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

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 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: 001-38984

CASTLE BIOSCIENCES, INC.

(Exact name of registrant as specified in its charter)

Delaware	**77-0701774**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
505 S. Friendswood Drive, Suite 401, Friendswood, Texas	**77546**
(Address of principal executive offices)	(Zip Code)

(866) 788-9007
(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	**CSTL**	**The Nasdaq Global Market**

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 the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

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

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

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

As of October 28, 2024, there were 28,007,301 shares of common stock, $0.001 par value per share, issued and outstanding.

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PART I—FINANCIAL INFORMATION

Item 1. Financial Statements.

CASTLE BIOSCIENCES, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(in thousands, except share and per share data)

ASSETS	September 30, 2024 (unaudited)	December 31, 2023
Current Assets		
Cash and cash equivalents	$ 94,959	$ 98,841
Marketable investment securities	184,826	144,258
Accounts receivable, net	50,261	38,302
Inventory	6,572	7,942
Prepaid expenses and other current assets	8,154	6,292
Total current assets	344,772	295,635
Long-term accounts receivable, net	1,106	1,191
Property and equipment, net	44,383	25,433
Operating lease assets	11,904	12,306
Goodwill and other intangible assets, net	110,569	117,335
Other assets – long-term	1,831	1,440
Total assets	$ 514,565	$ 453,340
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities		
Accounts payable	$ 6,810	$ 10,268
Accrued compensation	27,672	28,945
Operating lease liabilities	1,745	1,137
Other accrued and current liabilities	8,068	7,317
Total current liabilities	44,295	47,667
Long-term debt	10,015	—
Noncurrent operating lease liabilities	14,691	14,173
Noncurrent finance lease liabilities	289	25
Deferred tax liability	4,220	206
Total liabilities	73,510	62,071
Commitments and Contingencies (Note 12)		
Stockholders' Equity		
Preferred stock, $0.001 par value per share; 10,000,000 shares authorized as of September 30, 2024 and December 31, 2023; no shares issued and outstanding as of September 30, 2024 and December 31, 2023	—	—
Common stock, $0.001 par value per share; 200,000,000 shares authorized as of September 30, 2024 and December 31, 2023; 27,975,808 and 27,410,532 shares issued and outstanding as of September 30, 2024 and December 31, 2023, respectively	28	27
Additional paid-in capital	650,270	609,477
Accumulated deficit	(209,716)	(218,371)
Accumulated other comprehensive income	473	136
Total stockholders' equity	441,055	391,269
Total liabilities and stockholders' equity	$ 514,565	$ 453,340

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

CASTLE BIOSCIENCES, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(UNAUDITED)
(in thousands, except per share data)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
NET REVENUES	$ 85,782	$ 61,493	$ 245,758	$ 153,668
OPERATING EXPENSES				
Cost of sales (exclusive of amortization of acquired intangible assets)	15,609	11,319	44,022	32,559
Research and development	12,323	12,923	40,268	40,624
Selling, general and administrative	50,499	44,619	150,082	136,062
Amortization of acquired intangible assets	2,272	2,272	6,766	6,742
Total operating expenses, net	80,703	71,133	241,138	215,987
Operating income (loss)	5,079	(9,640)	4,620	(62,319)
Interest income	3,404	2,769	9,544	7,504
Interest expense	(201)	(2)	(485)	(9)
Income (loss) before income taxes	8,282	(6,873)	13,679	(54,824)
Income tax expense	6,013	32	5,024	62
Net income (loss)	$ 2,269	$ (6,905)	$ 8,655	$ (54,886)
Earnings (loss) per share:				
Basic	$ 0.08	$ (0.26)	$ 0.31	$ (2.05)
Diluted	$ 0.08	$ (0.26)	$ 0.30	$ (2.05)
Weighted-average shares outstanding:				
Basic	27,840	26,834	27,659	26,725
Diluted	29,401	26,834	28,838	26,725

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

CASTLE BIOSCIENCES, INC.
CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME (LOSS)
(UNAUDITED)
(in thousands)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Net income (loss)	$ 2,269	$ (6,905)	$ 8,655	$ (54,886)
Other comprehensive income:				
Net unrealized gain on marketable investment securities	645	73	337	310
Comprehensive income (loss)	$ 2,914	$ (6,832)	$ 8,992	$ (54,576)

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

CASTLE BIOSCIENCES, INC.
CONDENSED CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
(UNAUDITED)
(in thousands, except share data)

	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive (Loss) income	Total Stockholders' Equity
	Shares	Amount				
BALANCE, JANUARY 1, 2023	26,553,681	$ 27	$ 560,409	$ (160,905)	$ (381)	$ 399,150
Stock-based compensation expense	—	—	13,525	—	—	13,525
Exercise of common stock options	30,495	—	95	—	—	95
Issuance of common stock from vested restricted stock units and payment of employees' taxes	24,835	—	(314)	—	—	(314)
Issuance of common stock under the employee stock purchase plan	77,190	—	1,652	—	—	1,652
Net unrealized gain on marketable investment securities	—	—	—	—	245	245
Net loss	—	—	—	(29,204)	—	(29,204)
BALANCE, MARCH 31, 2023	26,686,201	$ 27	$ 575,367	$ (190,109)	$ (136)	$ 385,149
Stock-based compensation expense	—	—	12,849	—	—	12,849
Exercise of common stock options	15,606	—	89	—	—	89
Issuance of common stock from vested restricted stock units and payment of employees' taxes	82,201	—	(534)	—	—	(534)
Net unrealized loss on marketable investment securities	—	—	—	—	(8)	(8)
Net loss	—	—	—	(18,777)	—	(18,777)
BALANCE, JUNE 30, 2023	26,784,008	$ 27	$ 587,771	$ (208,886)	$ (144)	$ 378,768
Stock-based compensation expense	—	—	13,043	—	—	13,043
Exercise of common stock options	3,656	—	13	—	—	13
Issuance of common stock from vested restricted stock units and payment of employees' taxes	40,142	—	(271)	—	—	(271)
Issuance of common stock under the employee stock purchase plan	62,682	—	1,062	—	—	1,062
Net unrealized gain on marketable investment securities	—	—	—	—	73	73
Net loss	—	—	—	(6,905)	—	(6,905)
BALANCE, SEPTEMBER 30, 2023	26,890,488	$ 27	$ 601,618	$ (215,791)	$ (71)	$ 385,783

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

CASTLE BIOSCIENCES, INC.
CONDENSED CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
(UNAUDITED)
(in thousands, except share data)

	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive (Loss) income	Total Stockholders' Equity
	Shares	Amount				
BALANCE, JANUARY 1, 2024	27,410,532	$ 27	$ 609,477	$ (218,371)	$ 136	$ 391,269
Stock-based compensation expense	—	—	12,675	—	—	12,675
Exercise of common stock options	19,066	—	65	—	—	65
Issuance of common stock from vested restricted stock units and payment of employees' taxes	44,830	—	(474)	—	—	(474)
Issuance of common stock under the employee stock purchase plan	111,241	1	1,707	—	—	1,708
Net unrealized loss on marketable investment securities	—	—	—	—	(247)	(247)
Net loss	—	—	—	(2,534)	—	(2,534)
BALANCE, MARCH 31, 2024	27,585,669	$ 28	$ 623,450	$ (220,905)	$ (111)	$ 402,462
Stock-based compensation expense	—	—	13,179	—	—	13,179
Exercise of common stock options	1,779	—	8	—	—	8
Issuance of common stock from vested restricted stock units and payment of employees' taxes	123,576	—	(615)	—	—	(615)
Net unrealized loss on marketable investment securities	—	—	—	—	(61)	(61)
Net income	—	—	—	8,920	—	8,920
BALANCE, JUNE 30, 2024	27,711,024	$ 28	$ 636,022	$ (211,985)	$ (172)	$ 423,893
Stock-based compensation expense	—	—	13,027	—	—	13,027
Exercise of common stock options	90,378	—	1,571	—	—	1,571
Issuance of common stock from vested restricted stock units and payment of employees' taxes	117,959	—	(1,294)	—	—	(1,294)
Issuance of common stock under the employee stock purchase plan	56,447	—	944	—	—	944
Net unrealized gain on marketable investment securities	—	—	—	—	645	645
Net income	—	—	—	2,269	—	2,269
BALANCE, SEPTEMBER 30, 2024	27,975,808	$ 28	$ 650,270	$ (209,716)	$ 473	$ 441,055

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

CASTLE BIOSCIENCES, INC.
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(UNAUDITED)
(in thousands)

	Nine Months Ended September 30,	
	2024	2023
OPERATING ACTIVITIES		
Net income (loss)	$ 8,655	$ (54,886)
Adjustments to reconcile net income (loss) to net cash provided by (used in) operating activities:		
Depreciation and amortization	10,229	9,106
Stock-based compensation expense	38,881	39,417
Deferred income taxes	3,708	13
Accretion of discounts on marketable investment securities	(5,072)	(3,851)
Other	208	284
Change in operating assets and liabilities:		
Accounts receivable	(11,874)	(13,779)
Prepaid expenses and other current assets	(1,679)	(892)
Inventory	1,370	(1,789)
Operating lease assets	1,002	(590)
Other assets	(35)	(455)
Accounts payable	(3,802)	2,693
Operating lease liabilities	(863)	1,093
Accrued compensation	(1,273)	(1,953)
Other accrued and current liabilities	1,046	1,376
Net cash provided by (used in) operating activities	40,501	(24,213)
INVESTING ACTIVITIES		
Purchases of property and equipment	(20,759)	(9,828)
Proceeds from sale of property and equipment	11	10
Purchases of marketable investment securities	(158,409)	(136,693)
Proceeds from maturities of marketable investment securities	123,250	138,000
Net cash used in investing activities	(55,907)	(8,511)
FINANCING ACTIVITIES		
Proceeds from exercise of common stock options	1,644	197
Payment of employees' taxes on vested restricted stock units	(2,383)	(1,119)
Proceeds from contributions to the employee stock purchase plan	2,334	2,027
Repayment of principal portion of finance lease liabilities	(71)	(106)
Proceeds from issuance of term debt	10,000	—
Net cash provided by financing activities	11,524	999
NET CHANGE IN CASH AND CASH EQUIVALENTS	(3,882)	(31,725)
Beginning of period	98,841	122,948
End of period	$ 94,959	$ 91,223

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

CASTLE BIOSCIENCES, INC.
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS (CONTINUED)
(UNAUDITED)
(in thousands)

	Nine Months Ended September 30,	
	2024	2023
DISCLOSURE OF NON-CASH INVESTING AND FINANCING ACTIVITIES:		
Accrued purchases of property and equipment	$ 1,570	$ 902
Operating lease assets obtained in exchange for lease obligations	$ 607	$ 499
Decrease in operating lease assets with corresponding change in lease liabilities	$ (7)	$ —
Finance lease assets obtained in exchange for lease obligations	$ 166	$ —
Property and equipment acquired with tenant improvement allowance	$ 1,389	$ 1,281

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

CASTLE BIOSCIENCES, INC.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(UNAUDITED)

1. Organization and Description of Business

Castle Biosciences, Inc. (the ‘‘Company”, “we”, “us” or “our”) was incorporated in the state of Delaware on September 12, 2007. We are a commercial-stage diagnostics company focused on providing clinicians and their patients with personalized, clinically actionable information to inform treatment decisions and improve health outcomes. We are based in Friendswood, Texas (a suburb of Houston, Texas) and our laboratory operations are conducted at our facilities located in Phoenix, Arizona and Pittsburgh, Pennsylvania.

