whether the manufacturing processes and facilities comply with GMPs. The FDA will not approve the product unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. The FDA also may inspect the sponsor and one or more clinical trial sites to assure compliance with GCP requirements and the integrity of the clinical data submitted to the FDA.

Additionally, the FDA may refer a BLA, including applications for novel product candidates which present difficult questions of safety or efficacy, to an advisory committee for review, evaluation, and recommendation as to whether the application should be approved and under what conditions. Typically, an advisory committee is a panel of independent experts, including clinicians and other scientific experts. The FDA is not bound by the recommendation of an advisory committee, but it considers such recommendations when making final decisions on approval. The FDA also may require submission of a risk evaluation and mitigation strategy, or REMS, if it determines that a REMS is necessary to ensure that the benefits of the product outweigh its risks and to assure the safe use of the biological product. If the FDA concludes a REMS is needed, the sponsor of the BLA must submit a proposed REMS and the FDA will not approve the BLA without a REMS.

The FDA reviews a BLA to determine, among other things, whether the product is safe, pure, and potent and whether the facility in which it is manufactured, processed, packed, or held meets standards designed to assure the product's continued safety, purity, and potency. The approval process is lengthy and often difficult, and the FDA may refuse to approve a BLA if the applicable regulatory criteria are not satisfied or may require additional clinical or other data and information. After evaluating the application and all related information, including the advisory committee recommendations, if any, and inspection reports of manufacturing facilities and clinical trial sites, the FDA may issue either an approval letter or a Complete Response Letter, or CRL.

An approval letter authorizes commercial marketing of the product with specific prescribing information for specific indications. A CRL indicates that the review cycle of the application is complete, and the application will not be approved in its present form. A CRL generally outlines the deficiencies in the submission and may require substantial additional testing or information for the FDA to reconsider the application. The CRL may require additional clinical or other data, additional pivotal Phase 3 clinical trial(s) and/or other significant and time-consuming requirements related to clinical trials, pre-clinical studies, or manufacturing. If a CRL is issued, the applicant may either resubmit the BLA addressing all the deficiencies identified in the letter or withdraw the application. If and when those deficiencies have been addressed to the FDA's satisfaction in a resubmission of the BLA, the FDA will issue an approval letter. The FDA has committed to reviewing and acting on 90 percent of such resubmissions in response to an issued CRL in either two or six months depending on the type of information included. Even with the submission of this additional information, however, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval.

If a product receives marketing approval from the FDA, the approval is limited to the conditions of use (e.g., patient population, indication) described in the FDA-approved labeling. Further, depending on the specific risk(s) to be addressed, the FDA may require that contraindications, warnings, or precautions be included in the product labeling, require that post-approval trials, including Phase 4 clinical trials, be conducted to further assess a product's safety after

approval, require testing and surveillance programs to monitor the product after commercialization or impose other conditions, including distribution and use restrictions or other risk management mechanisms under a REMS which can materially affect the potential market and profitability of the product. The FDA may prevent or limit further marketing of a product based on the results of post-marketing trials or surveillance programs. After approval, some types of changes to the approved product, such as adding new indications, manufacturing changes, and additional labeling claims, are subject to further testing requirements and FDA review and approval.

Reference Product Exclusivity for Biological Products

With approval of a BLA, a biological product is licensed for marketing by FDA, and the product may be entitled to certain types of market and data exclusivity barring FDA from approving competing products for certain periods of time. For example, in March 2010, the Patient Protection and Affordable Care Act was enacted in the United States and included the Biologics Price Competition and Innovation Act of 2009, or the BPCIA. The BPCIA amended the PHSA to create an abbreviated approval pathway for biological products that are biosimilar to or interchangeable with an FDA-licensed biological reference product. To date, the FDA has approved several biosimilars, and in 2021, the FDA approved the first interchangeable biologic. The FDA has also issued several guidance documents outlining its approach to reviewing and approving biosimilars and interchangeable biologics.

Under the BPCIA, a manufacturer may apply for a product that is "biosimilar to" or "interchangeable with" a previously approved biological product or "reference product." For the FDA to approve a biosimilar product, it must find that there are no clinically meaningful differences between the reference product and the proposed biosimilar product in terms of safety, purity, and potency. For the FDA to approve an interchangeable biological product, the agency must find that the biological product is biosimilar to the reference product, can be expected to produce the same clinical results as the reference product, and "for a biological product that is administered more than once to an individual, the risk in terms of safety or diminished efficacy of alternating or switching between use of the biological product and the reference product is not greater than the risk of using the reference product without such alternation or switch." Upon licensure by the FDA, an interchangeable biosimilar may be substituted for the reference product without the intervention of the healthcare provider who prescribed the reference product, although the substitutability of drug and biological products are determined at the state level.

The biosimilar applicant generally must demonstrate that the product is biosimilar based on data from analytical studies showing that the biosimilar product is highly like the reference product, data from animal studies (including toxicity) and data from one or more clinical studies to demonstrate safety, purity, and potency in one or more appropriate conditions of use for which the reference product is approved. The FDA, however, may waive any of these data requirements upon a finding that the data are "unnecessary." In addition, the applicant must show that the biosimilar and reference products have the same mechanism of action for the approved conditions of use, route of administration, dosage and strength, and the production facility must meet standards designed to assure product safety, purity, and potency.

In the US, a reference biological product is granted 12 years of exclusivity from the time of first licensure of the product, and the first approved interchangeable biological product will be granted an exclusivity period of up to one year after it is first commercially marketed. The FDA will not accept an application for a biosimilar or interchangeable product until four years after the date of first licensure of the reference product.

The BPCIA is complex, and there have been various legislative proposals to change certain aspects of the BPCIA. As a result, the ultimate impact, implementation, and meaning of aspects of the BPCIA are subject to significant uncertainty.

Orphan Drug Designation and Exclusivity

Orphan drug designation in the United States is designed to encourage sponsors to develop products intended for treatment of rare diseases or conditions. In the United States, a rare disease or condition is statutorily defined as a condition that affects fewer than 200,000 individuals in the United States or that affects more than 200,000 individuals in the United States and for which there is no reasonable expectation that the cost of developing and making available the drug for the disease or condition will be recovered from sales of the product in the United States.

Orphan drug designation may qualify a company for certain tax credits and market exclusivity for seven years following the date of the product's marketing approval if granted by the FDA. An application for designation as an

orphan product can be made any time prior to the filing of an application for approval to market the product. A product that has received orphan drug designation must go through the review and approval process like any other product.

A sponsor may request orphan drug designation of a previously unapproved product or new orphan indication for an already marketed product. In addition, a sponsor of a product that is otherwise the same drug as an already approved orphan drug may seek and obtain orphan drug designation for the subsequent product for the same rare disease or condition if it can present a plausible hypothesis that its product may be clinically superior to the first drug. More than one sponsor may receive orphan drug designation for the same drug for the same rare disease or condition, but each sponsor seeking orphan drug designation must file a complete request for designation.

If a product with orphan drug designation receives the first FDA approval for the rare disease or condition for which it has such designation, the product generally will receive orphan drug exclusivity. Orphan drug exclusivity means that the FDA may not approve another sponsor's marketing application for the same drug for the same disease or condition for seven years, except in certain limited circumstances.

The period of exclusivity begins on the date that the marketing application is approved by the FDA. Orphan drug exclusivity will not bar approval of another product under certain circumstances, including if the company with orphan drug exclusivity is not able to meet market demand or the subsequent product that is otherwise considered the same drug for the same disease or condition is shown to be clinically superior to the approved product based on greater efficacy or safety, or providing a major contribution to patient care. Additionally, the statute requires that a sponsor must demonstrate clinical superiority in order to receive orphan drug exclusivity for a product that is considered the same drug as a previously approved product for the same rare disease or condition.

Patent Term Restoration and Extension

In the United States, a patent claiming a new biological product, its method of use or its method of manufacture may be eligible for a limited patent term extension under the Hatch Waxman Act, which permits a patent extension of up to five years for patent term lost during product development and FDA regulatory review. Assuming grant of the patent for which the extension is sought, the restoration period for a patent covering a product is typically one half the time between the effective date of the IND involving human beings and the submission date of the BLA, plus the time between the submission date of the BLA and the ultimate approval date. Patent term restoration cannot be used to extend the remaining term of a patent past a total of 14 years from the product's approval date in the United States. Only one patent applicable to an approved product is eligible for the extension, and the application for the extension must be submitted prior to the expiration of the patent for which extension is sought. A patent that covers multiple products for which approval is sought can only be extended in connection with one of the approvals. The USPTO reviews and approves the application for any patent term extension in consultation with the FDA.

Post-approval Requirements

Following approval of a new product, the manufacturer and the approved product are subject to pervasive and continuing regulation by the FDA, governing, among other things, monitoring and recordkeeping activities, reporting of adverse experiences with the product and product problems to the FDA, product sampling and distribution, manufacturing, and promotion and advertising. Although physicians may prescribe legally available products for unapproved uses or patient populations (i.e., "off-label uses"), manufacturers may not market or promote such uses. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant liability.

Specifically, if a company is found to have promoted off-label uses, it may become subject to adverse public relations and administrative and judicial enforcement by the FDA, the Department of Justice, or the Office of the Inspector General of the Department of Health and Human Services, as well as state authorities. This could subject a company to a range of penalties that could have a significant commercial impact, including civil and criminal fines and agreements that materially restrict the way a company promotes or distributes drug products. The federal government has levied large civil and criminal fines against companies for alleged improper promotion and has also requested that companies enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed.

Further, if there are any modifications to the product, including changes in indications, labeling, or manufacturing processes or facilities, the applicant may be required to submit and obtain FDA approval of a new BLA or a BLA

supplement, which may require the applicant to develop additional data or conduct additional pre-clinical studies and clinical trials. The FDA may also place other conditions on approvals including the requirement for a REMS to assure the safe use of the product, which may require substantial commitment of resources post-approval to ensure compliance. A REMS could include medication guides, physician communication plans, or elements to assure safe use, such as restricted distribution methods, patient registries, and other risk minimization tools. Any of these limitations on approval or marketing could restrict the commercial promotion, distribution, prescription, or dispensing of products. Product approvals may be withdrawn for non-compliance with regulatory standards or if problems occur following initial marketing.

In addition, FDA regulations require that biological products be manufactured in specific approved facilities and in accordance with cGMPs. The cGMP regulations include requirements relating to organization of personnel, buildings and facilities, equipment, control of components and drug product containers and closures, production and process controls, packaging and labeling controls, holding and distribution, laboratory controls, records and reports, and returned or salvaged products. The manufacturing facilities for our product candidates must meet cGMP requirements and satisfy the FDA or comparable foreign regulatory authorities' satisfaction before any product is approved and our commercial products can be manufactured.

We rely, and expect to continue to rely, on third parties to produce clinical (and, in the future, commercial) supplies of our product candidate in accordance with cGMP regulations. These manufacturers must comply with cGMP regulations, including requirements for quality control and quality assurance, the maintenance of records and documentation, and the obligation to investigate and correct any deviations from cGMP. Manufacturers and other entities involved in the manufacture and distribution of approved drugs or biologics are required to register their establishments with the FDA and certain state agencies and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMP and other laws. Accordingly, manufacturers must continue to expend time, money, and effort in the area of production and quality control to maintain cGMP compliance. Inspections by the FDA and other regulatory agencies may identify compliance issues at facilities that may disrupt production or distribution or require substantial resources to correct. In addition, the discovery of conditions that violate these rules, including failure to conform to cGMPs, could result in enforcement actions, and the discovery of problems with a product after approval may result in restrictions on a product, manufacturer, or holder of an approved BLA, including voluntary recall and regulatory sanctions as described below.

The FDA may withdraw approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in mandatory revisions to the approved labeling to add new safety information, imposition of post-market clinical trials requirement to assess new safety risks or imposition of distribution or other restrictions under a REMS program. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of the product, complete withdrawal of the product from the market or product recalls;
- safety alerts, Dear Healthcare Provider letters, press releases, or other communications containing warnings or other safety information about a product;
- mandated modification of promotional materials and labeling and issuance of corrective information;
- fines, warning letters, untitled letters or other enforcement-related letters, or clinical holds on post-approval clinical trials;
- refusal of the FDA to approve pending NDAs/BLAs or supplements to approved NDAs/BLAs, or suspension or revocation of product approvals;
- product seizure or detention or refusal to permit the import or export of products;
- injunctions or the imposition of civil or criminal penalties; and
- consent decrees, corporate integrity agreements, debarment, or exclusion from federal health care programs; or mandated modification of promotional materials and labeling and the issuance of corrective information.

In addition, the distribution of prescription pharmaceutical products is subject to the Prescription Drug Marketing Act, or PDMA, which regulates the distribution of samples at the federal level and sets minimum standards for the registration and regulation of drug distributors by the states. Additionally, the Drug Supply Chain Security Act, or DSCSA, imposes requirements related to identifying and tracing certain prescription products distributed in the United States, including most biological products.

Other U.S. Healthcare Laws and Regulations

In the United States, biopharmaceutical manufacturers and their products are subject to extensive regulation at the federal and state level, such as laws intended to prevent fraud and abuse in the healthcare industry. These laws, some of which apply only to approved products, include:

- federal false claims, false statements, and civil monetary penalties laws prohibiting, among other things, any person from knowingly presenting, or causing to be presented, a false claim for payment of government funds or knowingly making, or causing to be made, a false statement to get a false claim paid;
- federal healthcare program anti-kickback law, which prohibits, among other things, persons from offering, soliciting, receiving, or providing remuneration, directly or indirectly, to induce either the referral of an individual for, or the purchasing or ordering of, a good or service for which payment may be made under federal healthcare programs such as Medicare and Medicaid;
- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which, in addition to privacy protections applicable to healthcare providers and other entities, prohibits executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;
- FDCA, which among other things, strictly regulates marketing, prohibits manufacturers from marketing such products prior to approval or for off-label use, and regulates the distribution of samples;
- federal laws that require pharmaceutical manufacturers to report certain calculated product prices to the government or provide certain discounts or rebates to government authorities or private entities, often as a condition of reimbursement under government healthcare programs;
- federal transparency law, which requires pharmaceutical companies to report certain payments to healthcare providers;
- state laws and regulations analogous to the above; and
- laws and regulations prohibiting bribery and corruption such as the Foreign Corrupt Practices Act ("FCPA"), which, among other things, prohibits U.S. companies and their employees and agents from authorizing, promising, offering, or providing, directly or indirectly, corrupt or improper payments or anything else of value to foreign government officials, employees of public international organizations or foreign government-owned or affiliated entities, candidates for foreign public office, and foreign political parties or officials thereof.

Violations of these laws are punishable by criminal and/or civil sanctions, including, in some instances, exclusion from participation in federal and state health care programs, such as Medicare and Medicaid. Ensuring compliance is time consuming and costly.

Similar healthcare laws and regulations exist in the European Union (the "EU") and other jurisdictions, including reporting requirements detailing interactions with and payments to healthcare providers and laws governing the privacy and security of personal information.

U.S. Privacy Law

In the U.S., there are numerous state and federal laws and regulations governing the security and privacy of personal information. Additionally, state and federal regulators have begun to pay more attention to companies' data processing activities.

At the state level, laws require companies to safeguard personal information and take action in the event of a data breach (e.g., notifying governmental authorities and data subjects). State attorneys general have been active in using their consumer protection authority to investigate companies' data security practices. A number of states have passed

laws governing data privacy and many others have similar legislation under consideration. Although many of these laws contain exceptions for certain health data, these exceptions are not comprehensive. All of these laws give rights to residents in their states and require businesses to take certain actions with respect to those rights (similar to the General Data Protection Regulation in effect in the EU, but with notable differences).

At the federal level, the Federal Trade Commission has been active in using its Section 5 authority to bring enforcement actions against companies for deceptive or unreasonable data processing activities.

Registrational Clinical Trials Process

Described below is the traditional registrational drug development track.

Phase 1 includes the initial introduction of an investigational new drug or biologic into humans. These studies are closely monitored and may be conducted in patients but are usually conducted in a small number of healthy volunteer patients. These studies are designed to determine the metabolic and pharmacologic actions of the investigational product in humans, the side effects associated with increasing doses, and, if possible, to gain early evidence on effectiveness. During Phase 1, sufficient information about the investigational product's pharmacokinetics and pharmacological effects are obtained to permit the design of well-controlled, scientifically valid, Phase 2 studies. Phase 1 studies of PRO 140 were conducted and completed by or on behalf of Progenics by certain principal investigators prior to our acquisition of PRO 140.

Phase 2 includes the early controlled clinical studies conducted to obtain some preliminary data on the effectiveness of the drug for a particular indication or indications in patients with the disease or condition. This phase of testing also helps determine the common short-term side effects and risks associated with the drug. Phase 2 studies are typically well-controlled, closely monitored, and conducted in a relatively small number of patients, typically no more than several hundred people. In some cases, depending upon the need for a new drug, a particular drug candidate may be licensed for sale in interstate commerce after a "pivotal" Phase 2 trial. Phase 2 is often broken into Phase 2a, which can be used to refer to "pilot trials," or more limited trials evaluating exposure response in patients, and Phase 2b trials that are designed to evaluate dosing efficacy and ranges.

Phase 3 studies are expanded controlled clinical studies. They are performed after preliminary evidence suggesting effectiveness of the drug has been obtained in Phase 2 and are intended to gather the additional information about effectiveness and safety that is needed to evaluate the overall benefit/risk relationship of the drug. Phase 3 studies also provide an adequate basis for extrapolating the results to the general population and transmitting that information in the physician labeling. Phase 3 studies usually involve significantly larger groups of patients, and considerable additional expense. We were required to pay significant fees to third parties upon the first patient dosing in a Phase 3 trial of leronlimab, and we may be required to make additional fee payments to third parties upon the completion of additional milestones. Refer to Part II, Item 8, Note 9, *Commitments and Contingencies - PRO 140 Acquisition and Licensing Arrangements,* for further information.

Manufacturing

We do not own or operate manufacturing facilities to produce leronlimab or perform CMC related activities. As such, we must depend on third-party manufacturing organizations and suppliers for all of our CMC activities. We continue to explore alternative CMC partners and sources to obtain access to adequate resources to support our CMC efforts for leronlimab in a cost-efficient manner.

We previously engaged two global contract manufacturing organizations ("CMOs"), to initiate the scale-up to commercial batch quantities of product and develop the necessary controls and specifications to manufacture product on a consistent and reproducible manner. We also contracted with suitable CMOs to fill, finish, label, and package product into the final commercial package for commercial use. To commercialize product, this scaled-up material will need to be validated under best practices and demonstrated to meet approved specifications on an ongoing basis. GMP material will be produced as needed to support clinical trials for all therapeutic indications and until commercial product is approved by the FDA. We will continue to rely on active CMO relationships for all of our developmental and commercial needs.

Research and Development Costs

The Company's research and development expenses totaled approximately ($16.9) million and $7.2 million for the fiscal years ended May 31, 2025, and 2024, respectively. Refer to Part II, Item 7, *Management's Discussion and Analysis of Financial Condition and Results of Operations* in this Form 10-K for further information.

Employees and Human Capital Resources

As of June 30, 2025, we had 13 employees, as well as a number of independent consultants and other individuals assisting us with the Company's regulatory, quality, and medical matters. Our research and development team is geographically dispersed throughout the United States. We are committed to pay equity regardless of gender or race/ethnicity. We invest in our workforce by offering competitive salaries and benefits. We may award stock options or other stock-based awards to selected employees and consultants under our equity incentive plan. We also offer various benefits to all eligible employees, including health care coverage and a 401(k) plan. None of our employees are subject to a collective bargaining agreement. We consider our relationship with our employees to be good. There can be no assurance, however, that we will be able to identify or hire and retain additional employees or consultants on acceptable terms in the future.

Item 1A. RISK FACTORS

Our business is subject to numerous risks and uncertainties, including those highlighted in this section, which represent challenges we face in our efforts to successfully implement our strategy. You should carefully consider the risks described below in addition to other information set forth in this Form 10-K, including Part II, Item 7, *Management's Discussion and Analysis of Financial Condition and Results of Operations* and the consolidated financial statements and related notes in Part II, Item 8. These risks, some of which have occurred and any of which may occur, alone or in combination with other events or circumstances in the future, may have a material adverse effect on our business, financial condition, cash flows, results of operations, or the trading price of our common stock. The risks described below are not the only risks we face. Additional risks and uncertainties not currently known to us, or that we currently deem to be immaterial, may occur or become material in the future. Therefore, historical financial and business performance, events and trends are often not a reliable indicator of future operating results, financial and business performance, events or trends.

Summary of Risk Factors

Risks Related to Our Financial Position and Need for Additional Capital

- Our cash reserves are low and we do not expect to receive substantial, if any, revenues for the foreseeable future such that we will need to raise substantial additional financing to fund our ongoing operations and manage our payment obligations, which financing continues to be extremely difficult to secure in light of the low trading price of our common stock.
- We are a clinical stage biotechnology company with a history of significant operating losses; we expect to continue to incur operating losses, and we may never achieve profitability.
- The amount of financing we require will depend on various factors, many of which are beyond our control. The results of our operations, financial condition, and stock price are likely to be adversely affected if we are unable to obtain additional funding on improved terms compared to previous financings.
- Our future cash requirements may differ significantly from our current estimates.
- Our auditors have issued a going concern opinion, and we will not be able to achieve our objectives and will have to cease operations if we cannot find adequate financing.
- We have written off the value of our pre-launch inventories of leronlimab and related raw materials, the costs of which were previously capitalized, and may be unable to use all or a portion of those inventories in the development of our product candidate.

Risks Related to Our Ability to Maintain an Effective Operational and Internal Controls Environment

- The recruitment and retention of skilled directors, executives, employees and consultants may be difficult and expensive, may result in dilution to our stockholders, and any failure to attract and retain such individuals may adversely affect our drug development and commercialization activities.
- The loss, temporary loss, or transition of members of our senior management team or any other key employees may adversely affect our business.
- If we are unable to maintain an effective system of internal control over financial reporting, we may not be able to accurately or timely report our financial results and our stock price could be adversely affected.
- Our information technology systems could fail to perform adequately or experience data corruption, cyber-based attacks, or network security breaches.

Risks Related to Legal Proceedings

- Our business, operating results, and financial condition could be negatively affected as a result of litigation and other demands made by stockholders.
- The class-action litigation filed against us could harm our business, and insurance coverage may not be sufficient to cover all related costs and damages.
- We are subject to oversight by the SEC, FDA, and other regulatory agencies. Investigations and proceedings by those agencies may divert management's focus and have a material adverse effect on our reputation and financial condition.
- We face risks and uncertainties related to litigation and other claims.

Risks Related to Development and Commercialization of Our Drug Candidate

- Certain agreements and related license agreements require us to make significant milestone, royalty, and other payments, which will require additional financing and, in the event we do commercialize leronlimab, will decrease the revenues we may ultimately receive on sales. To the extent that such milestone, royalty and other payments are not timely made, the counterparties to such agreements in certain cases have repurchase and termination rights thereunder with respect to leronlimab.
- If we are unable to obtain all required regulatory approvals for leronlimab, we will not be able to commercialize our primary product candidate, which would materially and adversely affect our business, financial condition, and stock price.
- Disruptions at the FDA and other government agencies caused by funding shortages, Executive Orders, or global health concerns could hinder their ability to hire, retain, or deploy key leadership and other personnel, or otherwise prevent new or modified products from being developed, approved, or commercialized in a timely manner or at all, which could negatively impact our business.
- We are dependent on the success of leronlimab. If we, either alone or with collaborators, are unable to complete the clinical development of, obtain and maintain marketing approval for, or successfully commercialize leronlimab, including with respect to adequate coverage and reimbursement, or if we continue to experience significant delays in doing so, our business will be harmed.
- Our competitors may develop drugs that are more effective, safer, and less expensive than ours.
- We may not be able to identify, negotiate, and maintain the strategic alliances necessary to develop and commercialize our products and technologies, and we will be dependent on our corporate partners if we do.
- Known third-party patent rights could delay or otherwise adversely affect our planned development and sale of leronlimab. We have identified but not exhaustively analyzed other patents that could relate to our proposed products.

