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

FORM 10-Q

☒ **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the quarterly period ended July 31, 2024
or
☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the transition period from _____ to _____

Commission file number: **001-32839**

AVID BIOSERVICES, INC.

(Exact name of Registrant as specified in its charter)

Delaware	**95-3698422**
(State or other jurisdiction of incorporation or organization)	*(I.R.S. Employer Identification No.)*

14191 Myford Road, Tustin, California, 92780
(Address of principal executive offices, Zip Code)

(714) 508-6100
(Registrant's telephone number, including area code)

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, $0.001 par value per share	**CDMO**	**The NASDAQ Stock Market LLC**

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

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

Large accelerated filer	☐	Accelerated filer	☒
Non-accelerated filer	☐	Smaller reporting company	☐
		Emerging growth company	☐

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

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

63,795,108 shares of registrant's common stock were outstanding as of September 3, 2024.

AVID BIOSERVICES, INC.
Form 10-Q

For the Fiscal Quarter Ended July 31, 2024

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As used in this Quarterly Report on Form 10-Q, except where the context otherwise requires or where otherwise indicated, the terms "we," "us," "our," and the "Company" refer to Avid Bioservices, Inc. and its subsidiary.

PART I—FINANCIAL INFORMATION

Item 1. Condensed Consolidated Financial Statements

AVID BIOSERVICES, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS (Unaudited)
(In thousands, except par value)

	July 31, 2024	April 30, 2024
ASSETS		
Current assets:		
Cash and cash equivalents	$ 33,381	$ 38,106
Accounts receivable, net	20,962	16,644
Contract assets	14,209	12,364
Inventory	29,196	30,375
Prepaid expenses and other current assets	5,872	6,513
Total current assets	103,620	104,002
Property and equipment, net	185,617	186,514
Operating lease right-of-use assets	40,741	41,157
Other assets	4,664	4,884
Total assets	$ 334,642	$ 336,557
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 19,999	$ 20,667
Accrued compensation and benefits	5,608	5,437
Contract liabilities	37,659	39,887
Current portion of operating lease liabilities	1,399	1,354
Other current liabilities	6,417	3,221
Total current liabilities	71,082	70,566
Convertible senior notes, net	153,867	153,593
Operating lease liabilities, less current portion	43,971	44,336
Finance lease liabilities, less current portion	6,725	7,101
Other liabilities	361	72
Total liabilities	276,006	275,668
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, $0.001 par value; 5,000 shares authorized; no shares issued and outstanding at respective dates	–	–
Common stock, $0.001 par value; 150,000 shares authorized; 63,790 and 63,568 shares issued and outstanding at respective dates	64	64
Additional paid-in capital	635,977	632,696
Accumulated deficit	(577,405)	(571,871)
Total stockholders' equity	58,636	60,889
Total liabilities and stockholders' equity	$ 334,642	$ 336,557

See accompanying notes to condensed consolidated financial statements.

AVID BIOSERVICES, INC.
CONDENSED CONSOLIDATED STATEMENTS OF LOSS AND COMPREHENSIVE LOSS (Unaudited)
(In thousands, except per share information)

	Three Months Ended July 31,	
	2024	**2023**
Revenues	$ 40,173	$ 37,726
Cost of revenues	34,460	33,626
Gross profit	5,713	4,100
Operating expenses:		
Selling, general and administrative	8,169	6,263
Total operating expenses	8,169	6,263
Operating loss	(2,456)	(2,163)
Interest expense	(2,454)	(825)
Other income (expense), net	(624)	258
Net loss before income taxes	(5,534)	(2,730)
Income tax benefit	–	(608)
Net loss	$ (5,534)	$ (2,122)
Comprehensive loss	$ (5,534)	$ (2,122)
Net loss per share:		
Basic and diluted	$ (0.09)	$ (0.03)
Weighted average common shares outstanding:		
Basic and diluted	63,639	62,838

See accompanying notes to condensed consolidated financial statements.

AVID BIOSERVICES, INC.
CONDENSED CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY (Unaudited)
(In thousands)

	Three Months Ended July 31, 2024				
	Common Stock		Additional Paid-In	Accumulated	Total Stockholders'
	Shares	Amount	Capital	Deficit	Equity
Balance at April 30, 2024	63,568	$ 64	$ 632,696	$ (571,871)	$ 60,889
Common stock issued under equity compensation plans	222	–	616	–	616
Stock-based compensation expense	–	–	2,665	–	2,665
Net loss	–	–	–	(5,534)	(5,534)
Balance at July 31, 2024	63,790	$ 64	$ 635,977	$ (577,405)	$ 58,636

	Three Months Ended July 31, 2023				
	Common Stock		Additional Paid-In	Accumulated	Total Stockholders'
	Shares	Amount	Capital	Deficit	Equity
Balance at April 30, 2023	62,692	$ 63	$ 620,224	$ (431,118)	$ 189,169
Common stock issued under equity compensation plans	419	–	878	–	878
Stock-based compensation expense	–	–	2,343	–	2,343
Net loss	–	–	–	(2,122)	(2,122)
Balance at July 31, 2023	63,111	$ 63	$ 623,445	$ (433,240)	$ 190,268

See accompanying notes to condensed consolidated financial statements.

AVID BIOSERVICES, INC.
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS (Unaudited)
(In thousands)

	Three Months Ended July 31,	
	2024	**2023**
Cash flows from operating activities:		
Net loss	$ (5,534)	$ (2,122)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	2,824	2,649
Stock-based compensation	2,665	2,343
Amortization of debt issuance costs	305	339
Deferred income taxes	–	(620)
Loss on disposal of property and equipment	–	46
Changes in operating assets and liabilities:		
Accounts receivable, net	(4,318)	2,089
Contract assets	(1,845)	(4,845)
Inventory	1,179	3,042
Prepaid expenses and other assets	830	(131)
Accounts payable	(451)	4,684
Accrued compensation and benefits	171	(4,113)
Contract liabilities	(2,228)	(4,333)
Other accrued expenses and liabilities	2,722	736
Net cash used in operating activities	(3,680)	(236)
Cash flows from investing activities:		
Purchase of property and equipment	(1,311)	(14,156)
Net cash used in investing activities	(1,311)	(14,156)
Cash flows from financing activities:		
Proceeds from issuance of common stock under equity compensation plans	616	878
Principal payments on finance leases	(350)	(130)
Net cash provided by financing activities	266	748
Net decrease in cash and cash equivalents	(4,725)	(13,644)
Cash and cash equivalents, beginning of period	38,106	38,892
Cash and cash equivalents, end of period	$ 33,381	$ 25,248
Supplemental disclosures of cash flow information:		
Cash paid for interest	$ 173	$ 27
Cash paid for income taxes	$ 31	$ 12
Supplemental disclosures of non-cash activities:		
Unpaid purchases of property and equipment	$ 1,807	$ 7,636
Unpaid interest capitalized as construction-in-progress	$ 1,281	$ 93

See accompanying notes to condensed consolidated financial statements.

Note 1 – Description of Company and Basis of Presentation

We are a dedicated contract development and manufacturing organization ("CDMO") that provides a comprehensive range of services from process development to Current Good Manufacturing Practices ("CGMP") clinical and commercial manufacturing of biologics for the biotechnology and biopharmaceutical industries.

Basis of Presentation

The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States ("U.S. GAAP") and with the rules and regulations of the U.S. Securities and Exchange Commission ("SEC") related to quarterly reports on Form 10-Q, and accordingly, they do not include all the information and disclosures required by U.S. GAAP for annual financial statements. These unaudited condensed consolidated financial statements and notes thereto should be read in conjunction with the audited consolidated financial statements and notes thereto included in our Annual Report on Form 10-K for the fiscal year ended April 30, 2024, as filed with the SEC on July 2, 2024. The unaudited financial information for the interim periods presented herein reflects all adjustments which, in the opinion of management, are necessary for a fair presentation of the financial condition and results of operations for the periods presented, with such adjustments consisting only of normal recurring adjustments. Results of operations for interim periods covered by this Quarterly Report on Form 10-Q may not necessarily be indicative of results of operations for the full fiscal year or any other interim period.

The unaudited condensed consolidated financial statements include the accounts of Avid Bioservices, Inc. and its subsidiary. All intercompany accounts and transactions among the consolidated entities have been eliminated in the unaudited condensed consolidated financial statements.

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts, as well as disclosures of commitments and contingencies in the financial statements and accompanying notes. Actual results could differ materially from those estimates and assumptions.

Note 2 – Summary of Significant Accounting Policies

Information regarding our significant accounting policies is contained in Note 2, "Summary of Significant Accounting Policies," of the consolidated financial statements in our Annual Report on Form 10-K for the fiscal year ended April 30, 2024.

Revenue Recognition

Revenue recognized from services provided under our customer contracts is disaggregated into manufacturing and process development revenue streams.

Manufacturing revenue

Manufacturing revenue generally represents revenue from the manufacturing of customer products recognized over time utilizing an input method that compares the cost of cumulative work-in-process to date to the most current estimates for the entire cost of the performance obligation. Under a manufacturing contract, a quantity of manufacturing runs is ordered at a specified scale with prescribed dates, where the product is manufactured according to the customer's specifications and typically includes only one performance obligation. Each manufacturing run represents a distinct service that is sold separately and has stand-alone value to the customer. The products are manufactured exclusively for a specific customer and have no alternative use. The customer retains control of its product during the entire manufacturing process and can make changes to the process or specifications at its request. Under these agreements, we are entitled to consideration for progress to date that includes an element of profit margin.

Process development revenue

Process development revenue generally represents revenue from services associated with the custom development of a manufacturing process and analytical methods for a customer's product. Process development revenue is recognized over time utilizing an input method that compares the cost of cumulative work-in-process to date to the most current estimates for the entire cost of the performance obligation. Under a process development contract, the customer owns the product details and process, which has no alternative use. These process development projects are customized to each customer to meet its specifications and typically includes only one performance obligation. Each process represents a distinct service that is sold separately and has stand-alone value to the customer. The customer also retains control of its product as the product is being created or enhanced by our services and can make changes to its process or specifications upon request. Under these agreements, we are entitled to consideration for progress to date that includes an element of profit margin.

The following table summarizes our revenue streams (in thousands):

	Three Months Ended July 31,	
	2024	**2023**
Manufacturing revenues	$ 33,971	$ 33,420
Process development revenues	6,202	4,306
Total revenues	$ 40,173	$ 37,726

The timing of revenue recognition, billings and cash collections results in billed accounts receivable, contract assets (unbilled receivables), and contract liabilities (customer deposits and deferred revenue). Contract assets are recorded when our right to consideration is conditioned on something other than the passage of time. Contract assets are reclassified to accounts receivable on the consolidated balance sheet when our rights become unconditional. Contract liabilities represent customer deposits and deferred revenue billed and/or received in advance of our fulfillment of performance obligations. Contract liabilities convert to revenue as we perform our obligations under the contract.

During the three months ended July 31, 2024 and 2023, we recognized revenues of $20.5 million and $16.8 million, respectively, for which the contract liability was recorded in a prior period.

The transaction price for services provided under our customer contracts reflects our best estimates of the amount of consideration to which we are entitled in exchange for providing goods and services to our customers. For contracts with multiple performance obligations, we allocate transaction price to each performance obligation identified in a contract on a relative standalone selling price basis. For contracts in which we receive noncash consideration, such as in the form of a customer's equity securities, we utilize the quoted market price for such noncash consideration to determine the transaction price. We generally determine relative standalone selling prices based on the price observed in the customer contract for each distinct performance obligation. If observable standalone selling prices are not available, we may estimate the applicable standalone selling price based on the pricing of other comparable services or on a price that we believe the market is willing to pay for the applicable service.

In determining the transaction price, we also considered the different sources of variable consideration including, but not limited to, discounts, credits, refunds, price concessions or other similar items. We have included in the transaction price some or all of an amount of variable consideration, utilizing the most likely method, only to the extent that it is probable that a significant reversal in the amount of cumulative revenue recognized will not occur when the uncertainty associated with the variable consideration is subsequently resolved. The actual amount of consideration ultimately received may differ.

In addition, our customer contracts generally include provisions entitling us to a cancellation or postponement fee when a customer cancels or postpones its commitments prior to our initiation of services, therefore not utilizing their reserved capacity. The determination of such cancellation and postponement fees are based on the terms stated in the related customer contract but are generally considered substantive for accounting purposes and create an enforceable right and obligation due to us when the cancellation or postponement occurs. Accordingly, we recognize such fees, subject to variable consideration, as revenue upon the cancellation or postponement date utilizing the most likely method.

Management may be required to exercise judgement in estimating revenue to be recognized. Judgement is required in identifying performance obligations, estimating the transaction price, estimating the stand-alone selling prices of identified performance obligations, estimating variable consideration, and estimating the progress towards the satisfaction of performance obligations. If actual results in the future vary from our estimates, the estimates will be adjusted, which will affect revenues in the period that such variances become known.

There were no material adjustments in estimates for variable consideration for the three months ended July 31, 2024. During the three months ended July 31, 2023, changes in estimates for variable consideration resulted in a decrease in revenues of $1.4 million, as a result of an insolvent customer.

We apply the practical expedient available under ASC 606 that permits us not to disclose the value of unsatisfied performance obligations for contracts with an original expected length of one year or less. As of July 31, 2024, we do not have any unsatisfied performance obligations for contracts greater than one year.

Costs incurred to obtain a contract are not material. These costs are generally employee sales commissions, which are expensed as incurred and included in selling, general and administrative expense in the consolidated statements of loss and comprehensive loss.

Accounts Receivable, Net

Accounts receivable is primarily comprised of amounts owed to us for services provided under our customer contracts and are recorded at the invoiced amount net of an allowance for doubtful accounts, if necessary. We apply judgement in assessing the ultimate realization of our receivables, that includes an assessment of expected credit losses, and we estimate our allowance for doubtful accounts based on various factors, including our historical collection experience, aging of our customer receivable balances, current and future economic market conditions, and the financial condition of our customers.

Based on our analysis of our accounts receivable balance as of July 31, 2024 and April 30, 2024, we determined an allowance for doubtful accounts of $1.9 million and $2.3 million, respectively, was deemed necessary.

Inventory

Inventory consists of raw materials inventory and is valued at the lower of cost, determined by the first-in, first-out method, or net realizable value. We periodically review raw materials inventory for potential impairment and adjust inventory to its net realizable value based on the estimate of future use and reduce the carrying value of inventory as deemed necessary.

Property and Equipment

Property and equipment is recorded at cost, less accumulated depreciation and amortization. Depreciation and amortization are computed using the straight-line method over the estimated useful lives of the related asset, which are generally as follows:

Description	Estimated Useful Life
Leasehold improvements	Shorter of estimated useful life or lease term
Laboratory and manufacturing equipment	5 – 15 years
Computer equipment and software	3 – 5 years
Furniture, fixtures and office equipment	5 – 10 years

Costs for property and equipment not yet placed into service have been capitalized as construction-in-progress. These costs are primarily related to equipment and leasehold improvements associated with our manufacturing facilities and will be depreciated in accordance with the above guidelines once placed into service. Interest costs incurred during construction of major capital projects are capitalized as construction-in-progress until the underlying asset is ready for its intended use, at which point the interest costs are amortized as depreciation expense over the life of the underlying asset. Interest capitalized as construction-in-progress for the three months ended July 31, 2024 and 2023 was $0.8 million and $0.1 million, respectively. All of our property and equipment are located in the United States. Property and equipment consist of the following (in thousands):

	July 31, 2024	April 30, 2024
Leasehold improvements	$ 103,178	$ 103,178
Laboratory and manufacturing equipment	42,476	41,497
Computer equipment and software	4,236	4,236
Furniture, fixtures and office equipment	1,730	1,730
Construction-in-progress	73,437	72,502
Total property and equipment, gross	225,057	223,143
Less: accumulated depreciation and amortization	(39,440)	(36,629)
Total property and equipment, net	$ 185,617	$ 186,514

Depreciation and amortization expense for the three months ended July 31, 2024 and 2023 was $2.8 million and $2.6 million, respectively.