2. Summary of Significant Accounting Policies

Basis of Presentation

Our unaudited condensed consolidated financial statements include the accounts of Castle Biosciences, Inc. and our wholly owned subsidiaries and have been prepared in conformity with accounting principles generally accepted in the United States of America (‘‘U.S. GAAP’’). All intercompany accounts and transactions have been eliminated in consolidation.

We have a history of recurring net losses and negative cash flows and as of September 30, 2024, we had an accumulated deficit of $209.7 million. We believe our $95.0 million of cash and cash equivalents and $184.8 million of marketable investment securities as of September 30, 2024, and anticipated revenue from our test reports, will be sufficient to meet our cash requirements through at least the 12-month period following the date that these unaudited condensed consolidated financial statements were issued.

Unaudited Interim Financial Information

The accompanying condensed consolidated balance sheet as of September 30, 2024; the condensed consolidated statements of operations, the condensed consolidated statements of comprehensive income (loss) and the condensed consolidated statements of stockholders’ equity, each for the three and nine months ended September 30, 2024 and 2023; and the condensed consolidated statements of cash flows for the nine months ended September 30, 2024 and 2023 are unaudited. The unaudited interim condensed consolidated financial statements have been prepared on the same basis as the audited annual financial statements and, in the opinion of management, reflect all adjustments, which include only normal recurring adjustments, necessary for the fair statement of our consolidated financial position as of September 30, 2024, the results of our consolidated operations for the three and nine months ended September 30, 2024 and 2023 and our consolidated cash flows for the nine months ended September 30, 2024 and 2023. The financial data and other information disclosed in these notes related to the three and nine months ended September 30, 2024 and 2023 are also unaudited. The results for the three and nine months ended September 30, 2024 are not necessarily indicative of results to be expected for the year ending December 31, 2024, any other interim periods, or any future year or period. The balance sheet as of December 31, 2023 included herein was derived from the audited financial statements as of that date. Certain disclosures have been condensed or omitted from the unaudited interim consolidated financial statements. These unaudited condensed consolidated financial statements should be read in conjunction with our audited consolidated financial statements included in our Annual Report on Form 10-K for the year ended December 31, 2023 filed with the Securities and Exchange Commission (“SEC”) on February 28, 2024 (the “2023 10-K”).

Use of Estimates

The preparation of consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities as of the date of the consolidated financial statements and the reported amounts of revenues and expenses during the reporting period. Significant items subject to such estimates include revenue recognition, the valuation of stock-based compensation, assessing future tax exposure and the realizability of deferred tax assets, the useful lives and recoverability of long-lived assets, the goodwill impairment test, the valuation of acquired intangible assets and the valuation of contingent consideration and other contingent liabilities. We base these estimates on historical and anticipated results, trends, and various other assumptions that we believe are reasonable under the circumstances, including assumptions as to future events. These estimates form the basis for making judgments about the carrying values of assets and liabilities and recorded revenues and expenses that are not readily apparent from other sources. Actual results could differ from those estimates and assumptions.

Cash and Cash Equivalents including Concentrations of Credit Risk

Cash equivalents consist of short-term, highly liquid investments with original maturities of three months or less. Our cash equivalents consist of money market funds, which are not insured by the Federal Deposit Insurance Corporation ("FDIC"), that are primarily invested in short-term U.S. government obligations. Cash deposits at financial institutions may exceed the amount of insurance provided by the FDIC. Management believes that we are not exposed to significant credit risk on our cash deposits due to the financial position of the financial institutions in which deposits are held.

Marketable Investment Securities

All debt securities are recognized in accordance with Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") Topic 320, *Investments-Debt Securities* ("ASC 320"). Management determines the appropriate classification of securities at the time of purchase and re-evaluates such determination at each balance sheet date. All debt securities are classified as available-for-sale and are recorded at fair value in accordance with ASC 320. We recognize the unrealized gains and losses related to changes in fair value as a separate component of accumulated other comprehensive loss within total stockholders' equity, net of any related deferred income tax effects, on our condensed consolidated balance sheets. Premiums or discounts from par value are amortized to interest income over the life of the underlying investment. Realized gains and losses on available-for-sale securities are calculated at the individual security level and included in interest income in the condensed consolidated statements of operations. Impairments of available-for-sale debt securities, if any, are recorded in our unaudited condensed consolidated statements of operations. See Notes 5 and 11 for further details.

Revenue Recognition

In accordance with ASC Topic 606, *Revenue from Contracts with Customers* ("ASC 606"), we follow a five-step process to recognize revenues: (1) identify the contract with the customer, (2) identify the performance obligations, (3) determine the transaction price, (4) allocate the transaction price to the performance obligations and (5) recognize revenues when the performance obligations are satisfied. We have determined that we have a contract with the patient when the treating clinician orders the test. Our contracts generally contain a single performance obligation, which is the delivery of the test report, and we satisfy our performance obligation at a point in time upon the delivery of the test report to the treating clinician, at which point we can bill for the report. The amount of revenue recognized reflects the amount of consideration to which we expect to be entitled, or the transaction price, and considers the effects of variable consideration. See Note 3 for further details.

Accounts Receivable and Allowance for Credit Losses

We classify accounts receivable balances that are expected to be paid more than one year from the consolidated balance sheet date as noncurrent assets. The estimated timing of payment utilized as a basis for classification as noncurrent is determined by analyses of historical payor-specific payment experience, adjusted for known factors that are expected to change the timing of future payments.

We accrue an allowance for credit losses against our accounts receivable based on management's current estimate of amounts that will not be collected. Management's estimates are typically based on historical loss information adjusted for current conditions. We generally do not perform evaluations of customers' financial condition and generally do not require collateral. Historically, our credit losses have not been significant given our application of the constraint to variable consideration. The allowance for credit losses was zero as of September 30, 2024 and December 31, 2023. Adjustments for implicit price concessions attributable to variable consideration, as discussed below, are incorporated into the measurement of the accounts receivable balances and are not part of the allowance for credit losses.

Property and Equipment

Property and equipment are stated at cost less accumulated depreciation and amortization. Depreciation is computed using the straight-line method over the estimated useful lives of the assets, generally between five and ten years. Leasehold improvements are amortized using the straight-line method over the shorter of the estimated useful life of the asset or the term of the lease. Our leasehold improvements primarily relate to our office and laboratory facilities in Friendswood, Texas, Phoenix, Arizona and Pittsburgh, Pennsylvania, and are generally being depreciated through the end of the lease terms in 2025 and 2033, respectively. Maintenance and repairs are charged to expense as incurred, and material improvements are capitalized. Interest costs incurred during the construction of major capital projects are capitalized until the underlying asset is ready for its intended use, at which

point the capitalized interest costs are amortized using the straight-line method over the estimated useful life of the underlying asset. When assets are retired or otherwise disposed of, the cost and accumulated depreciation are removed from the consolidated balance sheet and any resulting gain or loss is reflected in the consolidated statements of operations in the period realized.

Goodwill

Goodwill represents the excess of the purchase price over the fair value of the net tangible and intangible assets acquired in a business combination. In accordance with ASC Topic 350, *Intangibles—Goodwill and Other*, our goodwill is not amortized but is tested for impairment on an annual basis or whenever events or changes in circumstances indicate that it may be impaired. We perform annual impairment reviews of our goodwill balance during the fourth quarter of each fiscal year. We may perform a qualitative assessment to determine if it is necessary to perform a quantitative impairment test. If we determine that a quantitative impairment test is necessary, we apply the guidance in Accounting Standards Update ("ASU") No. 2017-04, *Intangibles—Goodwill and Other* (Topic 350): Simplifying the Test for Goodwill Impairment, by comparing the fair value of the reporting unit to its carrying value, including the goodwill. If the carrying value exceeds the fair value, we recognize an impairment loss for the amount by which the carrying value exceeds fair value, up to the total amount of goodwill allocated to the reporting unit. We did not incur any goodwill impairment losses in any of the periods presented.

Factors that could result in a future impairment of goodwill include declines in the price of our common stock, increased competition, changes in macroeconomic developments, unfavorable government or regulatory developments and changes in coverage or reimbursement conditions.

Accrued Compensation

We accrue for liabilities under discretionary employee and executive bonus plans. Our estimated compensation liabilities are based on progress against corporate objectives approved by our board of directors, compensation levels of eligible individuals and target bonus percentage levels. Our board of directors reviews and evaluates the performance against these objectives and ultimately determines the actual achievement levels attained. We also accrue for liabilities under employee sales incentive bonus plans with accruals based on performance achieved to date compared to established targets. As of September 30, 2024 and December 31, 2023, we accrued approximately $17.9 million and $21.7 million, respectively, for liabilities associated with these bonus plans. These amounts are classified as current or noncurrent accrued liabilities in the unaudited condensed consolidated balance sheets based on the expected timing of payment.

Stock-Based Compensation

Stock-based compensation expense for equity instruments issued to employees is measured based on the grant-date fair value of the awards. The fair value of employee stock options and offerings under the 2019 Employee Stock Purchase Plan (the "ESPP") are estimated on the date of grant using the Black-Scholes option-pricing valuation model. For restricted stock units ("RSUs") and performance-based restricted stock units ("PSUs"), the fair value is equal to the closing price of our common stock on the date of grant. For awards with graded vesting and only service conditions, we recognize compensation costs on a straight-line basis over the requisite service period of the awards. For options and RSUs, the requisite service period is generally the award's vesting period (typically four years). PSUs vest upon the achievement of certain performance conditions and the provision of service with us through a specified period. Accruals of compensation cost for PSUs are based on the probable outcome of the performance conditions and are reassessed each reporting period. We recognize compensation cost for PSUs separately for each vesting tranche on a ratable basis over the requisite service period. The requisite service period for PSUs is based on an analysis of vesting requirements and performance conditions for the particular award. Certain employees are entitled to acceleration of vesting of a portion of their awards upon retirement, subject to age, service and notice requirements. In these cases, the requisite service period takes into consideration the employee's retirement eligibility, and is reassessed at each reporting date. For the ESPP, the requisite service period is generally the period of time from the offering date to the purchase date. Forfeitures are accounted for as they occur.