Risks Related to Our Dependence on Third Parties

- We have a limited number of internal research and development personnel, making us dependent on consulting relationships and strategic alliances with industry partners.

- We may continue to rely on third parties, such as CROs and third-party manufacturers, to conduct clinical trials for our product candidate, leronlimab, and to produce our pre-clinical and clinical product candidate supplies. Such third parties are subject to significant regulation. A failure by such third parties to perform their obligations properly and successfully to us, or failure of manufacturers on which we rely to meet regulatory requirements, may result in our inability to obtain regulatory approvals for or commercialize our product candidate.

Risks Related to Our Intellectual Property Rights

- Our success depends upon our ability to obtain and maintain intellectual property protection relating to our product candidate and future product candidates.
- If we are sued for infringing on third-party intellectual property rights, it will be costly and time-consuming, and an unfavorable outcome would have a significant adverse effect on our business. We may also undertake infringement or other legal proceedings against third parties, causing us to spend resources on litigation and exposing our own intellectual property portfolio to challenge.
- We may become involved in disputes with our present or future contract partners over intellectual property ownership or other matters, which could have a significant adverse effect on our business.

Risks Related to Ownership of Our Common Stock

- Our common stock is classified as "penny stock" and trading of our shares may be restricted by the SEC's penny stock regulations.
- The trading price of our common stock has been and could remain volatile, and the market price of our common stock may decrease.
- Since our inception, we have been insolvent and have required debt and equity financing to maintain operations. We expect our debt service obligations and our need for additional funding to finance operations will cause additional dilution to our existing stockholders and could adversely affect the trading price of our common stock.
- Our certificate of incorporation permits our Board of Directors (the "Board") to create new series of preferred stock without further approval by our stockholders, which could adversely affect the rights of the holders of our common stock.
- Anti-takeover provisions of our certificate of incorporation, our bylaws, and Delaware law could make an acquisition of us, which may be beneficial to our stockholders, more difficult, and may prevent attempts by our stockholders to replace or remove the current members of our Board and management.
- We do not expect to pay cash dividends on our common shares in the foreseeable future.

Risks Related to Our Financial Position and Need for Additional Capital

Our cash reserves are low and we do not expect to receive substantial, if any, revenues for the foreseeable future such that we will need to raise substantial additional financing to fund our ongoing operations and manage our payment obligations, which financing continues to be extremely difficult to secure in light of the low trading price of our common stock.

As of June 30, 2025, we had an unrestricted cash balance of approximately $12.1 million and no reserved cash balance. We must continue to raise 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 June 30, 2025, we had approximately 172.8 million shares of common stock unreserved for other purposes and available for issuance in new financing transactions. Our outstanding accounts payable and accrued liabilities totaled approximately $16.1 million on June 30, 2025. 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: conducting a study of leronlimab in patients with relapsed/refractory microsatellite stable colorectal cancer; conducting a study of leronlimab in patients with metastatic triple-negative breast cancer; pursuing research and development of longer-acting molecules; and evaluating

other opportunities for pre-clinical studies and publishing data from previously conducted studies. Any delay or inability to pursue our planned activities likely will adversely affect our business, financial condition, and stock price. The continued low trading price of our common stock (with a closing price of $0.27 per share on June 30, 2025) 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.

We are a clinical stage biotechnology company with a history of significant operating losses; we expect to continue to incur operating losses, and we may never achieve profitability.

We have not generated revenue from product sales, licensing, or other income opportunities to date. Since our inception, we have incurred operating losses each year due to costs incurred for research and development activities and general and administrative expenses related to our operations. We expect to incur losses for the foreseeable future, with no or only minimal revenues as we continue to pursue development of, and seek regulatory approvals for, leronlimab. If leronlimab fails to gain regulatory approval, or if it or other drug or biologic candidates we may acquire or license in the future do not achieve approval or market acceptance, we will not be able to generate revenue or explore other opportunities to enhance stockholder value, such as through a sale. If we fail to generate revenue or if we are unable to fund our continuing operations, our stockholders could lose a portion or all of their investments.

The amount of financing we require will depend on various factors, many of which are beyond our control. The results of our operations, financial condition, and stock price are likely to be adversely affected if we are unable to obtain additional funding on improved terms compared to previous financings.

Our future funding requirements will depend on many factors, including, but not limited to:

- the costs of preparing required regulatory submissions, as well as any clinical trial programs and pre-clinical studies we may pursue and other development activities conducted by us directly,
- the costs involved with our chemistry, manufacturing and controls (“CMC”) activities,
- the satisfaction of payment obligations we have already incurred,
- the costs and timing of obtaining regulatory approvals and making related milestone payments due to third parties with whom we have licensing or similar agreements,
- the costs of filing, prosecuting, maintaining, and enforcing patents and other intellectual property rights and defending against potential claims of infringement,
- the costs associated with hiring and retaining needed scientific and administrative employees, advisors, and consultants,
- the cost of legal and other professional advisors needed to support our development efforts, responsibilities as a public reporting company, regulatory compliance and investigations, and legal proceedings,
- the costs of compliance with laws, regulations, or judicial decisions applicable to us, and
- the costs of general and administrative infrastructure required to manage our business and protect corporate assets and stockholder interests.

If any of these factors cause our funding needs to be greater than expected, our ability to continue operations, financial condition, and stock price may be adversely affected.

Our future cash requirements may differ significantly from our current estimates.

Our cash requirements may differ significantly from our estimates from time to time, depending on a number of factors, including:

- our ability to attract strategic partners to pay for or share costs related to our product development efforts,
- whether our outstanding convertible notes are converted into equity,
- whether we receive additional cash upon the exercise of our outstanding warrants and stock options for common stock, and

- our ability to obtain funding under future licensing agreements or other collaborative relationships.

If we deplete our cash reserves and are unable to obtain additional funding, we may be forced to discontinue our operations and liquidate our assets.

Our auditors have issued a going concern opinion, and we will not be able to achieve our objectives and will have to cease operations if we cannot find adequate financing.

Our auditors issued an opinion, which includes a going concern explanatory paragraph, in connection with the audit of our annual consolidated financial statements for the fiscal year ended May 31, 2025. A going concern paragraph in an audit opinion means that there is substantial doubt that we can continue as an ongoing business for the 12 months from the date the consolidated financial statements are issued. If we are unable to continue as an ongoing business, we might have to liquidate our assets and the values we receive for our assets in liquidation or dissolution could be significantly lower than the values reflected in our financial statements. In addition, the inclusion of an explanatory paragraph regarding substantial doubt about our ability to continue as a going concern and our lack of cash resources may materially adversely affect our share price and our ability to raise new capital or to enter into critical contractual relations with third parties. There is no assurance that we will be able to adequately fund our operations in the future.

We have written off the value of our pre-launch inventories of leronlimab and related raw materials, the costs of which were previously capitalized, and may be unable to use all or a portion of those inventories in the development of our product candidate.

Pre-launch inventories consist of costs of raw materials and work-in-progress related to our product candidate leronlimab. As of May 31, 2023, our inventories had been written off in full for accounting purposes. Although a portion of the inventories that were written off continue to be physically maintained and currently may be eligible for use in certain clinical contexts, we may be unable to use all or a portion of these inventories in the development of our product candidate, which may require us to engage a third party to produce additional clinical supplies of leronlimab to pursue our planned studies and clinical trials.

Risks Related to Our Ability to Maintain an Effective Operational and Internal Controls Environment

The recruitment and retention of skilled directors, executives, employees, and consultants may be difficult and expensive, may result in dilution to our stockholders, and any failure to attract and retain such individuals may adversely affect our drug development and commercialization activities.

Our business depends on the skills, performance, and dedication of our officers and key scientific and technical advisors, as well as our directors. All of our current scientific advisors are independent contractors and are either self-employed or employed by other organizations. As a result, they may have conflicts of interest or other commitments, such as consulting or advisory contracts with other organizations, that may affect their ability to provide services to us in a timely manner. We likely will need to recruit additional directors, executive management, employees, and advisors, particularly scientific and technical personnel. In addition, there is currently intense competition for skilled directors, executives, and employees with relevant scientific and technical expertise, and this competition is likely to continue. We compete for these qualified personnel against companies with greater financial resources than ours. These recruitment and retention efforts likely will require additional financial resources. To successfully recruit and retain qualified employees, we will need to offer a combination of salary, cash incentives, and equity compensation. Future issuances of our equity securities for compensatory purposes will dilute existing stockholders' ownership interests and reduce the shares available for future funding transactions. If we are unable to attract and retain individuals with relevant scientific, technical, and managerial experience, we may be forced to limit or delay our product development activities or may experience difficulties in successfully conducting our business, which would adversely affect our operations and financial condition.

The loss, temporary loss, or transition of members of our senior management team or any other key employees may adversely affect our business.

We currently have only three executive officers. Jacob Lalezari, M.D., our current Chief Executive Officer, entered into an employment agreement with us in January 2024 that can be terminated by either party at any time. Our current Chief Financial Officer, Robert E. Hoffman, joined the Company on May 15, 2025. The complexity inherent in integrating additional key members of the senior management team with existing senior management may limit the effectiveness of any such successor or otherwise adversely affect our business. Leadership transitions and any disruptions that result are inherently difficult to manage and may cause uncertainty or a disruption to our business or increase the likelihood of turnover of other key officers and employees. Further, we may incur significant expenses related to any executive transitions. Finding suitable replacements for senior management and other key employees can be difficult, and there is no assurance we will be successful in attracting or retaining qualified personnel.

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

If we are unable to maintain an effective system of internal control over financial reporting, we may not be able to accurately or timely report our financial results and our stock price could be adversely affected.

Section 404 of the Sarbanes-Oxley Act of 2002 and related regulations require us to evaluate the effectiveness of our internal control over financial reporting as of the end of each fiscal year, and to include a management report assessing the effectiveness of our internal control over financial reporting in our Form 10-K for that fiscal year. Failure to maintain our controls or operation of these controls may harm our operations, decrease the reliability of our financial reporting, and cause us to fail to meet our financial reporting obligations, which could adversely affect our business and reduce our stock price.

Our information technology systems could fail to perform adequately or experience data corruption, cyber-based attacks, or network security breaches.

We rely on information technology networks and systems, including the internet, to process, transmit, and store electronic information. In particular, we depend on our information technology infrastructure to effectively manage our business data, finance, and other business processes and electronic communications between our personnel and corporate partners. If we do not allocate and effectively manage the resources necessary to build and sustain an appropriate technology infrastructure, security breaches or system failures of this infrastructure may result in system disruptions, shutdowns, or unauthorized disclosure of confidential information, including patient information in violation of HIPAA requirements. In addition, our employees, contractors, and other corporate partners increasingly are working from remote locations. As a result, we rely on information technology systems that are outside our direct control. These systems are potentially vulnerable to cyber-based attacks and security breaches. In addition, cyber criminals are increasing their attacks on individual employees, including scams designed to trick victims into transferring sensitive data or funds or stealing credentials that compromise information systems. If one of our employees falls victim to these attacks, or our information technology systems or those of our partners are compromised, our operations could be disrupted, or we may suffer financial loss, loss or misappropriation of intellectual property or other critical assets, reputational harm, and regulatory fines and intervention, and our business and financial condition may be adversely affected.

Risks Related to Legal Proceedings

Our business, operating results, and financial condition could be negatively affected as a result of litigation and other demands made by stockholders.

We are and have been involved in legal proceedings and other claims brought by stockholders, including class actions alleging securities law violations, derivative actions alleging waste of corporate assets, unjust enrichment, other breaches of fiduciary duties by former directors and current and former executive officers, and demands by activist investors. Similar actions may occur in the future. While the Company welcomes opinions of all stockholders, responding to demands, litigation, proxy contests, or other initiatives by stockholders or activist investors may divert the attention of our Board, management team, and employees from their regular duties in the pursuit of business opportunities to enhance stockholder value. Such actions may also cause our existing or potential employees, strategic partners, and stockholders to have questions or doubts about the future direction of the Company and may provide our competitors with an opportunity to exploit these concerns. Such circumstances could cause significant fluctuations in our stock price based on temporary or speculative market perceptions or other factors that do not necessarily reflect the underlying fundamentals and prospects of our business. Refer to Part II, Item 8, Note 9, *Commitments and Contingencies – Legal Proceedings* in this Form 10-K for additional information.

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

The securities class action lawsuits filed against the Company in March 2021 have exhausted certain coverage allowances under the Company's D&O insurance applicable to the relevant time period. This litigation, whether or not successful, may require us to incur substantial costs, which could harm our business and financial condition. During the course of litigation, negative public announcements regarding the results of hearings, motions, or other interim proceedings or developments may occur, which could have a further negative effect on the market price of our common stock. Refer to Part II, Item 8, Note 9, *Commitments and Contingencies – Securities Class Action Lawsuits* in this Form 10-K for further information.

We are subject to oversight by the SEC, FDA, and other regulatory agencies. Investigations and proceedings by those agencies may divert management's focus and have a material adverse effect on our reputation and financial condition.

We are subject to the regulation and oversight by the SEC and state regulatory agencies, in addition to the FDA and other federal regulatory agencies. As a result, we may face legal or administrative proceedings by these agencies. We have received subpoenas from the SEC and the U.S Department of Justice (the "DOJ") requesting documents and information concerning, among other matters, leronlimab, our 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, our retention of investor relations consultants, and trading in our securities. On December 20, 2022, the DOJ announced the unsealing of a criminal indictment charging both our former CEO, Nader Z. Pourhassan, and Kazem Kazempour, CEO of Amarex, our former CRO. That same day, the SEC announced charges against both Mr. Pourhassan and Mr. Kazempour for alleged violations of federal securities laws. In December 2024, a federal jury convicted Mr. Pourhassan and Mr. Kazempour on a number of counts. Mr. Pourhassan and Mr. Kazempour are currently scheduled to be sentenced in September 2025. The Company is cooperating fully with the DOJ and SEC investigations. We are unable to predict the effect of any governmental investigations on our business, financial condition, or reputation. In addition, publicity surrounding any investigation, even if ultimately resolved favorably, could have a material adverse effect on our business. Refer to Part II, Item 8, Note 9, *Commitments and Contingencies – Legal Proceedings* in this Form 10-K for further information.

We face risks and uncertainties related to litigation and other claims.

We are parties to a variety of litigation and other claims, in addition to the regulatory investigations and related proceedings described above. For example, two putative class action lawsuits have been filed against us and certain former officers and directors, asserting violations of federal securities laws under Section 10(b) and Section 20(a) of the Exchange Act, and alleging that the Company and certain former officers and directors made purportedly false or misleading statements and that some of 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. Separately, three purported stockholder derivative actions have been filed against certain former officers and directors; the Company was named as a nominal defendant. Refer to Part II, Item 8, Note 9, *Commitments and Contingencies – Legal Proceedings* in this Form 10-K for further information.

In addition, from time to time, we may also be involved in legal proceedings and investigations arising in the ordinary course of business, including those relating to employment matters, relationships with partners, intellectual property disputes, and other business matters. Any such claims or investigations may be time-consuming, costly, divert management resources, or otherwise have a material adverse effect on our business, financial condition, or results of operations. Any claims or litigation, even if fully indemnified or insured, could damage our reputation and make it more difficult to compete effectively or obtain adequate insurance in the future.

Risks Related to Development and Commercialization of Our Drug Candidate

Certain agreements and related license agreements require us to make significant milestone, royalty, and other payments, which will require additional financing and, in the event we do commercialize leronlimab, decrease the revenues we may ultimately receive on sales. To the extent that such milestone, royalty, and other payments are not timely made, the counterparties to such agreements in certain cases have repurchase and termination rights thereunder with respect to leronlimab.

Under agreements we have with Progenics Pharmaceuticals, Inc. ("Progenics") and Lonza Sales AG ("Lonza"), as well as a Development and License Agreement (the "PDL License") between Protein Design Labs (now AbbVie Inc. ("AbbVie")) and Progenics, we are required to pay significant milestone payments, license fees for "system know-how" technology, and royalties related to leronlimab upon the occurrence of specified events. To make these milestone and license payments, we will need to raise additional funds. In addition, our royalty obligations will reduce the economic benefits to us of future sales, if any. To the extent that such milestone payments and royalties are not timely made, under their respective agreements, Progenics has certain repurchase rights relating to the assets sold to us, and AbbVie has certain termination rights relating to our license of leronlimab under the PDL License. Refer to Part II, Item 8, Note 9, *Commitments and Contingencies – PRO 140 Acquisition and Licensing Arrangements* in this Form 10-K for further information.

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

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

approval for the use of leronlimab for one or more indications is subject to a number of risks which include, among others:

- the FDA or comparable foreign regulatory authorities or IRBs may disagree with the future design or implementation of our clinical trials,
- we may not be able to provide acceptable evidence of the safety and efficacy of our drug candidate,
- the results of our clinical trials may not be satisfactory or may not meet the level of statistical or clinical significance required by the FDA or foreign regulatory authorities for marketing approval,
- patients in our clinical trials may suffer adverse effects for reasons that may or may not be related to our drug candidate,
- the data collected from clinical trials may not be sufficient to support the submission of an application for marketing approval in the United States or elsewhere,
- the FDA or foreign regulatory authorities may not approve the manufacturing processes or facilities of third-party manufacturers with which we contract for clinical and commercial supplies, and
- the approval policies or regulations of the FDA or foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval.

We cannot guarantee that regulators will agree with our assessment of the results of our past or future clinical trials or that such trials will be considered by regulators to have shown safety or efficacy of our product candidate. The FDA has substantial discretion in the approval process and may refuse to accept any application or may require additional clinical trials or pre-clinical or other studies. Additionally, we have limited experience in filing the applications necessary to gain regulatory approvals and expect to continue to rely on consultants and our CROs to assist us in this process. Securing FDA approval requires the submission of pre-clinical, clinical, and/or pharmacokinetic data, information about product manufacturing processes and inspection of facilities, and supporting information for each therapeutic indication to establish a product candidate's safety and efficacy for each indication. Our drug candidate may prove to have undesirable or unintended side effects, toxicities, or other characteristics that may preclude us from obtaining regulatory approval or prevent or limit commercial use with respect to one or all intended indications. Failure to obtain regulatory approval for leronlimab will prevent us from commercializing it as a prescription product, and our ability to generate revenue will be seriously impaired.

Disruptions at the FDA and other government agencies caused by funding shortages, Executive Orders, or global health concerns could hinder their ability to hire, retain, or deploy key leadership and other personnel, or otherwise prevent new or modified products from being developed, approved, or commercialized in a timely manner or at all, which could negatively impact our business.

The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, statutory, regulatory, and policy changes, the FDA's ability to hire and retain key personnel and accept the payment of user fees, and other events that may otherwise affect the FDA's ability to perform routine functions. In addition, government funding of other government agencies that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable. President Trump has issued Executive Orders that may significantly reduce the federal workforce and could adversely affect the FDA's ability to attract and retain qualified scientific reviewers, which could result in longer review times for our applications. Additionally, the Trump Administration is seeking to reduce research funding by the NIH for medical research. If the funding is reduced for studies related to the medical indications on which we are focused or on which researchers were or may have been considering applying for federal grants, our research and development initiatives could be delayed or otherwise affected.

We are dependent on the success of leronlimab. If we, either alone or with collaborators, are unable to complete the clinical development of, obtain and maintain marketing approval for, or successfully commercialize leronlimab, including with respect to adequate coverage and reimbursement, or if we continue to experience significant delays in doing so, our business will be harmed.

We currently have no products approved for sale and are investing a significant portion of our resources in the development of leronlimab for marketing approval in the United States and potentially other countries. Our prospects are substantially dependent on our ability to develop, obtain marketing approval for, and successfully commercialize leronlimab in the United States in one or more disease indications. The success of our Company will depend on a number of factors, including the following:

- a safety, tolerability, and efficacy profile for leronlimab that is satisfactory to the FDA and potential foreign regulatory authorities,
- timely receipt of marketing approvals for leronlimab from applicable regulatory authorities, including the FDA,
- the performance of third-party contractors that we engage to manage our clinical studies and the resulting data,
- obtaining and maintaining patent, trade secret protection, and regulatory exclusivity, both in the United States and internationally, including our ability to maintain our license agreement with AbbVie, as successor to Progenics,
- protection of our rights in our intellectual property portfolio, including our ability to maintain our license agreement with AbbVie,
- a continued acceptable safety profile for leronlimab following marketing approval, if any,
- commercial acceptance of leronlimab by patients, the medical community, and third-party payors, and
- our ability to position leronlimab to compete with other therapies.

Many of these factors are beyond our control. If we are unable to develop, receive marketing approval for, and successfully provide for commercialization of leronlimab on our own or through third parties, or if we continue to experience delays as a result of any of these factors or otherwise, our business will be substantially harmed.

Our competitors may develop drugs that are more effective, safer, and less expensive than ours.

The biopharmaceutical industry is competitive, and our future success depends on our ability to demonstrate and maintain a competitive advantage with respect to the design, development, and commercialization of product candidates. For example, new or improved therapies in the oncology and immunology arenas are the subject of frequent announcements. If approved for marketing by the FDA, depending on the approved clinical indication, leronlimab may be competing with existing and future treatments. Our competitors may:

- develop drug candidates and market drugs that increase the levels of safety or efficacy that our product candidate will need to show to obtain regulatory approval,
- develop drug candidates and market drugs that are less expensive or more effective than ours,
- commercialize competing drugs before we or our partners can launch any products we are working to develop,
- hold or obtain proprietary rights that could prevent us from commercializing our products, and
- introduce therapies or market drugs that render our product candidate obsolete.

We expect to compete against large pharmaceutical and biotechnology companies and smaller companies that are collaborating with larger pharmaceutical companies, new companies, academic institutions, government agencies, and other public and private research organizations. These competitors, in nearly all cases, operate research and development programs that have greater financial resources than we do. Our competitors also have significantly greater experience in:

- developing drug and other product candidates,

- undertaking pre-clinical testing and clinical trials,
- building relationships with key customers and opinion-leading physicians,
- obtaining and maintaining FDA and other regulatory approvals,
- formulating and manufacturing drugs,
- launching, marketing, and selling drugs, and
- providing management oversight for all of the above-listed operational functions.

If we fail to achieve superiority over other existing or newly developed treatments, we may be unable to obtain regulatory approval. If our competitors market drugs that are less expensive, safer, or more effective than our product candidate, or which gain or maintain greater market acceptance, we may not be able to compete effectively.

We may not be able to identify, negotiate, and maintain the strategic alliances necessary to develop and commercialize our products and technologies, and we will be dependent on our corporate partners if we do.

We may seek to enter into a strategic alliance with a pharmaceutical company for further development and approval of our product candidate in one or more indications. Strategic alliances could potentially provide us with additional funds, expertise, access, and other resources in exchange for exclusive or non-exclusive licenses or other rights to the technologies and products that we are currently developing or may explore in the future. We cannot give any assurance we will be able to enter into strategic relationships with a pharmaceutical company or other strategic partner in the near future or at all or maintain our current relationships. In addition, we cannot assure that any agreements we may reach will achieve our goals or be on terms that prove to be economically beneficial to us. We anticipate that if we were to enter into strategic or contractual relationships, we may become dependent on the successful performance of our partners or counterparties. If they fail to perform as expected, such failure could adversely affect our financial condition, lead to increases in our capital needs, or hinder or delay our development efforts.