Leases

We determine if an arrangement is or contains a lease at inception. Our operating leases with a term greater than one year are included in operating lease right-of-use ("ROU") assets, operating lease liabilities and operating lease liabilities, less current portion in our consolidated balance sheets. ROU assets represent our right to use an underlying asset during the lease term and lease liabilities represent our obligation to make lease payments arising from the lease. Operating lease ROU assets and liabilities are recognized at the lease commencement date, based on the present value of lease payments over the lease term. In determining the net present value of lease payments, we use our incremental borrowing rate which represents an estimated rate of interest that we would have to pay to borrow equivalent funds on a collateralized basis at the lease commencement date.

Our operating leases may include options to extend the lease which are included in the lease term when it is reasonably certain that we will exercise a renewal option. Operating lease expense is recognized on a straight-line basis over the expected lease term.

Our finance leases with a term greater than one year are included as assets within property and equipment, net and a lease liability equal to the present value of the minimum lease payments is included in other current liabilities and finance lease liabilities, less current portion in our consolidated balance sheets. The present value of the finance lease payments is calculated using the implicit interest rate in the lease. Finance lease ROU assets are amortized on a straight-line basis over the expected useful life of the asset and the carrying amount of the lease liability is adjusted to reflect interest, which is recorded as interest expense.

Leases with an initial term of 12 months or less are not recorded on our consolidated balance sheets and lease expense for these short-term leases is recognized on a straight-line basis over the lease term. We have also elected the practical expedient to not separate lease components from non-lease components.

Impairment

Long-lived assets are reviewed for impairment in accordance with authoritative guidance for impairment or disposal of long-lived assets. Long-lived assets are reviewed for events or changes in circumstances that indicate that their carrying value may not be recoverable. If such events or changes in circumstances arise, we compare the carrying amount of the long-lived assets to the estimated future undiscounted cash flows expected to be generated by the long-lived assets. If the long-lived assets are determined to be impaired, any excess of the carrying value of the long-lived assets over its estimated fair value is recognized as an impairment loss. For the three months ended July 31, 2024 and 2023, there were no indicators of impairment of the value of our long-lived assets and no cumulative impairment losses were recognized.

Stock-Based Compensation

We account for stock options, restricted stock units, performance stock units and other stock-based awards granted under our equity compensation plans in accordance with the authoritative guidance of ASC 718, *Compensation – Stock Compensation*. The estimated fair value of stock options granted to employees in exchange for services is measured at the grant date, using a fair value-based method, such as a Black-Scholes option valuation model, and is recognized as an expense on a straight-line basis over the requisite service periods. The fair value of restricted stock units and performance stock units is measured at the grant date based on the closing market price of our common stock on the date of grant. For restricted stock units, the fair value is recognized as an expense on a straight-line basis over the requisite service periods. For performance stock units, which are subject to performance conditions, the fair value is recognized as expense on a straight-line basis over the requisite service periods when the achievement of such performance condition is determined to be probable. If a performance condition is not determined to be probable or is not met, no stock-based compensation expense is recognized, and any previously recognized expense is reversed. Forfeitures are recognized as a reduction of stock-based compensation expense as they occur.

Debt Issuance Costs

Debt issuance costs related to convertible senior notes are recorded as a deduction that is netted against the principal value of the debt and are amortized to interest expense using the effective interest method over the contractual term of the debt other than when new convertible senior notes are considered a modification of convertible senior notes for the same creditor, then the debt issuance costs are expensed as incurred (Note 3).

Debt issuance costs related to the revolving credit facility are included in prepaid expenses and other current assets in the unaudited condensed consolidated balance sheets and are amortized to interest expense over the contractual term of the revolving credit facility (Note 3).

Comprehensive Loss

Comprehensive loss is the change in equity during a period from transactions and other events and circumstances from non-owner sources. Comprehensive loss is equal to our net loss for all periods presented.

Fair Value Measurements

Fair value is defined as the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. The guidance prioritizes the inputs used in measuring fair value into the following hierarchy:

- Level 1 – Observable inputs, such as unadjusted quoted prices in active markets for identical assets or liabilities.
- Level 2 – Observable inputs other than quoted prices included in Level 1, such as assets or liabilities whose values are based on quoted market prices in markets where trading occurs infrequently or whose values are based on quoted prices of instruments with similar attributes in active markets.
- Level 3 – Unobservable inputs that are supported by little or no market activity and significant to the overall fair value measurement of the assets or liabilities; therefore, requiring the company to develop its own valuation techniques and assumptions.

As of July 31, 2024 and April 30, 2024, our Level 1 financial assets consisted of our cash equivalents invested in money market funds of $30.2 million and $27.6 million, respectively, and our other current assets related to investments in equity securities of $3.4 million and $4.4, respectively. Our Level 1 financial assets are carried at fair value based on quoted market prices for identical securities (Level 1 inputs). We did not have any Level 2 or Level 3 financial assets as of July 31, 2024 and April 30, 2024.

We consider the fair value of our convertible senior notes to be a Level 2 financial liability due to limited trading activity of the convertible senior notes (Note 3). We did not have any other Level 2 or Level 3 financial liabilities as of July 31, 2024 and April 30, 2024.

Accounting Standards Not Yet Adopted

In November 2023, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") No. 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 entities to disclose significant segment expenses that are regularly provided to the chief operating decision maker and included with each reported measure of segment profit and loss. ASU 2023-07 is effective for annual reporting periods beginning after December 15, 2023, which will be our fiscal year ending April 30, 2025, and interim reporting periods within fiscal years beginning after December 15, 2024, which will be our fiscal year 2026 beginning May 1, 2025. Early adoption is permitted and the amendments in this update should be applied retrospectively to all periods presented. We are currently evaluating the impact the adoption of ASU 2023-07 will have on our consolidated financial statements and related disclosures.

In December 2023, the FASB issued ASU No. 2023-09, Income Taxes (Topic 740): *Improvements to Income Tax Disclosures* ("ASU 2023-09"). The standard requires disaggregated information about a reporting entity's effective tax rate reconciliation as well as additional information on income taxes paid, among other enhancements to improve the effectiveness of income tax disclosures. ASU 2023-09 is effective for annual periods beginning after December 15, 2024, which will be our fiscal year 2026 beginning May 1, 2025; however, early adoption is permitted. ASU 2023-09 should be applied on a prospective basis, but retrospective application is permitted. We are currently evaluating the impact the adoption of ASU 2023-09 will have on our consolidated financial statements and related disclosures.

Note 3 – Debt

Convertible Senior Notes Due 2029

In March 2024, we completed a private offering (the "Offering") of $160.0 million aggregate principal amount of 7.00% convertible senior notes due 2029 (the "2029 Notes") to qualified institutional buyers pursuant to Section 4(a)(2) of the Securities Act. We received net proceeds from the Offering of approximately $153.5 million, after deducting placement agent's commissions and other debt issuance related expenses of approximately $6.5 million.

Subsequent to the closing of the Offering, during March 2024, we used approximately $146.1 million of the net proceeds to (i) repurchase for cash, $141.0 million aggregate principal amount of the 2026 Notes (as defined below) in privately negotiated transactions with certain holders of the 2026 Notes plus accrued and unpaid interest of $2.3 million, and (ii) repay in full, the remaining outstanding 2026 Notes balance by depositing the required payoff amount of $2.8 million, representing principal and accrued and unpaid interest, with the trustee under the 2026 Notes Indenture (as defined below), following which no 2026 Notes remained outstanding.

The 2029 Notes are senior unsecured obligations and accrue interest at a rate of 7.00% per annum, payable semi-annually in arrears on March 1 and September 1 of each year, beginning on September 1, 2024. The 2029 Notes mature on March 1, 2029, unless earlier repurchased by us or converted at the option of the holders. The 2029 Notes are convertible into cash, shares of our common stock or a combination of cash and shares of our common stock, at our election in the manner and subject to the terms and conditions provided in the indenture (the "2029 Notes Indenture") governing the 2029 Notes.

The initial conversion rate for the 2029 Notes is approximately 101.1250 shares of our common stock per $1,000 principal amount, which represents an initial conversion price of approximately $9.89 per share of our common stock. The conversion rate is subject to adjustments upon the occurrence of certain events in accordance with the terms of the 2029 Notes Indenture. In addition, following certain corporate events that occur prior to the maturity date, we will, in certain circumstances, increase the conversion rate for a holder who elects to convert their 2029 Notes in connection with such a fundamental change, as defined in the 2029 Notes Indenture.

Holders of the 2029 Notes may convert their 2029 Notes at their option at any time prior to the close of business on the business day immediately preceding September 1, 2028, only under the following circumstances: (1) during any fiscal quarter commencing after the fiscal quarter ending July 31, 2024 (and only during such fiscal quarter), if the last reported sale price of our common stock for at least 20 trading days (whether or not consecutive) during any 30 consecutive trading days ending on, and including, the last trading day of the immediately preceding fiscal quarter is greater than or equal to 130% of the conversion price for the 2029 Notes on each applicable trading day; (2) during the five business day period after any five consecutive trading day period (the "measurement period") in which the trading price (as defined in the 2029 Notes Indenture) per $1,000 principal amount of the 2029 Notes for each trading day of the measurement period was less than 98% of the product of the last reported sale price of our common stock and the conversion rate on each such trading day; or (3) upon the occurrence of specified corporate events as described in the 2029 Notes Indenture.

On or after September 1, 2028 until the close of business on the second scheduled trading day immediately preceding the maturity date, holders at their option may convert all or any portion of their 2029 Notes at any time, regardless of the foregoing circumstances. We may not redeem the 2029 Notes prior to the March 1, 2029 maturity date.

If we undergo a fundamental change (as defined in the 2029 Notes Indenture), holders may require us to repurchase for cash all or any portion of their 2029 Notes at a fundamental change repurchase price equal to 100% of the principal amount of the 2029 Notes to be repurchased, plus accrued and unpaid interest to, but excluding the fundamental change repurchase date.

The 2029 Notes Indenture includes customary terms and covenants, including that upon certain events of default occurring and continuing, if we fail to comply with any of our other agreements contained in the 2029 Notes or the 2029 Notes Indenture for 60 days after receipt of written notice of such failure from the trustee or the holders of at least 25% in aggregate principal amount of the outstanding 2029 Notes, then the trustee or the holders of at least 25% in aggregate principal amount of the outstanding 2029 Notes may declare the entire principal of all the 2029 Notes plus accrued and unpaid interest to be immediately due and payable.

As of July 31, 2024, the conditions allowing holders of the 2029 Notes to convert had not been met and, therefore, the 2029 Notes are classified as a long-term liability on the unaudited condensed consolidated balance sheets at July 31, 2024 and April 30, 2024.

Convertible Senior Notes Due 2026

In March 2021, we issued $143.8 million in aggregate principal amount of 1.25% exchangeable senior notes due 2026 (the "2026 Notes") in a private offering to qualified institutional buyers pursuant to Rule 144A under the Securities Act. The net proceeds we received from the issuance of 2026 Notes was $138.5 million, after deducting initial purchaser discounts and other debt issuance related expenses of $5.3 million.

The 2026 Notes were senior unsecured obligations and accrued interest at a rate of 1.25% per annum, payable semi-annually in arrears on March 15 and September 15 of each year. The 2026 Notes were to mature on March 15, 2026, unless earlier redeemed or repurchased by us or converted at the option of the holders. The 2026 Notes were convertible into cash, shares of our common stock or a combination of cash and shares of our common stock, at our election in the manner and subject to the terms and conditions provided in the indenture governing the 2026 Notes.

Subsequent to the closing of the Offering described above, during March 2024, we repurchased and paid off the remaining balance of the 2026 Notes.

Net Carrying Amount of 2029 Notes

The net carrying amount of the 2029 Notes is as follows (in thousands):

	July 31, 2024	April 30, 2024
Principal	$ 160,000	$ 160,000
Unamortized issuance costs	(6,133)	(6,407)
Net carrying amount	$ 153,867	$ 153,593

As of July 31, 2024, the estimated fair value of the 2029 Notes was approximately $216.7 million. The fair value was determined based on the last actively traded price per $100 of the 2029 Notes for the period ended July 31, 2024 (Level 2).

The following table summarizes the components of interest expense related to the 2029 Notes for the three months ended July 31, 2024, and the 2026 Notes for the three months ended July 31, 2023 (in thousands):

	Three Months Ended July 31, 2024	Three Months Ended July 31, 2023
Contractual interest expense	$ 1,964	$ 458
Amortization of issuance costs	274	265
Total interest expense for the 2029 Notes and 2026 Notes, respectively	$ 2,238	$ 723

The effective interest rate of the 2029 Notes for the three months ended July 31, 2024 was 8.00%. The effective interest rate of the 2026 Notes for the three months ended July 31, 2023 was 2.31%.

Revolving Credit Facility

In March 2023, we entered into a credit agreement with Bank of America, N.A., as administrative agent and letter of credit issuer, which was subsequently amended on October 27, 2023 and March 12, 2024 (as amended, the "Credit Agreement"). The Credit Agreement provides for a revolving credit facility (the "Revolving Credit Facility") in an amount equal to the lesser of (i) $50 million and (ii) a borrowing base calculated as the sum of (a) 80% of the value of certain of our eligible accounts receivable, plus (b) up to 100% of the value of eligible cash collateral. The Revolving Credit Facility will mature on October 25, 2024 and is secured by substantially all of our assets. As of July 31, 2024, there were no outstanding loans under the Revolving Credit Facility.

Loans under the Revolving Credit Facility will bear interest at either (1) a term Secured Overnight Financing Rate ("SOFR") rate for a specified interest period plus a SOFR adjustment (equal to 0.10%) plus a margin of 1.60% or (2) base rate plus a margin of 0.60% at our option. Interest on any outstanding loans is due and payable monthly and the principal balance is due at maturity. In addition, we pay a quarterly unused revolving line facility fee of 0.25% per annum on the average unused facility.

The Credit Agreement includes certain customary affirmative and negative covenants, including limitations on mergers, consolidations and sales of assets, limitations on liens, limitations on certain restricted payments and investments, limitations on transactions with affiliates and limitations on incurring additional indebtedness. In addition, the Credit Agreement requires maintenance of a minimum consolidated EBITDA, as defined in the Credit Agreement, of $15 million for the most recently completed four fiscal quarters as measured at the end of each fiscal quarter. As of July 31, 2024, we were in compliance with the Credit Agreement's financial covenant.

The Credit Agreement also provides for certain customary events of defaults, including, among others, failure to make payments, breach of representations and warranties, and default of covenants.

Note 4 – Leases

We lease certain office, manufacturing, laboratory and warehouse space located in Orange County, California under operating lease agreements. Our leased facilities have original lease terms ranging from 7 to 12 years, contain multi-year renewal options, and scheduled rent increases of 3% on either an annual or biennial basis. Multi-year renewal options were included in determining the right-of-use asset and lease liability for each of our leases as we considered it reasonably certain that we would exercise such renewal options. In addition, certain of our leases provide for periods of free rent, lessor improvements and tenant improvement allowances, of which certain of these improvements have been classified as leasehold improvements and/or are being amortized over the shorter of the estimated useful life of the improvements or the remaining life of the lease.