Comprehensive Income (Loss)

Comprehensive income (loss) is defined as a change in equity during a period from transactions and other events and circumstances from non-owner sources. Comprehensive income (loss) is made up of net income (loss) plus net

unrealized gain (loss) on marketable investment securities, which is our only other item of other comprehensive income (loss).

Accounting Pronouncements Yet to be Adopted

In December 2023, the FASB issued ASU No. 2023-09, Income Taxes (Topic 740)—Improvements to Income Tax Disclosures ("ASU 2023-09"), which is intended to enhance the transparency and decision usefulness of income tax disclosures. The amendments in ASU 2023-09 provide for enhanced income tax information primarily through changes to the rate reconciliation and income taxes paid information. ASU 2023-09 is effective for the Company prospectively to all annual periods beginning after December 15, 2024. Early adoption is permitted. We are currently evaluating the impact this update will have on our consolidated financial statements and disclosures.

In November 2023, the FASB issued ASU No. 2023-07, Segment Reporting (Topic 280)—Improvements to Reportable Segment Disclosure, which require public companies disclose significant segment expenses and other segment items on an annual and interim basis and to provide in interim periods all disclosures about a reportable segment's profit or loss and assets that are currently required annually. The guidance is effective for public entities for fiscal years beginning after December 15, 2023, and interim periods within fiscal years beginning after December 15, 2024. Early adoption is permitted. The guidance is applied retrospectively to all periods presented in the financial statements, unless it is impracticable. We are currently evaluating the impact this update will have on our consolidated financial statements and disclosures.

We have evaluated all other recently issued, but not yet effective, accounting pronouncements and do not believe that these accounting pronouncements will have any material impact on our consolidated financial statements or disclosures upon adoption.

3. Revenue

All of our revenues from contracts with customers are associated with the provision of testing services. Our revenues are primarily attributable to our DecisionDx®-Melanoma test for cutaneous melanoma. We also provide a test for patients with cutaneous squamous cell carcinoma, DecisionDx®-SCC, a test for use in patients with suspicious pigmented lesions, MyPath® Melanoma, a test for uveal melanoma, DecisionDx®-UM, a test for patients diagnosed with Barrett's esophagus, the TissueCypher® Barrett's Esophagus Test and a pharmacogenomics testing service focused on mental health, IDgenetix®. We previously offered a second test for patients with suspicious pigmented lesions, DiffDx®-Melanoma, which we suspended in February 2023. Information on the disaggregation of revenues is included below.

Once we satisfy our performance obligations and bill for the service, the timing of the collection of payments may vary based on the payment practices of the third-party payor and the existence of contractually established reimbursement rates. The payments for our services are primarily made by third-party payors, including Medicare and commercial health insurance carriers. Certain contracts contain a contractual commitment of a reimbursement rate that differs from our list prices. However, absent a positive coverage policy, with or without a contractually committed reimbursement rate, with a commercial carrier or governmental program, our diagnostic tests may or may not be paid by these entities. In addition, patients do not enter into direct agreements with us that commit them to pay any portion of the cost of the tests in the event that their insurance provider declines to reimburse us. We may pursue, on a case-by-case basis, reimbursement from such patients in the form of co-payments and co-insurance, in accordance with the contractual obligations that we have with the insurance carrier or health plan. These situations may result in a delay in the collection of payments.

The Medicare claims that are covered by Medicare are generally paid at a rate established on Medicare's Clinical Laboratory Fee Schedule or by the respective Medicare contractor within 30 days from receipt. Medicare claims that were either submitted to Medicare prior to the local coverage determination or other coverage commencement date or are not covered but meet the definition of being medically reasonable and necessary pursuant to the controlling Section 1862(a)(1)(A) of the Social Security Act are generally appealed and may ultimately be paid at the first (termed ''redetermination''), second (termed ''reconsideration'') or third level of appeal (*de novo* hearing with an Administrative Law Judge). A successful appeal at any of these levels may result in prompt payment.

In the absence of Medicare coverage, contractually established reimbursements rates or other coverage, we have concluded that our contracts include variable consideration because the amounts paid by Medicare or commercial health insurance carriers may be paid at less than our standard rates or not paid at all, with such differences considered implicit price concessions. Variable consideration attributable to these price concessions is measured at

the expected value using the ‘‘most likely amount’’ method under ASC 606. The amounts are estimated using historical average collection rates by test type and payor category taking into consideration the range of possible outcomes, the predictive value of our past experiences, the time period of when uncertainties expect to be resolved and the amount of consideration that is susceptible to factors outside of our influence, such as the judgment and actions of third parties. Such variable consideration is included in the transaction price only to the extent it is probable that a significant reversal in the amount of cumulative revenue recognized will not occur when the uncertainties with respect to the amount are resolved. Variable consideration may be constrained and excluded from the transaction price in situations where there is no contractually agreed upon reimbursement coverage or in the absence of a predictable pattern and history of collectability with a payor. Accordingly, in such situations revenues are recognized on the basis of actual cash collections. Variable consideration for Medicare claims that are not covered by Medicare, including those claims undergoing appeal, is deemed to be fully constrained due to factors outside our influence (e.g., judgment or actions of third parties) and the uncertainty of the amount to be received is not expected to be resolved for a long period of time. Variable consideration is evaluated each reporting period and adjustments are recorded as increases or decreases in revenues. Included in revenues for the three months ended September 30, 2024 and 2023 were $0.6 million of net negative revenue adjustments and $0.9 million of net positive revenue adjustments, respectively, associated with changes in estimated variable consideration. Included in revenues for the nine months ended September 30, 2024 and 2023 were $1.3 million and $3.1 million of net negative revenue adjustments, respectively, associated with changes in estimated variable consideration. These amounts include (i) adjustments for actual collections versus estimated amounts and (ii) cash collections and the related recognition of revenue in current period for tests delivered in prior periods due to the release of the constraint on variable consideration.

Because our contracts with customers have an expected duration of one year or less, we have elected the practical expedient in ASC 606 to not disclose information about our remaining performance obligations. Any incremental costs to obtain contracts are recorded as selling, general and administrative expenses as incurred due to the short duration of our contracts. Contract balances consisted solely of accounts receivable (both current and noncurrent) as of September 30, 2024 and December 31, 2023.

Disaggregation of Revenues

The table below provides the disaggregation of revenue by type (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Dermatologic[1]	$ 65,060	$ 51,151	$ 193,223	$ 130,097
Non-Dermatologic[2]	20,722	10,342	52,535	23,571
Total net revenues	$ 85,782	$ 61,493	$ 245,758	$ 153,668

(1) Consists of DecisionDx-Melanoma, DecisionDx-SCC and our Diagnostic Gene Expression Profile offering (MyPath Melanoma and DiffDx-Melanoma).
(2) Consists of TissueCypher Barrett's Esophagus Test, DecisionDx-UM and IDgenetix.

Payor Concentration

We rely upon reimbursements from third-party government payors (primarily Medicare) and private-payor insurance companies to collect accounts receivable related to sales of our tests.

Our significant third-party payors and their related revenues as a percentage of total revenues and accounts receivable balances are as follows:

	Percentage of Revenues					
	Nine Months Ended September 30,		Percentage of Accounts Receivable (current) as of		Percentage of Accounts Receivable (noncurrent) as of	
	2024	2023	September 30, 2024	December 31, 2023	September 30, 2024	December 31, 2023
Medicare	47 %	49 %	21 %	20 %	*	*
Payor A	15 %	14 %	18 %	19 %	16 %	15 %
Payor B	*	*	14 %	10 %	11 %	11 %

* Less than 10%

There were no other third-party payors that individually accounted for more than 10% of our total revenue or accounts receivable for the periods shown in the table above.

4. Earnings (Loss) Per Share

Basic earnings (loss) per share is computed by dividing net income (loss) for the period by the weighted-average number of common shares outstanding during the period. Diluted earnings (loss) per share reflects the additional dilution from potential issuances of common stock, such as stock issuable pursuant to the exercise of stock options, vesting of RSUs and PSUs or purchases under the ESPP. The treasury stock method is used to calculate the potential dilutive effect of these common stock equivalents. Contingently issuable PSU awards are included in the computation of diluted earnings (loss) per share when the applicable performance criteria would be met and the common shares would be issuable if the end of the reporting period were the end of the contingency period. However, potentially dilutive shares are excluded from the computation of diluted loss per share when their effect is antidilutive.

The following table shows the computation of basic and diluted earnings (loss) per share for the following three and nine months ended September 30, 2024 and 2023 (in thousands, except per share data):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Numerator:				
Net income (loss)	$ 2,269	$ (6,905)	$ 8,655	$ (54,886)
Denominator:				
Weighted-average common shares outstanding, basic	27,840	26,834	27,659	26,725
Assumed exercise of stock options	457	—	447	—
Assumed vesting of RSUs	1,041	—	663	—
Assumed vesting of PSUs	42	—	55	—
Assumed issuance of shares under the ESPP	21	—	14	—
Weighted-average common shares outstanding, diluted	29,401	26,834	28,838	26,725
Earnings (loss) per share:				
Basic	$ 0.08	$ (0.26)	$ 0.31	$ (2.05)
Diluted	$ 0.08	$ (0.26)	$ 0.30	$ (2.05)

Due to the Company reporting a net loss attributable to common stockholders for the three and nine months ended September 30, 2023, all potentially dilutive securities are antidilutive and are excluded from the computations of diluted loss per share.