Known third-party patent rights could delay or otherwise adversely affect our planned development and sale of leronlimab. We have identified but not exhaustively analyzed other patents that could relate to our proposed products.

We are aware of patent rights held by a third party that may cover certain compositions within our leronlimab candidate. The patent holder has the right to prevent others from making, using, or selling a drug that incorporates the patented compositions, while the patent remains in force. While we believe that the third party's patent rights will not affect our planned development, regulatory clearance, and eventual commercial production, marketing, and sale of leronlimab, there can be no assurance that this will be the case. We believe the relevant patent expires before we expect to commercially introduce leronlimab. In addition, the Hatch-Waxman exemption to U.S. patent law permits all uses of compounds in clinical trials and for other purposes reasonably related to obtaining the FDA clearance of drugs that will be sold only after patent expiration; we believe our use of leronlimab in those FDA-related activities would not infringe the patent holder's rights. However, were the patent holder to assert its rights against us before expiration of the patent for activities unrelated to the FDA clearance, the development and ultimate sale of a leronlimab product could be significantly delayed, and we could incur expenses for defending a patent infringement suit and for damages that may relate to periods prior to the patent's expiration. In connection with our acquisition of rights to leronlimab, our patent counsel conducted a freedom-to-operate search that identified other patents that could relate to our proposed leronlimab candidate. Based upon research and analysis to date, we believe leronlimab likely does not infringe those patent rights. If any of the holders of the identified patents were to assert patent rights against us, the development and sale of leronlimab could be delayed, we could be required to spend time and money defending patent litigation, and we could incur liability for infringement or be enjoined from producing our products if the patent holders prevailed in an infringement suit.

Risks Related to Our Dependence on Third Parties

We have a limited number of internal research and development personnel, making us dependent on consulting relationships and strategic alliances with industry partners.

We have few employees dedicated to quality control and CMC activities. We rely and intend to continue to rely on third parties to supplement many of these critical functions. If we commence additional clinical trials, we will contract

with third-party, full-service CROs to manage our trials. As a result, we are likely to be dependent on consultants and strategic partners in our development activities, and it may be administratively challenging for us to monitor and coordinate these relationships. If we do not appropriately manage our relationships with third parties, we may not be able to successfully manage development, testing, and preparation of regulatory filings for our product or commercialize any approved product, which would have a material and adverse effect on our business, financial condition and stock price.

We may continue to rely on third parties, such as CROs and third-party manufacturers, to conduct clinical trials for our product candidate, leronlimab, and to produce our pre-clinical and clinical product candidate supplies. Such third parties are subject to significant regulation. A failure by such third parties to perform their obligations properly and successfully to us, or failure of manufacturers on which we rely to meet regulatory requirements, may result in our inability to obtain regulatory approvals for or commercialize our product candidate.

We are dependent on third parties for important aspects of our product development strategy. We do not have the required financial and human resources to independently conduct the pre-clinical and clinical development of our current product candidate. We also do not have the capability or resources to manufacture, store, market or sell our current product candidate. As a result, we contract with and rely on third parties to perform such essential functions. We compete with larger companies for the resources of these third parties. Although we plan to continue to rely on these third parties to conduct any future clinical trials and manufacturing, we are responsible for ensuring that each of our clinical trials is conducted in accordance with its general investigational plan and protocol and adheres to the FDA's regulations regarding Good Laboratory Practice and that the manufacturing of our product complies with the FDA's current good manufacturing practices ("cGMP") enforced through its facilities inspection program. Moreover, we are required to comply with regulations and standards, including good clinical practices, for designing, conducting, monitoring, recording, analyzing, and reporting the results of clinical trials to assure that the data and results are credible and accurate and that the rights, integrity, and confidentiality of trial participants are protected. Our reliance on third parties that we do not control does not relieve us of these responsibilities and requirements. The third parties on whom we rely generally may terminate their engagements with us at any time. If these third parties do not successfully carry out their duties under their agreements with us, if the quality or accuracy of the data they obtain, process, and analyze is compromised for any reason, or if they otherwise fail to comply with clinical trial protocols or meet expected deadlines, future clinical trials that we may undertake may experience delays or may fail to meet regulatory requirements. If our clinical trials do not meet regulatory requirements or if these third parties need to be replaced, our pre-clinical development activities or clinical trials may be extended, delayed, suspended, or terminated. If any of these events occur, or if problems develop in our relationships with third parties, or if such parties fail to perform as expected, we may experience delays or lack of progress, significant cost increases, changes in our strategies, and even failure of our product initiatives, potentially resulting in our inability to obtain regulatory approval of our product candidate and harming our reputation.

Risks Related to Our Intellectual Property Rights

Our success depends upon our ability to obtain and maintain intellectual property protection relating to our product candidate and future product candidates.

Due to evolving legal standards relating to the patentability, validity, and enforceability of patents covering pharmaceutical inventions and the claim scope of patents, our ability to enforce our existing patents and to obtain and enforce patents that may issue from any pending or future patent applications is uncertain and involves complex legal, scientific, and factual questions. To date, no consistent policy has emerged regarding the breadth of claims allowed in biotechnology and pharmaceutical patents. We have pending patents for certain indications for our core product candidate and continue to seek patent coverage for various potential therapeutic applications for leronlimab. However, we cannot be sure that any patents will issue from any pending or future patent applications owned by or licensed to us. Even if patents do issue, we cannot be sure that the claims of these patents will be held valid or enforceable by a court of law, will provide us with any significant protection against competing products, or will afford us a commercial advantage over competitive products. If one or more products resulting from our product candidate is approved for sale by the FDA and we do not have adequate intellectual property protection for those products, competitors could duplicate

them for approval and sale in the United States without repeating the extensive testing required of us or our partners to obtain FDA approval, once our data exclusivity period has expired.

If we are sued for infringing on third-party intellectual property rights, it will be costly and time-consuming, and an unfavorable outcome would have a significant adverse effect on our business. We may also undertake infringement or other legal proceedings against third parties, causing us to spend resources on litigation and exposing our own intellectual property portfolio to challenge.

Our ability to commercialize our product candidate depends on our ability to use, manufacture, and sell that product without infringing on the patents or other proprietary rights of third parties. Numerous U.S. and foreign issued patents and pending patent applications owned by third parties exist in the monoclonal antibody therapeutic area in which we are developing our product candidate and seeking new potential product candidates. There may be existing patents, unknown to us, on which our activities with our product candidate could infringe.

If a third party claims our actions or products or technologies infringe on its patents or other proprietary rights, we could face a number of issues that could harm our competitive position, including, but not limited to:

- infringement and other intellectual property claims that, even if meritless, can be costly and time-consuming, delay the regulatory approval process, and divert management's attention from our core business operations,
- substantial damages for infringement if a court determines that our products or technologies infringe a third party's patent or other proprietary rights,
- a court prohibiting us from selling or licensing our products or technologies unless the holder licenses the patent or other proprietary rights to us, which it is not required to do, and
- even if a license is available from a holder, we may have to pay substantial royalties or grant cross-licenses to our patents or other proprietary rights.

If any of these events occur, it could significantly harm our operations and financial condition and negatively affect our stock price. Additionally, although no third party asserted a claim of infringement against us, others may hold proprietary rights that could prevent our product candidate from being marketed. Any patent-related legal action against us claiming damages and seeking to enjoin commercial activities relating to our product candidate or our processes could subject us to potential liability for damages and require us to obtain a license to continue to manufacture or market leronlimab or any other product candidates. We cannot predict whether we would prevail in any such actions or that any license required under any of these patents would be made available on commercially acceptable terms, if at all. Further, we cannot be sure that we could redesign leronlimab or any other product candidates or processes to avoid infringement, if necessary. Accordingly, an adverse determination in a judicial or administrative proceeding, or the failure to obtain necessary licenses, could prevent us from developing and commercializing leronlimab or another product candidate, which could harm our business, financial condition, and operating results.

We may come to believe that third parties are infringing on our patents or other proprietary rights. To prevent infringement or unauthorized use, we may need to file infringement and/or misappropriation suits, which are extremely expensive and time-consuming and would distract management's attention. Also, in an infringement or misappropriation proceeding, a court may decide that one or more of our patents is invalid, unenforceable, or both, in which case third parties may be able to use our technology without paying license fees or royalties. Even if the validity of our patents is upheld, a court may refuse to stop the other party from using the technology at issue on the ground that the other party's activities are not covered by our patents.

We may become involved in disputes with our present or future contract partners over intellectual property ownership or other matters, which could have a significant adverse effect on our business.

Inventions discovered in the course of performance of contracts with third parties may become jointly owned by our strategic partners and us, in some cases, and the exclusive property of one of us, in other cases. Under some circumstances, it may be difficult to determine who owns a particular invention or whether it is jointly owned, and

disputes could arise regarding ownership or use of those inventions. Other disputes may also arise relating to the performance or alleged breach of our agreements with third parties. Any disputes could be costly and time-consuming, and an unfavorable outcome could have a significant adverse effect on our business.

Risks Related to Ownership of Our Common Stock

Our common stock is classified as "penny stock" and trading of our shares may be restricted by the SEC's penny stock regulations.

Rules 15g-1 through 15g-9 promulgated under the Exchange Act impose sales practice and disclosure requirements on certain brokers-dealers who engage in transactions involving a "penny stock." The SEC has adopted regulations which generally define "penny stock" to be any equity security that has a market price of less than $5.00 per share or an exercise price of less than $5.00 per share, subject to certain exceptions. Our common stock is covered by the penny stock rules, which impose additional sales practice requirements on broker-dealers who sell to persons other than established customers and "accredited investors." The penny stock rules require a broker-dealer, prior to a transaction in a penny stock not otherwise exempt from the rules, to deliver a standardized risk disclosure document in a form prepared by the SEC that provides information about penny stocks and the nature and level of risks in the penny stock market. The broker-dealer also must provide the prospective investor with current bid and offer quotations for the penny stock, the compensation of the broker-dealer and its salesperson in the transaction, and monthly account statements showing the market value of each penny stock held in the investor's account. In addition, the penny stock rules require that, prior to a transaction in a penny stock that is not otherwise exempt, the broker-dealer must make a special written determination that the penny stock is a suitable investment for the purchaser and receive the purchaser's written agreement to the transaction. These disclosure requirements may have the effect of reducing the level of trading activity in the secondary market for stock that is subject to these penny stock rules. Consequently, these penny stock rules may affect the ability of broker-dealers to trade our securities. We believe that the penny stock rules may discourage investor interest in and limit the marketability of our common stock.

The trading price of our common stock has been and could remain volatile, and the market price of our common stock may decrease.

The market price of our common stock has historically experienced and may continue to experience significant volatility. From June 1, 2024, through June 30, 2025, the market price of our common stock has fluctuated from a high of $0.49 per share to a low of $0.10 per share. The volatile nature of our common share price may cause investment losses for our stockholders. In addition, the market price of stock in small capitalization biotech companies is often driven by investor sentiment, expectation, and perception, all of which may be independent of fundamental, objective, and intrinsic valuation metrics or traditional financial performance metrics, thereby exacerbating volatility. In addition, our common stock is quoted on the OTCQB of the OTC Markets marketplace, which may increase price quotation volatility and could limit liquidity, all of which may adversely affect the market price of our shares.

Since our inception, we have been insolvent and have required debt and equity financing to maintain operations. We expect our debt service obligations and our need for additional funding to finance operations will cause additional dilution to our existing stockholders and could adversely affect the trading price of our common stock.

Since our inception, we have not achieved cash flows from revenues sufficient to cover basic operating costs. As a result, we have relied heavily on debt and equity financing. Equity financing, including securities convertible into equity, in particular has had a dilutive effect on our common stock, which has hampered our ability to attract reasonable financing terms.

The terms of our convertible note financings require us to make periodic debt repayments to reduce the outstanding balance of our debt. As a result, we likely will be required to use a significant portion of our available cash to satisfy our payment obligations, which will reduce the amount of capital available to finance our operations and other business activities. We expect to continue to seek to exchange all or part of our outstanding debt for shares of common stock. If the Company enters into any future exchange offers, they will likely be negotiated at a discount to the market price of

our common stock and will cause additional dilution to our existing stockholders. If the convertible noteholders sell the common stock they receive in exchange for outstanding debt, this could result in downward pressure on our stock price. In addition, the exercise of our outstanding warrants and stock options for shares of our common stock, which we have encouraged from time to time through public or private warrant exchange offers, including in July 2024, will result in further dilution of our existing common stockholders.

Issuances of additional equity or convertible debt securities will continue to reduce the percentage ownership of our then-existing stockholders. We may also be required to grant potential investors new securities rights, preferences, or privileges senior to those possessed by our then-existing stockholders to induce them to invest in our company. The issuance of these senior securities may adversely affect the holders of our common stock as a result of preferential dividend and liquidation rights over the common stock and dilution of the voting power of the common stock.

As the result of these and other factors, the issuance of additional equity or convertible debt securities may have an adverse impact on the market price of our common stock. For the foreseeable future, we will be required to continue to rely on debt and equity financing to maintain our operations.

Our certificate of incorporation permits our Board to create new series of preferred stock without further approval by our stockholders, which could adversely affect the rights of the holders of our common stock.

Our Board has the authority to fix and determine the relative rights and preferences of preferred stock. Currently, our Board has the authority to designate and issue approximately 4.9 million additional shares of our preferred stock without further stockholder approval. As a result, our Board could authorize the issuance of another series of preferred stock that would grant to holders the preferred right to our assets upon liquidation, the right to receive dividend payments before dividends are distributed to the holders of common stock, and the right to redemption of the shares, together with a premium, prior to the redemption of our common stock. In addition, our Board could authorize the issuance of a series of preferred stock that has greater voting power than our common stock or that is convertible into our common stock, which could decrease the relative voting power of our common stock or result in dilution to our existing stockholders.

Anti-takeover provisions of our certificate of incorporation, our bylaws, and Delaware law could make an acquisition of us, which may be beneficial to our stockholders, more difficult, and may prevent attempts by our stockholders to replace or remove the current members of our Board and management.

Certain provisions of our amended and restated certificate of incorporation and bylaws could discourage, delay or prevent a merger, acquisition, or other change of control that stockholders may consider favorable, including transactions in which stockholders might otherwise receive a premium for shares of common stock. Furthermore, these provisions could frustrate attempts by our stockholders to replace or remove members of our Board. These provisions also could limit the price that investors might be willing to pay in the future for our common stock, thereby depressing the market price of our common stock. Stockholders who wish to participate in these transactions may not have the opportunity to do so. Among other things, these provisions:

- allow us to designate and issue shares of preferred stock, without stockholder approval, which could adversely affect the rights, preferences, and privileges of the holders of our common stock and could make it more difficult or less economically beneficial to acquire or seek to acquire us,
- provide that special meetings of stockholders may be called only by the Board acting pursuant to a resolution approved by the affirmative majority of the entire Board, and
- do not include a provision for cumulative voting in the election of directors. Under cumulative voting, a minority stockholder holding a sufficient number of shares may be able to ensure the election of one or more directors. The absence of cumulative voting may have the effect of limiting the ability of minority stockholders to effect changes in the composition of our Board.

In addition, we are governed by the provisions of Section 203 of the Delaware General Corporation Law (the "DGCL"), which may, unless certain criteria are met, prohibit large stockholders, particularly those owning 15% or more of our voting stock, from merging or combining with us for a prescribed period.

We do not expect to pay cash dividends on our common shares in the foreseeable future.

We have never declared or paid a cash dividend on our common shares, and we do not anticipate declaring or paying dividends on our common shares for the foreseeable future. We expect to use future financing proceeds and earnings, if any, to fund operating expenses. Consequently, common stockholders' only opportunity to achieve a return on their investment is if the price of our stock appreciates and they sell their shares at a profit. We cannot assure common stockholders of a positive return on their investment when they sell their shares or that stockholders will not lose the entire amount of their investment.

Item 1B. UNRESOLVED STAFF COMMENTS

None.

Item 1C. CYBERSECURITY

We have established processes for assessing, identifying and managing cybersecurity risks, which are built into our information technology function and are designed to safeguard our information assets and operations from internal and external cyber threats, including protecting employee and patient information from unauthorized access to or attacks on our networks and systems. These processes include physical, procedural and technical safeguards, response plans, regular tests on our systems, incident simulations and routine reviews of our policies and procedures to identify risks and enhance our practices. We also employ processes to identify material risks from cybersecurity threats associated with our use of third-party service providers.

We have engaged external parties, including risk management consultants and computer security firms, to enhance our cybersecurity oversight. In an effort to deter and detect cyber threats, we periodically provide training programs to our employees on issues related to privacy and data protection, cybersecurity risks, and the importance of reporting all incidents immediately. Topics include identifying phishing, password protection, securing confidential data, and mobile security. In addition, we use technology-based tools to mitigate cybersecurity risks and to bolster our employee-based cybersecurity programs. We also perform annual vulnerability assessments, conducted by independent, third-party cybersecurity firms.

Additionally, as part of our overall risk mitigation strategy, the Company obtains certain insurance policies. However, such insurance may not be sufficient in type or amount to cover us fully against claims related to security breaches, cyber-attacks and other related breaches.

The Audit Committee of our Board of Directors provides direct cybersecurity risk oversight. Our management provides timely disclosure and related updates to the Audit Committee regarding potential cybersecurity threats, incidents and general risks.

Our management periodically evaluates information provided by consultants on evolving cybersecurity risks and, based on management's assessment of the processes the Company has put in place, does not believe there are currently any known risks from cybersecurity threats that are reasonably likely to materially affect us or our business strategy, results of operations, or financial condition.

Item 2. PROPERTIES

Our principal office location is 1111 Main Street, Suite 660, Vancouver, Washington 98660. The space is subject to a lease effective through April 30, 2026. We do not own or lease any other properties.

Item 3. LEGAL PROCEEDINGS

For a description of material legal proceedings, refer to Part II, Item 8, Note 9, *Commitments and Contingencies – Legal Proceedings* in this Form 10-K.

Item 4. MINE SAFETY DISCLOSURES

Not applicable.

Part II

Item 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

Market Information

Our common stock is quoted on the OTCQB of the OTC Markets marketplace under the trading symbol CYDY. Over-the-counter market quotations reflect inter-dealer prices, without retail mark-up, mark-down, or commission, and may not necessarily represent actual transactions. Historically, trading in our stock has been limited and the trades that occurred cannot be characterized as those in the established public trading market. As a result, the trading prices of our common stock may not reflect the price that would result if our stock was more actively traded.

Holders

The number of record holders of our common stock on June 30, 2025 was approximately 1,000.

Dividends

Holders of our common stock are entitled to receive dividends if declared by our Board. While we have no contractual restrictions or restrictions in our governing documents on our ability to pay dividends, other than the preferential rights provided to the holders of our outstanding preferred stock, we have never paid cash dividends to holders of common stock and do not anticipate paying any in the foreseeable future as we retain earnings, if any, for use in our operations.

Also, under Section 170 of the DGCL, due to the Company's accumulated deficit of approximately $887.8 million as of May 31, 2025, the Company is not able to pay any dividends, whether in cash, other property, or in shares of capital stock, unless and until the deficiency in the amount of capital represented by the Company's issued and outstanding preferred stock has been addressed.

Refer to Part II, Item 8, Note 4, *Convertible Instruments and Accrued Interest* in this Form 10-K for additional information.

Unregistered Sales of Equity Securities

Issuances of Shares in Convertible Note Exchange Transactions

In April through July 2025, the Company and the holder of its April 23, 2021 Note, in partial satisfaction of the holder's redemption rights, entered into exchange agreements pursuant to which portions of the original note was partitioned into new notes with an aggregate principal amount of $3.0 million. The new note was exchanged concurrently with issuance of a total of approximately 10.4 million shares of common stock. The Company relied on the exemption provided by Section 3(a)(9) of the Securities Act in connection with the exchange transactions.

Item 6. [Reserved]

Item 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with the other sections of this Form 10-K, including our consolidated financial statements and related notes set forth in Part II, Item 8. This discussion and analysis contains forward-looking statements, including information about possible or assumed results of our operations, our performance, financial condition, plans, and objectives, that

involve risks, uncertainties, and assumptions. The actual results may differ materially from those anticipated and set forth in such forward-looking statements. See *Forward-Looking Statements* preceding Part I and Item 1A, *Risk Factors* in this Form 10-K.

Overview

The Company is a clinical stage biotechnology company focused on the clinical development and potential commercialization of its product candidate, leronlimab, which is being studied for its potential in solid-tumor oncology.

Our current business strategy is the clinical development of leronlimab, which may include the following:

1. Continue the Phase II trial of leronlimab in patients with relapsed/refractory micro-satellite stable colorectal cancer;

2. Conduct additional studies exploring leronlimab and its therapeutic potential in other solid-tumor oncology indications, including but not limited to metastatic triple-negative breast cancer; and

3. Continuing our work researching and developing a new or modified long-acting version of leronlimab.

We may need significant additional funding to execute the above business strategy in full, which may include conducting a variety of additional pre-clinical studies and clinical trials, in furtherance of our efforts to obtain FDA approval to commercialize leronlimab. In addition to traditional fundraising, the Company will pursue non-dilutive financing opportunities, such as license agreements and co-development or strategic partnerships, to help implement its strategy.

Fiscal 2025 Overview

Actions taken by the Company during fiscal 2025 included:

- Revamping our clinical strategy to focus on solid-tumor oncology;
- Entering into several strategic partnerships with academic institutions to further the development of leronlimab on a cost-effective basis;
- Entering into several strategic partnerships with private foundations and/or organizations that are and will continue to help fund leronlimab on a cost-effective basis;
- Hiring of Robert E. Hoffman as Chief Financial Officer;
- Resolution of our dispute with Amarex Clinical Research LLC on terms favorable to the Company;
- Furthering the development of a long-acting modified therapeutic; and
- Closing multiple financing transactions to provide funding for the Company's business operations and initiatives.

Leronlimab and Colorectal Cancer ("CRC")

In August 2024, the Company completed a meeting with the U.S. Food and Drug Administration (FDA) to gain alignment on the rationale and proposed dosing for a Phase II study investigating the preliminary safety and activity of leronlimab in combination with trifluridine plus tipiracil (TAS-102) and bevacizumab in participants with CCR5+, microsatellite stable ("MSS"), relapsed or refractory metastatic colorectal cancer (mCRC).

In October 2024, the Company engaged Syneos Health as the contract research organization ("CRO") for its Phase II trial, which will evaluate the efficacy of leronlimab in patients with relapsed/refractory micro-satellite stable colorectal cancer ("CRC"). Syneos Health is a leading fully integrated biopharmaceutical solutions organization that supports customers in accelerating the delivery of life-saving therapies to market. Syneos Health leverages advanced data analytics and AI/ML capabilities to improve outcomes at every stage of the asset lifecycle, from clinical development to commercialization.

In November 2024, the Company received clearance from the US Food and Drug Administration ("FDA") to commence its Phase II CRC trial, evaluating the efficacy of leronlimab in patients with relapsed/refractory microsatellite stable colorectal cancer. This milestone reflected the continued positive development of the Company's improved relationship with the FDA.

In December 2024, the Company announced that Dr. Ben Weinberg from Georgetown University and the MedStar Health Alliance had agreed to be the lead Principal Investigator for the CRC study. As requested by FDA, the first five patients enrolled in this study will receive 350 mg of leronlimab SQ once/week in combination with TAS-102 and Bevacizumab. After a preliminary safety review, subsequent patients will then be randomized to 350 or 700 mg of weekly leronlimab with the same background regimen. The Data and Safety Monitoring Board (DSMB) will perform a second safety review after the first 20 patients have completed at least 1 cycle of therapy. The DSMB could then recommend restricting further enrollment to a single dose level, should they identify a signal of superior activity in either one of the treatment arms.