Certain of our operating facility leases require us to pay property taxes, insurance and common area maintenance. While these payments are not included as part of our lease liabilities, they are recognized as variable lease cost in the period they are incurred.

We also lease certain manufacturing equipment under finance lease agreements that have terms ranging from 5 to 7 years.

The components of our lease costs are summarized as follows (in thousands):

	Three Months Ended July 31,	
	2024	2023
Operating leases	$ 1,133	$ 1,140
Variable leases	463	351
Short-term leases	31	36
Finance leases:		
Amortization of right-of-use assets	127	54
Interest on lease liabilities	137	27
Total lease costs	$ 1,891	$ 1,608

Supplemental consolidated balance sheet and other information related to our leases were as follows (in thousands, expect weighted average data):

Leases	Classification	July 31, 2024	April 30, 2024
Assets			
Operating	Operating lease right-of-use assets	$ 40,741	$ 41,157
Finance	Property and equipment, net	8,984	9,270
Total leased assets		$ 49,725	$ 50,427
Liabilities			
Current:			
Operating	Current portion of operating lease liabilities	$ 1,399	$ 1,354
Finance	Other current liabilities	1,472	1,450
Non-current:			
Operating	Operating lease liabilities, less current portion	43,971	44,336
Finance	Finance lease liabilities, less current portion	6,725	7,101
Total lease liabilities		$ 53,567	$ 54,241
Weighted average remaining lease term (years):			
Operating leases		15.5	15.7
Finance lease		5.6	5.8
Weighted average discount rate:			
Operating leases		6.0%	6.0%
Finance lease		6.5%	6.5%

Supplemental cash flow information related to our leases were as follows (in thousands):

	Three Months Ended July 31,	
	2024	2023
Cash paid for amounts included in the measurement of lease liabilities:		
Operating cash flows from operating leases	$ 973	$ 1,119
Operating cash flows from finance leases	141	27
Financing cash flows from finance leases	350	130
Non-cash transaction:		
Unpaid finance lease obligation	263	–

As of July 31, 2024, the maturities of our lease liabilities, which includes those derived from lease renewal options that we considered it reasonably certain that we would exercise, were as follows (in thousands):

Fiscal Year Ending April 30,	Operating Leases	Finance Leases	Total
2025 (remaining period)	$ 3,056	$ 1,473	$ 4,529
2026	4,167	1,963	6,130
2027	4,199	1,754	5,953
2028	4,036	1,334	5,370
2029	4,147	1,334	5,481
Thereafter	52,272	2,002	54,274
Total lease payments	71,877	9,860	81,737
Less: imputed interest	(26,507)	(1,663)	(28,170)
Total lease liabilities	$ 45,370	$ 8,197	$ 53,567

Note 5 – Equity Compensation Plans

Stock Incentive Plans

As of July 31, 2024, we had an aggregate of 7,429,246 shares of our common stock reserved for issuance under our stock incentive plans, of which 6,528,876 shares were subject to outstanding stock options, restricted stock units ("RSUs") and performance stock units ("PSUs") and 900,370 shares were available for future grants of stock-based awards.

Stock Options

The following summarizes our stock option transaction activity for the three months ended July 31, 2024:

	Stock Options	Grant Date Weighted Average Exercise Price
	(in thousands)	
Outstanding at May 1, 2024	1,986	$ 6.68
Granted	–	$ –
Exercised	(15)	$ 5.52
Canceled or expired	(77)	$ 12.26
Outstanding at July 31, 2024	1,894	$ 6.46

Restricted Stock Units

The following summarizes our RSUs transaction activity for the three months ended July 31, 2024:

	Shares	Weighted Average Grant Date Fair Value
	(in thousands)	
Outstanding at May 1, 2024	1,311	$ 14.08
Granted	1,438	$ 7.59
Vested and issued	(102)	$ 15.72
Forfeited	(17)	$ 14.23
Outstanding at July 31, 2024	2,630	$ 10.46

Performance Stock Units

The Compensation Committee of the Board of Directors grants PSUs to our executives. The PSUs are subject to annual vesting over three consecutive fiscal year performance periods with the first one-third vesting on April 30 of the year following the grant date, and each successive one-third vesting on April 30 of the following two years respectively (each a "Performance Period"). Each PSU that vests represent the right to receive one share of our common stock. The number of shares that will vest for each Performance Period, if any, is based upon the attainment of certain predetermined financial metrics for each such Performance Period. Depending on the actual financial metrics achieved relative to the target financial metrics for such Performance Periods, the number of PSUs issued could range from 0% to 200% of the target amount. The number of granted shares included in the table below is based on a maximum 200% achievement of each financial metric during each Performance Period (the "Maximum Performance Target"). If a financial metric is achieved at a rate below the Maximum Performance Target, or is not achieved, the corresponding portions of the PSUs that do not vest are forfeited.

The following summarizes our PSUs transaction activity for the three months ended July 31, 2024:

	Shares	Weighted Average Grant Date Fair Value
	(in thousands)	
Outstanding at May 1, 2024	611	$ 15.30
Granted	1,239	$ 7.58
Vested and issued	–	$ –
Forfeited	–	$ –
Outstanding at July 31, 2024	1,850	$ 10.13

Employee Stock Purchase Plan

The Avid Bioservices, Inc. 2010 Employee Stock Purchase Plan (the "ESPP") is a stockholder-approved plan under which employees can purchase shares of our common stock, based on a percentage of their compensation, subject to certain limits. The purchase price per share is equal to the lower of 85% of the fair market value of our common stock on the first trading day of the six-month offering period or on the last trading day of the six-month offering period. During the three months ended July 31, 2024, a total of 98,948 shares of our common stock were purchased under the ESPP at a purchase price of $5.41 per share. As of July 31, 2024, we had 750,270 shares of our common stock reserved for issuance under the ESPP.

Stock-Based Compensation

Stock-based compensation expense included in our unaudited condensed consolidated statements of loss and comprehensive loss for the three months ended July 31, 2024 and 2023 was comprised of the following (in thousands):

	Three Months Ended July 31,	
	2024	2023
Cost of revenues	$ 1,131	$ 954
Selling, general and administrative	1,534	1,389
Total	$ 2,665	$ 2,343

As of July 31, 2024, the total estimated unrecognized compensation cost related to non-vested stock options and RSUs was $0.1 million and $25.5 million, respectively. These costs are expected to be recognized over weighted average vesting periods of 0.72 and 3.18 years, respectively. As of July 31, 2024, there was $10.6 million of total estimated unrecognized compensation cost related to non-vested PSUs associated with the Performance Periods ending April 30, 2025, 2026 and 2027. This cost is expected to be recognized over the weighted average vesting period of 1.53 years, however, we will assess the likelihood of achieving the predetermined financial metrics associated with each Performance Period on a quarterly basis and the expense recognized, if any, will be adjusted accordingly.

Note 6 – Deferred Compensation Plan

In July 2023, our Board of Directors approved and adopted the Avid Bioservices, Inc. Deferred Compensation Plan (the "DC Plan"). The DC Plan allows non-employee directors and certain highly compensated employees to defer a portion of their base compensation, cash bonuses, and certain RSU and PSU awards. As of July 31, 2024 and April 30, 2024, contributions to the DC Plan were $0.3 million and $0.2 million, respectively, and are included in other non-current liabilities and accrued compensation and benefits, respectively, on the unaudited condensed consolidated balance sheets at July 31, 2024 and April 30, 2024.

The RSU and PSU awards deferred under the DC Plan are required to be settled through the issuance of the Company's common stock. The deferred compensation obligation for these awards is accounted for in accordance with the authoritative guidance of ASC 718, *Compensation – Stock Compensation*. As of July 31, 2024 and April 30, 2024, there were 94,961 and nil shares, respectively, of vested and deferred stock awards under the DC Plan. To date, no stock awards vested and deferred under the DC Plan have been settled through the issuance of the Company's common stock.

Note 7 – Income Taxes

We are subject to taxation in the United States and various states jurisdictions in which we conduct our business.

Our tax provision for interim periods is determined using an estimate of our annual effective tax rate, adjusted for discrete items arising in that quarter. On a quarterly basis, we update our estimate of the annual effective tax rate, and if the estimated annual tax rate changes, we make a cumulative adjustment in that quarter.

The provision/(benefit) for income taxes recorded for the three months ended July 31, 2024 and 2023 differs from the U.S. federal statutory tax rate of 21% due primarily to the tax impact of stock-based compensation, non-deductible officers' compensation, transportation fringe benefits, and valuation allowance (current year period only).

For the three months ended July 31, 2024 and 2023, we recorded an income tax expense/(benefit) of nil and $(0.6) million, respectively, resulting in an effective tax rate of approximately 0% and 22%, respectively.

We have no material uncertain tax position liabilities as of July 31, 2024 and April 30, 2024. It is our policy to recognize interest and penalties related to income tax matters in interest expense and other income (expense), net, respectively, in our unaudited condensed consolidated statements of loss and comprehensive loss. There was no accrued interest or penalties associated with uncertain tax positions as of July 31, 2024 and April 30, 2024.

Note 8 – Net Loss Per Common Share

Basic net loss per common share is computed by dividing our net loss by the weighted average number of shares of common stock outstanding during the period. Diluted net loss per common share is computed by dividing our net loss by the sum of the weighted average number of shares of common stock outstanding during the period plus the potential dilutive effects of stock options, unvested RSUs, unvested PSUs, shares of common stock expected to be issued under our ESPP, and the 2026 Notes and 2029 Notes.

The potential dilutive effect of stock options, unvested RSUs, unvested PSUs, and shares of common stock expected to be issued under our ESPP during the period are calculated in accordance with the treasury stock method but are excluded if their effect is anti-dilutive. The potential dilutive effect of our 2026 Notes and 2029 Notes are calculated using the if-converted method assuming the conversion of our 2026 Notes and 2029 Notes as of the earliest period reported or at the date of issuance, if later, but are excluded if their effect is anti-dilutive.

The following table presents the potential dilutive securities excluded from the calculation of diluted net loss per share for the periods presented as the effect of their inclusion would have been anti-dilutive (in thousands):

	Three Months Ended July 31,	
	2024	**2023**
Stock options	687	1,138
RSUs, PSUs and ESPP	1,225	907
2026 Notes	–	6,776
2029 Notes	16,180	–
Total potential dilutive securities	18,092	8,821

Note 9 – Commitments and Contingencies

In the ordinary course of business, we are at times subject to various legal proceedings and disputes. We make provisions for liabilities when it is both probable that a liability has been incurred and the amount of the loss can be reasonably estimated. Such provisions, if any, are reviewed at least quarterly and adjusted to reflect the impact of any settlement negotiations, judicial and administrative rulings, advice of legal counsel, and other information and events pertaining to a particular case. We currently are not a party to any legal proceedings, the adverse outcome of which, in management's opinion, individually or in the aggregate, would have a material adverse effect on our consolidated financial condition or results of operations.

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

The following discussion and analysis of the financial condition and results of our operations should be read together with the unaudited condensed consolidated financial statements and related notes of Avid Bioservices, Inc. included in Part I Item 1 of this Quarterly Report on Form 10-Q and with our audited consolidated financial statements and the related notes included in our Annual Report on Form 10-K for the fiscal year ended April 30, 2024, as filed with the SEC on July 2, 2024 (the "Annual Report on Form 10-K") .

Cautionary Statement Regarding Forward-Looking Statements

This Quarterly Report on Form 10-Q contains forward-looking statements that involve risks and uncertainties, as well as assumptions that, if they never materialize or prove incorrect, could cause our results of operations to differ materially from those expressed or implied by such forward-looking statements. The statements contained in this Quarterly Report on Form 10-Q that are not purely historical are "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). Forward-looking statements are often identified by the use of words such as, but not limited to, "anticipate," "believe," "can," "continue," "could," "estimate," "expect," "intend," "may," "plan," "project," "seek," "should," "target," "will," "would" and similar expressions or variations intended to identify forward-looking statements. These statements are based on the beliefs and assumptions of our management based on information currently available to management. These forward-looking statements are subject to numerous risks and uncertainties, including the risks and uncertainties described under the section titled "Risk Factors" in our Annual Report on Form 10-K, those identified in this "Management's Discussion and Analysis of Financial Condition and Results of Operations" and elsewhere in this Quarterly Report on Form 10-Q, and in other filings we may make with the Securities and Exchange Commission from time to time. Moreover, we operate in an evolving environment. New risk factors and uncertainties emerge from time to time, and it is not possible for our management to predict all risk factors and uncertainties, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statement. We qualify all of our forward-looking statements by these cautionary statements and, except as required by law, assume no obligation and do not intend to update these forward-looking statements.

Overview

We are a dedicated contract development and manufacturing organization ("CDMO") that provides a comprehensive range of services from process development to Current Good Manufacturing Practices ("CGMP") clinical and commercial manufacturing of biologics for the biotechnology and biopharmaceutical industries. With over 30 years of experience producing biologics, our services include clinical and commercial drug substance manufacturing, bulk packaging, release and stability testing and regulatory submissions support. We also provide a variety of process development services, including cell line development, upstream and downstream development and optimization, analytical methods development, testing and characterization.

Strategic Objectives

We have a growth strategy that seeks to align with the growth of the biopharmaceutical drug substance contract services market. That strategy encompasses the following objectives:

- Invest in additional capacity, capabilities and resources required for us to achieve our long-term growth strategy and meet the growth-demand of our customers' programs, moving from development through to commercial manufacturing;
- Broaden our market awareness through a diversified yet flexible marketing strategy;
- Expand our customer base and programs with existing customers for both process development and manufacturing service offerings;
- Explore and invest in strategic opportunities both within our core business as well as in adjacent and/or synergistic service offerings in order to enhance and/or broaden our capabilities; and
- Increase our operating profit margin to best-in-class within our industry.

First Fiscal Quarter Highlights

The following summarizes select highlights from our first fiscal quarter ended July 31, 2024:

- Reported revenues of $40.2 million, an increase of 6%, or $2.4 million, compared to the same prior year period; and
- Expanded our customer base and programs with existing customers and ended the quarter with a backlog of approximately $219 million compared to approximately $189 million at the end of the same quarter in fiscal 2024.

Performance and Financial Measures

In assessing the performance of our business, we consider a variety of performance and financial measures. The key indicators of the financial condition and operating performance of our business are revenues, gross profit, selling, general and administrative expenses, operating income (loss), interest expense, other income (expense), net, and income tax (benefit) expense.

We intend for this discussion to provide the reader with information that will assist in understanding our unaudited condensed consolidated financial statements, the changes in certain key items in those unaudited condensed consolidated financial statements from period to period and the primary factors that accounted for those changes.

Revenues

Revenues are derived from services provided under our customer contracts and are disaggregated into manufacturing and process development revenue streams. Manufacturing revenue generally represents revenue from the manufacturing of customer products derived from mammalian cell culture covering clinical through commercial manufacturing runs. Process development revenue generally represents revenue from services associated with the custom development of a manufacturing process and analytical methods for a customer's product.

Gross Profit

Gross profit is equal to revenues less cost of revenues. Cost of revenues reflects the direct cost of labor, overhead and material costs. Direct labor costs include compensation, benefits, recruiting fees, and stock-based compensation within the manufacturing, process and analytical development, quality assurance, quality control, validation, supply chain and facilities functions. Overhead costs primarily include the rent, common area maintenance, utilities, property taxes, security, materials and supplies, software, small equipment and deprecation costs incurred at our manufacturing and laboratory locations.