The table below provides the weighted-average number of potential common shares associated with outstanding securities not included in our calculation of diluted earnings (loss) per share for the three and nine months ended September 30, 2024 and 2023 because to do so would be antidilutive. With regard to the PSUs, we assume that the associated performance targets will be met at the target level of performance for purposes of calculating diluted net income per common share until such time that it is probable that actual performance will be above or below target (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Stock options	2,430	3,302	2,466	3,339
RSUs and PSUs	474	3,422	553	3,403
ESPP	155	371	207	320
Total	3,059	7,095	3,226	7,062

In addition, in connection with our acquisition of AltheaDx, Inc. (“AltheaDx”) in April 2022, we may be required to issue shares of our common stock to satisfy the contingent consideration obligations, pending the outcome of certain commercial and regulatory milestones, as required by the definitive agreement to acquire AltheaDx. For purposes of calculating diluted earnings (loss) per share, no such shares were assumed to have been issued because none of the applicable conditions have been met to date. See Note 11 for additional information.

5. Marketable Investment Securities

The following tables present our available-for-sale debt securities (in thousands):

	September 30, 2024			
		Unrealized		Estimated Fair Value
	Amortized Cost	Gains	Losses	
U.S. government securities	$ 184,353	$ 473	$ —	$ 184,826
Total	$ 184,353	$ 473	$ —	$ 184,826

	December 31, 2023			
		Unrealized		Estimated Fair Value
	Amortized Cost	Gains	Losses	
U.S. government securities	$ 144,122	$ 143	$ (7)	$ 144,258
Total	$ 144,122	$ 143	$ (7)	$ 144,258

Although available to be sold to meet operating needs or otherwise, securities are generally held through maturity. We classify all investments as current assets, as these are readily available for use in current operations. The cost of securities sold is determined based on the specific identification method for purposes of recording gains and losses.

There were no realized gains or losses on sales of investments for the three and nine months ended September 30, 2024 and 2023.

We evaluated our investment portfolio under the available-for-sale debt securities impairment model guidance and determined our investment portfolio is comprised of low-risk, investment grade securities. As of September 30, 2024, unrealized losses on our available-for-sale investments are not attributed to credit risk. We believe that an allowance for credit losses is unnecessary because the unrealized losses on certain of our marketable investment securities are due to market factors. No credit-related or noncredit-related impairment losses were recorded for the three and nine months ended September 30, 2024 and 2023. The allowance for credit losses was zero as of September 30, 2024 and December 31, 2023.

As of September 30, 2024, all of our available-for-sale debt securities had contractual maturities of one year or less. Accrued interest receivable is included in prepaid expenses and other current assets in our unaudited condensed consolidated balance sheets. As of September 30, 2024 and December 31, 2023, the accrued interest receivable balance was immaterial.

Additional information relating to the fair value of marketable investment securities can be found in Note 11.

6. Property and Equipment, Net

Property and equipment, net consisted of the following (in thousands):

	September 30, 2024	December 31, 2023
Land[(1)]	$ 7,245	$ —
Lab equipment	22,201	16,472
Leasehold improvements	14,438	9,990
Computer equipment	5,103	4,060
Furniture and fixtures	3,521	2,385
Construction-in-progress	3,350	637
Total	55,858	33,544
Less accumulated depreciation	(11,475)	(8,111)
Property and equipment, net	$ 44,383	$ 25,433

(1) On February 9, 2024, we purchased approximately 23 acres of land in Friendswood, Texas for purpose of developing a commercial office building to be used as our future corporate headquarters.

Depreciation expense was recorded in the unaudited condensed consolidated statements of operations as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Cost of sales (exclusive of amortization of acquired intangible assets)	$ 766	$ 505	$ 2,058	$ 1,205
Research and development	89	84	258	246
Selling, general and administrative	414	313	1,147	913
Total	$ 1,269	$ 902	$ 3,463	$ 2,364

7. Goodwill and Other Intangible Assets, Net

Goodwill

The balance of our goodwill was $10.7 million as of September 30, 2024 and December 31, 2023. There were no accumulated impairments of goodwill as of September 30, 2024 or December 31, 2023.

Other Intangible Assets, Net

Our other intangible assets, net consist of the following (in thousands):

	September 30, 2024			
	Gross carrying value	Accumulated amortization	Net	Weighted-Average Remaining Life (in years)
Developed technology	$ 125,317	$ (25,684)	$ 99,633	11.5
Assembled workforce	563	(319)	244	2.2
Total other intangible assets, net	$ 125,880	$ (26,003)	$ 99,877	

	December 31, 2023			
	Gross carrying value	Accumulated amortization	Net	Weighted-Average Remaining Life (in years)
Developed technology	$ 125,317	$ (19,003)	$ 106,314	12.2
Assembled workforce	563	(234)	329	2.9
Total other intangible assets, net	$ 125,880	$ (19,237)	$ 106,643	

Amortization expense of intangible assets was $2.3 million and $6.8 million for the three and nine months ended September 30, 2024, respectively, and $2.3 million and $6.7 million for the three and nine months ended September 30, 2023, respectively.

8. Other Accrued and Current Liabilities

Other accrued and current liabilities consisted of the following (in thousands):

	September 30, 2024	December 31, 2023
Clinical studies	$ 3,023	$ 3,475
Accrued service fees	3,410	2,097
ESPP contributions	577	896
Accrued benefits	418	199
Other	640	650
Total	$ 8,068	$ 7,317

9. Long-Term Debt

We had no debt as of December 31, 2023. Our long-term debt as of September 30, 2024 is presented in the table below (in thousands):

	September 30, 2024
Term debt	$ 10,200
Unamortized discount	(185)
Total long-term debt	10,015
Less: Current portion of long-term debt	—
Total	$ 10,015

Borrowings under our 2024 LSA approximate their fair value as the interest rate is variable and reflects market rates (Level 2 instrument). As of September 30, 2024, the carrying amount of borrowings under our 2024 LSA, exclusive of unamortized discount, and their estimated fair value were $10.2 million.

Future maturities of principal amounts on long-term debt as of September 30, 2024 are as follows (in thousands):

Years Ending December 31,	
2024	$ —
2025	278
2026	3,333
2027	3,333
2028	3,056
Total	$ 10,000

2024 Loan and Security Agreement

On March 26, 2024 (the "Closing Date"), we entered into a Loan and Security Agreement (the "2024 LSA"), by and between us, our wholly owned subsidiary, Castle Narnia Real Estate Holding 1, LLC and Silicon Valley Bank, a division of First-Citizens Bank & Trust Company (the "Lender"). The 2024 LSA provides for (i) on the Closing Date, $10.0 million aggregate principal amount of term loans (discussed in the "2024 Term Loan" section below), and (ii) from the Closing Date until March 31, 2025, an additional line of credit of $25.0 million with the same interest rate and maturity as the term debt available (discussed in the "2024 Credit Line" section below) at our option.

The obligations under the 2024 LSA are secured by substantially all of our assets, excluding intellectual property, the real property held by us, and are subject to certain other exceptions and limitations. We have the right to prepay the 2024 LSA in whole, subject to a prepayment fee of approximately 1.50% if prepaid prior to March 26, 2026. Amounts repaid under the 2024 LSA may not be reborrowed.

In addition, the 2024 LSA contains customary conditions of borrowing, events of default and covenants, including covenants that restrict our ability to dispose of assets, merge with or acquire other entities, incur indebtedness and make distributions to holders of our capital stock. Should an event of default occur, including the occurrence of a

material adverse change, we could be liable for immediate repayment of all obligations under the 2024 LSA. Should we seek to amend the terms of the 2024 LSA, the consent of the Lender would be required. As of September 30, 2024, we were in compliance with all of the covenants.

The 2024 LSA bears interest at a floating rate equal to the greater of (a) the WSJ Prime Rate plus 0.25% or (b) 6.00% per annum. The Term Loans are interest only from the Closing Date through November 30, 2025, which may be extended at our option through November 30, 2026 as long as no event of default under the 2024 LSA has occurred. After the end of the interest only period, we are required to pay equal monthly installments of principal through the maturity date of November 1, 2028.

We are also obligated to make an additional final payment of 2.00% of the aggregate original principal amounts of Term Loans advanced by the Lender, due at the earlier of the maturity date or date the Term Loans are repaid in full.

2024 Term Loan

On March 26, 2024, we drew $10.0 million in Term Loans under the terms and provisions of the 2024 LSA. We are obligated to make a final payment of $0.2 million under the terms of the 2024 LSA final payment provisions. A discount on debt equal to this obligation was recorded on the draw date and is being amortized as additional interest expense using the effective interest method over the term of the debt. As of September 30, 2024, no payment on principal has been made. As of September 30, 2024, the weighted average effective interest rate for all outstanding debt under the 2024 Term Loan was 8.60%.

2024 Credit Line

We have a $25.0 million line of credit under the terms and provisions of the 2024 LSA available from the Closing Date until March 31, 2025. Amounts repaid under the 2024 Credit Line may not be reborrowed. As of September 30, 2024, no draws had been made on the line of credit.

Interest Expense on Long-Term Debt

The table below shows the components of interest expense for the three and nine months ended September 30, 2024 (in thousands):

	Three Months Ended September 30, 2024	Nine Months Ended September 30, 2024
Interest expense on long term debt	$ 229	$ 470
Less: Capitalized interest	(37)	(49)
Total	$ 192	$ 421

There was no interest expense on long term debt or capitalized interest for the three and nine months ended September 30, 2023.

10. Leases

Lease Amendment

On August 1, 2024 (“the Modification Date”) we amended our lease agreement for our Pittsburgh facilities to take early possession of additional square footage under an expansion provision in the original contract at an earlier date than provided for under the original agreement. The expansion option provided us with 23,821 additional square feet, most of which will be dedicated laboratory space, in exchange for an incremental increase in our fixed monthly payments. The amendment did not change the end date under the original lease term, or provide any additional options not already provided for under the original agreement. We evaluated the amendment under ASC Topic 842, Leases, and determined that it constituted a modification to an existing contract and assessed the classification remained an operating lease. Following the modification, our obligations for the remaining lease term increased and we used $1.3 million of lease incentives for leasehold improvements. As of September 30, 2024, we had no remaining credits for leasehold improvements under this contract. In our remeasurement, we recognized an additional $0.6 million in operating lease assets in exchange for an equal amount of additional lease liabilities.

Discount Rate

We remeasured our lease obligations using our incremental borrowing rate as of the Modification Date. The incremental borrowing rate is the rate of interest we would have to pay to borrow on a collateralized basis over a similar term an amount equal to the lease payments in a similar economic environment. As of the Modification Date, we had outstanding borrowings under the "2024 LSA" and referred to the interest rate of such debt for use as our incremental borrowing rate.

11. Fair Value Measurements

Fair value is defined as the price that would be received to sell an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market in an orderly transaction between market participants at the measurement date. The fair value hierarchy prioritizes the inputs to valuation techniques used in measuring fair value. There are three levels to the fair value hierarchy based on the reliability of inputs, as follows:

Level 1 – Observable inputs that reflect quoted prices (unadjusted) for identical assets or liabilities in active markets.