In June 2025, the Company announced that the first patient has been dosed in its Phase II trial evaluating the efficacy of leronlimab in patients with relapsed/refractory microsatellite stable colorectal cancer ("CRC"), and that patient enrollment and opening additional clinical sites was underway through Syneos Health.

In July 2025, the Company announced encouraging historical clinical findings among patients with advanced mCRC, previously treated with leronlimab. The final results indicated that three of five patients treated with leronlimab had at least a partial response, as measured by radiologic criteria, including one patient with a complete response who remains alive five years later. The results, from patients treated under a prior compassionate use protocol, reiterate a favorable safety profile of leronlimab as well as its potential for clinical benefit in patients with mCRC. The results also support the rationale for the design and therapeutic potential of the Phase II CRC trial.

As of July 25, 2025, nine clinical sites had been approved to participate in the Phase II CRC trial, and two patients had received at least one dose in the trial. For additional information, the CRC trial protocol is posted on the NCI Clinical Trials website, and can be viewed here: https://clinicaltrials.gov/study/NCT06699836?cond=colorectal%20cancer&intr=leronlimab&rank=1

Leronlimab and Metastatic Triple-Negative Breast Cancer ("mTNBC")

In February and March 2025, the Company announced encouraging survival outcomes among a group of patients with mTNBC treated with leronlimab in the Company's 2019 trial(s). Although mTNBC patients typically have a poor prognosis, observed survival rates at 12, 24, 36, and 48 months after treatment with leronlimab compare favorably with reported life expectancy after treatment with currently approved therapies. In addition, the Company confirmed that a small group of patients who failed treatment after developing metastatic disease survived more than 48 months after receiving leronlimab, are alive today, and currently identify as having no evidence of ongoing disease.

In May 2025, the Company announced new data suggesting a novel mechanism of action of leronlimab for the treatment of solid tumors. The Company analyzed data from its prior clinical trials of patients with mTNBC and found that leronlimab treatment correlated with increased expression of an immune cell protein or "checkpoint inhibitor" known as programmed death-ligand 1 ("PD-L1") on patient's circulating tumor cells ("CTCs"). The results indicated that 15 of 17 (88%) of patients who received a weekly dose of 525 mg or higher experienced a significant increase in PD-L1 expression on their CTCs over a 30-to-90-day period after starting leronlimab. Increasing expression of PD-L1 can be likened to turning "cold" tumors "hot", elevating PD-L1 levels to the level necessary for patients to potentially derive benefit from further treatment with a class of drugs known as immune checkpoint inhibitors ("ICIs"). The Company also confirmed that all five patients (100%) who demonstrated a significant increase in PD-L1 expression after receiving leronlimab and received treatment with any ICI remain alive today.

The Company is currently in the process of resuming its clinical development in mTNBC, with the intention to prospectively confirm the retrospective observations in mTNBC outlined above. In early 2025, the Company announced several preclinical studies in TNBC intended to identify treatment strategies to optimize the design of a future Phase II

study, and to further examine the apparent mechanism behind the observed increase in survival as compared to existing treatment paths. In the interim, ongoing discussions with KOLs are being conducted towards initiating a study in patients with mTNBC on an abbreviated timeline.

Pre-Clinical Development of Long-Acting CCR5 Antagonist

The Company has an active and ongoing joint development agreement with a third-party company with generative AI drug discovery and development tools in an effort to develop one or more longer-acting molecules. The Company believes this collaboration will result in the expedited development of a modified, longer-acting therapeutic, and could lead to greater acceptance by patients due to the requirement for less frequent injections. The services provided by the third party may yield extended intellectual property protection, thereby increasing the value of the Company's patent portfolio.

If successful, such a modified therapeutic would require less frequent injections for patients on drug, furthering the convenience and overall marketability of the product. Working with a company with established AI-capabilities allows for a robust development path for this modified, longer-acting therapeutic for the Company. This joint development initiative remains in progress at this time and the Company will provide further updates when appropriate.

Additional information regarding corporate and clinical developments is included in Part I, Item 1, *Business* in this Form 10-K.

Results of operations for the fiscal years ended May 31, 2025, and 2024

Fluctuations in Operating Results

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

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

(in thousands, except for per share data)	Years ended, May 31 2025	2024	Change $	%
Operating expenses:				
General and administrative	$ 7,260	$ 10,818	$ (3,558)	(33)%
Research and development	(16,921)	7,240	(24,161)	(334)
Total operating expenses	(9,661)	18,058	(27,719)	(153)
Operating gain (loss)	9,661	(18,058)	27,719	153
Interest and other income (expense):				
Interest income	565	217	348	160
Interest on convertible notes	(4,424)	(4,659)	235	5
Amortization of discount on convertible notes	(407)	(1,076)	669	62
Amortization of debt issuance costs	—	(572)	572	100
Issuance costs for private placement of shares and warrants through placement agent	—	(2,819)	2,819	100
Loss on induced conversion	(1,180)	(6,680)	5,500	82
Finance charges	(25)	(2,584)	2,559	99
Loss on note extinguishment	—	(13,374)	13,374	100
Gain on restructuring of payables	407	—	407	100
Loss on derivatives	(852)	(236)	(616)	(261)
Total interest and other income (expense)	(5,916)	(31,783)	25,867	81
Gain (loss) before income taxes	3,745	(49,841)	53,586	108
Income tax benefit	—	—	—	—
Net income (loss)	$ 3,745	$ (49,841)	$ 53,586	108 %
Income (loss) per share:				
Basic	$ 0.00	$ (0.05)	$ 0.05	104 %
Diluted	$ 0.00	$ (0.05)	$ 0.05	104 %
Weighted average common shares used in calculation of income (loss) per share:				
Basic	1,205,755	969,509	236,246	24 %
Diluted	1,242,922	969,509	273,413	28 %

General and administrative expenses

G&A expenses consisted of the following:

(in thousands)	Years ended, May 31 2025	2024	Change $	%
Salaries, benefits, and other compensation	$ 1,554	$ 2,507	$ (953)	(38)
Stock-based compensation	826	2,415	(1,589)	(66)
Legal fees	1,663	2,089	(426)	(20)
Insurance	1,239	1,850	(611)	(33)
Other	1,978	1,957	21	1
Total general and administrative	$ 7,260	$ 10,818	$ (3,558)	(33)

The decrease in G&A expenses for the fiscal year ended May 31, 2025, compared to the prior fiscal year, was primarily due to a reduction in stock-based compensation and salaries, benefits and other compensation due to classifying clinical employees' compensation as a research and development expense in the current fiscal year.

Research and development expenses

R&D expenses consisted of the following:

	Years ended, May 31		Change	
(in thousands)	2025	2024	$	%
Clinical	$ 5,790	$ 1,898	$ 3,892	205 %
Non-clinical	1,066	493	573	116
CMC	1,091	3,867	(2,776)	(72)
License and patent fees	117	982	(865)	(88)
Return of clinical expenses	(24,985)	—	(24,985)	—
Total research and development	$ (16,921)	$ 7,240	$ (24,161)	(334)%

The decrease in R&D expenses in the fiscal year ended May 31, 2025, compared to the prior fiscal year, was primarily due to a return of clinical expenses related to the settlement of the Company's litigation with Amarex in July 2024. Refer to Note 9, *Commitments and Contingencies – Legal Proceedings – Settlement of Amarex Dispute* for further information.

The future trend of our R&D expenses is dependent on the costs of any future clinical trials and our decisions regarding which indications on which to focus our future efforts toward the development and study of leronlimab, which may include pre-clinical and clinical studies for oncology and inflammation, as well as efforts to develop a long-acting new or modified therapeutic, the timing and outcomes of such efforts, and the timing of the final close-out of closed studies.

Interest and other expense

Interest and other expenses consisted of the following:

	Years ended, May 31		Change	
(in thousands)	2025	2024	$	%
Interest income	565	217	348	160
Interest on convertible notes	$ (4,424)	$ (4,659)	$ 235	5 %
Amortization of discount on convertible notes	(407)	(1,076)	669	62
Amortization of debt issuance costs	—	(572)	572	100
Issuance costs for private placement of shares and warrants through placement agent	—	(2,819)	2,819	100
Loss on induced conversion	(1,180)	(6,680)	5,500	82
Finance charges	(25)	(2,584)	2,559	99
Loss on note extinguishment	—	(13,374)	13,374	100
Gain on restructuring of payables	407	—	407	100
Loss on derivatives	(852)	(236)	(616)	(261)
Total interest and other income (expense)	$ (5,916)	$ (31,783)	$ 25,867	(81)%

The decrease in interest and other expenses for the fiscal year ended May 31, 2025, compared with the prior fiscal year, was primarily due to the decreases in loss on induced conversion, loss on note extinguishment and finance charges. The decrease in loss on induced conversion is due to recent note payments classified as gains on restructuring of payables. The decrease in loss on note extinguishment is due to note extinguishments occurring in the prior period. The decrease in finance charges is due to restructuring the balance due to Samsung, which removed any future interest.

Refer to Part II, Item 8, Note 4, *Convertible Instruments and Accrued Interest* and Note 13, *Subsequent Events* in this report for additional information.

Liquidity and Capital Resources

As of May 31, 2025, we had a total of approximately $11.9 million in cash and cash equivalents, and approximately $70.5 million in short-term liabilities consisting primarily of approximately $45.4 million representing the principal of and accrued interest on convertible notes payable, net of unamortized debt discount, and approximately $16.9 million in accounts payable and accrued liabilities and compensation. We will continue to incur operating losses and the Company

will require a significant amount of additional capital in the future as we continue to seek approval to commercialize leronlimab. Despite the Company's negative working capital position, vendor relations remain relatively accommodative given 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 and Cash equivalents

The Company's cash and cash equivalents position of approximately $11.9 million and zero restricted cash, respectively, on May 31, 2025, increased by approximately $8.8 million and decreased by $6.7 million, respectively, compared to the cash balance of approximately $3.1 million and restricted cash balance of approximately $6.7 million on May 31, 2024.

Summary of cash flows and changes between the periods presented is as follows:

(in thousands)	Years ended, May 31 2025	2024	Change $
Net cash provided by (used in):			
Net cash used in operating activities	$ (8,765)	$ (10,982)	$ 2,217
Net cash provided by financing activities	$ 10,854	$ 11,748	$ (894)

Cash used in operating activities

Net cash used in operating activities totaled approximately $8.8 million during the fiscal year ended May 31, 2025, representing an improvement of approximately $2.2 million compared to the prior year. The increase in the net amount of cash provided by operating activities was due primarily to a legal settlement of approximately $10.0 million, offset by additional clinical research payments. Refer to Note 9, *Commitments and Contingencies – Legal Proceedings – Settlement of Amarex Dispute* for further information.

Cash provided by financing activities

Net cash provided by financing activities totaled approximately $10.9 million, a decrease of approximately $0.9 million compared to the prior year. The decrease in net cash provided was primarily the result of raising less funds from private placements of common stock and warrants, offset by an increase in funds raised from warrant exchange transactions.

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 as amended in April 2025 accrues interest daily at a rate of 6% per annum, has a stated conversion price of $10.00 per share, and matures in April 2026. As of May 31, 2025, the outstanding balance of the April 2, 2021 Note, including accrued interest, was approximately $8.2 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 as amended in April 2025 accrues interest daily at a rate of 6% per annum, has a stated conversion price of $10.00 per share, and matures in April 2026. As of May 31, 2025, the outstanding balance of the April 23, 2021 Note, including accrued interest, was approximately $37.1 million.

Refer to Part II, Item 8, Note 4, *Convertible Instruments and Accrued Interest* and Note 13, *Subsequent Events* in this report for additional information.

Common stock

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

(in millions)	As of May 31, 2025
Issuable upon:	
Warrant exercises	213.1
Convertible preferred stock and undeclared dividends conversion	40.0
Outstanding stock option exercises or vesting of outstanding RSUs	41.8
Reserved for issuance pursuant to future stock-based awards under equity incentive plan	6.2
Reserved and issuable upon conversion of outstanding convertible notes	12.0
Total shares reserved for future uses	313.1
Common stock outstanding	1,249.2

As a result, as of May 31, 2025, we had approximately 187.7 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.

Refer to Part II, Item 8, Note 13, *Subsequent Events* in this report for additional information.

Off-Balance Sheet Arrangements

As of May 31, 2025, 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, *Convertible Instruments and Accrued Interest,* Note 9, *Commitments and Contingencies* and Note 13, *Subsequent Events* included in Part II, Item 8 of this Form 10-K.

Legal Proceedings

The Company is a party to various legal proceedings described in Part II, Item 8, Note 9, *Commitments and Contingencies - Legal Proceedings* of this Form 10-K. The Company recognizes 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 and the loss or range of loss can be estimated, the possible loss is disclosed.

It is not 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, 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, or if no accrual has been made, could be material to the Company's consolidated financial statements. Refer to Note 9, *Commitments and Contingencies – Legal Proceedings* for further discussion of legal proceedings.

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. Net income of $3.7 million for the fiscal year ended May 31, 2025 resulted from the recovery of approximately $25.0 million in clinical expenses due to the settlement of the Company's litigation with Amarex, which is a non-recurring event. The Company had an accumulated deficit of $887.8 million as of May 31, 2025. 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 had no activities that produced revenue in the periods presented and had operating losses 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, to pursue 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 strategies. 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 pursuing other development and commercialization initiatives and obtaining adequate funding to cover the costs of the legal proceedings in which we are involved, 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 and disrupt 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 development activities and its working capital needs primarily from the sale of equity and debt securities. As of June 30, 2025, the Company had approximately 172.8 million shares of common stock authorized for issuance under its certificate of incorporation, as amended, and available for future uses. 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 the common stock. 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.

In April 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. 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.

Refer to Part I, Item 1A, *Risk Factors* of this Form 10-K for additional information.

New Accounting Pronouncements

Refer to Part II, Item 8, Note 2, *Summary of Significant Accounting Policies – Recent Accounting Pronouncements* in this Form 10-K.

Critical Accounting Estimates

We prepare our consolidated financial statements in accordance with U.S. generally accepted accounting principles, which require our management to make estimates that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the balance sheet dates, as well as the reported amounts of revenues and expenses during the reporting periods. To the extent that there are material differences between these estimates and actual results, our financial condition or results of operations would be affected. We base our estimates on our own historical experience and other assumptions that we believe are reasonable after taking account of our circumstances and expectations for the future based on available information. We evaluate these estimates on an ongoing basis.

We consider an accounting estimate to be critical if: (i) the accounting estimate requires us to make assumptions about matters that were highly uncertain at the time the accounting estimate was made, and (ii) changes in the estimate that are reasonably likely to occur from period to period or use of different estimates that we reasonably could have used in the current period, would have a material impact on our financial condition or results of operations. There are items within our financial statements that require estimation but are not deemed critical, as defined above.

For a detailed discussion of our significant accounting policies and related judgments and estimates used in preparation of the consolidated financial statements, accounting policies and related judgments, see Part II, Item 8, Note 2, *Summary of Significant Accounting Policies,* in this Form 10-K.

Item 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Interest Rate Risk

We are exposed to market risks in the ordinary course of business. Our primary exposure to market risk is sensitivity to changes in interest rates. We hold our cash in interest-bearing money market accounts; due to the short-term maturities of such financial instruments, a 100 basis point change in interest rates would not have a material effect on the fair market value of our cash. As of May 31, 2025, we had $11.9 million in cash and cash equivalents.

Common Stock Price Volatility

The Compensation Committee of the Board of Directors has historically granted stock incentive awards to management and employees in the form of stock options. Stock-based compensation expense is recognized for stock options over the requisite service period using the fair value of these grants as estimated at the awards grant date using the Black-Scholes pricing model and the market value of our publicly traded common stock on the date of grant. In addition to the market value of our common stock, one of the inputs into this model that significantly impacts the fair value of the options is the expected volatility of our common stock over the estimated life of the option. We estimate expected volatility by using the most recent historical experience. Since November 2019, our common stock has experienced periods of high trading volatility. Grants of stock options during the fiscal year ended May 31, 2025, continued to reflect expected volatility as part of the estimated fair value of stock options. Additionally, we negotiate the settlement of debt payment obligations in exchange for equity securities of the Company, which can create a non-cash charge upon extinguishment of debt as the price of our common stock fluctuates. If we continue to enter into these settlements, the increased levels of volatility in our common stock trading price will result in increased dilution and extinguishment gains or losses.

Item 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

CYTODYN INC.

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Stockholders and Board of Directors of

CytoDyn Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheet of CytoDyn Inc. (the "Company") as of May 31, 2025, the related consolidated statements of operations, changes in stockholders' deficit and cash flows for the year ended May 31, 2025, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of May 31,2025, and the results of its operations and its cash flows for the year ended May 31, 2025, in conformity with accounting principles generally accepted in the United States of America.

Explanatory Paragraph – Going Concern

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As more fully described in Note 2, the Company has a significant working capital deficiency, has incurred significant losses and needs to raise additional funds to meet its obligations and sustain its operations. These conditions raise substantial doubt about the Company's ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 2. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audit. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) ("PCAOB") and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audit we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audit included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audit also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audit provides a reasonable basis for our opinion.

Prior Period Financial Statements

The financial statements of the Company as of and for the year ended May 31, 2024, were audited by Marcum LLP, whose report dated August 15, 2024, expressed an unmodified opinion on those statements, including an emphasis of matter paragraph assuming the Company will continue as a going concern.

Critical Audit Matters

Critical audit matters are matters arising from the current period audit of the financial statements that were communicated or required to be communicated to the audit committee and that: (1) relate to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective, or complex judgments. We determined that there are no critical audit matters.

/s/ CBIZ CPAs P.C.

We have served as the Company's auditor since 2024.

Hartford, CT

July 25, 2025

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Shareholders and Board of Directors of

CytoDyn, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheet of CytoDyn, Inc. (the "Company") as of May 31, 2024, the related consolidated statements of operations, changes in stockholders' deficit and cash flows for the year ended May 31, 2024, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of May 31, 2024, and the results of its operations and its cash flows for the year ended May 31, 2024, in conformity with accounting principles generally accepted in the United States of America.

Explanatory Paragraph – Going Concern

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As more fully described in Note 2, the Company has a significant working capital deficiency, has incurred significant losses and needs to raise additional funds to meet its obligations and sustain its operations. These conditions raise substantial doubt about the Company's ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 2. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audit. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) ("PCAOB") and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audit we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audit included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audit also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audit provides a reasonable basis for our opinion.

Critical Audit Matters

Critical audit matters are matters arising from the current period audit of the financial statements that were communicated or required to be communicated to the audit committee and that: (1) relate to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective, or complex judgments. We determined that there are no critical audit matters.

/s/ Marcum LLP

We have served as the Company's auditor since 2024.

Hartford, CT
August 15, 2024

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

	May 31, 2025	May 31, 2024
Assets		
Current assets:		
Cash and cash equivalents	$ 11,903	$ 3,110
Restricted cash	—	6,704
Prepaid expenses	252	463
Prepaid service fees	3,723	538
Other receivables (Note 9)	2,000	—
Total current assets	17,878	10,815
Other non-current assets	169	321
Total assets	$ 18,047	$ 11,136
Liabilities and Stockholders' Deficit		
Current liabilities:		
Accounts payable	$ 14,692	$ 29,561
Accrued liabilities and compensation	2,206	2,810
Accrued interest on convertible notes	18,151	15,227
Accrued dividends on convertible preferred stock	8,269	6,791
Convertible notes payable, net	27,200	29,793
Total current liabilities	70,518	84,182
Operating leases	—	141
Other liabilities (Note 9)	43,571	43,571
Total liabilities	114,089	127,894
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 May 31, 2025 and May 31, 2024	—	—
Series C convertible preferred stock, $0.001 par value; 8 authorized; 6 issued and outstanding at May 31, 2025 and May 31, 2024	—	—
Series D convertible preferred stock, $0.001 par value; 12 authorized; 9 issued and outstanding at May 31, 2025 and May 31, 2024	—	—
Common stock, $0.001 par value; 1,750,000 shares authorized; 1,249,460 and 1,059,002 issued, and 1,249,174 and 1,058,559 outstanding at May 31, 2025 and May 31, 2024, respectively	1,249	1,059
Treasury stock, $0.001 par value; 286 and 443 shares at May 31, 2025 and May 31, 2024, respectively	—	—
Additional paid-in capital	790,495	773,714
Accumulated deficit	(887,786)	(891,531)
Total stockholders' deficit	(96,042)	(116,758)
Total liabilities and stockholders' deficit	$ 18,047	$ 11,136

See accompanying notes to consolidated financial statements.

CytoDyn Inc.
Consolidated Statements of Operations
(In thousands, except per share amounts)

	Years ended May 31,	
	2025	**2024**
Operating expenses:		
General and administrative	$ 7,260	$ 10,818
Research and development	(16,921)	7,240
Total operating expenses	(9,661)	18,058
Operating gain (loss)	9,661	(18,058)
Interest and other income (expense):		
Interest income	565	217
Interest on convertible notes	(4,424)	(4,659)
Amortization of discount on convertible notes	(407)	(1,076)
Amortization of debt issuance costs	—	(572)
Issuance costs for private placement of shares and warrants through placement agent	—	(2,819)
Loss on induced conversion	(1,180)	(6,680)
Finance charges	(25)	(2,584)
Loss on note extinguishment	—	(13,374)
Gain on restructuring of payables	407	—
Loss on derivatives	(852)	(236)
Total interest and other income (expense)	(5,916)	(31,783)
Gain (loss) before income taxes	3,745	(49,841)
Income tax benefit	—	—
Net income (loss)	$ 3,745	$ (49,841)
Income (loss) per share:		
Basic	$ 0.00	$ (0.05)
Diluted	$ 0.00	$ (0.05)
Weighted average common shares used in calculation of income (loss) per share:		
Basic	1,205,755	969,509
Diluted	1,242,922	969,509

See accompanying notes to consolidated financial statements.

CytoDyn Inc.
Consolidated Statements of Stockholders' Deficit
(In thousands)

	Preferred stock		Common stock		Treasury stock		Additional paid-in capital	Accumulated deficit	Total stockholders' (deficit) equity
	Shares	Amount	Shares	Amount	Shares	Amount			
Balance May 31, 2023	34	$ —	919,053	$ 919	443	$ —	$ 731,270	$ (841,690)	$ (109,501)
Issuance of stock for convertible note repayment	—	—	34,309	34	—	—	5,216	—	5,250
Loss on induced conversion	—	—	—	—	—	—	6,680	—	6,680
Warrants issued in Note offering	—	—	—	—	—	—	359	—	359
Note Conversion	—	—	24,410	24	—	—	7,126	—	7,150
Stock issued for compensation	—	—	2,608	3	—	—	487	—	490
Stock issued for private offerings	—	—	75,622	76	—	—	21,621	—	21,697
Discount related to private offering modification	—	—	—	—	—	—	137	—	137
Warrant exercises	—	—	3,000	3	—	—	297	—	300
Preferred stock dividends accrued	—	—	—	—	—	—	(1,483)	—	(1,483)
Reclassification of warrants from liability to equity	—	—	—	—	—	—	79	—	79
Stock-based compensation	—	—	—	—	—	—	1,925	—	1,925
Net loss for May 31, 2024	—	—	—	—	—	—	—	(49,841)	(49,841)
Balance May 31, 2024	34	—	1,059,002	1,059	443	—	773,714	(891,531)	(116,758)
Issuance of stock for convertible note repayment	—	—	25,431	25	—	—	4,068	—	4,093
Loss on induced conversion	—	—	—	—	—	—	1,180	—	1,180
Stock issued for tender offer	—	—	152,505	153	—	—	13,873	—	14,026
Issuance costs related to stock issued for tender offer	—	—	—	—	—	—	(3,649)	—	(3,649)
Stock option exercises	—	—	500	1	—	—	105	—	106
Stock issued for compensation	—	—	435	—	—	—	100	—	100
Stock adjustment	—	—	(651)	(1)	(157)	—	1	—	—
Warrant exercises	—	—	12,238	12	—	—	1,069	—	1,081
Preferred stock dividends accrued	—	—	—	—	—	—	(1,478)	—	(1,478)
Stock-based compensation	—	—	—	—	—	—	1,512	—	1,512
Net income for May 31, 2025	—	—	—	—	—	—	—	3,745	3,745
Balance May 31, 2025	34	$ —	1,249,460	$ 1,249	286	$ —	$ 790,495	$ (887,786)	$ (96,042)

See accompanying notes to consolidated financial statements.