Selling, General and Administrative Expenses

Selling, general and administrative ("SG&A") expenses are composed of corporate-level expenses, including compensation, benefits, recruiting fees and stock-based compensation of corporate functions such as executive management, finance and accounting, business development, legal, human resources, information technology, and other centralized services. SG&A expenses also include corporate legal fees, audit and accounting fees, investor relation expenses, non-employee director fees, corporate facility related expenses, and other expenses relating to our general management, administration, and business development activities.

Interest Expense

Interest expense consists of interest costs related to our outstanding convertible senior notes, revolving credit facility and finance leases, including amortization of debt issuance costs.

Other Income (Expense), Net

Other income (expense), net primarily consists of interest earned on our cash and cash equivalents, net of gains (losses) from the disposal of long-lived assets, and unrealized loss from an investment in equity securities.

Income Tax (Benefit) Expense

We are subject to taxation in the United States and various state jurisdictions in which we conduct our business. We prepare our income tax provision based on our interpretation of the income tax accounting rules and each jurisdiction's enacted tax laws and regulations. For additional information refer to Note 7, *Income Taxes*, of the notes to unaudited condensed consolidated financial statements.

Results of Operations

The following table compares the results of our operations for the three months ended July 31, 2024 and 2023 (in thousands):

	Three Months Ended July 31,		
	2024	**2023**	**$ Change**
Revenues	$ 40,173	$ 37,726	$ 2,447
Cost of revenues	34,460	33,626	834
Gross profit	5,713	4,100	1,613
Operating expenses:			
Selling, general and administrative	8,169	6,263	1,906
Total operating expenses	8,169	6,263	1,906
Operating loss	(2,456)	(2,163)	(293)
Interest expense	(2,454)	(825)	(1,629)
Other income (expense), net	(624)	258	(882)
Net loss before income taxes	(5,534)	(2,730)	(2,804)
Income tax benefit	–	(608)	608
Net loss	$ (5,534)	$ (2,122)	$ (3,412)

Three Months Ended July 31, 2024 Compared to Three Months Ended July 31, 2023

Revenues

Revenues for the three months ended July 31, 2024 were $40.2 million compared to $37.7 million for the same period in the prior year, an increase of approximately $2.4 million, or 6%. The increase was primarily attributed to an increase in process development revenues. The following table compares revenues by revenue stream for the three months ended July 31, 2024 and 2023 (in thousands):

	Three Months Ended July 31,		
	2024	**2023**	**Change**
Manufacturing revenues	$ 33,971	$ 33,420	$ 551
Process development revenues	6,202	4,306	1,896
Total revenues	$ 40,173	$ 37,726	$ 2,447

Gross Profit

Gross profit for the three months ended July 31, 2024 was $5.7 million (14% gross margin) compared to a gross profit of $4.1 million (11% gross margin) for the same period in the prior year. The increase in gross profit during the three months ended July 31, 2024, as compared to the same prior year period was primarily driven by increased revenues and lower material costs used for customer programs, partially offset by increases in compensation and benefit related expenses, facility, manufacturing and other related expenses, and depreciation expense.

Selling, General and Administrative Expenses

SG&A expenses were $8.2 million for the three months ended July 31, 2024 compared to $6.3 million for the same period in the prior year, an increase of $1.9 million, or 30%. The net increase in SG&A expenses can be attributed to the following components:

	$ millions
Increase in compensation and benefit related expenses	$ 1.0
Increase in audit, legal, consulting and other consulting fees	0.7
Net increase in all other SG&A expenses	0.2
Total increase in SG&A expenses	$ 1.9

As a percentage of revenues, SG&A expenses for the three months ended July 31, 2024 and 2023 were 20% and 17%, respectively.

Operating Loss

Operating loss was $2.5 million for the three months ended July 31, 2024 compared to $2.2 million for the same period in the prior year. This $0.3 million increase in year-over-year operating loss can be attributed to the $1.9 million increase in SG&A expenses, offset by the $1.6 million increase in gross profit.

Interest Expense

Interest expense was $2.5 million for the three months ended July 31, 2024 compared to $0.8 million for the same period in the prior year. This increase of approximately $1.6 million can primarily be attributed to $2.3 million of increased interest expense associated with our 2029 Notes (as defined below), partially offset by $0.8 million of interest capitalized as construction-in-progress.

Other Income (Expense), net

Other income (expense), net ("OI&E") was expense of $0.6 million for the three months ended July 31, 2024 compared to income of $0.3 million for the same period in the prior year. This $0.9 million decrease in year-over-year OI&E can primarily be attributed to a $0.9 million unrealized loss from an investment in an equity security.

Income Tax (Benefit)

We recorded no income tax (benefit) expense for the three months ended July 31, 2024 compared to income tax (benefit) of $0.6 million for the same prior year period. This decrease in our income tax provision can primarily be attributed to the recording of a valuation allowance during the fourth quarter of fiscal 2024 to offset our deferred tax assets. Our effective tax rate for the current year period was approximately 0% and was computed based on the U.S. federal statutory rate of 21% adjusted primarily for the tax impact of stock-based compensation, non-deductible officers' compensation, transportation fringe benefits, and valuation allowance. Our effective tax rate for the same prior year period was approximately 22% and was computed based on the U.S. federal statutory rate of 21% adjusted primarily for the tax impact of stock-based compensation, non-deductible officers' compensation, and transportation fringe benefits.

Liquidity and Capital Resources

Our principal sources of liquidity are our existing cash and cash equivalents on hand. As of July 31, 2024, we had cash and cash equivalents of $33.4 million. We believe that our existing cash and cash equivalents on hand and our anticipated cash flows from operating activities will be sufficient to fund our operations for at least the next 12 months from the date of this Quarterly Report.

We expect our short-term (the next 12 months) operations and capital requirements will be supported by our existing cash and cash equivalents and anticipated cash flows from operations. If our existing cash and cash equivalents on hand and our actual or anticipated cash flows from operations are not sufficient to support our operations or capital requirements, either in the near-term (the next 12 months) or the long-term (beyond the next 12 months), then we may seek to access capital through borrowing arrangements and/or through the public or private offering of our equity or debt securities. We may raise these funds at the appropriate time, accessing the form of capital that we determine is most appropriate considering the markets available to us and their respective costs of capital. These financings may not be available on acceptable terms, or at all. Our ability to raise additional capital in the equity and debt markets is dependent on several factors including, but not limited to, the market demand for our common stock. The market demand or liquidity of our common stock is subject to a number of risks and uncertainties including, but not limited to, our financial results, economic and market conditions, and global financial crises and economic downturns, which may cause extreme volatility and disruptions in capital and credit markets. In addition, even if we are able to raise additional capital, it may not be at a price or on terms that are favorable to us, or it may contain restrictions on the operations of our business.

Cash Flows

The following table compares our cash flow activities for the three months ended July 31, 2024 and 2023 (in thousands):

	Three Months Ended July 31,		
	2024	**2023**	**$ Change**
Net cash used in operating activities	$ (3,680)	$ (236)	$ (3,444)
Net cash used in investing activities	$ (1,311)	$ (14,156)	$ 12,845
Net cash provided by financing activities	$ 266	$ 748	$ (482)

Net Cash Used in Operating Activities

Net cash used in operating activities for the three months ended July 31, 2024 was a result of a $5.5 million net loss combined with a reduction in working capital as a result of a net change in operating assets and liabilities of $3.9 million, offset by non-cash adjustments to net loss of $5.8 million primarily related to depreciation and amortization, stock-based compensation, and amortization of debt issuance costs.

Net cash used in operating activities for the three months ended July 31, 2023 was a result of a $2.1 million net loss combined with a reduction in working capital as a result of a net change in operating assets and liabilities of $2.9 million, offset by non-cash adjustments to net loss of $4.8 million primarily related to depreciation and amortization, stock-based compensation, amortization of debt issuance costs, and deferred income taxes.

Net Cash Used in Investing Activities

Net cash used in investing activities for the three months ended July 31, 2024 and 2023 consisted of $1.3 million and $14.2 million, respectively, used to acquire property and equipment primarily related to our facilities.

Net Cash Provided by Financing Activities

Net cash provided by financing activities for the three months ended July 31, 2024 consisted of $0.6 million in net proceeds from the issuance of common stock under our equity compensation plans, offset by $0.4 million in principal payments on finance leases.

Net cash provided by financing activities for the three months ended July 31, 2023 consisted of $0.9 million in net proceeds from the issuance of common stock under our equity compensation plans, offset by $0.1 million in principal payments on a finance lease.

Cash Requirements

Our material cash requirements include the following contractual and other obligations:

Convertible Senior Notes Due 2029

In March 2024, we completed the Offering of $160.0 million aggregate principal amount of 7.00% convertible senior notes due 2029 (the "2029 Notes"). We received net proceeds from the Offering of approximately $153.5 million, after deducting placement agent's commissions and other debt issuance related expenses of approximately $6.5 million.

The 2029 Notes are senior unsecured obligations and accrue interest at a rate of 7.00% per annum, payable semi-annually in arrears on March 1 and September 1 of each year, beginning on September 1, 2024. The 2029 Notes mature on March 1, 2029, unless earlier repurchased by us or converted at the option of the holders. The 2029 Notes are convertible into cash, shares of our common stock or a combination of cash and shares of our common stock, at our election in the manner and subject to the terms and conditions provided in the indenture governing the 2029 Notes.

We may not redeem the 2029 Notes prior to the March 1, 2029 maturity date. For additional information regarding the 2029 Notes, see Note 3, *Debt*, of the notes to unaudited condensed consolidated financial statements.

Leases

We lease certain office, manufacturing, laboratory, and warehouse space located in Orange County, California under operating lease agreements. Our leased facilities have original lease terms ranging from 7 to 12 years, contain multi-year renewal options, and scheduled rent increases of 3% on either an annual or biennial basis. We also lease certain manufacturing equipment under finance lease agreements that have lease terms ranging from 5 to 7 years. As of July 31, 2024, we had outstanding lease payment obligations of approximately $81.7 million, of which $4.5 million is payable in the remainder of fiscal 2025, $6.1 million is payable in fiscal 2026, $6.0 million is payable in fiscal 2027, $5.4 million is payable in fiscal 2028, $5.5 million is payable in fiscal 2029, and $54.2 million is payable thereafter.

Capital Expenditures

We currently anticipate that cash required for capital expenditures during fiscal 2025 will be approximately $5 million, which includes accrued and unpaid capital expenditures of approximately $3.1 million as of July 31, 2024.

Revolving Credit Facility

In March 2023, we entered into a credit agreement with Bank of America, N.A., as administrative agent and letter of credit issuer, which was subsequently amended on October 27, 2023 and March 12, 2024 (as amended, the "Credit Agreement"). The Credit Agreement provides for a revolving credit facility (the "Revolving Credit Facility") in an amount equal to the lesser of (i) $50 million, and (ii) a borrowing base calculated as the sum of (a) 80% of the value of certain of our eligible accounts receivable, plus (b) up to 100% of the value of eligible cash collateral. The Revolving Credit Facility will mature on October 25, 2024 and is secured by substantially all of our assets. As of July 31, 2024, there were no outstanding loans under the Revolving Credit Facility.

Loans under the Revolving Credit Facility will bear interest at either (1) a term Secured Overnight Financing Rate ("SOFR") rate for a specified interest period plus a SOFR adjustment (equal to 0.10%) plus a margin of 1.60% or (2) base rate plus a margin of 0.60% at our option. Interest on any outstanding loans is due and payable monthly and the principal balance is due at maturity. In addition, we pay a quarterly unused revolving line facility fee of 0.25% per annum on the average unused facility.

The Credit Agreement includes certain customary affirmative and negative covenants, including limitations on mergers, consolidations and sales of assets, limitations on liens, limitations on certain restricted payments and investments, limitations on transactions with affiliates and limitations on incurring additional indebtedness. In addition, the Credit Agreement requires maintenance of a minimum consolidated EBITDA, as defined in the Credit Agreement, of $15 million for the most recently completed four (4) fiscal quarters as measured at the end of each fiscal quarter. As of July 31, 2024, we were in compliance with the Credit Agreement's financial covenant.

The Credit Agreement also provides for certain customary events of defaults, including, among others, failure to make payments, breach of representations and warranties, and default of covenants.

Critical Accounting Policies and Estimates

Our discussion and analysis of our consolidated financial condition and results of operations are based on our consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States ("U.S. GAAP"). The preparation of our consolidated financial statements requires us to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenues, expenses, and related disclosures. We review our estimates and assumptions on an ongoing basis. We base our estimates on historical experience and on assumptions that we believe to be reasonable under the circumstances, the results of which form the basis for our judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may vary from what we anticipate and different assumptions or estimates about the future could change our reported results. During the three months ended July 31, 2024, there were no significant changes in our critical accounting policies as previously disclosed by us in Part II, Item 7 of our Annual Report on Form 10-K.

Recent Accounting Pronouncements

For a discussion of recent accounting pronouncements applicable to us, please refer to Note 2, *Summary of Significant Accounting Policies*, in the accompanying notes to our unaudited condensed consolidated financial statements.

Backlog

Our backlog represents, as of a point in time, expected future revenue from contracted work not yet completed. As of July 31, 2024, our backlog was approximately $219 million, as compared to approximately $193 million as of April 30, 2024. While we anticipate a significant amount of our backlog will be recognized as revenue over the next five fiscal quarters, our backlog is subject to a number of risks and uncertainties, including but not limited to: (i) the risk that a customer timely cancels its commitments prior to our initiation of services, in which case we may be required to refund some or all of the amounts paid to us in advance under those canceled commitments; (ii) the risk that a customer may experience delays in its program(s) or otherwise, which could result in the postponement of anticipated services; (iii) the risk that we may not successfully execute on all customer projects; and (iv) the risk that commencement of customer projects may be postponed due to supply chain delays, any of which could have a negative impact on our liquidity, reported backlog and future revenues and profitability.

Item 3. Quantitative and Qualitative Disclosures about Market Risk

During the three months ended July 31, 2024, there were no material changes in the market risks described in the "Quantitative and Qualitative Disclosures About Market Risk" section of our Annual Report on Form 10-K.

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

We maintain disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e)) under the Exchange Act that are designed to ensure that information required to be disclosed in our reports filed under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to our management, including our chief executive officer and chief financial officer, as appropriate, to allow timely decisions regarding required disclosure. In designing and evaluating the disclosure controls and procedures, management recognized that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives, and management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

We carried out an evaluation, under the supervision and with the participation of management, including our chief executive officer and chief financial officer, of the effectiveness of the design and operation of our disclosure controls and procedures as of July 31, 2024, the end of the period covered by this Quarterly Report. Based on that evaluation, our chief executive officer and chief financial officer concluded that our disclosure controls and procedures were effective at the reasonable assurance level as of July 31, 2024.

Changes in Internal Control over Financial Reporting

As described in Amendment No. 1 to our Annual Report on Form 10-K/A, filed with the SEC on April 24, 2024, management identified a material weakness in our internal control over financial reporting related to the lack of an effectively designed control activity in accounting for debt and related interest. Specifically, our debt internal controls did not include the periodic review of covenants, acceleration clauses, events of default, and other pertinent information in our debt agreements.

Management, under the oversight of the audit committee of our board of directors, implemented controls intended to remediate the foregoing material weakness. These controls include the initial and periodic review of covenants, acceleration clauses, events of default, and other pertinent information in our debt agreements to enable management to assess whether any of these provisions impact our financial reporting.

During the quarter ended July 31, 2024, we successfully completed the testing necessary to conclude that the material weakness has been remediated.