Level 2 – Inputs other than quoted prices included in Level 1 that are observable for the asset or liability, either directly or indirectly.

Level 3 – Unobservable inputs in which little or no market data exists, therefore requiring us to develop our own assumptions.

Financial instruments measured at fair value are classified in their entirety based on the lowest level of input that is significant to the fair value measurement. Our assessment of the significance of a particular input to the fair value measurement in its entirety requires management to make judgments and consider factors specific to the asset or liability. The use of different assumptions and/or estimation methodologies may have a material effect on estimated fair values. Accordingly, the fair value estimates disclosed, or amounts recorded, may not be indicative of the amount that we or holders of the instruments could realize in a current market exchange.

The tables below provide information, by level within the fair value hierarchy, of our financial assets and liabilities that are accounted for at fair value on a recurring basis as of September 30, 2024 and December 31, 2023 (in thousands):

	As of September 30, 2024			
	Quoted Prices in Active Markets for Identical Items (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Total
Assets				
Money market funds[1]	$ 89,571	$ —	$ —	$ 89,571
U.S. government securities[2]	$ 184,826	$ —	$ —	$ 184,826
Liabilities				
Contingent consideration[3]	$ —	$ —	$ —	$ —

	As of December 31, 2023			
	Quoted Prices in Active Markets for Identical Items (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Total
Assets				
Money market funds[1]	$ 89,308	$ —	$ —	$ 89,308
U.S. government securities[2]	$ 144,258	$ —	$ —	$ 144,258
Liabilities				
Contingent consideration[3]	$ —	$ —	$ —	$ —

(1) Classified as “Cash and cash equivalents” in the unaudited condensed consolidated balance sheets.

(2) Classified as “Marketable investment securities” in the unaudited condensed consolidated balance sheets.

(3) Current portion, if any, classified as “Other accrued and current liabilities” in the unaudited condensed consolidated balance sheets.

Contingent Consideration

In connection with our acquisition of AltheaDx, we agreed to pay contingent consideration of up to $75.0 million of commercial milestone payments based on the achievement of certain net revenue targets relating to the years ending December 31, 2022, 2023 and 2024 (“AltheaDx Earnout Payments”). The portion of the AltheaDx Earnout Payments associated with the commercial milestones for the year ended December 31, 2023 was $37.5 million and was not paid since the applicable commercial milestones were not met. The AltheaDx Earnout Payments included a 2022 catch-up provision for additional payment of up to $17.5 million that expired in 2023. Therefore, as of September 30, 2024, we have a potential payment obligation of up to $20.0 million with respect to the remaining commercial milestones for 2024. If the settlement of the remaining portion of the AltheaDx Earnout Payments would have occurred on September 30, 2024, no amounts would have been due because no commercial milestones had been achieved as of such date.

The contingent consideration was classified as a Level 3 fair value measurement due to the use of significant unobservable inputs and a Monte Carlo simulation to determine its fair value. The Monte Carlo simulation uses projections of the commercial milestones for the applicable period as well as the corresponding targets and approximate timing of payment based on the terms of the arrangement. The valuation of the AltheaDx contingent consideration was zero as of September 30, 2024 and December 31, 2023, and no gains or losses were recorded associated with changes in fair value during the three and nine months ended September 30, 2024 and 2023.

The contingent consideration liability is remeasured at fair value at each reporting period taking into account any updated assumptions or changes in circumstances. Any changes in the fair value are recorded as gains or losses in our unaudited condensed consolidated statement of operations.

12. Commitments and Contingencies

From time to time, we may be involved in legal proceedings arising in the ordinary course of business. We believe there is no threatened litigation or litigation pending that could have, individually or in the aggregate, a material adverse effect on our financial position, results of operations or cash flows. On February 1, 2024, we received a Subpoena from the Department of Health and Human Services, Office of Inspector General, seeking documents and information concerning claims submitted for payment under federal healthcare programs. The Subpoena requested that we produce documents relating primarily to interactions with medical providers and billing to government-funded healthcare programs for our tests. The time period covered by the Subpoena is January 1, 2015 through February 1, 2024. We are continuing to cooperate with the government’s request and are in the process of responding to the Subpoena. We are unable to predict what action, if any, might be taken in the future by the Department of Health and Human Services, Office of Inspector General, or any other governmental authority as a result of the matters related to this Subpoena. No claims have been made against us at this time. Any potential claims could subject us to significant liability for damages and harm our reputation. Our insurance and indemnities may not cover all claims that may be asserted against us. We are unable to predict the outcome and are unable to make a meaningful estimate of the amount or range of loss, if any, that could result from any unfavorable outcome.

13. Stock Incentive Plans and Stock-Based Compensation

Stock Incentive Plans

Effective January 1, 2024, an additional 1,370,526 shares became available under our 2019 Equity Incentive Plan (the "2019 Plan") pursuant to an automatic annual increase. The 2019 Plan provides for automatic annual increases to the number of shares authorized for issuance, equal to 5% of our common shares outstanding as of the immediately preceding year end, through January 1, 2029. As of September 30, 2024, 556,925 shares remained available for grant under the 2019 Plan.

On December 22, 2022, our board of directors approved the 2022 Inducement Plan (the "Inducement Plan"). Our Inducement Plan provides for the grant of RSU awards and other stock awards made as an inducement material to the grantee's entering into employment with us to the extent such grantee was not previously an employee of ours or is entering into employment following a bona fide period of non-employment with us. As of September 30, 2024, there were 348,917 shares available for grant under the Inducement Plan.

Stock Options

Stock option activity under our stock plans for the nine months ended September 30, 2024 is set forth below:

	Stock Options Outstanding	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value (in thousands)
Balance as of December 31, 2023	3,208,979	$ 35.38		
Granted	3,379	$ 71.22		
Exercised	(111,223)	$ 14.78		
Forfeited/Cancelled	(61,197)	$ 39.96		
Balance as of September 30, 2024	3,039,938	$ 36.09	5.8	$ 13,365
Exercisable at September 30, 2024	2,789,681	$ 35.29	5.7	$ 13,310

Restricted Stock Units

RSUs represent the right to receive shares of our common stock at a specified future date, subject to vesting. Our RSUs generally vest annually from the grant date in four equal installments subject to the holder's continued service with us. We issue new shares of common stock upon the vesting of RSUs.

The following table summarizes our RSU activity for the nine months ended September 30, 2024:

	Restricted Stock Units Outstanding	Weighted-Average Grant Date Fair Value
Balance as of December 31, 2023	2,805,075	$ 25.48
Granted	1,515,966	$ 21.52
Vested[(1)]	(290,337)	$ 25.60
Forfeited/Cancelled	(299,980)	$ 21.78
Balance as of September 30, 2024	3,730,724	$ 24.16

(1) The aggregate number of shares withheld upon vesting for employee tax obligations was 71,944 for the nine months ended September 30, 2024.

Performance-Based Restricted Stock Units

PSUs represent the right to receive shares of our common stock contingent upon the achievement of certain financial performance measures. We issue new shares of common stock upon the vesting of PSUs.

On August 9, 2024 (the "Initial Vesting Date"), the Board certified that the revenue goal for the PSUs granted on December 23, 2022 ("2022 PSUs") was achieved. Therefore, 50% of the 2022 PSUs were vested and we immediately recognized $0.1 million of stock-based compensation related to this performance metric. The remaining 50% of the 2022 PSUs are all subject to time-based vesting and will vest in full on the one-year anniversary of the Initial Vesting Date.

The following table summarizes our PSU activity for the nine months ended September 30, 2024:

	Performance-Based Restricted Stock Units Outstanding	Weighted-Average Grant Date Fair Value
Balance as of December 31, 2023	196,033	$ 23.23
Granted	177,513	$ 21.23
Vested[(1)]	(98,018)	$ 23.23
Forfeited/Cancelled	—	$ —
Balance as of September 30, 2024	275,528	$ 21.94

(1) The aggregate number of shares withheld upon vesting for employee tax obligations was 30,046 for the nine months ended September 30, 2024.

Retirement Policy

In January 2023, our board of directors approved a retirement policy (the "Retirement Policy") that provides for acceleration of a portion of unvested awards that were granted to certain eligible employees upon meeting age, service and notice requirements. We considered the adoption of the Retirement Policy to be a modification of existing awards under ASC Topic 718**,** *Compensation – Stock Compensation*. The modification did not result in any incremental compensation cost. However, the adoption of the policy resulted in a new estimate of the requisite service period for certain awards, which we reassess at each balance sheet date. In connection with the Retirement Policy, we accelerated the recognition of compensation expense of $0.4 million and $0.5 million during the three months ended September 30, 2024 and 2023, respectively, and accelerated the recognition of compensation expense of $0.8 million and $1.6 million for the nine months ended September 30, 2024 and 2023, respectively.

Employee Stock Purchase Plan

The ESPP provides for certain automatic increases in the number of shares of common stock reserved for issuance, which resulted in an additional 274,105 shares becoming available under the ESPP effective January 1, 2024. During the nine months ended September 30, 2024, we issued 167,688 shares of common stock pursuant to scheduled purchases under the ESPP. As of September 30, 2024, 1,046,680 shares remained available for issuance under the ESPP.

Determining Fair Value - Summary of Assumptions

We use the Black-Scholes option pricing model to estimate the fair value of each option grant on the date of grant or any other measurement date. The following table sets forth the assumptions used to determine the fair value of stock options:

	Nine Months Ended September 30,	
	2024	2023
Average expected term (years)	5.0	5.0
Expected stock price volatility	80.20% - 80.20%	75.57% - 76.01%
Risk-free interest rate	4.39% - 4.39%	3.57% - 3.57%
Dividend yield	—%	—%

The following table sets forth assumptions used to determine the fair value of the purchase rights issued under the ESPP:

	Nine Months Ended September 30,	
	2024	2023
Average expected term (years)	1.2	1.3
Expected stock price volatility	59.85% - 130.95%	93.17% - 130.95%
Risk-free interest rate	3.82% - 5.33%	4.74% - 5.33%
Dividend yield	—%	—%

We use the closing price of our common stock on the date of grant to determine the fair value of RSUs and PSUs.