CytoDyn Inc.
Consolidated Statements of Cash Flows
(In thousands)

	Years ended May 31,	
	2025	**2024**
Cash flows from operating activities:		
Net income (loss)	$ 3,745	$ (49,841)
Adjustments to reconcile net income (loss) to net cash used in operating activities:		
Depreciation	18	29
Amortization of debt issuance costs	—	572
Issuance costs for private placement of shares and warrants through placement agent	—	2,819
Amortization of discount on convertible notes	407	1,076
Gain on restructuring of payables	(407)	—
Loss on derivatives	852	236
Loss on induced conversion	1,180	6,680
Loss on note extinguishment	—	13,374
Stock-based compensation	1,612	2,415
Changes in operating assets and liabilities:		
Prepaid expenses and other assets	(4,840)	893
Accounts payable, accrued expenses, and other liabilities	(11,332)	10,765
Net cash used in operating activities	(8,765)	(10,982)
Cash flows from investing activities:		
Net cash provided by/used in investing activities	—	—
Cash flows from financing activities:		
Proceeds from warrant transactions, net of offering costs	10,377	—
Proceeds from sale of common stock and warrants, net of issuance costs	—	9,137
Proceeds from warrant exercises	1,081	300
Proceeds from convertible note and warrant issuances, net of offering costs	—	2,011
Proceeds from exercise of stock options	106	—
Proceeds held in trust	—	300
Cash paid for note payable	(710)	—
Net cash provided by financing activities	10,854	11,748
Net change in cash and restricted cash	2,089	766
Cash, cash equivalents, and restricted cash at beginning of period	9,814	9,048
Cash, cash equivalents, and restricted cash at end of period	$ 11,903	$ 9,814
Cash, cash equivalents, and restricted cash consisted of the following:		
Cash and cash equivalents	$ 11,903	$ 3,110
Restricted cash	—	6,704
Total cash, cash equivalents, and restricted cash	$ 11,903	$ 9,814
Supplemental disclosure:		
Cash paid for interest	$ 25	$ 45
Non-cash investing and financing transactions:		
Derivative liability associated with warrants	$ —	$ 102
Issuance of common stock for principal of convertible notes	$ 4,500	$ 5,250
Accrued dividends on Series C and D convertible preferred stock	$ 1,478	$ 1,483
Cashless exercise of warrants	$ 2	$ —
Warrants issued to placement agent	$ —	$ 1,783
Note conversion to common stock and warrants	$ —	$ 3,302

See accompanying notes to consolidated financial statements.

CYTODYN INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
AS OF MAY 31, 2025

Note 1. Organization

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

The Company is currently working to further establish leronlimab via clinical development of its viability in solid-tumor oncology, and several other potential exploratory indications. Historically, the Company has investigated leronlimab as a viral entry inhibitor for treatment of 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. Leronlimab is being or has been studied in solid tumors in oncology, as well as other indications where CCR5 is believed to play an integral role in the pathogenesis of disease.

Note 2. Summary of Significant Accounting Policies

Principles of Consolidation

The consolidated financial statements include the accounts of CytoDyn Inc. and its wholly owned subsidiary, CytoDyn Operations Inc. Intercompany transactions and balances are eliminated in consolidation.

Reclassifications

During the year ended May 31, 2025, the Company modified the consolidated statements of income to include depreciation expense as part of general and administrative expense. Previously, depreciation expense was presented as a separate line item. In addition, we modified the prior period interest income line item to conform to the current period presentation.

Going Concern

The accompanying consolidated financial statements have been prepared on a going concern basis, which contemplates 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, except for the year ended May 31, 2025. The Company had an accumulated deficit of approximately $887.8 million as of May 31, 2025. These factors, among others, including the various matters discussed in Note 9, *Commitments and Contingencies,* raise substantial doubt about the Company's ability to continue as a going concern. The consolidated financial statements do not include any adjustments relating to the recoverability of assets and classification of liabilities that might be necessary should the Company be unable to continue as a going concern.

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

Use of Estimates

The preparation of the consolidated financial statements in accordance with accounting principles generally accepted in the United States ("U.S. GAAP" or "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 other assumptions that are believed to be reasonable under the circumstances. Significant estimates include, but are not limited to, those relating to stock-based compensation, the assumptions used to value warrants and warrant modifications. Actual results could differ from these estimates.

Cash and Cash Equivalents

Cash and cash equivalents are short-term, highly liquid investments with original maturities of three months or less when purchased and comprise bank deposits and money market funds. Our investments in money market funds are measured at fair value on a recurring basis and are classified within Level 1 of the fair value hierarchy because they are valued using quoted market prices. The value of the money market fund as of May 31, 2025, was approximately $11.4 million. The Company did not have a money market fund balance as of May 31, 2024.

Cash is maintained at federally insured financial institutions and, at times, balances may exceed federally insured limits. The Company has never experienced any losses related to cash balances. Balances in excess of federally insured limits were approximately $11.7 million of the cash balance at May 31, 2025. Balances in excess of federally insured limits were approximately $2.9 million of the cash balance and approximately $6.7 million of the restricted cash balance at May 31, 2024.

Restricted Cash

As of May 31, 2025, the Company had no restricted cash. The $6.7 million restricted cash balance as of May 31, 2024 was related to cash that was being held as collateral as required in the Amarex litigation and was released in full on July 2, 2024, as part of the settlement agreement.

Research and Development

Research and development expenses include (i) employee-related expenses, including salaries, benefits, stock-based compensation expense and travel; (ii) external research and development expenses incurred under arrangements with third parties, such as contract research organization agreements and consultants; (iii) the cost of acquiring, developing and manufacturing clinical study materials; (iv) costs associated with preclinical and clinical activities and regulatory operations; and (v) costs incurred in development of intellectual property. Costs incurred in connection with research and development activities are expensed as incurred.

Clinical trial costs incurred through third parties are expensed commensurate with the contracted work performed. Contingent milestone payments that are due to third parties under research and development collaboration arrangements or other contractual agreements are expensed when the milestone conditions are probable and the payment amount is reasonably estimable. See Note 9, *Commitments and Contingencies* for additional discussion.

Fair Value of Financial Instruments

The Company's financial instruments consist primarily of cash, accounts payable and accrued liabilities, and debt. As of May 31, 2025, the carrying value of the Company's assets and liabilities approximate their fair value due to the short-term maturity of the instruments. Debt is reported at amortized cost in the consolidated balance sheets which approximate fair value. The remaining financial instruments are reported in the consolidated balance sheets at amounts that approximate current fair values. The fair value hierarchy specifies three levels of inputs that may be used to measure fair value as follows:

- 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 which 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 cannot be corroborated with observable market data.

In accordance with the prescribed accounting guidance, the Company measured the fair value of money market funds and derivatives using the fair value hierarchy during the fiscal year ended May 31, 2025.

Leases

Operating lease right-of-use ("ROU") 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 leases on the consolidated balance sheets. Lease ROU assets and liabilities are recognized based on the present value of the future minimum lease payments over the lease term at commencement date. As the Company's leases do not provide an implicit rate, the Company uses its incremental borrowing rate based on the information available at commencement date in determining the present value of future payments. The operating lease ROU asset also includes any lease payments made and excludes lease incentives and initial direct costs incurred. The Company's lease terms do not include options to extend or terminate the lease as it is not reasonably certain that it would exercise these options. Lease expense for minimum lease payments is recognized on a straight-line basis over the lease term.

Stock-Based Compensation

U.S. GAAP requires companies to measure the cost of services received in exchange for the award of equity instruments based on their fair value at the date of grant. The related expense is recognized over the period during which services are expected to be performed in exchange for the award (requisite service period), when designated milestones have been achieved or when pre-defined performance conditions are met.

The Company values its stock-based awards using the Black-Scholes option pricing model utilizing assumptions that include stock price volatility, expected term of the award, and risk-free interest rates. The Company estimates forfeitures at the time of grant and makes revisions in subsequent periods, if necessary, if actual forfeitures differ from those estimates. The Company estimated future unvested forfeitures at zero for all periods presented.

Debt

The Company issued promissory notes at a discount and incurred direct debt issuance costs. Debt discount and issuance costs are netted against the debt and amortized over the life of the promissory note.

Warrants

The Company accounts for warrants as either equity-classified or liability-classified instruments based on an assessment of the warrant's specific terms and applicable authoritative guidance included in ASC 480, *Distinguishing Liabilities from Equity* and ASC 815, *Derivatives and Hedging*. The assessment considers whether the warrants are freestanding financial instruments pursuant to ASC 480, whether the warrants meet the definition of a liability pursuant to ASC 480, and whether the warrants meet all of the requirements for equity classification under ASC 815. This assessment, which requires the use of professional judgment, is conducted at the time of warrant issuance and as of each subsequent quarterly period end date while the warrants are outstanding. Warrants that meet all of the criteria for equity classification are required to be recorded as a component of additional paid-in capital at the time of issuance. For issued or modified warrants that do not meet all the criteria for equity classification, the warrants are required to be recorded at their initial fair value on the date of issuance and remeasured each balance sheet date thereafter.

Offering Costs

The Company periodically incurs direct incremental costs associated with the sale of shares of common stock and warrants to purchase shares of common stock; refer to Note 5*, Private Placements of Common Stock and Warrants* for additional information. The costs are recorded as a component of equity upon receipt of the proceeds if the security is classified as equity when the sale occurs or expensed as issuance costs if the security is classified as a liability when the sale occurs.

Income Taxes

Deferred taxes are recorded using the asset and liability method, whereby deferred tax assets are recognized for deductible temporary differences and operating loss and tax credit carry forwards; deferred tax liabilities are recognized for taxable temporary differences. Temporary differences are the differences between the reported amounts of assets and liabilities and their tax basis. Future tax benefits for net operating loss carryforwards are recognized to the extent that realization of these benefits is considered more likely than not. Deferred tax assets are reduced by a valuation allowance when it is more likely than not that some portion or all the deferred tax assets will not be realized.

The Company follows the provisions of ASC 740-10, *Uncertainty in Income Taxes*. A reconciliation of the beginning and ending amount of unrecognized tax benefits has not been provided since there are no unrecognized benefits for all periods presented. The Company has not recognized interest expense or penalties from the implementation of ASC 740-10. If there were an unrecognized tax benefit, the Company would recognize interest accrued related to unrecognized tax benefit in interest expense and penalties in operating expenses.

In accordance with Section 15 of the Internal Revenue Code, the Company utilized a federal statutory rate of 21% for our fiscal 2025 and 2024 tax years. The net tax expense for the fiscal years ended May 31, 2025, and 2024, was zero. As of May 31, 2025, and 2024, the Company has a full valuation allowance as management does not consider it more likely than not that the benefits from the deferred tax assets will be realized.

Basic and Diluted Net Earnings (Loss) Per Share

The Company calculates basic net earnings (loss) per share by dividing the net earnings (loss) by the weighted-average number of common shares outstanding during the period, without consideration of potential dilutive securities. Diluted net earnings (loss) per share is computed by dividing the net earnings (loss) by the sum of the weighted-average number of common shares outstanding during the period plus the dilutive effects of potentially dilutive securities outstanding during the period. Potentially dilutive securities include warrants to purchase shares of common stock, stock options, convertible shares of preferred stock, and convertible notes. For periods in which the Company has generated a net loss, the basic and diluted net loss per share are the same, as the inclusion of the potentially dilutive securities would be anti-dilutive.

Recent Accounting Pronouncements

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

In November 2023, the FASB issued ASU 2023-07, *Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures* ("ASU 2023-07"). The standard is intended to improve annual and interim reportable segment disclosure requirements regardless of the number of reporting units, primarily through enhanced disclosure of significant expenses. The amendment requires public companies to disclose significant segment expenses that are regularly provided to the Chief Operating Decision Maker ("CODM") and included with each reported measure of segment profit and loss. The standard is effective for annual periods beginning after December 15, 2023. Early adoption is permitted and the amendments in this update should be applied retrospectively to all periods presented. The Company adopted this ASU in fiscal year 2025, see Note 12, *Segment Information*.

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

In November 2024, the FASB issued ASU 2024-03, *"Income Statement (Topic 220): Reporting Comprehensive Income - Expense Disaggregation Disclosures, Disaggregation of Income Statement Expenses,"* which requires public companies to disclose, in interim and annual reporting periods, additional information about certain expenses in the financial statements. In January 2025, the FASB issued ASU 2025-01, "Income Statement—Reporting Comprehensive Income—Expense Disaggregation Disclosures (Subtopic 220-40) – Clarifying the Effective Date" to clarify the effective date for non-calendar year-end entities. The amendments in this ASU will be effective for annual periods beginning after December 15, 2026, and interim reporting periods within annual reporting periods beginning after December 15, 2027. Early adoption is permitted and is effective on either a prospective basis or retrospective basis. The Company is currently assessing the potential impacts of adoption on its consolidated financial statements and related disclosures.

In November 2024, the FASB issued ASU 2024-04, *"Debt—Debt with Conversion and Other Options (Subtopic 470-20): Induced Conversions of Convertible Debt Instruments,"* which clarifies the requirements for determining whether certain settlements of convertible debt instruments should be accounted for as an induced conversion or extinguishment of convertible debt. The new guidance is effective for annual reporting periods beginning after December 15, 2025, and interim periods within those annual periods. The Company is currently evaluating the impact of the standard on its consolidated financial statements and related disclosures.

Note 3. Accrued Liabilities

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

(in thousands)	May 31, 2025	May 31, 2024
Compensation and related expense	$ 278	$ 208
Legal fees and settlement	50	7
Clinical expense	487	329
License fees	1,105	1,799
Lease payable	141	142
Investor proceeds held in escrow	—	300
Other liabilities	145	25
Total accrued liabilities	$ 2,206	$ 2,810

As of May 31, 2025 and 2024, the accrued legal fees and settlement balance was primarily related to legal fees.

Note 4. Convertible Instruments and Accrued Interest

Convertible Preferred Stock

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

	May 31, 2025			May 31, 2024		
(in thousands except conversion rate)	Series B	Series C	Series D	Series B	Series C	Series D
Shares of preferred stock outstanding	19	6	9	19	6	9
Common stock conversion rate	10:1	2,000:1	1,250:1	10:1	2,000:1	1,250:1
Total shares of common stock if converted	190	12,670	10,565	190	12,670	10,565
Undeclared dividends	$ 24	$ —	$ —	$ 19	$ —	$ —
Accrued dividends	$ —	$ 3,769	$ 4,500	$ —	$ 3,135	$ 3,656
Total shares of common stock if dividends converted	48	7,538	9,000	38	6,270	7,312

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 election 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. Shares of common stock presented in the table above represent the number of shares that would have been issued had the dividend been paid in shares of the Company's common stock as of the end of each presented period; undeclared dividends of Series C Preferred Stock and Series D Preferred Stock are accrued as of May 31, 2025. Due to the Company's accumulated deficit of approximately $887.8 million as of May 31, 2025, under Section 170 of the Delaware General Corporation Law, the Company is prohibited from paying any dividends, whether in cash, other property, or in shares of capital stock, until the deficiency in the amount of capital represented by the Company's issued and outstanding preferred stock shall have been repaired. Refer to the discussion below for additional information.

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 payable to the Series B Preferred stockholders when and as declared by the Board at the rate of $0.25 per share per annum. Such dividends are cumulative and accrue whether or not declared and whether or not there are any profits, surplus, or other funds or assets of the Company legally available therefor. At the option of the Company, dividends on the Series B Preferred Stock may be paid in cash or restricted shares of the Company's common stock, valued at $0.50 per share. The preferred shareholders can only convert their shares to shares of common stock if the Company has sufficient authorized shares of common stock at the time of conversion. 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 holders have no voting rights. The Company does not accrue dividends on Series B preferred stock until such dividends are declared.

Series C Convertible Preferred Stock

The Series C Certificate of Designation provides, among other things, that holders of Series C 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 Preferred Stock, which is $1,000 per share (the "Series C Stated Value"). Any dividends paid by the Company will be paid to the holders of Series C Preferred Stock prior and in preference to any payment or distribution to holders of common stock. Dividends on the Series C 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. There are no sinking fund provisions applicable to the Series C Preferred Stock. The Series C Preferred Stock does not have redemption rights. Dividends, if declared by the Board, are payable to holders in arrears on December 31 of each year. Subject to the provisions of applicable Delaware law, the holder may elect to be paid in cash or in restricted shares of common stock, with the number of shares to be based on the conversion price then in effect. In the event of liquidation, dissolution, or winding up of the Company, the holders of Series C Preferred Stock will be entitled to receive, on a pari passu basis with the holders of the Series D Preferred Stock and in preference to any payment or distribution to any holders of the Series B Preferred Stock or common stock, an amount per share equal to the Series C Stated Value plus the amount of any accrued and unpaid dividends. If, at any time while the Series C Preferred Stock is outstanding, the Company effects a 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 Certificate of Designation, a "Fundamental Transaction"), a holder of the Series C 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 Preferred Stock immediately prior to the Fundamental Transaction. Each share of Series C Preferred Stock is convertible at any time at the holder's option into that number of fully paid and nonassessable shares of common stock determined by dividing the Series C Stated Value by the conversion price of $0.50 (subject to adjustment as set forth in the Series C Certificate of Designation). No fractional shares will be issued upon the conversion of the Series C Preferred Stock. Except as otherwise provided in the Series C Certificate of Designation or as otherwise required by law, the Series C Preferred Stock has no voting rights.

Series D Convertible Preferred Stock

The Series D Certificate of Designation provides, among other things, that holders of Series D Preferred Stock shall be entitled to receive, when and as declared by the Company's Board of Directors 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 D Preferred Stock, which is $1,000 per share (the "Series D Stated Value"). Any dividends paid by the Company will first be paid to the holders of Series D Preferred Stock prior and in preference to any payment or distribution to holders of common stock. Dividends on the 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. There are no sinking fund provisions applicable to the Series D Preferred Stock. The Series D Preferred Stock does not have redemption rights. Dividends, if declared by the Board, are payable to holders in arrears on December 31 of each year. Subject to the provisions of applicable Delaware law, the holder may elect to be paid in cash or in restricted shares of common stock, with the number of shares to be based on the conversion price then in effect. 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 any holders of the Series B Preferred Stock, $0.001 par value per share, or common stock, an amount per share equal to the Series D Stated Value plus the amount of any accrued and unpaid dividends. If, at any time while the 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 D Certificate of Designation, a "Fundamental Transaction"), a holder of the 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 D Preferred Stock immediately prior to the Fundamental Transaction. Each share of Series D Preferred Stock is convertible at any time at the holder's option into that number of fully paid and nonassessable shares of common stock determined by dividing the Series D Stated Value by the conversion price of $0.80 (subject to adjustment as set forth in the Series D Certificate of Designation). No fractional shares will be issued upon the conversion of the Series D Preferred Stock. Except as otherwise provided in the Series D Certificate of Designation or as otherwise required by law, the Series D Preferred Stock has no voting rights.

Convertible Notes and Accrued Interest

The outstanding balance of convertible notes, the terms of which are described in more detail below, including accrued interest, were as follows:

	May 31, 2025			May 31, 2024		
(in thousands)	April 2, 2021 Note	April 23, 2021 Note	Total	April 2, 2021 Note	April 23, 2021 Note	Total
Convertible notes payable outstanding principal	$ 2,831	$ 24,369	$ 27,200	$ 2,831	$ 27,369	$ 30,200
Less: Unamortized debt discount and issuance costs	—	—	—	(45)	(362)	(407)
Convertible notes payable, net	2,831	24,369	27,200	2,786	27,007	29,793
Accrued interest on convertible notes	5,378	12,773	18,151	4,634	10,593	15,227
Outstanding convertible notes payable, net and accrued interest	$ 8,209	$ 37,142	$ 45,351	$ 7,420	$ 37,600	$ 45,020

Changes in 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, 2024	$ 7,420	$ 37,600	$ 45,020
Amortization of issuance discount and costs	45	362	407
Interest expense	744	3,680	4,424
Fair market value of shares and warrants exchanged for repayment	—	(4,273)	(4,273)
Difference between market value of common shares and reduction of principal	—	(227)	(227)
Outstanding balance at May 31, 2025	$ 8,209	$ 37,142	$ 45,351

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 in the initial principal amount of $28.5 million (the "April 2, 2021 Note"). The current maturity date is April 5, 2026. See *April 2, 2021 and April 23, 2021 Note Extensions* below. The Company received consideration of $25.0 million, reflecting an original issue discount of $3.4 million and issuance costs of $0.1 million.

Beginning in April 2025, in connection with extension of the maturity date, interest accrues at an annual rate of 6% on the outstanding balance, a decrease from an annual rate of 10%; provided that the rate would increase 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, and listed as Exhibit 4.6 in Item 15 to this report. 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 securities purchase agreement and 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 of 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, as amended. 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.

The conversion feature of the April 2, 2021 Note was analyzed under ASC 815, *Derivatives and Hedging*, to determine if it achieved equity classification or required bifurcation as a derivative instrument. The embedded conversion feature was considered indexed to the Company's own stock and met the conditions for equity classification. Accordingly, the embedded conversion feature did not require bifurcation from the host instrument. The Company determined there was no beneficial conversion feature since the effective conversion rate was greater than the market value of the Company's common stock upon issuance. Certain default put provisions were considered not to be clearly and closely related to the host instrument, but the Company concluded that the value of these default put provisions was de minimis. The Company evaluates the value of the default put provisions each reporting period to determine if the value has become material to the financial statements.

During the fiscal year ended May 31, 2024, in satisfaction of redemptions, the Company and the April 2, 2021 Noteholder entered into six exchange agreements, pursuant to which the April 2, 2021 Note was partitioned into new notes (the "Partitioned Notes") with an aggregate principal amount of approximately $3.3 million, which was exchanged concurrently with the issuance of an aggregate amount of approximately 20.4 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 $2.8 million. The Company accounted for the Partitioned Notes and exchange settlements as induced conversions, and, accordingly, in the fiscal year ended May 31, 2024, the Company recorded a non-cash loss on convertible debt induced conversion of $4.7 million.

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 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 current maturity date is April 23, 2026. See *April 2, 2021 and April 23, 2021 Note Extensions* below. The Company received consideration of $25.0 million, reflecting an original issue discount of $3.4 million and issuance costs of $0.1 million. The April 23, 2021 Note is secured by all the assets of the Company, excluding the Company's intellectual property.

Interest accrues at an annual rate of 6% on the outstanding balance of the April 23, 2021 Note, amended from an annual rate of 10%, 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, and listed as Exhibit 4.7 in Item 15 to this report.

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.

Pursuant to the terms of the securities purchase agreement and 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 conversion feature in the April 23, 2021 Note was analyzed under ASC 815, *Derivatives and Hedging*, to determine if it achieved equity classification or required bifurcation as a derivative instrument. The embedded conversion feature was considered indexed to the Company's own stock and met the conditions for equity classification. Accordingly, the embedded conversion feature does not require bifurcation from the host instrument. The Company determined there was no beneficial conversion feature since the effective conversion rate was greater than the market value of the Company's common stock upon issuance. Certain default put provisions were not considered to be clearly and closely related to the host instrument, but the Company concluded that the value of these default put provisions was de minimis. The Company evaluates the value of the default put provisions each reporting period to determine if the value has become material to the financial statements.