Except those described above, there were no significant changes in our internal control over financial reporting, during the quarter ended July 31, 2024, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II —OTHER INFORMATION

Item 1. Legal Proceedings

In the ordinary course of business, we are at times subject to various legal proceedings and disputes. We make provisions for liabilities when it is both probable that a liability has been incurred and the amount of the loss can be reasonably estimated. Such provisions, if any, are reviewed at least quarterly and adjusted to reflect the impact of any settlement negotiations, judicial and administrative rulings, advice of legal counsel, and other information and events pertaining to a particular case. We currently are not a party to any legal proceedings, the adverse outcome of which, in management's opinion, individually or in the aggregate, would have a material adverse effect on our consolidated financial condition or results of operations.

Item 1A. Risk Factors

Risk Factor Summary

Below is a summary of the principal factors that make an investment in our common stock speculative or risky. This summary does not address all of the risks that we face. Additional discussion of the risks summarized in this risk factor summary, and other risks that we face, can be found under the heading "Risk Factors" below and should be carefully considered, together with other information in this Quarterly Report and our other filings with the Securities and Exchange Commission ("SEC") before making investment decisions regarding our common stock.

Risks Related to Our Business

- A significant portion of our revenues comes from a limited number of customers.
- We generally do not have long-term customer contracts and our backlog cannot be relied upon as a future indicator of revenues.
- We are making a significant investment by expanding our CDMO service offering into the development and manufacture of viral vectors which will subject us to a number of risks and uncertainties that could adversely affect our operations and financial results.
- We have made a significant capital investment in our facilities in order to meet potential future biologics development and manufacturing needs and, as a result, we depend on the success of attracting new and retaining existing customers' business.
- We rely on third parties to supply most of the necessary raw materials and supplies for the products we manufacture on behalf of our customers and our inability to obtain such raw materials or supplies may adversely impact our business, financial condition, and results of operations.
- All of our manufacturing facilities are situated in Orange County, California, which increases our exposure to significant disruption to our business as a result of unforeseeable developments in a single geographic area.
- Our manufacturing services are highly complex, and if we are unable to provide quality and timely services to our customers, our business could suffer.
- If we do not enhance our existing, or introduce new, service offerings in a timely manner, our offerings may become obsolete or noncompetitive over time, customers may not buy our offerings and our revenues and profitability may decline.
- Any claims beyond our insurance coverage limits, or that are otherwise not covered by our insurance, may result in substantial costs and a reduction in our available capital resources.

- Third parties may claim that our services or our customers' products infringe on or misappropriate their intellectual property rights.

- We may be subject to various litigation claims and legal proceedings.

- We and the third parties with whom we work are subject to stringent and evolving laws, regulations, and rules, contractual obligations, industry standards, policies and other obligations related to data privacy and security. Our (or the third parties with whom we work) actual or perceived failure to comply with such obligations could lead to regulatory investigations or actions; litigation (including class claims); fines and penalties; disruptions of our business operations; reputational harm; loss of revenue or profits; and other adverse business consequences.

- Our information technology systems, or those of the third parties with whom we work, or our data are or were compromised, and we could experience adverse consequences resulting from such compromise, including but not limited to regulatory investigations or actions; litigation; fines and penalties; disruptions of our business operations; reputational harm; loss or revenue or profits; and other adverse consequences that which could have a material adverse effect on our business, financial condition, results of operations and cash flows.

Risks Related to Our Customers

- The consumers of the products we manufacture for our customers may significantly influence our business, financial condition, and results of operations.

- Our customers' failure to receive or maintain regulatory approval for their product candidates could negatively impact our revenues and profitability.

- We depend on spending and demand from our customers for our contract manufacturing and development services and any reduction in spending or demand, whether due to a deterioration in macroeconomic conditions or unfavorable research and development results, could have a material adverse effect on our revenues and profitability.

Risks Related to the Industry in Which We Operate

- Failure to comply with existing and future regulatory requirements could adversely affect our business, financial condition, and results of operations.

- We operate in a highly competitive market and competition may adversely affect our business.

Risks Related to the Ownership of Our Common Stock

- Our issuance of additional capital stock pursuant to our stock incentive plan, or in connection with financings, acquisitions, or otherwise will dilute the interests of other security holders and may depress the price of our common stock.

- The price of our common stock has been and may continue to be highly volatile and may adversely affect the liquidity of our common stock.

Risks Related to Our Outstanding 2029 Notes

- We may not have sufficient cash flow from our business to make payments on our significant debt when due, and we may incur additional indebtedness in the future.

- The conditional conversion feature of our 2029 Notes, if triggered, may adversely affect our financial condition and operating results.

- Our failure to comply with the covenants under our Indenture applicable to the 2029 Notes could trigger an event of default under the Indenture and result in the 2029 Notes being declared immediately due and payable.

Risk Factors

You should carefully consider the risks and uncertainties described below, together with all of the other information contained in this Quarterly Report, including our consolidated financial statements and the related notes thereto and "Management's Discussion and Analysis of Financial Condition and Results of Operations," before making a decision to invest in our securities. The risks and uncertainties described below are not the only ones we face. Additional risks and uncertainties not presently known to us, or that we currently believe are not material, also may become important factors that affect us and impair our business operations. The occurrence of any of the events or developments discussed in the risk factors below could have a material and adverse impact on our business, financial condition, results of operations and cash flows and, in such case, our future prospects would likely be materially and adversely affected. The risk factors set forth below marked with an asterisk (*) next to the title contain changes to the similarly titled risk factor included in, Part I, Item 1A of our Annual Report on Form 10-K for the year ended April 30, 2024.

Risks Related to Our Business

A significant portion of our revenues comes from a limited number of customers.

Our revenues have historically been derived from a limited number of customers. Although we continue to expand our customer base, we remain dependent on a limited number of customers for a substantial majority of our revenues. For example, for the fiscal years ended April 30, 2024, 2023 and 2022, we derived approximately 55%, 65% and 60% of our revenues from our top three customers, respectively. The loss of, or a significant reduction of business from, any of our primary customers could have a material adverse effect on our business, financial condition, and results of operations.

We generally do not have long-term customer contracts and our backlog cannot be relied upon as a future indicator of revenues.

We generally do not have long-term contracts with our customers, and existing contracts and purchase commitments may be canceled under certain circumstances. As a result, we are exposed to market and competitive price pressures on every order, and our agreements with customers do not provide assurance of future revenues. Our customers are not required to make minimum purchases and, in certain circumstances, may cease using our services at any time without penalty. Our backlog should not be relied on as a measure of anticipated demand or future revenue, because the orders constituting our backlog may be subject to changes in delivery schedules or cancellation without significant penalty to the customer. Any reductions, cancellations or deferrals in customer orders would negatively impact our business.

We are making a significant investment by expanding our CDMO service offering into the development and manufacture of viral vectors which will subject us to a number of risks and uncertainties that could adversely affect our operations and financial results.

Our expansion of our CDMO service offering into viral vector development and manufacturing services for the cell and gene therapy market involves a number of risks that could adversely affect our operations and financial results, including the following risks:

- we may experience delays in the construction of the manufacturing facility, including delays in the receipt, installation and/or validation of necessary equipment;
- we may experience significant cost overruns associated with the construction of the facility;
- our entry into a new service offering may distract our executive teams' focus on our core mammalian cell culture operations;
- we may be unable to timely hire qualified individuals to manage and our viral vector operations; and
- we may experience delays and other challenges engaging viral vector customers due to our lack of operating experience in the viral vector market.

In addition to the foregoing, we have commenced a service offering that is currently dominated by a small number of larger organizations with established viral vector operations and significantly greater financial resources with whom we may experience difficulties in competing for talent and customers. If we are unable to manage these risks, our business and operating results could be materially harmed.

We have made a significant capital investment in our facilities in order to meet potential future biologics development and manufacturing needs and, as a result, we depend on the success of attracting new and retaining existing customers' business.

We recently completed several expansions to our facilities, which significantly expanded our production capacity and capabilities. These expansions represent a substantial investment in our development and manufacturing capabilities, and have resulted in a significant increase in our fixed costs. If we are not able to utilize the additional capacity and capabilities from these expansions, our margins could be adversely affected. Further, our future revenues may not be sufficient to ensure the economical operation of this expanded capacity and capabilities, in which case, our results of operations could be adversely affected.

Our rapid growth during the past several fiscal years may not be indicative of our future growth, and if we continue to grow rapidly, we may fail to manage our growth effectively.*

While fiscal 2024 revenues were down from the prior fiscal year, since the fiscal year ended April 30, 2020 through the fiscal year ended April 30, 2024, our revenues have grown approximately 134%. We believe our ability to continue to experience revenue growth will depend on a number of factors, including our ability to:

- continue to expand our customer base, including for our recently completed cell and gene facility, and identify and focus on additional development and manufacturing opportunities with existing customers;
- effectively compete with our competitors in the contract development and manufacturing sector;
- continue to broaden our market awareness through a diversified, yet flexible, marketing strategy; and
- selectively pursue complementary or adjacent service offerings, either organically or through acquisition.

Moreover, we continue to expand our headcount and operations. Since fiscal 2020 through fiscal 2024, our headcount has grown by 144 employees, or approximately 63%. We anticipate that we will continue to expand our operations and headcount in the near term and beyond. This potential future growth could place a significant strain on our management, administrative, operational and financial resources, company culture and infrastructure. Our success will depend in part on our ability to manage this growth effectively while retaining personnel. To manage the expected growth of our operations and personnel, we will need to continue to improve our operational, financial and management controls and our reporting systems and procedures. Failure to effectively manage growth could result in difficulty or delays in adding new customers, maintaining our strong quality systems, declines in quality or customer satisfaction, increases in costs, system failures, difficulties in introducing new features or solutions, the need for more capital than we anticipate or other operational difficulties, and any of these difficulties could harm our business performance and results of operations.

We rely on third parties to supply most of the necessary raw materials and supplies for the products we manufacture on behalf of our customers and our inability to obtain such raw materials or supplies may adversely impact our business, financial condition, and results of operations.

Our operations require various raw materials, including proprietary media, resins, buffers, and filters, in addition to numerous additional raw materials supplied primarily by third parties. We or our customers specify the raw materials and other items required to manufacture their product and, in some cases, specify the suppliers from whom we must purchase these raw materials. In certain instances, the raw materials and other items can only be supplied by a limited number of suppliers and, in some cases, a single source, or in limited quantities. If third-party suppliers do not supply raw materials or other items on a timely basis, it may cause a manufacturing run to be delayed or canceled which would adversely impact our financial condition and results of operations. Additionally, we do not have long-term supply contracts with any of our single source suppliers. If we experience difficulties acquiring sufficient quantities of required materials or products from our existing suppliers, or if our suppliers are found to be non-compliant with the FDA's quality system regulation, CGMPs or other applicable laws or regulations, we would be required to find alternative suppliers. If our primary suppliers become unable or unwilling to perform, any resulting delays or interruptions in the supply of raw materials required to support our manufacturing of CGMP pharmaceutical-grade products would ultimately delay our manufacture of products for our customers, which could materially and adversely affect our financial condition and operating results. Furthermore, third-party suppliers may fail to provide us with raw materials and other items that meet the qualifications and specifications required by us or our customers. If third-party suppliers are not able to provide us with raw materials that meet our or our customers' specifications on a timely basis, we may be unable to manufacture their product or it could prevent us from delivering products to our customers within required timeframes. Any such delay in delivering our products may create liability for us to our customers for breach of contract or cause us to experience order cancellations and loss of customers. In the event that we manufacture products with inferior quality components and raw materials, we may become subject to product liability claims caused by defective raw materials or components from a third-party supplier or from a customer, or our customer may be required to recall its products from the market.

All of our manufacturing facilities are situated in Orange County, California, which increases our exposure to significant disruption to our business as a result of unforeseeable developments in a single geographic area.

We operate our manufacturing facilities in Orange County, California. It is possible that we could experience prolonged periods of reduced production due to unforeseen catastrophic events occurring in or around our facilities. It is also possible that operations could be disrupted due to other unforeseen circumstances such as power outages, explosions, fires, floods, earthquakes or accidents. As a result, we may be unable to shift manufacturing capabilities to alternate locations, accept materials from suppliers, meet customer shipment needs or address other severe consequences that may be encountered, and we may suffer damage to our reputation. Our financial condition and results of our operations could be materially adversely affected were such events to occur.

Our manufacturing services are highly complex, and if we are unable to provide quality and timely services to our customers, our business could suffer.

The manufacturing services we offer are highly complex, due in part to strict regulatory requirements. A failure of our quality control systems in our facilities could cause problems to arise in connection with facility operations for a variety of reasons, including equipment malfunction, viral contamination, failure to follow specific manufacturing instructions, protocols and standard operating procedures, problems with raw materials or environmental factors. Such problems could affect production of a single manufacturing run or a series of runs, requiring the destruction of products, or could halt manufacturing operations altogether. In addition, our failure to meet required quality standards may result in our failure to timely deliver products to our customers, which, in turn, could damage our reputation for quality and service. Any such incident could, among other things, lead to increased costs, lost revenue, reimbursement to customers for lost drug substance, damage to and possibly termination of existing customer relationships, time and expense spent investigating the cause and, depending on the cause, similar losses with respect to other manufacturing runs. With respect to our commercial manufacturing, if problems are not discovered before the product is released to the market, we may be subject to regulatory actions, including product recalls, product seizures, injunctions to halt manufacture and distribution, restrictions on our operations, civil sanctions, including monetary sanctions, and criminal actions. In addition, such issues could subject us to litigation, the cost of which could be significant.

If we do not enhance our existing, or introduce new, service offerings in a timely manner, our offerings may become obsolete or noncompetitive over time, customers may not buy our offerings and our revenues and profitability may decline.

Demand for our manufacturing services may change in ways that we may not anticipate due to evolving industry standards and customer needs that are increasingly sophisticated and varied, as well as the introduction by others of new offerings and technologies that provide alternatives to our offerings. In the event we are unable to offer or enhance our service offerings or expand our manufacturing infrastructure to accommodate requests from our customers and potential customers, our offerings may become obsolete or noncompetitive over time, in which case our revenue and operating results would suffer. For example, if we are unable to respond to changes in the nature or extent of the technological or other needs of our customers through enhancing our offerings, our competition may develop offerings that are more competitive than ours, and we could find it more difficult to renew or expand existing agreements or obtain new agreements. Potential innovations intended to facilitate enhanced or new offerings generally will require a substantial capital investment before we can determine their commercial viability, and we may not have financial resources sufficient to fund all desired innovations. Even if we succeed in creating enhanced or new offerings, however, they may still fail to result in commercially successful offerings or may not produce revenue in excess of our costs of development, and they may be rendered obsolete by changing customer preferences or the introduction by our competitors of offerings embodying new technologies or features. Finally, the marketplace may not accept our innovations due to, among other things, existing patterns of clinical practice, the need for regulatory clearance and/or uncertainty over market access or government or third-party reimbursement.

If we use hazardous and biological materials in a manner that causes injury or violates applicable law, we may be liable for damages.

Our contract manufacturing operations involve the controlled use of hazardous materials and chemicals. We are subject to federal, state and local laws and regulations in the United States governing the use, manufacture, storage, handling and disposal of hazardous materials and chemicals. Although we believe that our procedures for using, handling, storing and disposing of these materials comply with legally prescribed standards, we may incur significant additional costs to comply with applicable laws in the future. Also, even if we are in compliance with applicable laws, we cannot completely eliminate the risk of contamination or injury resulting from hazardous materials or chemicals. As a result of any such contamination or injury, we may incur liability, or local, city, state or federal authorities may curtail the use of these materials and interrupt our business operations. In the event of an accident, we could be held liable for damages or penalized with fines, and the liability could exceed our resources. Compliance with applicable environmental laws and regulations is expensive, and current or future environmental regulations may impair our contract manufacturing operations, which could materially harm our business, financial condition and results of operations.