Stock-Based Compensation Expense

Stock-based compensation expense is included in the unaudited condensed consolidated statements of operations as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Cost of sales (exclusive of amortization of acquired intangible assets)	$ 1,464	$ 1,245	$ 4,179	$ 3,719
Research and development	2,345	2,682	7,611	7,755
Selling, general and administrative	9,218	9,116	27,091	27,943
Total stock-based compensation expense	$ 13,027	$ 13,043	$ 38,881	$ 39,417

For the nine months ended September 30, 2024 and 2023 the weighted-average grant date fair value of stock options granted was $9.23 and $15.99 per option, respectively. For the nine months ended September 30, 2024 and 2023, the weighted-average grant date fair value of the purchase rights granted under the ESPP was $12.28 and $11.51 per share, respectively. As of September 30, 2024, the total unrecognized stock-based compensation cost related to outstanding awards was $77.6 million, which is expected to be recognized over a weighted-average period of 2.2 years. The total unrecognized compensation cost will be adjusted for forfeitures in future periods as they occur.

14. Income Taxes

For the three and nine months ended September 30, 2024, our effective income tax rate was 72.6% and 36.7%, respectively.

For the three months ended September 30, 2024, differences in our effective rate and the federal statutory rate of 21% was due to revisions in estimated pre-tax income, reflecting uncertainty in continued Medicare coverage for our DecisionDx-SCC test and updated information, as well as stock-based compensation, permanent differences, changes in valuation allowance, research and development tax credit and state income taxes. For the nine months ended September 30, 2024, differences in our effective rate and the federal statutory rate of 21% was due to stock-based compensation, permanent differences, changes in valuation allowance, research and development tax credit and state income taxes.

For the three and nine months ended September 30, 2023, our effective income tax rate was immaterial.

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

You should read the following discussion and analysis of financial condition and results of operations together with our unaudited condensed consolidated financial statements and the related notes and other financial information included in this Quarterly Report on Form 10-Q with our audited financial statements and notes thereto as of and for the years ended December 31, 2023 and 2022 and the related Management's Discussion and Analysis of Financial Condition and Results of Operations, including the section entitled "Critical Accounting Estimates," included in our Annual Report on Form 10-K for the year ended December 31, 2023 (the "2023 10-K"), as filed with the Securities and Exchange Commission (the "SEC") on February 28, 2024. Unless the context requires otherwise, references in this Quarterly Report on Form 10-Q to "Castle," "we," "us" and "our" refer to Castle Biosciences, Inc.

Forward-Looking Statements

The information in this discussion contains forward-looking statements and information within the meaning of Section 27A of the Securities Act of 1933, as amended (the "Securities Act"), and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), which are subject to the "safe harbor" created by those sections. These forward-looking statements include, but are not limited to, statements concerning our strategy, future operations, future financial position, future revenues, projected costs, prospects and plans and objectives of management. The words "anticipate," "believe," "estimate," "expect," "may," "plan," "potential," "will," "would" or the negative or plural of these terms or other similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. We may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements and you should not place undue reliance on our forward-looking statements. Actual results or events could differ materially from the plans, intentions or expectations disclosed in the forward-looking statements that we make. These forward-looking statements involve risks and uncertainties that could cause our actual results to differ materially from those in the forward-looking statements, including, without limitation, the risks set forth in Part I, Item 1A, "Risk Factors" in the 2023 10-K,
Part II, Item 1A, "Risk Factors" in this Quarterly Report on Form 10-Q and in our other filings with the SEC. The forward-looking statements are applicable only as of the date on which they are made, and we do not assume any obligation to update any forward-looking statements, except as may be required by law.

Overview

Castle Biosciences is a molecular diagnostics company offering innovative test solutions to aid clinicians in the diagnosis and treatment of dermatologic cancers, Barrett's esophagus ("BE"), uveal melanoma ("UM"), and in the treatment of mental health conditions.

Our Test Portfolio

We currently offer five commercially available proprietary multi-analyte assays with algorithmic analysis ("MAAA") tests for use in the dermatologic, gastroenterology and ocular fields. We also offer a proprietary pharmacogenomics ("PGx") test to guide optimal drug treatment for patients diagnosed with depression, anxiety and other mental health conditions.

Currently, our revenue is primarily generated by our DecisionDx-Melanoma risk stratification test for cutaneous melanoma ("CM"), which is supplemented by revenue generated from our DecisionDx-SCC risk stratification test for cutaneous squamous cell carcinoma ("SCC"), our TissueCypher risk stratification test for BE and our DecisionDx-UM risk stratification test for UM.

All five of our MAAA tests have been granted Advanced Diagnostic Laboratory Test ("ADLT") status by the Centers for Medicare & Medicaid Services ("CMS") which means each test has demonstrated that (i) when combined with an empirically derived algorithm, it yields a result that predicts the probability a specific individual patient will develop a certain condition or conditions, or will respond to a particular therapy or therapies; and (ii) it provides new clinical diagnostic information that cannot be obtained from any other test or combination of tests. We believe this designation not only demonstrates our focus on developing and validating innovative tests but also enables our Medicare reimbursement rate to be set, over the long term, by the median private payor rate, which we believe provides a fair exchange of value. Further information about Medicare coverage and ADLT status with respect to each of our tests is set forth below.

Test Overview

Our Dermatologic Tests

DecisionDx-Melanoma is our proprietary risk stratification gene expression profile ("GEP") test that is designed to predict the risk of metastasis or recurrence for patients diagnosed with invasive CM. In a typical year, we estimate approximately 130,000 patients are diagnosed with invasive CM in the United States, representing an estimated

U.S. total addressable market ("TAM") of approximately $540 million. We estimate that approximately 50% of patients diagnosed with CM are 65 years of age or older.

DecisionDx-SCC is our proprietary GEP test for use in patients with SCC, with one or more risk factors (also referred to as "high-risk" SCC). We estimate that 20% of SCC patients, or 200,000 annually in the United States, are classified as high risk, representing an estimated U.S. TAM of approximately $820 million.

MyPath Melanoma is our proprietary GEP test for use in patients with a melanocytic lesion and uncertainty related to the malignancy of the lesion. We estimate approximately 300,000 patients each year present with a diagnostically ambiguous lesion, representing an estimated U.S. TAM of approximately $600 million. We began offering MyPath Melanoma following our acquisition of the Myriad MyPath Laboratory in May 2021 at which point we offered both our MyPath Melanoma test and our DiffDx-Melanoma test under an offering that we referred to as our Diagnostic GEP offering. However, following an internal assessment of the clinical value of offering both tests, we made the decision to suspend the clinical offering of DiffDx-Melanoma in February 2023 and now the focus of this offering is MyPath Melanoma.

Our Gastroenterology Test

TissueCypher is our proprietary risk stratification spatial omics test designed to predict future development of high-grade dysplasia and/or esophageal cancer in patients with non-dysplastic, indefinite dysplasia or low-grade dysplasia BE. We estimate a U.S. TAM of approximately $1 billion.

Our Uveal Melanoma Test

DecisionDx-UM is a proprietary, risk stratification GEP test that is designed to predict the risk of metastasis for patients with UM. We believe DecisionDx-UM is the standard of care in the management of newly diagnosed UM in the majority of ocular oncology practices in the United States. We estimate a U.S. TAM of approximately $10 million.

Our Mental Health Test

IDgenetix is a PGx test that guides personalized mental health medication selection and management for patients with depression, anxiety and other mental health conditions. We estimate a U.S. TAM of approximately $5 billion.

Commercial Expansion Efforts

In September 2022, we established a new commercial sales team dedicated to our Diagnostic GEP offering and added additional outside territories for our TissueCypher test, which were fully integrated into our commercial operations by the end of the second quarter of 2023.

During the year ended December 31, 2023, we continued to expand our dermatologic and gastrointestinal commercial sales forces through territory and headcount expansions with focus being on our DecisionDx-Melanoma, DecisionDx-SCC, and TissueCypher tests.

During the nine months ended September 30, 2024, we further expanded our sales and marketing team for our TissueCypher test. We will continue to assess market response in determining further commercial expansions and commercial team structure.

Reimbursement

The primary source of revenue for our products is reimbursement from third-party payors, which includes government payors, such as Medicare, and commercial payors, such as insurance companies. Achieving broad coverage and reimbursement of our current products by third-party payors and continued Medicare coverage are key components of our financial success.

We bill third-party payors and patients for the tests we perform. We have received Medicare coverage for our DecisionDx-Melanoma, DecisionDx-SCC, MyPath Melanoma, DecisionDx-UM, TissueCypher and IDgenetix tests which meet certain criteria for Medicare and Medicare Advantage beneficiaries.

The Medicare rates discussed below are prior to giving effect to applicable sequestration in effect from time to time as described in further detail under "Government Regulation and Product Approval—Healthcare Reform" included in Item 1, Business, of the 2023 10-K.

DecisionDx-Melanoma

DecisionDx-Melanoma tests are processed from our Phoenix laboratory and since the second quarter of 2022, have been covered under "foundational" local coverage determinations ("LCD") finalized by Medicare Administrative Contractors ("MACs") Palmetto GBA MolDX ("Palmetto") and Noridian Health Solutions ("Noridian").

DecisionDx-Melanoma has met ADLT status, as determined by the CMS, since 2019. Since 2022, the rate for DecisionDx-Melanoma is set annually based upon the median private payor rate for the first half of the second preceding calendar year. For example, the rate for 2023 was set using median private payor rate data from January 1, 2021 to June 30, 2021. Our rate for 2023 was $7,193 per test and is $7,193 for 2024.

DecisionDx-UM

DecisionDx-UM tests are processed from our Phoenix laboratory and are covered under LCDs finalized by MAC administrators Palmetto and Noridian in July 2017.

DecisionDx-UM has met the criteria of "existing advanced diagnostic laboratory test" status, also referred to as "existing ADLT" status, as determined by the CMS, since May 2019. Our rate is set annually based upon the median private payor rate for the first half of the second preceding calendar year. For example, the rate for 2023 was set using median private payor rate data from January 1, 2021 to June 30, 2021. Our rate for 2023 was $7,776 per test and is $7,776 for 2024.

MyPath Melanoma and DiffDx-Melanoma

MyPath Melanoma was covered under a test-specific LCD policy through Noridian that became effective in June 2019. Effective August 6, 2023, Palmetto and Noridian issued LCDs that converted the test-specific MyPath Melanoma LCD to a "foundational" LCD and provided coverage for both MyPath Melanoma and DiffDx-Melanoma.

MyPath Melanoma was approved as a "new ADLT" in September 2019. The rate for our MyPath Melanoma test is set annually based upon the median private payor rate for the first half of the second preceding calendar year. Our 2023 rate was set at $1,755 per test, based on data submitted by the predecessor owner of the Myriad MyPath Laboratory relating to the first half of 2021. Our 2024 rate is set at $1,950 per test.