During the fiscal year ended May 31, 2025, in satisfaction of redemptions, the Company and the April 23, 2021 Noteholder entered into seven exchange agreements, pursuant to which the April 23, 2021 Note was partitioned into the Partitioned Notes with an aggregate principal amount of $4.5 million, which was exchanged concurrently with the issuance of an aggregate amount of approximately 25.4 million shares of common stock. The outstanding balance of the April 23, 2021 Note was reduced by the Partitioned Notes to a principal amount of $24.4 million. The Company accounted for the Partitioned Notes and exchange settlements where the shares exchanged were worth more than principal extinguished as induced conversions, and, accordingly, in the fiscal years ended May 31, 2025 and May 31, 2024, the Company recorded a non-cash loss on convertible debt induced conversion of approximately $1.2 million and $1.9 million, respectively. The Company recognized an approximate $0.4 million gain on restructuring of payables

during the fiscal year ended May 31, 2025 for the Partitioned Notes and the exchange settlements where the shares exchanged were worth less than principal extinguished.

The holders of the April 2 and April 23 Notes have waived provisions in the notes that would have resulted in the imposition of a default interest rate, a downward adjustment in the conversion price, or any other default, breach, or imposition of a penalty. The related transactions consisted of the issuance of shares of common stock and warrants issued through a placement agent.

April 2, 2021 Note and April 23, 2021 Note Extensions

In April 2023 the Company and the April 2, 2021 and April 23, 2021 noteholders entered into an amendment to each note that extended the maturity date an additional two years. In exchange, the Company agreed to pay the noteholders an extension fee equal to two and one-half percent (2.5%) of the outstanding balance of each note as of April 10, 2023. As a result, the balances of the April 2, 2021 Note and April 23, 2021 Note increased by $0.3 million and $0.9 million, respectively.

The Company accounted for the note extensions as an increase to the discount on the convertible notes payable and amortized the note extension fee until the extended maturity date, April 2025.

In April 2025, the Company and the April 2, 2021 and April 23, 2021 noteholders agreed to extend the maturity date of each of the notes by one year to April 2026 (the "Extension Period") and to reduce the annual interest rate to 6%. The Company also agreed to make total monthly payments of $750,000 covering both notes during the Extension Period by issuing shares of common stock equal in value to each $750,000 monthly payment calculated based on the lower of (i) the previous trading day's closing price, or (ii) the average of the five previous trading day closing prices.

In the event of a conflict, the terms in the April 2025 extensions supersede the terms of the original Notes and all prior amendments thereto.

Note 5. Private Placements of Common Stock and Warrants

Liability classified warrants

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

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

During November 2023, in connection with the issuance of the short-term notes, the Company agreed to issue warrants to the placement agent as part of the issuance costs, with the ultimate number of warrants and exercise price to be determined as of the final closing date. The value of the warrants was recorded as a derivative liability on the balance sheet until the final closing date in December 2023, and the change in the fair value of the warrants was recorded as a gain or loss on derivatives.

On December 29, 2023, the short-term notes were converted into units that had similar terms to units being offered in a private placement of shares and warrants through a placement agent. As the unit price was not determinable until the final closing date of the subsequent private placement, the units related to the conversion of the short-term notes were recorded as a liability and at fair value. The change in the fair value of the units was recorded as a gain or loss on derivatives. On May 3, 2024, the private placement was concluded, which finalized the unit purchase price at $0.10, and the fair value of the units became equity-classified.

In accordance with the prescribed accounting guidance, the Company measured fair value of liability classified warrants using fair value hierarchy included in Note 2, *Summary of Significant Accounting Policies – Fair Value of Financial Instruments*.

As of May 31, 2024, in accordance with ASC 815, *Derivatives and Hedging,* the Company reclassified warrants to equity when the warrants no longer qualified as liabilities. The Company recorded a loss on derivatives of approximately $0.2 million in the fiscal year ended May 31, 2024, due to a change in fair market value of the liability classified shares of common stock and warrants. The table below presents a reconciliation of the beginning and ending balances for liabilities measured at fair value as of May 31, 2023, and during the fiscal year ended May 31, 2024. There were no liability-classified warrants in the fiscal year ended May 31, 2025.

(in thousands)	Liability Classified Warrants
Balance at May 31, 2023	$ 79
Classified as liability	6,970
Reclassified as equity	(7,285)
Loss on derivative due to change in fair market value	236
Balance at May 31, 2024	—

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.

The Company estimated the fair value of the warrant derivatives using the following assumptions:

		Inputs at Liability Classification			Inputs at Equity Classification			
	April Placement Agent warrants at May 31, 2023	July Note conversion warrants	November Placement Agent warrants	December Note conversion warrants	April Placement Warrants	July Note conversion warrants	November Placement Agent conversion warrants	December Note conversion warrants
Fair value of underlying stock	$ 0.26	$ 0.21	$ 0.18	$ 0.20	$ 0.27	$ 0.17	$ 0.30	$ 0.15
Risk free rate	3.64%	4.18%	4.42%	3.84%	3.74%	4.81%	4.14%	4.48%
Expected term (in years)	10.00	5.00	10.00	5.00	10.00	5.00	10.00	5.00
Stock price volatility	97.90%	124.55%	95.82%	124.25%	97.45%	124.70%	96.18%	124.04%
Expected dividend yield	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%

Tender Offer

On July 19, 2024, the Company closed a tender offer in which warrants to purchase approximately 127.1 million shares of common stock were exercised at a $0.09387 exercise price, resulting in gross proceeds of approximately $11.9 million and net proceeds of approximately $10.4 million. The Company also issued approximately 25.4 million shares of common stock as bonus shares in the tender offer. The Company paid the placement agent a total cash fee of approximately $1.4 million, equal to 13% of the gross proceeds of the offering, as well as repricing all warrants previously issued to the placement agent to an exercise price of $0.09387 per share. In connection with the tender offer, the Company recognized the following issuance costs: $1.4 million in cash paid to the placement agent, $0.1 million in legal fees, a $1.7 million change in fair value of the exercised warrants, and a $0.4 million change in fair value due to repricing the placement agent warrants.

Warrants

Warrant activity is presented in the table below:

(in thousands, except for exercise price and years)	Number of shares	Weighted average exercise price	Weighted average remaining contractual life in years	Aggregate intrinsic value
Warrants outstanding at May 31, 2023	259,910	$ 0.37	4.57	$ 7,276
Granted	115,582	$ 0.28		
Exercised	(3,000)	$ 0.10		$ 480
Forfeited, expired, and cancelled	(11,047)	$ 0.63		
Warrants outstanding at May 31, 2024	361,445	$ 0.34	4.21	$ 2,697
Granted	—	$ —		
Exercised	(140,106)	$ 0.09		$ 7,615
Forfeited, expired, and cancelled	(8,211)	$ 0.56		
Warrants outstanding at May 31, 2025	213,128	$ 0.27	3.71	$ 27,923
Warrants outstanding and exercisable at May 31, 2025	213,128	$ 0.27	3.71	$ 27,923

Warrant exercises

During the fiscal year ended May 31, 2025, the Company issued approximately 10.4 million shares of common stock in connection with the exercise of an equal number of warrants. The stated exercise prices ranged from $0.10 to $0.21 per share, which resulted in aggregate gross proceeds of approximately $1.1 million. Additionally, during the fiscal year ended May 31, 2025, the Company issued approximately 1.9 million shares of common stock in connection with the cashless exercise of approximately 2.6 million warrants with a stated exercise price of $0.09387 per share.

Note 6. Equity Incentive Plan

Equity Incentive Plan

As of May 31, 2025, the Company had one active equity incentive plan, the *CytoDyn Inc. Amended and Restated 2012 Equity Incentive Plan* (the "2012 Plan"). The 2012 Plan contains an "evergreen provision" whereby the total number of shares available to be issued automatically increases annually on the first day of each fiscal year in an amount equal to 1.0% of the total outstanding shares on the last day of the prior fiscal year, unless the Board determines otherwise before the fiscal year end. As of May 31, 2025, the 2012 Plan covered a total of 66.8 million shares of common stock.

Stock options

Stock option activity is presented in the table below:

(in thousands, except exercise price and years)	Number of shares	Weighted average exercise price	Weighted average remaining contractual life in years	Aggregate intrinsic value
Options outstanding at May 31, 2023	19,823	$ 0.99	7.87	$ —
Granted	14,251	$ 0.21		
Exercised	—	$ —		
Forfeited, expired, and cancelled	(8,225)	$ 0.87		
Options outstanding at May 31, 2024	25,849	$ 0.60	7.77	$ —
Granted	13,025	$ 0.17		
Exercised	(500)	$ 0.21		$ 72
Forfeited, expired, and cancelled	(50)	$ 0.66		
Options outstanding at May 31, 2025	38,324	$ 0.46	7.65	$ 4,039
Options outstanding and exercisable at May 31, 2025	28,594	$ 0.54	7.23	$ 2,653

The fair value of the equity awards granted is estimated using the Black-Scholes option-pricing model based on the closing stock prices at the grant date and the assumptions specific to the underlying award. Expected volatility assumptions are based on the historical volatility of the Company's common stock. The expected term assumption is based on the contractual and vesting term of the equity award. The risk-free interest rate is based on the U.S. Treasury yield curve with a maturity equal to the expected life assumed at the grant date. The following table summarizes the assumptions used in the determination of fair value:

	Years ended May 31,	
	2025	2024
Expected Volatility	123.2% - 130.4 %	108.6% - 115.7 %
Weighted-Average Volatility	127.02 %	112.24 %
Expected Dividends	— %	— %
Expected Term (In years)	5.1 - 6.1	5.1 - 6.0
Risk-Free Rate	3.96 %	3.96 %

In the fiscal years ended May 31, 2025, and 2024, stock-based compensation expense related to equity instruments totaled $1.3 million and $2.4 million, respectively; stock-based compensation expense is presented in general and administrative expense and research and development expense in the Company's consolidated statements of operations. The grant date fair value of options vested during the same periods was approximately $1.3 million and $3.3 million, respectively. As of May 31, 2025, there was approximately $1.7 million of unrecognized compensation expense related to share-based payments for unvested options, which is expected to be recognized over a weighted-average period of approximately 1.5 years.

During the fiscal year ended May 31, 2025, the Company granted stock options covering a total of approximately 13.0 million shares of common stock to directors, employees, and consultants, with exercise prices ranging between $0.13 and $0.41 per share. Of the options granted during the fiscal year ended May 31, 2025, approximately 7.0 million vest over four years, and approximately 6.0 million vest over one year, with a ten-year term. The grant date fair values of the stock options ranged between $0.11 and $0.37 per share. As of May 31, 2025, and May 31, 2024, there were approximately 28.6 million and 19.7 million vested stock options and approximately 9.7 million and 6.1 million unvested stock options outstanding, respectively.

RSUs and PSUs

The 2012 Plan provides for equity instruments, such as RSUs and PSUs, which grant the right to receive a specified number of shares over a specified period of time. RSUs and PSUs are service-based awards that vest according to the terms of the grant. PSUs have performance-based payout conditions.

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

(shares in thousands)	Number of RSUs and PSUs (1)	Weighted average grant date fair value	Weighted average remaining contractual life in years
Unvested RSUs and PSUs at May 31, 2023	1,293	$ 0.58	0.81
RSUs and PSUs granted	—		
RSUs and PSUs forfeited	(1,293)	0.58	
RSUs and PSUs vested	—		
Unvested RSUs and PSUs at May 31, 2024	—		
RSUs and PSUs granted	3,500	0.41	
RSUs and PSUs forfeited	—		
RSUs and PSUs vested	—		
Unvested RSUs and PSUs at May 31, 2025	3,500	$ 0.41	1.75

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

In May 2025, the Company awarded 3.5 million PSUs to Robert Hoffman, the Company's Chief Financial Officer, in connection with the commencement of his employment. The vesting of the PSUs is contingent on the achievement of specified performance-based conditions, with a potential payout percentage ranging from 0% to 100%.

Based on the estimated level of achievement of the performance targets associated with the PSUs as of May 31, 2025, unrecognized compensation expense related to the unvested portion of the Company's RSUs and PSUs totaled approximately $1.4 million, which is expected to be recognized over a weighted-average period of 1.75 years.

Issuance of shares to consultants

In March 2022, the Board approved the issuance under the 2012 Plan of shares of common stock to consultants as payment for services provided. During the fiscal years ended May 31, 2025 and 2024, a total of approximately 0.4 million and 2.5 million shares of common stock, respectively, were issued pursuant to the respective award agreements with the consultants.

Note 7. Income (loss) per Common Share

Basic income (loss) per share is computed by dividing the net income (loss) adjusted for preferred stock dividends by the weighted average number of common shares outstanding during the period. Diluted income (loss) per share includes the weighted average common shares outstanding and potentially dilutive common stock equivalents. For periods in which the Company has generated a net loss, the basic and diluted weighted average shares outstanding are the same, since including the additional shares would have an anti-dilutive effect on the loss per share.

The reconciliation of the numerators and denominators of the basic and diluted net income (loss) per share computations are as follows:

(in thousands, except per share amounts)	Years ended May 31, 2025	2024
Numerator:		
Net income (loss)	$ 3,745	$ (49,841)
Less: Accrued preferred stock dividends	(1,483)	(1,483)
Net income (loss) applicable to common stockholders	$ 2,261	$ (51,324)
Denominator:		
Basic weighted average common shares outstanding	1,205,755	969,509
Effect of dilutive securities:		
Warrant exercises	34,821	—
Option exercises	2,346	—
Diluted weighted average common shares outstanding	1,242,922	969,509
Basic income (loss) per share	0.00	(0.05)
Diluted income (loss) per share	0.00	(0.05)

Refer to Note 13, *Subsequent Events* for additional information regarding the shares issued subsequent to May 31, 2025.

The table below shows the numbers of shares of common stock issuable upon the exercise, vesting, or conversion of outstanding options, warrants, unvested restricted stock (including those subject to performance conditions), convertible preferred stock (including undeclared dividends), and convertible notes that were not included in the computation of the diluted weighted average number of shares of common stock outstanding for the periods presented:

(in thousands)	Years ended, May 31 2025	2024
Stock options, PSUs, and warrants	217,785	387,294
Convertible notes	12,000	12,000
Convertible preferred stock	40,013	37,046

Note 8. Income Taxes

Income (loss) before provision for income taxes was $3.7 million and ($49.8) million for the years ended May 31, 2025 and 2024, respectively, all of which was generated in the United States.

The Company's provision for income taxes consists of the following:

	Years Ended May 31, 2025	2024
Current:		
Federal	$ —	$ —
State	—	—
Total Current	—	—
Deferred:		
Federal	(2,433)	57
State	—	—
Change in valuation allowance	2,433	(57)
Total deferred	—	—
Total income tax benefit (expense)	$ —	$ —

The Company's provision for income tax differs from the amount computed by applying the statutory federal income tax rate to income before taxes as follows:

	Years ended May 31,	
	2025	2024
Statutory federal income tax rate	21.0 %	21.0 %
Derivative loss	4.8	(0.1)
Non-deductible debt issuance costs	(2.3)	(7.1)
Non-deductible interest on convertible notes	24.8	(2.0)
Non-deductible loss on induced conversion	6.6	(2.8)
Non-deductible debt discount amortization	2.3	(0.5)
Stock Compensation	6.2	(7.2)
NOL expiration	1.5	(0.0)
Other	(0.0)	(1.2)
Valuation allowance	(64.9)	(0.1)
Total provision for income taxes	0.0 %	0.0 %

As of May 31, 2025 and 2024, the net deferred tax assets consisted of the following:

	As of May 31,	
	2025	2024
Deferred tax assets:		
Net operating loss	$ 97,626	$ 100,897
Credits	2,063	2,063
ASC 718 expense on non-qualified stock options	2,724	2,665
Accrued expenses	272	411
Lease liability	30	59
Inventory charges	6,173	6,173
Inventory write-off	1,953	1,953
Contingent liability	9,150	9,202
Issued warrants	2,901	3,000
Section 174 R&D costs	3,179	2,056
Amortization	155	207
Fixed assets	4	5
Other	—	—
Total gross deferred tax asset	126,230	128,691
Less valuation allowance	(126,203)	(128,636)
Total deferred tax assets	27	55
Deferred tax liabilities:		
Right-of-use asset	(27)	(55)
Total deferred tax liabilities	(27)	(55)
Net deferred tax asset (liability)	$ —	$ —

Valuation allowances are established when necessary to reduce deferred tax assets, including temporary differences and net operating loss carryforwards, to the amount expected to be realized in the future. FASB guidance indicates that forming a conclusion that a valuation allowance is not needed is difficult when there is negative evidence such as cumulative losses in recent years. The Company had cumulative losses from continuing operations in the United States for the three-year period ended May 31, 2025. The Company considered this negative evidence along with all other available positive and negative evidence and concluded that, at May 31, 2025, it is more likely than not that the Company's U.S. deferred tax assets will not be realized. As of May 31, 2025, a valuation allowance has been recorded on the Company's deferred tax assets to recognize only the proportion of the deferred tax asset that is more likely than not to be recognized. The Company's total valuation allowance was $126.2 million at May 31, 2025 and $128.6 million at May 31, 2024. The Company's valuation allowance decreased $2.4 million and increased $0.1 million during the fiscal years ended May 31, 2025 and 2024, respectively. A reconciliation of the beginning and ending amount of the valuation allowance is as follows:

	May 31,	
	2025	2024
Valuation allowance at beginning of year	$ 128,636	$ 128,579
Change in valuation allowance	(2,433)	57
Valuation allowance at end of year	$ 126,203	$ 128,636

As of May 31, 2025, the Company had cumulative federal net operating losses of approximately $464.9 million. Of these losses, $78.8 million were generated in 2005 through 2017, prior to the Tax Cuts and Jobs Act enactment, and will expire between fiscal 2026 to fiscal 2037 if not utilized. The remaining net operating losses have an indefinite carryforward period. As of May 31, 2024, the Company had cumulative federal net operating losses of approximately $480.5 million.

As of May 31, 2025, the Company had a $2.1 million deferred tax asset related to a federal research and development credit carryforward. If not utilized, the credits will expire between fiscal 2034 through fiscal 2037. As of May 31, 2024, the Company had a $2.1 million deferred tax asset related to a federal research and development credit carryforward.

As of May 31, 2024, the U.S. tax returns for fiscal year 2005 through fiscal year 2024 remain subject to examination. Annual tax provisions include amounts considered necessary to pay assessments that may result from examination of prior year tax returns; however, the amount ultimately paid upon resolution of issues may differ materially from the amount accrued. As of May 31, 2025, there are no income tax returns currently under audit.

On August 16, 2022, the Inflation Reduction Act ("IRA") was signed into law by President Biden. The IRA includes a corporate minimum tax of 15% on certain large corporations with greater than $1B in average adjusted financial statement income and an excise tax on certain stock repurchases executed after December 31, 2022. There are no impacts to the Company in 2025, and the Company does not expect a material impact on its consolidated financial statements in the future for the IRA.

On July 4, 2025, President Trump signed the One Big Beautiful Bill Act, which includes a broad range of tax reform provisions affecting businesses, including extending and modifying certain key Tax Cuts & Jobs Act provisions (both domestic and international), expanding certain Inflation Reduction Act incentives while accelerating the phase-out of others, and modifying the endowment excise tax for higher education institutions. The Company is currently evaluating the impact of this new bill.

Note 9. Commitments and Contingencies

Other Liabilities

The $43.6 million balance recorded in other liabilities is conditional, and will only be due and payable, upon the Company achieving a qualifying "Revenue" event, as defined below. The Company has agreed to pay 20% of its qualifying Revenue generated in each calendar year, if any, with such payments to be applied to reduce the balance until it is repaid in full. Interest will not accrue on the balance throughout the prospective repayment period. Revenue is defined as:

> "…the gross revenue generated by Client and its Affiliates, less the following items (if not previously deducted from the amount invoiced): (a) reasonable and customary trade, quantity, and cash discounts actually

granted and legally permitted wholesaler chargebacks actually paid or credited by Client and its Affiliates to wholesalers of products; (b) reasonable, customary, and legally permitted rebates and retroactive price reductions actually granted; (c) freight charges for the delivery of products; (d) the portion of the administrative fees paid during the relevant time period to group purchasing organizations, pharmaceutical benefit managers and/or government-mandated Medicare or Medicaid Prescription Drug Plans relating specifically to the product; and (e) sales, use or excise taxes imposed and actually paid in connection with the sale of products (but excluding any value added taxes or taxes based on income or gross receipts)."

PRO 140 Acquisition and Licensing Arrangements

We originally acquired leronlimab, as well as certain other related assets, including the existing inventory of PRO 140 bulk drug substance, intellectual property, and FDA regulatory filings, pursuant to an Asset Purchase Agreement, dated as of July 25, 2012, and effective October 16, 2012 (the "Progenics Purchase Agreement"), between the Company and Progenics. Pursuant to the Progenics Purchase Agreement, we are required to pay Progenics a milestone payment and royalties as follows: (i) $5,000,000 at the time of the first U.S. new drug application approval by the FDA or other non-U.S. approval for the sale of leronlimab; and (ii) royalty payments of up to 5% on net sales during the period beginning on the date of the first commercial sale of leronlimab until the later of (a) the expiration of the last to expire patent included in the acquired assets, and (b) 10 years, in each case determined on a country-by-country basis. To the extent that such remaining milestone payment and royalties are not timely made, under the terms of the Progenics Purchase Agreement, Progenics has certain repurchase rights relating to the assets sold to us thereunder.

Payments to Progenics are in addition to payments due under the PDL License, between Protein Design Labs (now AbbVie Inc.) and Progenics, which was assigned to us in the Progenics Purchase Agreement, pursuant to which we have an exclusive worldwide license to develop, make, have made, import, use, sell, offer to sell, or have sold products that incorporate the humanized form of the leronlimab antibody developed under the agreement. Pursuant to the PDL License, we are required to pay AbbVie Inc. milestone payments and royalties as follows: (i) $500,000 upon filing a Biologic License Application with the FDA or non-U.S. equivalent regulatory body; (ii) $500,000 upon FDA approval or approval by another non-U.S. equivalent regulatory body; and (iii) royalties of up to 3.5% of net sales for the longer of 10 years and the date of expiration of the last to expire licensed patent. Additionally, the PDL License provides for an annual maintenance fee of $150,000 until royalties paid exceed that amount. To the extent that such remaining milestone payments and royalties are not timely made, under the terms of the PDL License, AbbVie Inc. has certain termination rights relating to our license of leronlimab thereunder.

Effective July 29, 2015, we entered into a License Agreement (the "Lonza Agreement") with Lonza covering Lonza's "system know-how" technology with respect to our use of proprietary cell lines to manufacture new leronlimab material. The Lonza Agreement provides for an annual license fee and future royalty payments, both of which vary based on whether Lonza, or we or our strategic partner manufactures leronlimab. We currently use two independent parties as contract manufacturers for leronlimab, and continually review this arrangement. Should the arrangement continue as-is, an annual license fee of £0.3 million (approximately $0.35 million given current exchange rate) would continue to apply, as well as a royalty, up to 2% of the net selling price upon commercialization of leronlimab, excluding value added taxes and similar amounts.