Our business, financial condition, and results of operations may be adversely affected by pandemics or similar public health crises.

Public health crises such as pandemics or similar outbreaks may affect our operations and those of third parties on which we rely, including our customers and suppliers. Our business, financial condition, and results of operations may be affected by: disruptions in our customers' abilities to fund, develop, or bring to market products as anticipated; delays in or disruptions to the conduct of clinical trials by our customers; cancellations of contracts or confirmed orders from our customers; and inability, difficulty, or additional cost or delays in obtaining key raw materials, components, and other supplies from our existing supply chain; among other factors caused by a public health crises.

For example, the COVID-19 pandemic led to the implementation of various responses, including government-imposed quarantines, travel restrictions and other public health safety measures. The extent to which future pandemics impact our operations and/or those of our customers and suppliers will depend on future developments, which are highly uncertain and unpredictable, including the duration or recurrence of outbreaks, potential future government actions, new information that will emerge concerning the severity and impact of that pandemic and the actions to contain the pandemic or address its impact in the short and long term, among others.

The business disruptions associated with a global pandemic could impact the business, product development priorities and operations of our customers and suppliers. For example, disruptions in supply chains and disruptions to the operations of the FDA and other drug regulatory authorities, could result in, among other things, delays of inspections, reviews, and approvals of our customers' products, as well as the volume and timing of orders from these customers. Such disruptions could result in delays in the development programs of our customers or impede the commercial efforts for our customers' approved products, resulting in potential reductions or delays in orders from our customers which could have a material negative effect on our business in the future.

Potential product liability claims, errors and omissions claims in connection with services we perform and potential liability under indemnification agreements between us and our officers and directors could adversely affect us.

We manufacture products intended for use in humans. These activities could expose us to risk of liability for personal injury or death to persons using such products. We seek to reduce our potential liability through measures such as contractual indemnification provisions with customers (the scope of which may vary by customer, and the performances of which are not secured) and insurance maintained by us and our customers. We could be materially adversely affected if we are required to pay damages or incur defense costs in connection with a claim that is outside the scope of the indemnification agreements, if the indemnity, although applicable, is not performed in accordance with its terms or if our liabilities exceed the amount of applicable insurance or indemnity. In addition, we could be held liable for errors and omissions in connection with the services we perform. Although we currently maintain product liability and errors and omissions insurance with respect to these risks, such coverage may not be adequate or continue to be available on terms acceptable to us.

We also indemnify our officers and directors for certain events or occurrences while the officer or director is serving at our request in such capacity. The maximum potential amount of future payments we could be required to make under these indemnification agreements is unlimited. Although we have a director and officer insurance policy that covers a portion of any potential exposure, we could be materially and adversely affected if we are required to pay damages or incur legal costs in connection with a claim above such insurance limits.

Any claims beyond our insurance coverage limits, or that are otherwise not covered by our insurance, may result in substantial costs and a reduction in our available capital resources.

We maintain property insurance, employer's liability insurance, product liability insurance, general liability insurance, business interruption insurance, and directors' and officers' liability insurance, among others. Although we maintain what we believe to be adequate insurance coverage, potential claims may exceed the amount of insurance coverage or may be excluded under the terms of the policy, which could cause an adverse effect on our business, financial condition and results from operations. Generally, we would be at risk for the loss of inventory that is not within customer specifications. These amounts could be significant. In addition, in the future we may not be able to obtain adequate insurance coverage or we may be required to pay higher premiums and accept higher deductibles in order to secure adequate insurance coverage.

Third parties may claim that our services or our customers' products infringe on or misappropriate their intellectual property rights.

Any claims that our services infringe the rights of third parties, including claims arising from any of our customer engagements, regardless of their merit or resolution, could be costly and may divert the efforts and attention of our management and technical personnel. We may not prevail in such proceedings, given the complex technical issues and inherent uncertainties in intellectual property litigation. If such proceedings result in an adverse outcome, we could be required, among other things, to pay substantial damages, discontinue the use of the infringing technology, expend significant resources to develop non-infringing technology, license such technology from the third party claiming infringement (which license may not be available on commercially reasonable terms or at all) and/or cease the manufacture, use or sale of the infringing processes or offerings, any of which could have a material adverse effect on our business.

In addition, our customers' products may be subject to claims of intellectual property infringement and such claims could materially affect our business if their products cease to be manufactured and they have to discontinue the use of the infringing technology which we may provide. Any of the foregoing could affect our ability to compete or could have a material adverse effect on our business, financial condition and results of operations.

We depend on key personnel and the loss of key personnel could harm our business and results of operations.

We depend on our ability to attract and retain qualified scientific and technical employees, as well as a number of key executives. These employees may voluntarily terminate their employment with us at any time. We may not be able to retain key personnel, or attract and retain additional qualified employees. We do not maintain key-man or similar policies covering any of our senior management or key personnel. Our inability to attract and retain key personnel would have a material adverse effect on our business.

Our ability to use net operating loss, or NOL, carryforwards and certain other tax attributes to offset future taxable income or taxes may be limited.

As of April 30, 2024, we had federal and state NOL carry-forwards of approximately $454.6 million and $281.1 million, respectively. The federal NOL carryforwards generated prior to January 1, 2018 expire in various fiscal years through 2038, unless previously utilized. The federal NOL carryforwards generated after January 1, 2018 of $95.6 million can be carried forward indefinitely under current law, but can only be utilized to offset up to 80% of future taxable income. In addition, utilization of NOL carryforwards may be subject to a substantial annual limitation pursuant to Section 382 of the Internal Revenue Code of 1986, as amended, as well as similar state provisions due to "ownership changes" that have occurred previously or that could occur in the future. In general, an "ownership change," as defined by Section 382, results from transactions increasing the ownership of certain stockholders or public groups in the stock of a corporation by more than 50 percentage points over a three-year period. A Section 382 analysis has been completed through the fiscal year ended April 30, 2024, that concluded no such ownership change had occurred. However, if there were any ownership changes occurring subsequent to April 30, 2024 that could impact the utilization of our NOL carryforwards and other tax attributes. Additionally, states may impose other limitations on the use of state NOL carryforwards. Any limitation may result in expiration of a portion of the NOL carryforwards before utilization. If we were not able to utilize our NOL carryforwards, we would be required to use our cash resources to pay taxes that would otherwise have been offset, thereby reducing our liquidity.

Our effective tax rate may fluctuate, and we may incur obligations in tax jurisdictions in excess of accrued amounts.

Our effective tax rate is derived from a combination of applicable tax rates in the various places that we operate. In preparing our financial statements, we estimate the amount of tax that will become payable in each such place. Nevertheless, our effective tax rate may be different than experienced in the past due to numerous factors, including the impact of stock-based compensation, changes in the mix of our profitability between tax jurisdictions, the results of examinations and audits of our tax filings, our inability to secure or sustain acceptable agreements with tax authorities, changes in accounting for income taxes and changes in tax laws. Any of these factors could cause us to experience an effective tax rate significantly different from previous periods or our current expectations and may result in tax obligations in excess of amounts accrued in our financial statements.

Our operating results may be harmed if we are required to collect sales, services or other related taxes for our products and services in jurisdictions where we have not historically done so.

We do not believe that we are required to collect sales, use, services or other similar taxes from our customers in certain jurisdictions. However, one or more states may seek to impose sales, use, services, or other tax collection obligations on us, including for past sales. A successful assertion by one or more jurisdictions that we should collect sales or other taxes on the sale of our products and services could result in substantial tax liabilities for past sales and decrease our ability to compete for future sales. Each state has different rules and regulations governing sales and use taxes and these rules and regulations are subject to varying interpretations that may change over time.

Providers of goods or services are typically held responsible by taxing authorities for the collection and payment of any applicable sales and similar taxes. If one or more taxing authorities determines that taxes should have, but have not, been paid with respect to our products and services, we may be liable for past taxes in addition to being required to collect sales or similar taxes in respect of our products and services going forward. Liability for past taxes may also include substantial interest and penalty charges. Our customer contracts generally provide that our customers must pay all applicable sales and similar taxes. Nevertheless, customers may be reluctant to pay back taxes and may refuse responsibility for interest or penalties associated with those taxes or we may determine that it would not be feasible to seek reimbursement. If we are required to collect and pay back taxes and the associated interest and penalties and if our customers do not reimburse us for all or a portion of these amounts, we will have incurred unplanned expenses that may be substantial. Moreover, imposition of such taxes on our products and services going forward will effectively increase the cost of such products and services to our customers.

Many states are also pursuing legislative expansion of the scope of goods and services that are subject to sales and similar taxes as well as the circumstances in which a vendor of goods and services must collect such taxes. Following the U.S. Supreme Court decision in South Dakota v. Wayfair, Inc., states are now free to levy taxes on sales of goods and services based on an "economic nexus," regardless of whether the seller has a physical presence in the state. Furthermore, legislative proposals have been introduced in Congress that would provide states with additional authority to impose such taxes. Accordingly, it is possible that either federal or state legislative changes may require us to collect additional sales and similar taxes from our customers in the future.

We may be subject to various litigation claims and legal proceedings.

We, as well as certain of our directors and officers, may be subject to claims or lawsuits during the ordinary course of business. Regardless of the outcome, these lawsuits may result in significant legal fees and expenses and could divert management's time and other resources. If the claims contained in these lawsuits are successfully asserted against us, we could be liable for damages and be required to alter or cease certain of our business practices. Any of these outcomes could cause our business, financial performance and cash position to be negatively impacted.

We and the third parties with whom we work are subject to stringent and evolving laws, regulations, and rules, contractual obligations, industry standards, policies and other obligations related to data privacy and security. Our (or the third parties with whom we work) actual or perceived failure to comply with such obligations could lead to regulatory investigations or actions; litigation (including class claims); fines and penalties; disruptions of our business operations; reputational harm; loss of revenue or profits; and other adverse business consequences.

In the ordinary course of business, we collect, receive, store, process, generate, use, transfer, disclose, make accessible, protect, secure, dispose of, transmit, and share (collectively, process) personal data and other sensitive information, including proprietary and confidential business data, trade secrets, intellectual property, business plans, transactions, and financial information (collectively, sensitive data).

Our data processing activities subject us to numerous data privacy and security obligations, such as various laws, regulations, guidance, industry standards, external and internal privacy and security policies, contractual requirements, and other obligations relating to data privacy and security.

In the United States, federal, state, and local governments have enacted numerous data privacy and security laws, including data breach notification laws, personal data privacy laws, consumer protection laws (e.g., Section 5 of the Federal Trade Commission Act), and other similar laws (e.g., wiretapping laws). In the past few years, numerous U.S. states—including California, Virginia, Colorado, Connecticut, and Utah—have enacted comprehensive privacy laws that impose certain obligations on covered businesses, including providing specific disclosures in privacy notices and affording residents with certain rights concerning their personal data. These state laws allow for statutory fines for noncompliance. For example, the California Consumer Privacy Act of 2018 ("CCPA"), applies to personal data of consumers, business representatives, and employees who are California residents, and requires businesses to provide specific disclosures in privacy notices and honor requests of such individuals to exercise certain privacy rights. The CCPA provides for fines of up to $7,500 per intentional violation and allows private litigants affected by certain data breaches to recover significant statutory damages. Similar laws are being considered in several other states, as well as at the federal and local levels, and we expect more states to pass similar laws in the future. These developments may further complicate compliance efforts and increase legal risk and compliance costs for us and the third parties upon whom we rely.

In addition to data privacy and security laws, we are bound by other contractual obligations related to data privacy and security, and our efforts to comply with such obligations may not be successful. We publish privacy policies, and other statements, such as compliance with certain certifications or self-regulatory principles, regarding data privacy and security. If these policies, materials or statements are found to be deficient, lacking in transparency, deceptive, unfair, or misrepresentative of our practices, we may be subject to investigation, enforcement actions by regulators or other adverse consequences.

Obligations related to data privacy and security (and consumers' data privacy expectations) are quickly changing, becoming increasingly stringent, and creating uncertainty. Additionally, these obligations may be subject to differing applications and interpretations, which may be inconsistent or conflict among jurisdictions. Preparing for and complying with these obligations requires us to devote significant resources and may necessitate changes to our services, information technologies, systems, and practices and to those of any third parties that process personal data on our behalf.

We may at times fail (or be perceived to have failed) in our efforts to comply with our data privacy and security obligations. Moreover, despite our efforts, our personnel or third parties with whom we work may fail to comply with such obligations, which could negatively impact our business operations. If we or the third parties with whom we work fail, or are perceived to have failed, to address or comply with applicable data privacy and security obligations, we could face significant consequences, including but not limited to: government enforcement actions (e.g., investigations, fines, penalties, audits, inspections, and similar); litigation (including class-action claims); additional reporting requirements and/or oversight; bans on processing personal data; and orders to destroy or not use personal data, loss of customers; interruptions or stoppages in our business operations (including, as relevant, clinical trials); limited ability to develop or commercialize our products; expenditure of time and resources to defend any claim or inquiry; adverse publicity; or substantial changes to our business model or operations.

Our information technology systems, or those of the third parties with whom we work, or our data are or were compromised, and we could experience adverse consequences resulting from such compromise, including but not limited to regulatory investigations or actions; litigation; fines and penalties; disruptions of our business operations; reputational harm; loss or revenue or profits; and other adverse consequences that which could have a material adverse effect on our business, financial condition, results of operations and cash flows.*

In the ordinary course of our business, we and the third parties with whom we work process sensitive data, and, as a result, we and the third parties with whom we work face a variety of evolving threats that could and have caused security incidents. We are also increasingly dependent upon sophisticated information technology systems and infrastructure in connection with the conduct of our business. We must constantly update our information technology infrastructure and our various current information technology systems may not continue to meet our current and future business needs. Furthermore, modification, upgrade or replacement of such systems may be costly. Due to the size and complexity of our information technology systems, any breakdown, interruption, corruption or unauthorized access to or cyber-attack on these systems could create system disruptions, shutdowns or unauthorized disclosure of sensitive data.

Cyber-attacks, malicious internet-based activity, online and offline fraud, and other similar activities threaten the confidentiality, integrity, and availability of our sensitive data and information technology systems, and those of the third parties with whom we work. Such threats are prevalent and continue to rise, are increasingly difficult to detect, and come from a variety of sources, including traditional computer "hackers," threat actors, "hacktivists," organized criminal threat actors, personnel (such as through theft or misuse), sophisticated nation states, and nation-state-supported actors. Some actors now engage and are expected to continue to engage in cyber-attacks, including without limitation nation-state actors for geopolitical reasons and in conjunction with military conflicts and defense activities. During times of war and other major conflicts, we and the third parties upon which we rely may be vulnerable to a heightened risk of these attacks, including retaliatory cyber-attacks, that could materially disrupt our systems and operations, supply chain, and ability to produce, sell and distribute our products and services.

We and the third parties with whom we work are subject to a variety of evolving threats, including but not limited to social-engineering attacks (including through deep fakes, which may be increasingly more difficult to identify as fake, and phishing attacks), malicious code (such as viruses and worms), malware (including as a result of advanced persistent threat intrusions), denial-of-service attacks, credential stuffing, credential harvesting, personnel misconduct or error, ransomware attacks, supply-chain attacks, software bugs, server malfunctions, software or hardware failures, loss of data or other information technology assets, adware, attacks enhanced or facilitated by AI, telecommunications failures, earthquakes, fires, floods, and other similar threats.