In the second quarter of 2022, we obtained a Proprietary Laboratory Analyses ("PLA") code for DiffDx-Melanoma. In 2023, DiffDx-Melanoma went through the CMS gapfill process which concluded in September 2023 with CMS posting a final MAC-specific gapfill rate of $1,950 per test. Our rate for 2024 is $1,950 per test.

Diagnostic GEP Offering

Our Diagnostic GEP offering included MyPath Melanoma and DiffDx-Melanoma. We began offering MyPath Melanoma following our acquisition of the Myriad MyPath Laboratory on May 28, 2021. Our internal data indicates that we have improved the technical performance of MyPath Melanoma and that it is comparable to the technical performance of DiffDx-Melanoma. As such, following an internal assessment of the clinical value of offering both tests, we made the decision to suspend the clinical offering of DiffDx-Melanoma in February 2023.

DecisionDx-SCC

We issue our DecisionDx-SCC tests from our Pittsburgh and Phoenix labs, with a majority of tests being issued from our Pittsburgh lab.

On June 2, 2023, Novitas Solutions ("Novitas"), the MAC responsible for administering claims for test reports issued by our Pittsburgh laboratory, posted a finalized oncology biomarker LCD pursuant to which the DecisionDx-SCC test would no longer be covered by Medicare effective July 17, 2023. However, on July 6, 2023, Novitas suspended the final version of the LCD and announced its intent to post a new proposed LCD for comment and presentation at an open meeting. On July 27, 2023, Novitas posted a nearly identical proposed oncology biomarker LCD that continues to intend to rely upon evidentiary reviews sourced from three databases: ClinGen, OncoKB and NCCN. The proposed LCD also recommends non-coverage for our DecisionDx-SCC test. The comment period for the proposed LCD ended on September 9, 2023. On July 26, 2024, Novitas posted a note that it had been granted an extension by CMS. We cannot predict whether this LCD will be finalized as proposed or what the timing of any final LCD might be.

Palmetto's MolDX program oversees MAAA tests that are reported from our Phoenix laboratory and Noridian is the MAC responsible for administering claims for test reports issued by our Phoenix laboratory. On June 8, 2023, both Palmetto and Noridian posted a preliminary draft LCD recommending no coverage for DecisionDx-SCC. The comment period for the draft LCDs ended on July 22, 2023. On July 4, 2024, the LCD was finalized as proposed with a future effective date of August 18, 2024.

DecisionDx-SCC was reimbursed at a rate of $3,873 per test under a PLA code from second quarter of 2022 through June 30, 2023 when CMS determined DecisionDx-SCC meets the criteria for “new ADLT” status. Effective July 1, 2023 and through March 31, 2024, CMS set the initial period rate equal to the list price of $8,500 per test. Effective April 1, 2024 and through December 31, 2025, the published CLFS rate for DecisionDx-SCC will be based on the median private payor rates received between July 1, 2023 and November 30, 2023. We submitted the median private payor data to CMS during the data reporting period in December 2023. Effective April 1, 2024, the updated CLFS rate will continue at $8,500 through December 31, 2025. Future rates will be set annually based upon the median private payor rate for the first half of the second preceding calendar year. ADLT status determines the process by which the rate is set and is not an indication of Medicare coverage.

TissueCypher

TissueCypher is processed in our Pittsburgh laboratory and falls under the Medicare jurisdiction managed by Novitas.

On March 24, 2022, CMS determined that TissueCypher meets the criteria for “new ADLT” status. ADLT status exempts TissueCypher from what is called the “14-day rule,” which simplifies the billing process for Medicare patients. Effective January 1, 2023, the published CLFS rate for TissueCypher was set at $4,950 per test, which will remain effective through December 31, 2024. This rate is based on the median private payor rates received between April 1, 2022 and August 31, 2022. Thereafter, the rate will be set annually based upon the median private payor rate for the first half of the second preceding calendar year.

IDgenetix

IDgenetix is currently covered under a Noridian LCD policy and accompanying billing and coding article developed by MolDX.

Our IDgenetix multi-gene panel was reimbursed by Medicare at approximately $1,500 per test from April 2022 through February 2023, when MolDX notified us that as part of its annual CPT code updates, IDgenetix should shift billing to a different generic gene sequencing CPT code (the “New CPT Code”) and continue using the IDgenetix Z-Code beginning in March 2023. The New CPT Code was set at $917 per test while the test went through CMS’s Gapfill pricing process. We believed the new CPT Code, in conjunction with the IDgenetix Z-Code, did not describe all of the components of the IDgenetix test and thus, was not appropriate for IDgenetix. We subsequently obtained a test-specific PLA CPT code which became effective October 1, 2023. In November 2023, CMS posted its final CLFS determination which crosswalks our PLA CPT code to an existing PLA code at a rate of $1,336 per test effective January 1, 2024.

Government Regulation and Oversight of Laboratory Developed Tests

On April 29, 2024, the U.S. Food and Drug Administration (“FDA”) published a final rule on the regulation of Laboratory Developed Tests (“LDTs”) which amends the FDA's regulations to make explicit that LDT's are devices under the Federal Food, Drug, and Cosmetic Act (“FD&C Act”). The FDA issued a policy to phase out, over the course of four years, its general enforcement discretion approach to LDTs and also issued targeted enforcement discretion policies for certain categories of LDTs. The FDA is continuing enforcement discretion for currently marketed tests offered as LDTs (that were first marketed before May 6, 2024) that are approved by the New York State Department of Health Clinical Laboratory Evaluation Program (“NYS CLEP”). Our proprietary tests, outlined above, are all NYS CLEP approved. We believe this final ruling will have no material impact on our existing test offerings given all of our tests were marketed before May 6, 2024.

Delivered Test Reports

The number of test reports we deliver is a key indicator that we use to assess our business. A test report is generated when we receive a sample in our laboratory, and then the relevant test information is entered into our Laboratory Information Management System, the laboratory portion of the test is performed, including proprietary algorithmic analysis of the combined biomarkers, and a report is then generated which is delivered to the clinician who ordered the test.

The number of test reports delivered by us during the nine months ended September 30, 2024 and 2023 and for the year ended December 31, 2023 are presented in the table below:

	Proprietary Dermatologic GEP Tests							
	DecisionDx-Melanoma	DecisionDx-SCC	Diagnostic GEP offering [1]	Dermatologic Total	DecisionDx-UM	TissueCypher[2]	IDgenetix	Grand Total
Q1 2024	8,384	3,577	998	12,959	422	3,429	4,078	20,888
Q2 2024	9,585	4,277	1,099	14,961	456	4,782	4,903	25,102
Q3 2024	9,367	4,195	933	14,495	397	6,073	5,045	26,010
For the nine months ended September 30, 2024	27,336	12,049	3,030	42,415	1,275	14,284	14,026	72,000
Q1 2023	7,583	2,411	980	10,974	409	1,383	2,150	14,916
Q2 2023	8,597	2,681	953	12,231	461	1,447	2,681	16,820
Q3 2023	8,559	2,820	1,011	12,390	399	2,829	2,791	18,409
For the nine months ended September 30, 2023	24,739	7,912	2,944	35,595	1,269	5,659	7,622	50,145
Q4 2023	8,591	3,530	1,018	13,139	405	3,441	3,299	20,284
For year ended December 31, 2023	33,330	11,442	3,962	48,734	1,674	9,100	10,921	70,429

(1) Includes MyPath Melanoma and DiffDx-Melanoma. We offered both MyPath Melanoma and DiffDx-Melanoma under our Diagnostic GEP offering until February 2023 when we suspended the offering of DiffDx-Melanoma, as discussed above.

(2) We temporarily paused accepting additional orders in July 2023, resumed accepting new orders in a phased approach in September 2023, and completed processing of our pre-existing backlog orders in October 2023. We have continued accepting new orders since September 2023.

For the three and nine months ended September 30, 2024, our test report volume increased by 41.3% and 43.6%, respectively, compared to the same period in 2023. Our dermatologic test report volume increased by 17% and 19.2% for the three and nine months ended September 30, 2024, respectively, compared to the prior period in 2023. For the nine months ended September 30, 2024, we have experienced higher test report volumes for all of our tests compared to the prior period in 2023. For a discussion of how we recognize revenue derived from our tests, refer to — “Components of Results of Operations—Net Revenues” below.

In August 2024, we amended our Pittsburgh commercial real estate lease to add 23,821 square feet to our existing facilities, most of which will be used as dedicated lab space for processing our TissueCypher test. As of September 30, 2024, substantially all leasehold improvements for this added space were complete and the added lab space was ready for use. We expect the additional space will allow us to continue developing our business through our TissueCypher product line.

For our DecisionDx-SCC product line, we continue to see opportunities for leverage, where many of the clinicians ordering our DecisionDx-Melanoma are the same clinicians who order our DecisionDx-SCC test. During each of the nine months ended September 30, 2024 and 2023, approximately 75% of all clinicians ordering DecisionDx-SCC had also ordered our DecisionDx-Melanoma test during that same period.

Information About Certain Metrics

The following provides additional information about certain metrics we have disclosed in this Management’s Discussion and Analysis of Financial Condition and Results of Operations.

Test Reports Delivered

Test reports delivered represent the number of completed test reports delivered by us during the reporting period indicated. The period in which a test report is delivered does not necessarily correspond with the period in which the related revenue, if any, is recognized, due to the timing and amount of adjustments for variable consideration under Accounting Standards Codification (“ASC”) Topic 606, *Revenue from Contracts with Customers* (“ASC 606”). We

use this metric to evaluate the growth in adoption of our tests and to measure against our internal performance objectives. We believe this metric is useful to investors in evaluating the volume of our business activity from period-to-period that may not be discernible from our reported revenues under ASC 606.

Other Events

Impact of Macroeconomic Conditions

Macroeconomic conditions, including uncertainties associated with the Israel-Hamas war, the ongoing conflict between Ukraine and Russia, the U.S. presidential election, economic slowdowns, public health crises, labor shortages, recessions or market corrections, supply chain disruptions, inflation and monetary policy shifts, liquidity concerns at, and failures of, banks and other financial institutions or other disruptions in the banking system or financing markets, changes to interest rates and financial and credit market fluctuations, volatility in the capital markets and other evolving macroeconomic developments, continue to have direct and indirect impacts on our business and could in the future materially impact our results of operations and financial condition. We continue to actively monitor the impact of these macroeconomic factors on our results of operations, financial condition and cash flows. The extent of the impact of these factors on our operational performance and financial condition, including our ability to execute our business strategies and initiatives in the expected timeframe, will depend on future developments, which are uncertain and cannot be predicted; however, any continued or renewed disruption resulting from these factors could negatively impact our business.