Operating Leases

We lease our principal office location in Vancouver, Washington (the "Vancouver Lease"). The Vancouver Lease expires on April 30, 2026. Consistent with the guidance in ASC 842, Leases, we have recorded this lease in our consolidated balance sheet as an operating lease. For the purpose of determining the right of use asset and associated lease liability, we determined that the renewal of the Vancouver lease was not reasonably probable. The lease does not include any restrictions or covenants requiring special treatment under ASC 842, Leases. Operating lease costs for the fiscal years ended May 31, 2025 and 2024 were approximately $0.1 million and $0.1 million, respectively. Operating lease right-of-use assets are included in other non-current assets and the current portion of operating lease liabilities are included in accrued liabilities and compensation on the consolidated balance sheets. The following table summarizes the operating lease balances.

(in thousands)	May 31, 2025	May 31, 2024
Assets		
Right-of-use asset	$ 130	$ 264
Liabilities		
Current operating lease liability	$ 141	$ 142
Non-current operating lease liability	—	141
Total operating lease liability	$ 141	$ 283

The minimum (base rental) lease payments reconciled to the carrying value of the operating lease liabilities as of May 31, 2025, are expected to be as follows (in thousands):

Fiscal Year	Amount
2026	$ 169
Thereafter	—
Total operating lease payments	169
Less: imputed interest	(28)
Present value of operating lease liabilities	$ 141

Supplemental information related to the operating leases was as follows:

	May 31, 2025
Weighted average remaining lease term	0.9 years
Weighted average discount rate	10.0 %

Legal Proceedings

As of May 31, 2025, the Company did not record any accruals related to the outcomes of the legal matters described below. It is not possible to determine the outcome of these proceedings, including the defense and other litigation-related costs and expenses that may be incurred by the Company, as the outcomes of legal proceedings are inherently uncertain. Therefore, it is possible that the ultimate outcome of any proceeding, if in excess of a recognized accrual, if any, could be material to the Company's consolidated financial statements

Securities Class Action Lawsuits

On March 17, 2021, a stockholder filed a putative class-action lawsuit (the "March 17, 2021 lawsuit") in the U.S. District Court for the Western District of Washington against the Company and certain former officers. The complaint generally alleges the defendants made false and misleading statements regarding the viability of leronlimab as a potential treatment for COVID-19. On April 9, 2021, a second stockholder filed a similar putative class action lawsuit in the same court, which the plaintiff voluntarily dismissed without prejudice on July 23, 2021. On August 9, 2021, the court appointed lead plaintiffs for the March 17, 2021 lawsuit. On December 21, 2021, lead plaintiffs filed an amended complaint, which is brought on behalf of an alleged class of those who purchased the Company's common stock between March 27, 2020 and May 17, 2021. The amended complaint generally alleges that the defendants violated Sections 10(b) and/or 20(a) of the Exchange Act and Rule

10b-5 promulgated thereunder by making purportedly false or misleading statements concerning, among other things, the safety and efficacy of leronlimab as a potential treatment for COVID-19, the Company's CD10 and CD12 clinical trials, and its HIV Biologic License Application ("BLA"). The amended complaint also alleges that the individual defendants violated Section 20A of the Exchange Act by selling shares of the Company's common stock purportedly while in possession of material nonpublic information. The amended complaint seeks, among other relief, a ruling that the case may proceed as a class action and unspecified damages and attorneys' fees and costs. On February 25, 2022, the defendants filed a motion to dismiss the amended complaint. On June 24, 2022, lead plaintiffs filed a second amended complaint. The second amended complaint is brought on behalf of an alleged class of those who purchased the Company's common stock between March 27, 2020 and March 30, 2022, makes similar allegations, names the same defendants, and asserts the same claims as the prior complaint, adds a claim for alleged violation of Section 10(b) of the Exchange Act and Rule 10b-5(a) and (c) promulgated thereunder, and seeks the same relief as the prior complaint. All defendants filed motions to dismiss the second amended complaint in whole or in part. By order dated June 25, 2025, the court denied defendants' motions to dismiss. Defendants' answers to the second amended complaint are due on August 25, 2025.

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.

Shareholder Derivative Lawsuits

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

On January 29, 2024, two purported stockholders filed a purported derivative lawsuit against certain of the Company's former officers, certain current and former directors, and the Company as a nominal defendant, in the Delaware Court of Chancery. The complaint generally makes allegations similar to those set forth in the Consolidated Derivative Suit and asserts that the individual defendants breached their fiduciary duties by allowing the Company to make false and misleading statements and by failing to maintain an adequate system of oversight and controls. The complaint also asserts claims against certain individual defendants for breach of fiduciary duty arising from alleged insider trading.

On June 20, 2025, two other purported stockholders filed a purported derivative lawsuit against certain of the Company's former officers, certain former and current directors, a third-party individual, and the Company as a nominal defendant, in the Delaware Court of Chancery. The complaint generally asserts that the individual defendants breached their fiduciary duties by allowing the Company to make false and misleading statements, by failing to maintain an adequate system of oversight and controls, and/or by purportedly wrongfully refusing plaintiffs' demands that the Company's board investigate and initiate claims against certain of the Company's former officers and directors based on allegations and claims similar to those set forth in the complaint. The complaint also asserts claims against certain individual defendants arising from alleged insider trading.

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 suit(s) is/are in an early stage and the claims do not specify

an amount of damages, the Company cannot predict the ultimate outcome of the matter(s) and cannot reasonably estimate the potential loss or range of loss the Company may incur.

Securities and Exchange Commission and Department of Justice Investigations

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

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

The Company is committed to cooperating fully with the DOJ and SEC and will continue to comply with the requests of each agency. In December 2024, a federal jury convicted Mr. Pourhassan and Mr. Kazempour after trial on a number of counts. Mr. Pourhassan and Mr. Kazempour are currently scheduled to be sentenced in September 2025. The Company cannot predict the ultimate outcome of the DOJ or SEC investigations. The investigations and any related legal and administrative proceedings could include a wide variety of outcomes, including the institution of administrative, civil injunctive or criminal proceedings involving the Company and/or former executives and/or former directors in addition to Mr. Pourhassan, the imposition of fines and other penalties, remedies and/or sanctions, modifications to business practices and compliance programs and/or referral to other governmental agencies for other appropriate actions. It is not possible to accurately predict at this time when matters relating to the investigations will be completed, the final outcome of the investigations, what additional actions, if any, may be taken by the DOJ or SEC or by other governmental agencies, or the effect that such actions may have on our business, prospects, operating results and financial condition, which could be material.

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

Settlement of Amarex Dispute

On July 2, 2024, the Company and Amarex, the Company's former CRO, entered into the Settlement Agreement.

The terms of the Settlement Agreement include: (i) the payment by Amarex of $12.0 million to the Company, of which $10.0 million was paid on execution of the Settlement Agreement and the remaining balance was to be paid on or before July 2, 2025; (ii) the release of the Company's surety bond posted in the lawsuit and the return of the Company's cash collateral in the amount of $6.5 million provided as security to the surety; (iii) the crediting of all amounts claimed by Amarex as due and payable for its CRO services, totaling approximately $14.0 million, reducing the Company's outstanding balance to zero, with no funds required to be paid by the Company; and (iv) a mutual release of claims,

resolving all legal claims between the parties. The effect of the Settlement Agreement is recorded in research and development expense.

In June 2025, Amarex paid the $2.0 million remaining due under the Settlement Agreement, such that this matter is now considered resolved and paid in full.

As part of the settlement with Amarex in July 2024, the Company owed approximately $0.9 million to investors that previously acquired an interest in the Amarex settlement as part of a securities purchase agreement in April to June 2023. The amount was recorded as a loss on derivatives, of which approximately $0.7 million was paid in the fiscal year ended May 31, 2025. In accordance with the prescribed accounting guidance, the Company measured the fair value of the derivative liability using fair value hierarchy included in Note 2, *Summary of Significant Accounting Policies – Fair Value of Financial Instruments*. The Company's derivative liability is classified within Level 3.

Investor Lawsuit Seeking Issuance of Additional Shares

In January 2025, two former investors and current shareholders, filed an action against the Company in relation to a dispute over how many shares were issued to them following their direct investment(s) with the Company. The former investors claim that the final pricing utilized to calculate the issuance of shares to them in 2022 was incorrect, and that they are entitled to more shares than were issued. The complaint presents legal claims sounding in breach of fiduciary duty, misrepresentation, fraud, negligence, theft, and breach of contract.

The Company's position is that the claims are without any factual support, or support under applicable law and/or the underlying investment documents. The Company views this action as an attempt to extract more shares without further/fair investment and plans to vigorously defend itself.

Note 10. Related Party Transactions

The Board's Audit Committee and the Board of Directors review and approve all related party transactions. The terms and amounts described below are not necessarily indicative of the terms and amounts that could have been incurred had comparable transactions been entered into with independent parties.

Dr. Lalezari, the Company's current CEO, owns Lalezari Medical Corp., dba Quest Clinical Research ("Quest"). In the years prior to Dr. Lalezari's appointment to CEO, Quest was one of several clinical locations for the Company's past COVID19 clinical trials. The Company entered into a Clinical Trial Agreement ("CTA") with Quest in relation to said clinical trials. Each CTA was negotiated in the ordinary course of business by Amarex, the Company's former CRO, during the years before Dr. Lalezari's appointment as CEO of the Company in November 2023, and the operational and financial terms of the CTA with Quest were comparable to the terms available to unrelated clinical locations. In addition, since Dr. Lalezari became CEO, the Company has incurred approximately $11.4 thousand for services from Quest conducted by another principal investigator for one of the Company's protocols. As of May 31, 2025 and May 31, 2024, the outstanding balance owed by the Company to Quest was approximately $0.3 million.

Note 11. Employee Benefit Plan

The Company has an employee savings plan (the "401(k) Plan"), organized under Section 401(k) of the Internal Revenue Code (the "Code"), covering all employees. The Company makes a qualified non-elective contribution of 3%, which vests immediately. In addition, participants in the 401(k) Plan may contribute a percentage of their compensation, but not greater than the maximum allowed under the Code. During the fiscal years ended May 31, 2025 and 2024, the Company incurred an expense of approximately $30.3 thousand and $59.9 thousand, respectively, for qualified non-elective contributions.

Note 12. Segment Information

Operating segments are defined as components of an entity for which separate financial information is available and that is regularly reviewed by the CODM in deciding how to allocate resources to an individual segment and in assessing performance. The Company operates as a single reporting segment, focused on the clinical development of leronlimab. The Company's measure of segment profit or loss is net earnings or loss. The measure of segment assets is reported on the consolidated balance sheets as total assets. The CODM is the chief executive officer ("CEO"). The CODM manages and allocates resources to the operations of the Company on a total company basis. Managing and allocating resources on a consolidated basis enables the CEO to assess the overall level of resources available and how to best deploy these

resources across research and development projects that are in line with the Company's long-term strategic goals. Consistent with this decision-making process, the CEO uses consolidated financial information for purposes of evaluating performance, forecasting future period financial results, allocating resources and setting incentive targets. Operating expenses are used to monitor budget versus actual results. The monitoring of budgeted versus actual results are used in assessing performance of the segment.

The following table is representative of the significant expense categories regularly provided to the CODM when managing the Company's single reporting segment. A reconciliation to the consolidated net income (loss) for the years ended May 31, 2025, and 2024 is included at the bottom of the table below.

	Years ended May 31,	
(in thousands, except for per share data)	**2025**	**2024**
Expenses[1]:		
General and administrative expense[2]	$ 6,434	$ 8,403
Research and development[3]	7,278	7,240
Return of clinical expenses	(24,985)	—
Stock-based compensation expense	1,612	2,415
Operating gain (loss)	9,661	(18,058)
Interest income	565	217
Interest on convertible notes	(4,424)	(4,659)
Amortization of discount on convertible notes	(407)	(1,076)
Amortization of debt issuance costs	—	(572)
Issuance costs for private placement of shares and warrants through placement agent	—	(2,819)
Loss on induced conversion	(1,180)	(6,680)
Finance charges	(25)	(2,584)
Loss on note extinguishment	—	(13,374)
Gain on restructuring of payables	407	—
Loss on derivatives	(852)	(236)
Provision (benefit) for income taxes	—	—
Segment net income (loss)	3,745	(49,841)
Reconciliation of profit or loss:		
Adjustments or reconciling items	—	—
Consolidated net income (loss)	3,745	(49,841)

(1) The significant expense categories and amounts align with the segment-level information that is regularly provided to the CODM.

(2) General and administrative expense for the years ended May 31, 2025, and 2024 is net of $0.8 million and $2.4 million of stock-based compensation expense, respectively.

(3) Research and development expense for the year ended May 31, 2025 is net of $0.8 million of stock-based compensation expense. No stock-based compensation was part of research and development expense for the year ended May 31, 2024. For the year ended May 31, 2025, research and development expense is net of $25.0 million return of clinical expenses due to the settlement with Amarex. See Note 9, *Commitments and Contingencies – Legal Proceedings – Settlement of Amarex Dispute* for additional discussion.

Note 13. Subsequent Events

Note conversions

In June and July 2025, in satisfaction of the required monthly payments, the Company and the April 23, 2021 Noteholder entered into exchange agreements, pursuant to which portions of the April 23, 2021 Note were partitioned into new notes with an aggregate principal amount of $1.5 million, which were exchanged concurrently for approximately 4.7 million shares.

Item 9. Changes In and Disagreements with Accountants on Accounting and Financial Disclosure.

None.

Item 9A. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

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

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) as of May 31, 2025. Our management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives, and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Our Chief Executive Officer and Chief Financial Officer have concluded, based upon the evaluation described above, that as of May 31, 2025, our disclosure controls and procedures were effective at the reasonable assurance level.

Management's Annual Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over our financial reporting. Internal control over financial reporting is defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act as the process designed by, or under the supervision of, our Chief Executive Officer and Chief Financial Officer and effected by the Company's board of directors, management, and other personnel, to provide reasonable assurance regarding the reliability of our financial reporting and the preparation of our financial statements for external purposes in accordance with GAAP, and includes those policies and procedures that:

(i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the acquisition and disposition of assets;

(ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with GAAP, and that our receipts and expenditures of the Company's assets are being made only in accordance with authorizations of management and the board of directors or a committee thereof as required; and

(iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of assets that could have a material effect on the financial statements.

Under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting based on the framework provided in Internal Control – Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on this evaluation, our management concluded that our internal control over financial reporting was effective as of May 31, 2025.

Changes in Internal Control Over Financial Reporting

Other than as described above, during the quarter ended May 31, 2025, there were 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.

Attestation Report of the Registered Public Accounting Firm

This annual report does not include an attestation report by our registered public accounting firm of management's report regarding internal control over financial reporting pursuant to SEC rules that permit us to provide only management's report in this annual report.

Item 9B. Other Information

None.

Part III

Item 10. Directors, Executive Officers and Corporate Governance.

The information required by Item 10 will be contained in, and is incorporated herein by reference to, our definitive proxy statement for our 2025 Annual Meeting of Stockholders under the captions *Proposal 1: Election of Directors, Information about our Executive Officers,* and *Delinquent Section 16(a) Reports*, to be filed with the SEC within 120 days of the end of the Company's fiscal year ended May 31, 2025 (the 2025 Proxy Statement").

We have adopted a code of ethics and business conduct that applies to all of our directors, officers, and employees, including our principal executive officer, principal financial officer, and principal accounting officer (our Chief Financial Officer), and senior financial officers, or persons performing similar functions. We have also adopted a Statement of Insider Trading Policy and Related Trading Procedures governing the purchase, sale, and other dispositions of our securities that is applicable to our directors, officers, and employees. We believe that our insider trading policy and procedures are reasonably designed to promote compliance with the insider trading laws, rules and regulations that apply to the Company, We make our code of ethics and business conduct and our Statement of Insider Trading Policy and Related Trading Procedures available free of charge on our website at www.cytodyn.com.

The Board has determined that Ryan C. Dunlap, who is chair of the Board's Audit Committee, is an "audit committee financial expert" as defined in Regulation S-K Item 407(d)(5)(ii) adopted by the SEC.

Item 11. Executive Compensation.

The information required by Item 11 relating to executive compensation will be contained in, and is incorporated herein by reference to, our 2025 Proxy Statement under the captions *Executive Compensation* (excluding *Pay versus Performance*) and *Director Compensation*.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.

The information required by Item 12 relating to security ownership of certain beneficial owners and management and related stockholders' matters will be contained in, and is incorporated herein by reference to, our 2025 Proxy Statement under the captions *Stock Ownership by Principal Stockholders, Directors and Executive Officers* and *Equity Compensation Plan Information*.

Item 13. Certain Relationships and Related Transactions and Director Independence.

The information required by Item 13 relating to certain relationships and related transactions and director independence will be contained in, and is incorporated herein by reference, to our 2025 Proxy Statement under the captions *Related Person Transactions* and *Director Independence*.

Item 14. Principal Accountant Fees and Services.

The information required by Item 14 relating to principal accountant fees and services will be contained in, and is incorporated herein by reference to, our 2025 Proxy Statement under the caption *Matters Relating to the Company's Independent Registered Public Accounting Firm*.

PART IV

Item 15. Exhibits and Financial Statement Schedules.

(a) The following documents are filed as part of this Annual Report on Form 10-K:

(1) Consolidated Financial Statements

The consolidated financial statements for the fiscal years ended May 31, 2025, and 2024 are included under Part II, Item 8 of this report.

(2) Financial Statement Schedules:

All schedules are omitted because they are not applicable, or the required information is shown in the financial statements or notes thereto.

(3) Exhibits

Exhibit No	Description	Filed Herewith	Incorporated by Reference Form	Exhibit No.	Filing Date
2.1	Asset Purchase Agreement, dated as of July 25, 2012, between CytoDyn Inc. and Progenics Pharmaceuticals, Inc		8-K	10.1	7/30/2012
3.1	Amended and Restated Certificate of Incorporation, as amended through November 9, 2023		S-1	3.1	2/7/2024
3.2	Amended and Restated Bylaws of CytoDyn Inc.		8-K12G3	3.2	11/19/2018
4.1	Description of the Registrant's Capital Stock		S-1	4.1	2/7/2024
4.2	Form of Common Stock Certificate		8-K12G3	4.1	9/1/2015
4.3	Form of Warrant to Purchase Common Stock		8-K	4.1	1/31/2019
4.4	Form of Common Stock Purchase Warrant		8-K	4.1	8/29/2019
4.5	Form of Common Stock Purchase Warrant		8-K	4.1	12/27/2019
4.6	Secured Convertible Promissory Note between CytoDyn Inc. and Streeterville Capital, LLC, dated April 2, 2021		8-K	4.1	4/8/2021
4.7	Secured Convertible Promissory Note between CytoDyn Inc. and Uptown Capital, LLC, dated April 23, 2021		8-K	4.1	4/29/2021
4.8	Form of Warrant		8-K	4.1	9/7/2021
4.9	Initial Warrant Issued under Surety Bond Backstop Agreement		8-K	4.1	2/17/2022
4.10	Make-Whole Warrant Issued under Surety Bond Backstop Agreement		8-K	4.2	2/17/2022
4.11	Warrant Issued to Richard G. Pestell		10-K	4.22	8/15/2022
4.12	Initial Warrant Issued under Surety Bond Backstop Extension		10-K	4.19	9/14/2023
4.13	Subsequent Warrant Issued under Surety Bond Backstop Extension		10-K	4.20	9/14/2023
4.14	Amendment to Secured Convertible Promissory Note between CytoDyn Inc. and Streeterville Capital, LLC, dated April 2, 2021		10-Q	10.1	4/14/2025

4.15	Amendment to Secured Convertible Promissory Note between CytoDyn Inc. and Uptown Capital, LLC dated April 23, 2021	10-Q	10.2	4/14/2025
10.1	Development and License Agreement between Protein Design Labs, Inc. (to which AbbVie Biotherapeutics Inc. is successor in interest) and Progenics Pharmaceuticals, Inc. (to which CytoDyn Inc. is successor in interest) effective as of April 30, 1999, as amended by letter agreement dated November 24, 2003	10-K	10.21	8/29/2013
10.2	License Agreement between CytoDyn Inc. and Lonza Sales AG dated July 29, 2015	8-K/A	10.1	8/19/2015
10.3	Development and Manufacturing Services Agreement, dated as of November 9, 2016, by and between CytoDyn Inc. and CMC ICOS Biologics, Inc.	10-Q	10.4	4/13/2017
10.4	Work Statement No. 01, dated as of November 9, 2016, by and between CytoDyn Inc. and CMC ICOS Biologics, Inc.	10-Q	10.5	4/13/2017
10.5	Form of Indemnification Agreement	10-Q	10.2	10/9/2018
10.6	Security Agreement between CytoDyn Inc. and Streeterville Capital, LLC, dated April 2, 2021	8-K	10.2	4/8/2021
10.7	Security Agreement between CytoDyn Inc. and Uptown Capital, LLC, dated April 23, 2021	8-K	10.2	4/29/2021
10.8*	CytoDyn Inc. Amended and Restated 2012 Equity Incentive Plan (the “2012 Plan”)	10-Q	10.4	1/9/2023
10.9*	Form of Stock Option Award Agreement for Executive Employees under the 2012 Plan	10-K	10.43	8/14/2020
10.10*	Form of Stock Option Award Agreement for Non-Employee Directors under the 2012 Plan	10-K	10.9	8/29/2013
10.11*	Form Stock Option Award Agreement (For Non-Employee Directors)	10-Q	10.2	1/9/2023
10.12*	Form Stock Option Award Agreement (For Executives)	10-Q	10.3	1/9/2023
10.13*	Employment Agreement between CytoDyn Inc. and Tyler Blok, effective August 15, 2023	10-Q	10.1	10/23/2023

10.14*	Consulting Agreement between the Company and Rapid Deployment LLC		10-Q	10.1	4/15/2024
10.15*	Employment Agreement between the Company and Jacob P. Lalezari, M.D., dated January 26, 2024		8-K	10.1	1/29/2024
10.16*	Employment Agreement between the Company and Robert E. Hoffman, dated May 2, 2025		8-K	10.1	5/6/2025
19.1	Statement of Insider Trading Policy and Related Trading Procedures	X			
21	Subsidiaries of the Registrant	X			
23.1	Consent of Marcum LLP	X			
23.2	Consent of CBIZ CPAs P.C.	X			
31.1	Certification of Principal Executive Officer under Rule 13a-14(a)	X			
31.2	Certification of Chief Financial Officer under Rule 13a-14(a)	X			
32	Certification of Principal Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350	X			
101.INS	Inline XBRL Instance Document	X			
101.SCH	Inline XBRL Taxonomy Extension Schema Document	X			
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document	X			
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document	X			
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document	X			
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document	X			
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101)	X			

* Management contract, compensatory plan or arrangement

Item 16. Form 10-K Summary.

None.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Date: July 25, 2025

CYTODYN INC.
(Registrant)

By: /s/ Jacob Lalezari
Jacob Lalezari
Chief Executive Officer

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities indicated on July 25, 2025.

Principal Executive Officer:

/s/ Jacob Lalezari
Jacob Lalezari
Chief Executive Officer

Principal Financial and Accounting Officer:

/s/ Robert Hoffman
Robert Hoffman
Chief Financial Officer

Directors

/s/ Tanya Durkee Urbach
Tanya Durkee Urbach, Chair

/s/ Lishomwa C. Ndhlovu
Lishomwa C. Ndhlovu, M.D., Ph.D.

/s/ Karen J. Brunke
Karen J. Brunke, Ph.D.

/s/ Ryan M. Dunlap
Ryan M. Dunlap

/s/ Stephen M. Simes
Stephen M. Simes

Exhibit 19.1

STATEMENT OF INSIDER TRADING POLICY AND RELATED TRADING PROCEDURES

CYTODYN INC.

Instructions.

You should carefully read and review this Statement of Insider Trading Policy and Related Trading Procedures ("Policy") to ensure your understanding of the obligations it places on you as an officer, director, employee or other "Covered Party", as defined in the Policy. Upon your review and execution of the Policy, one signed copy of the Acknowledgment and Certification page should be returned to:

Tyler Blok, Corporate Counsel CytoDyn Inc.