In particular, severe ransomware attacks are becoming increasingly prevalent and can lead to significant interruptions in our operations, ability to provide our products or services, loss of sensitive data and income, reputational harm, and diversion of funds. Extortion payments may alleviate the negative impact of a ransomware attack, but we may be unwilling or unable to make such payments due to, for example, applicable laws or regulations prohibiting such payments. For example, a third-party vendor's system previously experienced a ransomware attack that affected one of our non-production servers, which was not connected to our network. This incident was not material to us; however, there remains a risk that our data or systems could face future ransomware attacks or other cybersecurity incidents, and such incidents could potentially be material.

Remote work has become more common and has increased risks to our information technology systems and data, as more of our employees utilize network connections, computers, and devices outside our premises or network, including working at home, while in transit and in public locations. Additionally, future or past business transactions (such as acquisitions or integrations) could expose us to additional cybersecurity risks and vulnerabilities, as our systems could be negatively affected by vulnerabilities present in acquired or integrated entities' systems and technologies. We may discover security issues that were not found during due diligence of such acquired or integrated entities, and it may be difficult to integrate companies into our information technology environment and security program.

We rely on third-party service providers and technologies to operate critical business systems that process sensitive data. Our ability to monitor these third parties' information security practices is limited, and these third parties may not have adequate information security measures in place. If our third-party service providers experience a security incident or other interruption, we could experience adverse consequences. While we may be entitled to damages if our third-party service providers fail to satisfy their privacy or security-related obligations to us, any award may be insufficient to cover our damages, or we may be unable to recover such award.

We take steps designed to detect, mitigate, and remediate vulnerabilities in our information technology systems. We may not, however, detect and remediate all such vulnerabilities, including new vulnerabilities in technologies thought to be previously secure, on a timely basis or at all. Further, we may experience delays in deploying remedial measures and patches designed to address identified vulnerabilities. Vulnerabilities could be exploited and result in a security incident.

While we have implemented security measures designed to protect our sensitive data and information technology systems and to prevent such breakdowns and unauthorized breaches and cyber-attacks, these measures may not be successful and these breakdowns and breaches in, or attacks on, our systems and data may not be prevented. Such breakdowns, breaches or attacks may cause business interruption and could have a material adverse effect on our business, financial condition, results of operations and cash flows and could cause the market value of our shares of common stock to decline. If we (or a third party with whom we work) experience a security incident or are perceived to have experienced a security incident, we may experience adverse consequences, such as government enforcement actions (for example, investigations, fines, penalties, audits, and inspections); additional reporting requirements and/or oversight; restrictions on processing sensitive data (including personal data); litigation (including class claims); indemnification obligations; negative publicity; reputational harm; monetary fund diversions; diversion of management attention; interruptions in our operations (including availability of data); financial damage or other loss, including fines or criminal penalties because of lost or misappropriated information.

Applicable data privacy and security obligations may require us to notify relevant stakeholders, including affected individuals, customers, regulators, and investors, of security incidents, or to implement other requirements, such as providing credit monitoring. Such disclosures and compliance with such requirements are costly, and the disclosure or the failure to comply with such requirements could lead to adverse consequences. Security incidents and attendant consequences may prevent or cause customers to stop using our services, deter new customers from using our services, and negatively impact our ability to grow and operate our business.

We may expend significant resources or modify our business activities to try to protect against security incidents. Additionally, certain data privacy and security obligations may require us to implement and maintain specific security measures or industry-standard or reasonable security measures to protect our information technology systems and sensitive data.

Our contracts may not contain limitations of liability, and even where they do, there can be no assurance that limitations of liability in our contracts are sufficient to protect us from liabilities, damages, or claims related to our data privacy and security obligations. We cannot be sure that our insurance coverage will be adequate or sufficient to protect us from or to mitigate liabilities arising out of our privacy and security practices, that such coverage will continue to be available on commercially reasonable terms or at all, or that such coverage will pay future claims.

Increasing attention to ESG matters may impact our business, financial results or stock price.

Companies across all industries are facing increasing scrutiny from stakeholders related to their ESG practices and disclosures, including practices and disclosures related to climate change, diversity and inclusion and governance standards. Investor advocacy groups, certain institutional investors, lenders, investment funds and other influential investors are also increasingly focused on ESG practices and disclosures and in recent years have placed increasing importance on the implications and social cost of their investments. In addition, government organizations are enhancing or advancing legal and regulatory requirements specific to ESG matters. The heightened stakeholder focus on ESG issues related to our business requires the continuous monitoring of various and evolving laws, regulations, standards and expectations and the associated reporting requirements. A failure to adequately meet stakeholder expectations may result in noncompliance, the loss of business, reputational impacts, diluted market valuation, an inability to attract customers and an inability to attract and retain top talent. In addition, our adoption of certain standards or mandated compliance to certain requirements could necessitate additional investments that could have an adverse effect on our results of operations.

We may seek to grow our business through acquisitions of complementary businesses, and the failure to manage acquisitions, or the failure to integrate them with our existing business, could harm our financial condition and operating results.

From time to time, we may consider opportunities to acquire other companies, products or technologies that may enhance our manufacturing capabilities, expand the breadth of our markets or customer base, or advance our business strategies. Potential acquisitions involve numerous risks, including: problems assimilating the acquired service offerings, products or technologies; issues maintaining uniform standards, procedures, quality control and policies; unanticipated costs associated with acquisitions; diversion of management's attention from our existing business; risks associated with entering new markets in which we have limited or no experience; increased legal and accounting costs relating to the acquisitions or compliance with regulatory matters; and unanticipated or undisclosed liabilities of any target.

We do not know if we will be able to identify acquisitions we deem suitable, whether we will be able to successfully complete any such acquisitions on favorable terms or at all, or whether we will be able to successfully integrate any acquired service offerings, products or technologies. Our potential inability to integrate any acquired service offerings, products or technologies effectively may adversely affect our business, financial condition, and results of operations.

We, and certain of our customers may, maintain cash at financial institutions, often in balances that exceed federally-insured limits. The failure of financial institutions could adversely affect our access to our funds, our ability to pay operational expenses or make other payments, and the ability of our customers to pay us for our services.

We, and certain of our customers may, maintain cash in accounts that exceed the Federal Deposit Insurance Corporation ("FDIC") insurance limits. If such banking institutions were to fail, we and/or potentially certain of our customers could lose all or a portion of those amounts held in excess of such insurance limitations. For example, the FDIC took control of Silicon Valley Bank on March 10, 2023. Although we did not have any cash or cash equivalents at Silicon Valley Bank and the Federal Reserve subsequently announced that account holders would be made whole, the FDIC may not make all account holders whole in the event of future bank failures. In addition, even if account holders are ultimately made whole with respect to a future bank failure, account holders' access to their accounts and assets held in their accounts may be substantially delayed. Any material loss that we and/or our customers may experience in the future or inability for a material time period to access our or their cash and cash equivalents could have an adverse effect on our ability to pay our operational expenses or make other payments, and/or our customers' ability to pay us for services rendered (or may cause them to cancel scheduled services) which could adversely affect our business.

Risks Related to Our Customers

The consumers of the products we manufacture for our customers may significantly influence our business, financial condition, and results of operations.

We depend on, and have no control over, consumer demand for the products we manufacture for our customers. Consumer demand for our customers' products could be adversely affected by, among other things, delays in health regulatory approval, the inability of our customers to demonstrate the efficacy and safety of their products, the loss of patent and other intellectual property rights protection, the emergence of competing or alternative products, including generic drugs and the degree to which private and government payment subsidies for a particular product offset the cost to consumers and changes in the marketing strategies for such products. Additionally, if the products we manufacture for our customers do not gain market acceptance, our revenues and profitability may be adversely affected.

Our consumers, as well as various aspects of our business, may be subject to other U.S. healthcare laws, including U.S. federal Anti-Kickback Statute, the civil False Claims Act, the Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), HIPAA, as amended by Health Information Technology for Economic and Clinical Health Act of 2009, and similar state and local laws and regulations. Penalties for violating these laws can be significant.

We believe that continued changes to the healthcare industry, including ongoing healthcare reform, adverse changes in government or private funding of healthcare products and services, legislation or regulations governing the privacy of patient information or patient access to care, or the delivery, pricing or reimbursement of pharmaceuticals and healthcare services or mandated benefits, may cause healthcare industry participants to purchase fewer services from us or influence the price that others are willing to pay for our services. Changes in the healthcare industry's pricing, selling, inventory, distribution or supply policies or practices could also significantly reduce our revenue and profitability.

If production volumes of key products that we manufacture for our customers decline, our financial condition and results of operations may be adversely affected.

Our customers' failure to receive or maintain regulatory approval for their product candidates could negatively impact our revenues and profitability.

Our success depends upon the regulatory approval of the products we manufacture. As such, if our customers experience a delay in, or a failure to receive, approval for any of their product candidates or fail to maintain regulatory approval of their products, and we are not able to manufacture these products, our revenue and profitability could be adversely affected. Additionally, if the FDA or a comparable foreign regulatory authority does not approve of our facilities for the manufacture of a customer product, or if it withdraws such approval in the future, our customers may choose to identify alternative manufacturing facilities and/or relationships, which could significantly impact our ability to expand our manufacturing capacity and capabilities and achieve profitability.

We depend on spending and demand from our customers for our contract manufacturing and development services and any reduction in spending or demand, whether due to a deterioration in macroeconomic conditions or unfavorable research and development results, could have a material adverse effect on our revenues and profitability.

The amount that our customers spend on the development and manufacture of their products or product candidates, particularly the amount our customers choose to spend on outsourcing these services to us, substantially impacts our revenue and profitability. During times of greater economic uncertainty, such as the biopharmaceutical industry is currently experiencing, our smaller customers with products in earlier stages of development tend to be much more negatively impacted due to the tightening of the access to capital. As a result, such earlier stage customers may be forced to delay or cancel our services in an effort to conserve cash which could have a material adverse effect on our revenues and profitability. In addition, the outcomes of our customers' research, development and marketing also significantly influence the amount that our customers choose to spend on our services and offerings. Our customers determine the amounts that they will spend on our services based upon, among other things, the clinical and market success of their products, available resources and their need to develop new products which, in turn, depend upon a number of other factors, including their competitors' research, development and product initiatives and the anticipated market for any new products, as well as clinical and reimbursement scenarios for specific products and therapeutic areas. Further, increasing consolidation in the pharmaceutical industry may impact such spending, particularly in the event that any of our customers choose to develop or acquire integrated manufacturing operations. Any reduction in customer spending on biologics development and related services as a result of these and other factors could have a material adverse effect on our business, financial condition, and results of operations.

If we are unable to protect the confidentiality of our customers' proprietary information, we may be subject to claims.

Many of the formulations used and processes developed by us in the manufacture of our customers' products are subject to trade secret protection, patents or other intellectual property protections owned or licensed by such customer. While we make significant efforts to protect our customers' proprietary and confidential information, including requiring our employees to enter into agreements protecting such information, if any of our employees breach the non-disclosure provisions in such agreements, or if our customers make claims that their proprietary information has been disclosed, our reputation may suffer damage and we may become subject to legal proceedings that could require us to incur significant expense and divert our management's time, attention and resources.

Risks Related to the Industry in Which We Operate

Failure to comply with existing and future regulatory requirements could adversely affect our business, financial condition, and results of operations.

Our industry is highly regulated. We are required to comply with the regulatory requirements of various local, state, provincial, national and international regulatory bodies having jurisdiction in the countries or localities in which we manufacture products or in which our customers' products are distributed. In particular, we are subject to laws and regulations concerning development, testing, manufacturing processes, equipment and facilities, including compliance with CGMPs, import and export, and product registration and listing, among other things. As a result, most of our facilities are subject to regulation by the FDA, as well as regulatory bodies of other jurisdictions where our customers have marketing approval for their products including, but not limited to, the EMA, ANVISA, PMDA, Health Canada and/or the Australian Department of Health, depending on the countries in which our customers market and sell the products we manufacture on their behalf. As we expand our operations, we may be exposed to more complex and new regulatory and administrative requirements and legal risks, any of which may require expertise in which we have little or no experience. It is possible that compliance with new regulatory requirements could impose significant compliance costs on us. Such costs could have a material adverse effect on our business, financial condition and results of operations.

These regulatory requirements impact many aspects of our operations, including manufacturing, developing, storage, distribution, import and export and record keeping related to customers' products. Noncompliance with any applicable regulatory requirements can result in government refusal to approve: (i) facilities for testing or manufacturing products or (ii) products for commercialization. The FDA and other regulatory agencies can delay, limit or deny approval for many reasons, including:

- changes to the regulatory approval process, including new data requirements for product candidates in those jurisdictions, including the United States, in which our customers may be seeking approval;
- that a customer's product candidate may not be deemed to be safe or effective;
- the inability of the regulatory agency to provide timely responses as a result of its resource constraints; and
- that the manufacturing processes or facilities may not meet the applicable requirements.

In addition, if new legislation or regulations are enacted or existing legislation or regulations are amended or are interpreted or enforced differently, we may be required to obtain additional approvals or operate according to different manufacturing or operating standards. This may require a change in our development and manufacturing techniques or additional capital investments in our facilities. Any related costs may be significant. If we fail to comply with applicable regulatory requirements in the future, then we may be subject to warning letters and/or civil or criminal penalties and fines, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, restrictions on the import and export of our products, debarment, exclusion, disgorgement of profits, operating restrictions and criminal prosecution and the loss of contracts and resulting revenue losses. Inspections by regulatory authorities that identify any deficiencies could result in remedial actions, production stoppages or facility closure, which would disrupt the manufacturing process and supply of product to our customers. In addition, such failure to comply could expose us to contractual and product liability claims, including claims by customers for reimbursement for lost or damaged active pharmaceutical ingredients or recall or other corrective actions, the cost of which could be significant.

In addition, products we manufacture must undergo pre-clinical and clinical evaluations relating to product safety and efficacy before they are approved as commercial therapeutic products. The regulatory authorities having jurisdiction in the countries in which our customers intend to market their products may delay or put on hold clinical trials or delay approval of a product or determine that the product is not approvable. The FDA or other regulatory agencies can delay approval of a drug if our manufacturing facility, including any newly commissioned facility, is not able to demonstrate compliance with CGMPs, pass other aspects of pre-approval inspections or properly scale up to produce commercial supplies. The FDA and comparable government authorities having jurisdiction in the countries in which we or our customers intend to market their products have the authority to withdraw product approval or suspend manufacture if there are significant problems with raw materials or supplies, quality control and assurance or the product we manufacture is adulterated or misbranded. If our manufacturing facilities and services are not in compliance with FDA and comparable government authorities, we may be unable to obtain or maintain the necessary approvals to continue manufacturing products for our customers, which would materially adversely affect our financial condition and results of operations.

We operate in a highly competitive market and competition may adversely affect our business.

We operate in a market that is highly competitive. Our competition in the contract manufacturing market includes full-service contract manufacturers and large pharmaceutical companies offering third-party manufacturing services to fill their excess capacity. We may also compete with the internal operations of those pharmaceutical companies that choose to source their product offerings internally. In addition, most of our competitors may have substantially greater financial, marketing, technical or other resources than we do. Moreover, additional competition may emerge, particularly in lower-cost jurisdictions such as India, which could, among other things, result in a decrease in the fees paid for our services, which may adversely affect our financial condition and results of operations.

Risks Related to the Ownership of Our Common Stock

If our internal control over financial reporting is not effective, our business could be adversely affected.*

Our management is responsible for establishing and maintaining adequate internal control over financial reporting designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with GAAP. Our management is likewise required, on a quarterly basis, to evaluate the effectiveness of our internal controls and to disclose any changes and material weaknesses identified through such evaluation in those internal controls. A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected on a timely basis.

In March 2024, we identified a material weakness in our internal control over financial reporting related to the lack of an effectively designed control activity in accounting for debt and related interest. As a result of this material weakness, our management concluded that our internal control over financial reporting was not effective as of April 30, 2024.

Management, under the oversight of the audit committee of our board of directors, implemented controls intended to remediate the material weakness. These controls include the initial and periodic review of covenants, acceleration clauses, events of default, and other pertinent information in our debt agreements to enable management to assess whether any of these provisions impact our financial reporting. During the quarter ended July 31, 2024, we successfully completed the testing necessary to conclude that the material weakness has been remediated.

We can give no assurance that material weaknesses or restatements of financial results will not arise in the future due to a failure to implement and maintain adequate internal control over financial reporting or circumvention of these controls. Our controls and procedures may not be adequate to prevent or identify irregularities or errors or to facilitate the fair presentation of our financial statements.

Any failure to maintain effective internal control over financial reporting could adversely impact our ability to report our financial position and results from operations on a timely and accurate basis. If our financial statements are not accurate, investors may not have a complete understanding, or an inaccurate understanding, of our financial results or financial condition. Likewise, if our financial statements are not filed on a timely basis, we could be subject to sanctions or investigations by the Nasdaq Stock Market, the SEC or other regulatory authorities. In either case, a material adverse effect on our business could result from ineffective internal controls. Ineffective internal controls could also cause investors to lose confidence in our reported financial information, which could have a negative effect on the trading price of our common stock.

Our issuance of additional capital stock pursuant to our stock incentive plan, or in connection with financings, acquisitions, or otherwise will dilute the interests of other security holders and may depress the price of our common stock.

We expect to issue additional capital stock in the future that will result in dilution to all other stockholders. We expect to grant equity awards to employees, directors and consultants under our stock incentive plan. We may also raise capital through equity financings in the future. As part of our growth strategy, we may seek to acquire companies and issue equity securities to pay for any such acquisition. Any such issuances of additional capital stock may cause stockholders to experience significant dilution of their ownership interests and the per share value of our common stock to decline. Furthermore, if we issue additional equity or convertible debt securities, the new equity securities could have rights senior to those of our common stock. For example, if we elect to settle our conversion obligation under our 7.00% Convertible Senior Notes due 2029 (“2029 Notes”) in shares of our common stock or a combination of cash and shares of our common stock, the issuance of such common stock may dilute the ownership interests of our stockholders and sales in the public market could adversely affect prevailing market prices.

The price of our common stock has been and may continue to be highly volatile and may adversely affect the liquidity of our common stock.

The market price of our common stock has generally been highly volatile and may continue to be highly volatile.

The market price of our common stock may be significantly impacted by many factors including the following:

- the loss of a significant customer;
- significant changes in our financial results or that of our competitors, including our ability to continue as a going concern;
- the ability to meet our revenue guidance;
- the offering and sale of shares of our common stock or securities convertible into or exercisable for common stock;
- the incurrence of indebtedness and our ability to service our debt obligations;
- significant changes in our capital structure;
- published reports by securities analysts;
- actual or purported short trading activity;
- announcements of partnering transactions, joint ventures, strategic alliances, and any other transaction that involves the development, sale or use of our technologies or competitive technologies;
- regulatory developments, including possible delays in the regulatory approval of our customers' products which we manufacture;
- outcomes of significant litigation, disputes and other legal or regulatory proceedings;
- general stock trends in the biotechnology and pharmaceutical industry sectors;
- public concerns as to the safety and effectiveness of the products we manufacture;
- economic trends and other external factors including, but not limited to, interest rate fluctuations, economic recession, inflation, foreign market trends, national crisis, and disasters;
- healthcare reimbursement reform and cost-containment measures implemented by government agencies; and
- our ability to meet expectations related to future growth, profitability, or other market expectations.

These and other external factors have caused and may continue to cause the market price and demand for our common stock to fluctuate substantially, which may limit or prevent investors from readily selling their shares of our common stock, and may otherwise negatively affect the liquidity of our common stock.

Anti-takeover provisions in our certificate of incorporation, amended and restated bylaws, the Indenture (defined below), as well as provisions of Delaware law could prevent or delay a change in control of our company, even if such change in control would be beneficial to our stockholders.

Provisions of our certificate of incorporation and amended and restated bylaws could discourage, delay or prevent a merger, acquisition or other change in control of our company, even if such change in control would be beneficial to our stockholders. These include: authorizing the issuance of "blank check" preferred stock that could be issued by our board of directors to increase the number of outstanding shares and thwart a takeover attempt; no provision for the use of cumulative voting for the election of directors; limiting the ability of stockholders to call special meetings; requiring all stockholder actions to be taken at a meeting of our stockholders (i.e. no provision for stockholder action by written consent); and establishing advance notice requirements for nominations for election to the board of directors or for proposing matters that can be acted upon by stockholders at stockholder meetings.

Further, in connection with our 2029 Notes issuances, we entered into an indenture dated as of March 12, 2024 (as amended or supplemented, the "Indenture") with U.S. Bank Trust Company, National Association, as trustee. Certain provisions in the Indenture could make it more difficult or more expensive for a third party to acquire us. For example, if a takeover would constitute a fundamental change, holders of the 2029 Notes will have the right to require us to repurchase their 2029 Notes in cash. In addition, if a takeover constitutes a make-whole fundamental change, we may be required to increase the conversion rate for holders who convert their 2029 Notes in connection with such takeover. In either case, and in other cases, our obligations under the 2029 Notes and the Indenture could increase the cost of acquiring us or otherwise discourage a third party from acquiring us or removing incumbent management.

In addition, Section 203 of the Delaware General Corporation Law prohibits us, except under specified circumstances, from engaging in any mergers, significant sales of stock or assets or business combinations with any stockholder or group of stockholders who owns at least 15% of our common stock.

Our amended and restated bylaws provide that the Court of Chancery of the State of Delaware will be the exclusive forum for substantially all disputes between us and our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees.

Our amended and restated bylaws provide that, unless we consent in writing to an alternative forum and except for actions arising under the Exchange Act or Securities Act, the Court of Chancery of the State of Delaware is the exclusive forum for any derivative action or proceeding brought on our behalf, any action asserting a claim of breach of a fiduciary duty owed by any of our directors, officers, or other employees to us or our stockholders, any action asserting a claim against us arising pursuant to the Delaware General Corporation Law, our certificate of incorporation or our bylaws, or any action asserting a claim against us that is governed by the internal affairs doctrine. The choice of forum provision may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees, which may discourage such lawsuits against us and our directors, officers and other employees.

We do not intend to pay dividends on our common stock, so any returns will be limited to the value of our stock.

We have never declared or paid any cash dividend on our common stock. We currently anticipate that we will retain future earnings, if any, for the development, operation and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. Any return to stockholders will therefore be limited to the appreciation of the trading price of our common stock.

If securities or industry analysts do not publish research reports about us, or if they issue adverse opinions about our business, our stock price and trading volume could decline.

The research and reports that industry or securities analysts publish about us or our business will influence the market for our common stock. If one or more analysts who cover us issues an adverse opinion about us, our stock price would likely decline. If one or more of these analysts ceases research coverage of us or fails to regularly publish reports on us, we could lose visibility in the financial markets which, in turn, could cause our stock price or trading volume to decline. Further, if we fail to meet the market expectations of analysts who follow our stock, our stock price likely would decline.

Risks Related to Our Outstanding 2029 Notes

We may not have sufficient cash flow from our business to make payments on our significant debt when due, and we may incur additional indebtedness in the future.*

In March 2024, we issued the 2029 Notes (see Note 3, *Debt*, of the notes to unaudited condensed consolidated financial statements) in a private offering to qualified institutional buyers pursuant to Section 4(a)(2) under the Securities Act. We may be required to use a substantial portion of our cash flows from operations to pay interest and principal on our indebtedness. Our ability to make scheduled payments of the principal and to pay interest on or to refinance our indebtedness, including the 2029 Notes, depends on our future performance, which is subject to economic, financial, competitive and other factors beyond our control. Our business may not continue to generate cash flow from operations in the future sufficient to service our debt and make necessary capital expenditures. If we are unable to generate such cash flow, we may be required to adopt one or more alternatives, such as selling assets, restructuring debt or obtaining additional equity capital on terms that may be onerous or highly dilutive. Our ability to refinance our indebtedness will depend on the capital markets and our financial condition at such time. We may not be able to engage in any of these activities or engage in these activities on desirable terms, which could result in a default on our debt obligations.

In addition, we may incur substantial additional debt in the future, subject to the restrictions contained in our credit agreement with Bank of America entered into in March 2023 (see Note 3, *Debt*, of the notes to unaudited condensed consolidated financial statements) and any future debt agreements, some of which may be secured debt. We are not restricted under the terms of the Indenture governing the 2029 Notes, from incurring additional debt, securing existing or future debt, recapitalizing our debt, repurchasing our stock, pledging our assets, making investments, paying dividends, guaranteeing debt or taking a number of other actions that are not limited by the terms of the Indenture governing the 2029 Notes that could have the effect of diminishing our ability to make payments on the 2029 Notes when due.

The conditional conversion feature of our 2029 Notes, if triggered, may adversely affect our financial condition and operating results.

In the event the conditional conversion feature of the 2029 Notes is triggered, holders of the 2029 Notes will be entitled to convert the notes at any time during specified periods at their option. If one or more holders elect to convert their 2029 Notes, unless we elect to satisfy our conversion obligation by delivering solely shares of our common stock (other than paying cash in lieu of delivering any fractional share), we would be required to settle a portion or all of our conversion obligation through the payment of cash, which could adversely affect our liquidity. In addition, even if holders do not elect to convert their 2029 Notes when these conversion triggers are satisfied, we could be required under applicable accounting rules to reclassify all or a portion of the outstanding principal of the 2029 Notes as a current rather than long-term liability, which would result in a material reduction of our net working capital.

Our failure to comply with the covenants under our Indenture applicable to the 2029 Notes could trigger an event of default under the Indenture and result in the 2029 Notes being declared immediately due and payable.

The Indenture applicable to the 2029 Notes includes customary covenants and sets forth certain events of default after which the 2029 Notes may be declared immediately due and payable and sets forth certain types of bankruptcy or insolvency events of default involving us after which the 2029 Notes become automatically due and payable. Events of default under the Indenture include, but are not limited to, the following:

- default in any payment of interest (not including additional interest (as defined in the Indenture)) on any 2029 Note when due and payable, and the default continues for a period of 30 days;
- default in the payment of principal of any 2029 Note when due and payable at its stated maturity, upon any required repurchase, upon declaration of acceleration or otherwise;
- default by us with respect to any mortgage, agreement or other instrument of ours under which there may be outstanding, or by which there may be secured or evidenced, any indebtedness for money borrowed in excess of $10.0 million (or its foreign currency equivalent) in the aggregate, (i) resulting in such indebtedness becoming or being declared due and payable or (ii) constituting a failure to pay the principal or interest of any such debt when due and payable at its stated maturity, upon required repurchase, upon declaration of acceleration or otherwise, and in the cases of clauses (i) and (ii), such acceleration shall not have been rescinded or annulled or such failure to pay or default shall not have been cured or waived, or such indebtedness is not paid or discharged, as the case may be, within 45 days of the occurrence thereof;
- certain events of our bankruptcy, insolvency, or reorganization; and
- default in the payment of additional interest on any 2029 Note when due and payable, and such default continues for a period of 30 days after written notice of such default from any holder of the 2029 Notes then outstanding has been received by us or the trustee.

If, following the occurrence of an event of default 100% of the principal of, and accrued and unpaid interest on, the 2029 Notes, is declared immediately due and payable we may not have sufficient funds to pay or be able to obtain additional financing to make any accelerated payments.

Item 5. Other Information

There are no disclosures required by this Item, including those relating to Rule 10b5-1 trading arrangements and non-Rule 10b5-1 trading arrangements as those terms are defined in Item 408(a) of Regulation of S-K.

Item 6. Exhibits

(a) Exhibits:

3.1	Restated Certificate of Incorporation, as filed with the Delaware Secretary of State on July 2, 2021 (incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K, filed on July 7, 2021).
3.2	Certificate of Amendment to Restated Certificate of Incorporation, as filed with the Delaware Secretary of State on October 19, 2022 (incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K, filed on October 21, 2022).
3.3	Amended and Restated Bylaws, as adopted on June 19, 2023 (incorporated by reference to Exhibit 3.2 to the Registrant's Current Report on Form 8-K, filed on June 23, 2023).
10.1	Second Amendment to Avid Bioservices, Inc. Deferred Compensation Plan (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K, filed on August 29, 2024).
31.1	Certification of Chief Executive Officer pursuant to Rule 13a-14(a) and 15d-14(a) of the Securities Exchange Act of 1934, as amended.*
31.2	Certification of Chief Financial Officer pursuant to Rule 13a-14(a) and 15d-14(a) of the Securities Exchange Act of 1934, as amended.*
32.1	Certification of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.*
101.INS	Inline XBRL Instance Document (the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document).*
101.SCH	Inline XBRL Taxonomy Extension Schema Document.*
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document.*
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document.*
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document.*
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document.*
104	Cover Page Interactive Data File (formatted in iXBRL, and included in exhibit 101).*

* Filed herewith.

SIGNATURES

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

AVID BIOSERVICES, INC.

Dated: September 9, 2024

By: /s/ Nicholas S. Green
Nicholas S. Green
President and Chief Executive Officer
(Principal Executive Officer)

Dated: September 9, 2024

By: /s/ Daniel R. Hart
Daniel R. Hart
Chief Financial Officer
(Principal Financial Officer and Principal Accounting Officer)

Exhibit 31.1

CERTIFICATION OF CHIEF EXECUTIVE OFFICER PURSUANT TO RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934, AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Nicholas S. Green, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Avid Bioservices, 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 report is being prepared;

   b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the periods 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.

Dated: September 9, 2024

Signed: /s/ Nicholas S. Green
Nicholas S. Green
President and Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION OF CHIEF FINANCIAL OFFICER PURSUANT TO RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934, AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Daniel R. Hart, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Avid Bioservices, 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 report is being prepared;

   b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the periods 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.

Dated: September 9, 2024

Signed: /s/ Daniel R. Hart
Daniel R. Hart
Chief Financial Officer
(Principal Financial Officer)

Exhibit 32.1

CERTIFICATIONS OF CHIEF EXECUTIVE OFFICER AND CHIEF FINANCIAL OFFICER
PURSUANT TO 18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

I, Nicholas S. Green, certify, as of the date hereof, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that the Quarterly Report of Avid Bioservices, Inc. on Form 10-Q for the quarter ended July 31, 2024 fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 and that information contained in such Quarterly Report of Avid Bioservices, Inc. on Form 10-Q fairly presents in all material respects the financial condition and results of operations of Avid Bioservices, Inc. at the dates and for the periods indicated.

Dated: September 9, 2024

Signed: /s/ Nicholas S. Green
Nicholas S. Green
President and Chief Executive Officer
(Principal Executive Officer)

I, Daniel R. Hart, certify, as of the date hereof, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that the Quarterly Report of Avid Bioservices, Inc. on Form 10-Q for the quarter ended July 31, 2024 fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 and that information contained in such Quarterly Report of Avid Bioservices, Inc. on Form 10-Q fairly presents in all material respects the financial condition and results of operations of Avid Bioservices, Inc. at the dates and for the periods indicated.

Dated: September 9, 2024

Signed: /s/ Daniel R. Hart
Daniel R. Hart
Chief Financial Officer
(Principal Financial Officer)

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

This certification accompanies the Form 10-Q to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of Avid Bioservices, Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Form 10-Q), irrespective of any general incorporation language contained in such filing.