1111 Main Street, Suite 660

Vancouver, Washington 98660

Inquiries.

If you have any questions regarding any of the provisions of this Policy, please contact Tyler Blok, Corporate Counsel and/or the "Compliance Officer", as may be designated by the Board of Directors of CytoDyn Inc.

Compliance Officer.

The Company has appointed Antonio Migliarese as the Compliance Officer for this Policy. The duties of the Compliance Officer include, but are not limited to, the following:

(i) assisting with implementation and enforcement of this Policy;

(ii) circulating this Policy to all employees and ensuring that this Policy is amended as necessary to remain up-to-date with insider trading laws;

(iii) pre-clearing all trading in securities of the Company; and

(iv) providing approval of any Rule 10b5-1 plans.

Insider Trading Policy

CytoDyn Inc.

The Board of Directors of CytoDyn Inc. ("CytoDyn" or "Company") has adopted this Insider Trading Policy ("Policy") that applies to each officer, director and employee of the Company. It is the Company's policy that no director, officer, employee, certain outside service providers of the Company, or any other person designated by this Policy or by the Compliance Officer (each, respectively a "Covered Party"), who is aware of material nonpublic information related to the Company may, directly, or indirectly through family members or other persons or entities:

(i) engage in transactions in the securities of the Company (except as otherwise expressly provided in this Policy);

(ii) recommend that any other person engage in transactions in the securities of the Company;

(iii) disclose material nonpublic information to persons within the Company whose jobs do not require them to have that information or to persons outside of the Company, including, but not limited to, family, friends, business associates, investors and expert consulting firms, unless such disclosure is made in accordance with the Company's policies regarding the protection or authorized external disclosure of information regarding the Company; or

(iv) assist anyone engaged in the above activities.

In addition, it is the policy of the Company that no Covered Party who, in the course of working for the Company, learns of material nonpublic information about a company with which the Company does business, including a customer or supplier of the Company, may trade in that company's securities until the information becomes public or is no longer material.

PART I

Policy Overview

What is "Insider Trading"?

The term "insider trading" generally is used to refer to the use of material, nonpublic information to trade in securities or to communications of material, nonpublic information to others who may trade on the basis of such information. Insider trading is, in addition to being a violation of this Policy, a violation of securities laws.

While the law concerning insider trading is not static, it is generally understood the law prohibits insiders of the Company from doing the following:

(1) trading in the Company securities while in possession of material, nonpublic information concerning the Company;

(2) having others trade on the insider's behalf while he or she is in possession of material, nonpublic information; and

(3) communicating nonpublic information concerning the Company to others who may then trade in the Company securities or pass on the information to others who may trade in the Company securities. Such conduct, also known as "tipping," results in liability for the insider of the Company who communicated such information, even if such insider does not actually trade himself, and for the person who received the information if the person has reason to know it was an improper disclosure and acts on such information or passes it on to others who may act on it.

Who is an "Insider"?

The concept of "insider" generally includes any person who possesses nonpublic information about the Company and has a duty to keep this information confidential. This Policy applies to all directors, officers and employees of the Company, its subsidiaries and its affiliates. In addition, the Company may determine other persons should be subject to this Policy, such as service providers, contractors or consultants who have access to material nonpublic information in connection with such service. Outsiders who are subject to this Policy include, among others, the Company's attorneys, accountants, certain individual contractors and/or outside consultants, scientific advisory board members, investor relations firms, investment bankers and the employees of such organizations. All of the foregoing directors, officers and employees, and outside service providers are considered Covered Parties under this Policy.

This Policy also applies to family members who reside with you (including a spouse, child, child away at college, stepchildren, grandchildren, parents, stepparents, grandparents, siblings and in-laws), anyone else who lives in your household, and any family members whose transactions in the Company securities are directed by you or are subject to your influence or control (collectively referred to as "Family Members"). This Policy further applies to any entities you influence or control, including any corporations, partnerships, limited liability companies, or trusts (collectively referred to as "Controlled Entities").

What is Material Information?

"Material Information" generally is defined as information for which there is a substantial likelihood a reasonable investor would consider such information important in making his or her investment decisions, or information that could be reasonably expected to affect the price of a company's securities, whether it is positive or negative. It is important to remember materiality will always be judged with the benefit of hindsight.

Although there is no precise definition of materiality, information is likely to be "material" if it relates to:

- earnings or sales results or expectations for the quarter or the year;
- forecasts or projections of future earnings or losses, or other earnings guidance;
- changes to previously announced earnings guidance, or the decision to suspend earnings guidance;
- significant new products or product development milestones (such as major clinical trial results, Food and Drug Administration ("FDA") approvals or disapprovals, or other actions including but not limited to clinical trial initiation or termination);
- the initiation, material developments to, or termination of a material litigation matter or government investigation;

- changes in dividends, the declaration of a stock split, or an offering of additional securities;
- proposals or agreements involving a merger, acquisition, tender offer, joint venture, divestiture or leveraged buy-out;
- proposals or agreements involving research and development collaborations or licensing agreements;
- changes in relationships with major collaborators, or obtaining or losing important contracts;
- bank borrowings or other financing transactions out of the ordinary course;
- major financing developments;
- major personnel changes;
- criminal indictments or material civil litigation or government investigations;
- significant disputes with major collaborators, manufacturers or suppliers;
- substantial change in accounting methods;
- debt service or liquidity problems;
- bankruptcy or insolvency;
- public offerings or private sales of debt or equity securities;
- calls, redemptions or repurchases of Company securities;
- change in auditors or notification the auditor's reports may no longer be relied upon; and/or
- non-public communications with any regulatory agency, including but not limited to the: FDA, Securities and Exchange Commission ("SEC"), U.S. Department of Justice ("DOJ"), and state regulatory bodies.

"Inside" information could be material because of its expected effect on the price of the Company securities, the securities of another company, or the securities of several companies. Moreover, the resulting prohibition against the misuse of "inside" information includes not only restrictions on trading in the Company securities, but also restrictions on trading in the securities of other companies affected by the inside information.

Material information is not limited to historical facts and may also include projections and forecasts. With respect to a future event, such as a merger, acquisition or introduction of a new product, the point at which negotiations or product development are considered to be material is determined by balancing the probability the event will occur against the magnitude of the effect the event would have on a company's operations or stock price should it occur. Thus, information concerning an event that would have a large effect on stock price, such as a merger, may be material even if the possibility that the event will occur is relatively small. When in doubt about whether particular non-public information is material, presume it is material.

If you are unsure whether information is material, you should consult the Compliance Officer before making any decision to disclose such information (other than to persons who need to know it) or to trade in or recommend securities to which that information relates.

What is Considered Nonpublic Information?

In order for information to qualify as "inside" information it must not only be "material," it must be "nonpublic." For the purposes of this Policy, "Nonpublic" information should be broadly interpreted to include any information which has not been made public. This includes information received from sources or in circumstances indicating the information has not yet been generally circulated.

At such time as material, nonpublic information has been released to the investing public, it loses its status as "inside" information. However, for "nonpublic" information to become public information it must be disseminated through recognized channels of distribution designed to reach the securities marketplace or public disclosure documents filed with the SEC that are available on EDGAR, and sufficient time must pass for the information to become available in the market.

It is the policy of the Company not to consider material information public until the second full business day after appropriate public dissemination.

To show that "material" information is public, it is generally necessary to point to some fact verifying the information has become generally available, such as disclosure by filing of a Form 10-Q, Form 10-K, Form 8-K or other report with the SEC or disclosure by press release to a national business and financial wire service (such as Dow Jones or Reuters), a national news service, or a national newspaper (such as The Wall Street Journal). The circulation of rumors or "talk on the street," even if accurate, widespread and reported in the media, does not constitute the requisite public disclosure.

Material, nonpublic information is not made public by selective dissemination. Material information improperly disclosed only to institutional investors or to a favored analyst or a group of analysts retains its status as "nonpublic" information, the use of which is subject to insider trading laws. Similarly, partial disclosure does not constitute public dissemination. So long as any material component of the "inside" information has yet to be publicly disclosed, the information is deemed "nonpublic" and may not be misused.

It is the policy of the Company not to consider material information public until the second full business day after appropriate public dissemination.

As with questions of materiality, if you are not sure whether information is considered public, you should either consult with the Compliance Officer or assume the information is "non-public" and treat it as confidential.

What Transactions Are Subject to this Policy?

This Policy applies to all transactions in Company securities, including common stock, options or warrants to purchase common stock, convertible debt, preferred stock or any other securities the Company may issue, as well as derivative securities that are not issued by the Company, such as exchange-traded put or call options or swaps relating to Company securities.

This Policy does not apply to the following transactions, except as specifically noted:

Stock Option Exercises. This Policy does not apply to the exercise of any employee stock option acquired pursuant to the Company's equity plans, or to the exercise of a tax withholding right pursuant to which a person has the right to have the Company withhold shares subject to an option to satisfy tax withholding requirements. This Policy does apply, however, to any sale of stock as part of a broker-assisted cashless exercise of an option, or any other market sale for the purpose of generating the cash needed to pay the exercise price or tax due of an option.

Restricted Stock, Restricted Stock Unit and Performance Stock Unit Awards. This Policy does not apply to the vesting of restricted stock, restricted stock units and/or performance stock unit awards, or a tax withholding right pursuant to which you elect to have the Company withhold shares of stock to satisfy tax withholding requirements upon the vesting of any restricted stock, restricted stock unit or performance stock unit. This Policy, however, does apply to any market sale of restricted stock.

Transactions with the Company. This Policy does not apply to the purchase or issuance of Company securities from the Company or the sale of Company securities by directors or officers to the Company, as all such transactions with the Company require approval by the Board of Directors of the Company or an appropriate committee thereof.[1]

What Are the Consequences of Violations of This Policy?

Penalties for the purchase or sale of securities, while aware of material nonpublic information, or communicating material, nonpublic information to others who then trade in such securities, are severe, both for the individuals involved in such unlawful conduct and, potentially, for their employers. A person can be subject to some or all of the penalties below even if he or she does not personally benefit from the violation (i.e., if the violation was one for tipping information). Penalties include:

- Jail terms of up to 20 years;
- A civil penalty of up to three times the profit gained or loss avoided;
- Criminal fines of up to $5 million;
- A civil penalty for the employer or other controlling person, such as a supervisor, of up to the greater of $1 million or three times the amount of the profit gained or loss avoided, or a criminal fine of up to $2.5 million; and
- Orders barring the individual from serving as a director or officer of a public company.

In addition, a violation of this Policy can be expected to result in serious sanctions by the Company, which may include, in the case of directors, officers and employees, dismissal for cause, whether or not the failure to comply with this Policy results in a violation of law.

PART II

Trading Procedures Under Policy

The following procedural requirements in advance of engaging in a transaction involving the securities of the Company ("Trading Procedures") are applicable to all directors, officers and employees of the Company, and their respective Family Members and/or Controlled Entities.

[1] Transactions involving the purchase from or sale to the Company or withholding by the Company of Company securities, other than the exercise of stock options granted as compensation by the Board's Compensation Committee, may be subject to short-swing profit liability.

1. Trading Pre-Clearance Requirement for Any Prospective Trade.

As the Company is currently structured, all directors, officers and employees (collectively, "Company Insiders") are likely to obtain material nonpublic information on a regular basis and the Company therefore requires all such persons to refrain from trading without first pre-clearing all prospective transactions in the Company's securities with the Company's Compliance Officer. Company Insiders must abide by the following, specific procedures in order to engage in a transaction involving the securities of the Company:

a) Obtain prior written approval from the Compliance Officer. A Company Insider may not, directly or indirectly, purchase or sell (or otherwise make any transfer, gift, pledge or loan of) any Company security *at any time* without first obtaining prior approval from the Compliance Officer. These procedures also apply to transactions by a Company Insider's Family Members and/or Controlled Entities. The Compliance Officer will make reasonable efforts to timely respond to all requests for approval, generally within five business days.

b) Complete pre-approved trade not later than the close of trading two business days following written approval by the Compliance Officer. The Compliance Officer shall record the date each request is received and the date and time each request is approved or disapproved. Unless revoked, a grant of permission will normally remain valid until the close of trading two business days following the day on which it was granted. If the transaction does not occur during the two-day period, pre-clearance of the transaction must be re-requested.

c) Send confirmation statement evidencing completed transaction to Compliance Officer. With respect to any completed transaction, the third-party effecting transactions on behalf of the Company Insider should be instructed to send contemporaneous, duplicate confirmations of all such transactions to the Compliance Officer. In order to ensure the Company timely meets any disclosure obligations, the Compliance Officer must immediately receive a confirmation statement evidencing the completed transaction (see Part II, Section 4 below).

d) *10b5-1 Plan* exception. Pre-clearance is not required for purchases and sales of securities under a qualifying and established Approved 10b5-1 Plan (see Part II, Section 3 below). With respect to any purchase or sale under an Approved 10b5-1 Plan, the third-party effecting transactions on behalf of the Company Insider should be instructed to send contemporaneous, duplicate confirmations of all such transactions to the Compliance Officer. In order to ensure the Company timely meets any disclosure obligations, the Compliance Officer must immediately receive a confirmation statement evidencing the completed transaction (see Part II, Section 4 below).

The exercise of options to purchase for cash and hold common stock of the Company or the purchase from the Company of common stock of the Company is not subject to the Trading Procedures outlined above, but the shares so acquired may not be sold – including for the purpose of covering any associated tax consequences – unless and until written authorization is received from the Company's Compliance Officer. Accordingly, the exercise of options and immediate sale of some or all of the shares through a broker is covered by these Trading Procedures.

2. Ongoing Duty to Comply with the Company's Overall Policy Requirements.

Even if you receive preclearance from the Compliance Officer to trade pursuant to Part II, Section 1 above, you, your Family Members and your Controlled Entities may not trade in securities of the Company if you later come into possession of material, nonpublic information about the Company before completing the transaction. If you come into the possession of material, nonpublic information about the Company before completing a transaction, pre-clearance of the transaction must be re-requested. The obligations described in this Policy are ultimately the personal responsibility of the Covered Party, and each individual should therefore evaluate for himself or herself whether he or she acquired information that may reasonably be viewed as material nonpublic information.

3. Rule 10b5-1 Plans.

The SEC has established regulations under which individuals may purchase and sell securities in compliance with "insider trading" laws (more specifically, Rule 10b5-1 of the Securities Exchange Act of 1934) even if the individual subsequently comes in to the possession of material, nonpublic information about the issues of the securities.

In some instances, trading under a Rule 10b5-1 Plan may allow an individual to assert an affirmative defense to claims subsequently made against them that sound in insider trading. Company Insiders, and their Family Members or Controlled Entities that wish to establish such trading plan, and assert such a defense to prospective insider trading claims, must – each, respectively – comply with the applicable requirements of Rule 10b5-1(c)(1). Any such trading plan will only be deemed an "Approved 10b5-1 Plan" if (i) a copy of the proposed plan is delivered to the Compliance Officer at least 10 business days prior to the proposed date of adoption of the trading plan; (ii) the proposed date of adoption of the plan is during the time period commencing on the second full business day following the filing of the Company's Form 10-K or 10-Q, as applicable, and ending on the 14th day prior to the end of the current quarter; and (iii) the adoption of the plan is approved by the Compliance Officer.

To ensure compliance with all laws and regulations in establishing and trading under a Rule 10b5- 1 Plan, individuals are encouraged to seek their own, independent counsel. The Company's legal department and Compliance Officer are representatives of *only* the Company and therefore represent *only* the Company's interests. The mere fact that the Compliance Officer procedurally approves any proposed 10b5- 1 Plan is not conclusory as to the merits and/or sufficiency of the individual's plan under Rule 10b5-1(c)(1), and in no way guarantees that the Company Insider, and/or their Family Members or Controlled Entities will be able to assert any defenses pursuant Rule 10b5-1.

4. Post-Trade Reporting.

It is recommended that you immediately report to the Compliance Officer and provide a confirmation statement as it relates to any completed trade. You are absolutely required, however, to report to the Company's Compliance Officer any transaction in securities of the Company by you, your Family Members or Controlled Entities not later than the business day following the date of your transaction. Each report you make to the Company's Compliance Officer should include the date of the transaction, quantity, price, and broker through which the transaction was effected. This reporting requirement may be satisfied by sending (or having your broker send) duplicate confirmations of trades to the Company's Compliance Officer if such information is received by the required date.

The foregoing reporting requirement is designed to help monitor compliance with this Policy and to enable the Company to help those persons who are subject to reporting obligations under Section 16 of the Securities Exchange Act of 1934 to comply with such reporting obligations. Each officer and director, however, and not the Company, is personally responsible for ensuring the timely filing of reports of transactions with the SEC.

Prohibited Trading Practices

All directors, officers and employees of the Company, including any Family Members or Controlled Entities thereof, are prohibited from engaging in the following:

1. Any Transaction in Company Securities without Pre-Clearance from Compliance Officer. See Part II, Section 1 above.

2. Additionally, the following types of transactions are generally prohibited and will not be approved by the Compliance Officer:

    a) Short Sales. Neither you, your Family Members nor your Controlled Entities may sell any securities of the Company that are not owned by such person at the time of the sale (a "short sale") including a "sale against the box" (a sale with delayed delivery).

    b) Standardized Options. An "option" is the right either to buy or sell a specified amount or value of a particular underlying interest at a fixed exercise price by exercising the option before its specified expiration date. An option which gives a right to buy is a "call" option, and an option which gives a right to sell is a "put" option. Standardized options (which are so labeled as a result of their standardized terms) offer the opportunity to invest using substantial leverage and therefore lend themselves to significant potential for abusive trading on material inside information. Standardized options also expire soon after issuance and thus necessarily involve short-term speculation, even where the date of expiration of the option makes the option exempt from certain Securities and Exchange Commission restrictions. The writing of a call or the acquisition of a put also involves a "bet against the company" and therefore presents a clear conflict of interest for you. As a result, neither you, your Family Members nor any Controlled Entities may trade in standardized options relating to the Company securities at any time.

    c) Hedging Transactions. Certain forms of hedging or monetization transactions, such as zero- cost collars and forward sale contracts, allow "insiders" to lock in much of the value of his or her stock holdings, often in exchange for all or part of the potential for upside appreciation in the stock. These transactions allow "insiders" to continue to own the covered securities, but without the full risks and rewards of ownership. When that occurs, the "insiders" may no longer have the same objectives as the Company's other shareholders. Therefore, neither you, your Family Members nor any Controlled Entities may engage in any such transactions.

    d) Margin Accounts and Pledges. Securities held in a margin account may be sold by the broker without the customer's consent if the customer fails to meet a margin call. Similarly, securities pledged or hypothecated as collateral for a loan may be sold in foreclosure if the borrower defaults on the loan. Because a margin sale or foreclosure sale may occur at a

time when you are aware of material nonpublic information or otherwise are not permitted to trade in the Company securities, neither you, your Family Members nor your Controlled Entities may hold the Company securities in a margin account or pledge the Company securities as collateral for a loan unless such transaction has been pre-approved by the Company's Compliance Officer.

3. Discretion of Compliance Officer. The list of prohibited transaction types above is meant to be illustrative and may not be exhaustive. The Compliance Officer has sole discretion to approve or prohibit prospective transactions of directors, officers and employees of the Company, and any Family Members or Controlled Entities thereof.

PART III

Other Requirements Under Policy

Continued Obligations Following Termination of Employment.

This Policy continues to apply to transactions by a director, officer or an employee in the Company securities even after the officer or employee is terminated or the director resigns or is removed from the Board, or any other relationship with a Covered Party concludes or is terminated. If a Covered Party is aware of material, non-public information when such individual's employment or service relationship terminates, such individual may not trade in Company securities until that information has become public for two business days, or is no longer material.

Reporting of Violations.

If any Covered Party knows or has reason to believe this Policy has been or may be violated, the employee should bring the actual or potential violation to the attention of the Company's Compliance Officer.

Company-Imposed Penalties.

Officers and employees of the Company who violate this Policy may be subject to disciplinary action by the Company, up to and including termination for cause. Any exceptions to the Policy, if permitted, may only be granted by the Compliance Officer (in writing) and must be provided *before* any activity contrary to the above requirements takes place. An officer or employee may be held responsible for the actions of any Family Members and/or Controlled Entities for the purpose of evaluating potential violations of this Policy.

Modifications and Waivers.

The Company reserves the right to amend or modify the procedures set forth herein at any time. Waiver of any provision of this Policy in a specific instance must be documented in writing by the Company's Compliance Officer, who will have sole discretion to grant any such waiver.

Annual Acknowledgment and Certification.

All officers, directors, employees and certain Covered Parties are required to sign the attached acknowledgment and certification on an annual basis.

ACKNOWLEDGMENT AND CERTIFICATION

The undersigned does hereby acknowledge receipt of the Statement of Insider Trading Policy and Related Trading Procedures (the "Policy") of CytoDyn Inc., as updated and effective on March 17, 2023. The undersigned has read and understands (or has had explained) the Policy and agrees to be governed by the terms therein at all times in connection with the purchase and sale of securities and the confidentiality of non-public information.

The undersigned further understands that this document states a policy of CytoDyn Inc. and is not intended to be regarded as the rendering of legal advice. This Policy is intended to promote compliance with existing law and is not intended to create or impose liability that would not exist in the absence of the policy statement.

Date: _____

_____
(Signature)

_____
(Please print name)

Exhibit 21

SUBSIDIARIES

Name	Jurisdiction of Incorporation or Organization
CytoDyn Operations Inc.	Delaware

Exhibit 23.1

INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM'S CONSENT

We consent to the incorporation by reference in the Registration Statement of CytoDyn, Inc. on Form S-1 [FILE NO. 333-282000] and Form S-8 [FILE NOs. 333-206813, 333-223884, 333-237490 and 333-249179] of our report dated August 15, 2024, which includes an explanatory paragraph as to the Company's ability to continue as a going concern with respect to our audits of the consolidated financial statements of CytoDyn, Inc. as of May 31, 2024 and for the year ended May 31, 2024, which report is included in this Annual Report on Form 10-K of CytoDyn Inc. for the year ended May 31, 2024.

/s/ Marcum LLP

Hartford, CT

July 25, 2025

Exhibit 23.2

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in the Registration Statements on Form S-1 (No. 333-282000) and Form S-8 (Nos. 333-206813, 333-223884, 333-237490 and 333-249179) of our report dated July 25, 2025, with respect to the consolidated financial statements of CytoDyn Inc. included in this Annual Report on Form 10-K for the year ended May 31, 2025.

/s/ CBIZ CPAs P.C.

Hartford, CT

July 25, 2025

Exhibit 31.1

Certification of Principal Executive Officer

I, Jacob Lalezari, certify that:

1. I have reviewed this Annual Report on Form 10-K 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 annual 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 annual 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: July 25, 2025

/s/ Jacob Lalezari
Jacob Lalezari
Chief Executive Officer

Exhibit 31.2

Certification of Chief Financial Officer

I, Robert Hoffman, certify that:

1. I have reviewed this Annual Report on Form 10-K 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 annual 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 annual 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: July 25, 2025

/s/ Robert Hoffman
Robert Hoffman
Chief Financial Officer

Exhibit 32

CERTIFICATION PURSUANT TO

18 U.S.C. SECTION 1350

In connection with the Annual Report of CytoDyn Inc. (the "Company") on Form 10-K for the fiscal year ended May 31, 2025, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned certify, pursuant to 18 U.S.C. § Section 1350, that:

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

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

/s/ Jacob Lalezari
Jacob Lalezari
Chief Executive Officer
Date: July 25, 2025

/s/ Robert Hoffman
Robert Hoffman
Chief Financial Officer
Date: July 25, 2025

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.