Our Financial Results

Our net income may fluctuate significantly from period to period, depending on the timing of our planned development activities, the growth of our sales and marketing activities and the timing of revenue recognition under ASC 606. We expect our expenses will increase substantially over time as we:

- execute clinical studies to generate evidence supporting our current and future product candidates;
- execute our commercialization strategy for our current and future commercial products;
- continue our ongoing and planned development of new products in our pipeline;
- seek to discover and develop additional product candidates;
- hire additional scientific and research and development staff; and
- add additional operational, financial and management information systems and personnel.

Factors Affecting Our Performance

We believe there are several important factors that have impacted, and that we expect will continue to impact, our operating performance and results of operations, including:

- **Report volume.** We believe that the number of reports we deliver to clinicians is an important indicator of the growth of adoption among the healthcare provider community. Our revenue and costs are affected by the volume of testing and mix of customers. Our performance depends on our ability to retain and broaden adoption with existing prescribing clinicians, as well as attract new clinicians. Our report volume could be negatively impacted by developments related to evolving macroeconomic developments, as discussed above.
- **Reimbursement.** We believe that expanding reimbursement is an important indicator of the value of our products. Payors require extensive evidence of clinical utility, clinical validity, patient outcomes and health economic benefits in order to provide reimbursement for diagnostic products. Our revenue depends on our ability to demonstrate the value of our products to these payors.
- **Gross margin.** We believe that our gross margin is an important indicator of the operating performance of our business. Higher gross margins reflect the average selling price of our tests, as well as the operating efficiency of our laboratory operations.
- **Expansion of our sales force and marketing programs.** We believe the expansion of our direct sales force and marketing organization to educate clinicians and pathologists on the value of our molecular testing products will significantly impact our performance.
- **Integrating acquisitions.** Revenue growth, operational results and advances to our business strategy depends on our ability to integrate any acquisitions into our existing business and effectively scale their operations. The integration of acquired assets may impact our revenue growth, increase the cost of

operations or may require management resources that otherwise would be available for ongoing development of our existing business.

- **New product development.** A significant aspect of our business is our investment in research and development activities, including activities related to the development of new products. In addition to the development of new product candidates, we believe these studies are critical to gaining clinician adoption of new products and driving favorable coverage decisions by payors for such products.

Components of the Results of Operations

Net Revenues

We generate revenues from the sale of our products. Currently, our revenues are primarily derived from the sale of DecisionDx-Melanoma, DecisionDx-SCC, TissueCypher and DecisionDx-UM. We bill third-party payors and patients for the tests we perform.

Under ASC 606, we recognize revenue at the amount we expect to be entitled, subject to a constraint for variable consideration, in the period in which our tests are delivered to the treating clinicians. We have determined that our contracts contain variable consideration under ASC 606 because the amounts paid by third-party payors may be paid at less than our standard rates or not paid at all, with such differences considered implicit price concessions. Variable consideration is recognized only to the extent it is probable that a significant reversal of revenue will not occur in future periods when the uncertainties are resolved. Variable consideration is evaluated each reporting period and adjustments are recorded as increases or decreases in revenues. Variable consideration for Medicare claims that are not covered by Medicare, including those claims undergoing appeal, is deemed to be fully constrained due to factors outside our influence (e.g., judgment or actions of third parties) and the uncertainty of the amount to be received is not expected to be resolved for a long period of time. For these fully constrained claims, we generally recognize revenue in the period the uncertainty is favorably resolved, if at all. Due to potential future changes in Medicare coverage policies and appeal cycles, insurance coverage policies, contractual rates and other trends in the reimbursement of our tests, our revenues may fluctuate significantly from period to period. Our ability to recognize revenue for a test is dependent on the development of reimbursement experience and obtaining coverage decisions. For tests with limited reimbursement experience or no coverage, we recognize revenues on the basis of actual cash collections.

Our ability to increase our revenues will depend on our ability to further penetrate our target markets, and, in particular, generate sales through our direct sales force, maintain Medicare coverage for our currently marketed products, develop and commercialize additional tests, including through acquisitions, obtain reimbursement from additional third-party payors and increase our reimbursement rate for tests performed.

Cost of Sales (exclusive of amortization of acquired intangible assets)

The components of our cost of sales are material and service costs associated with testing samples, personnel costs (including salaries, bonuses, benefits and stock-based compensation expense), electronic medical record set up costs, order and delivery systems, shipping charges to transport samples, third-party test fees, and allocated overhead including rent, information technology costs, equipment and facilities depreciation and utilities. Costs associated with testing samples are recorded when the test is processed regardless of whether and when revenues are recognized with respect to that test. As a result, our cost of sales as a percentage of revenues may vary significantly from period to period because we do not recognize all revenues in the period in which the associated costs are incurred. We expect cost of sales in absolute dollars to increase as the number of tests we perform increases. Additionally, we expect cost of sales to increase with the expansion of laboratory capacity and staffing in advance of the anticipated growth of our more recently launched tests and tests acquired through acquisitions. For example, we commenced operations in a newly expanded laboratory facility in Pittsburgh, Pennsylvania in the second quarter of 2023 and subsequently amended the lease in August of 2024, adding 23,821 square feet to our existing facilities.

Gross margin and gross margin percentage are key indicators we use to assess our business. See the table in “—Results of Operations—Comparison of the Three Months Ended September 30, 2024 and 2023” and “—Results of Operations—Comparison of the Nine Months Ended September 30, 2024 and 2023” for details.

Research and Development

Research and development expenses include costs incurred to develop our tests, collect clinical samples and conduct clinical studies to develop and support our products. These costs consist of personnel costs (including salaries, bonuses, benefits and stock-based compensation expense), prototype materials, laboratory supplies, consulting costs, regulatory costs, electronic medical records set up costs, costs associated with setting up and

conducting clinical studies and allocated overhead, including rent, information technology, equipment depreciation and utilities. We expense all research and development costs in the periods in which they are incurred. We expect our research and development expenses to increase in absolute dollars as we continue to invest in research and development activities related to developing enhanced and new products.

We expect to use a portion of our cash and cash equivalents and marketable investment securities to further support and accelerate our research and development activities, including important studies that are underway to support our DecisionDx-Melanoma test. For instance, in February 2023, we announced the publication of data from the DECIDE study presenting DecisionDx-Melanoma test results influenced 85% of clinicians' decisions regarding the SLNB surgical procedure. Additionally, use of the tests' results within current guideline recommendations led to a significant reduction in SLNB procedures performed, demonstrating the clinical value of the test to guide risk-aligned patient care. Also, in 2021, we initiated our large prospective, multi-center clinical study to develop, validate and bring to market a pipeline genomic test, or tests, aimed at predicting response to systemic therapy in patients with moderate to severe psoriasis, atopic dermatitis and related inflammatory skin conditions. Since December 31, 2023, we continue to maintain active clinical study test sites and a consistent number of patients enrolled in this study. Assuming we are successful in validating a genomic test, or tests, for one or more of these uses, then we expect to launch this pipeline test by the end of 2025.

Selling, General and Administrative

Selling, general and administrative ("SG&A") expenses include executive, selling and marketing, legal, finance and accounting, human resources and billing functions. These expenses consist of personnel costs (including salaries, bonuses, benefits and stock-based compensation expense), direct marketing expenses, audit and legal expenses, consulting costs, payor outreach programs and allocated overhead, including rent, information technology, equipment depreciation, and utilities. Other administrative and professional services expenses within SG&A are expected to increase with the scale of our business, but selling and marketing-related expenses are expected to increase significantly, consistent with our growth strategy.

Amortization of Acquired Intangible Assets

Amortization of acquired intangible assets is primarily associated with developed technology obtained through acquisitions, such as our acquisitions of Cernostics in December 2021 and AltheaDx in April 2022.

Interest Income

Interest income consists primarily of earnings on cash and cash equivalents, primarily money market funds, and marketable investment securities, primarily short-term U.S. government obligations.

Interest Expense

Interest expense is primarily attributable to long-term debt and finance leases.

Income Tax Expense

Revisions in our estimate of annual pre-tax income, relating to uncertainty in continued Medicare coverage for our DecisionDx-SCC test and updated information, are sources of variability in our effective tax rates from period to period. As of December 31, 2023, we had federal net operating loss ("NOL") carryforwards of $197.1 million, of which $92.0 million will begin to expire in 2029 if not utilized to offset federal taxable income, and $105.1 million may be carried forward indefinitely. As of December 31, 2023, we also had state NOL carryforwards of $114.3 million, which begin to expire in 2028 if not utilized to offset state taxable income.

Results of Operations

Comparison of the Three Months Ended September 30, 2024 and 2023

The following table summarizes our results of operations for the periods indicated (in thousands, except percentages):

	Three Months Ended September 30,			
	2024	2023	Change	
	(unaudited)			
Net revenues	$ 85,782	$ 61,493	$ 24,289	39.5 %
Operating expenses				
Cost of sales (exclusive of amortization of acquired intangible assets)	15,609	11,319	4,290	37.9 %
Research and development	12,323	12,923	(600)	(4.6)%
Selling, general and administrative	50,499	44,619	5,880	13.2 %
Amortization of acquired intangible assets	2,272	2,272	—	— %
Total operating expenses, net	80,703	71,133	9,570	13.5 %
Operating income (loss)	5,079	(9,640)	14,719	152.7 %
Interest income	3,404	2,769	635	22.9 %
Interest expense	(201)	(2)	(199)	NM
Income (loss) before income taxes	8,282	(6,873)	15,155	220.5 %
Income tax expense	6,013	32	5,981	NM
Net income (loss)	$ 2,269	$ (6,905)	$ 9,174	132.9 %

NM = Not meaningful

The following table indicates the amount of stock-based compensation expense (non-cash) reflected in the line items above (in thousands):

	Three Months Ended September 30,		
	2024	2023	Change
	(unaudited)		
Cost of sales (exclusive of amortization of acquired intangible assets)	$ 1,464	$ 1,245	$ 219
Research and development	2,345	2,682	(337)
Selling, general and administrative	9,218	9,116	102
Total stock-based compensation expense	$ 13,027	$ 13,043	$ (16)

The following table provides a disaggregation of net revenues by type (in thousands):

	Three Months Ended September 30,		
	2024	2023	Change
	(unaudited)		
Dermatologic[1]	$ 65,060	$ 51,151	$ 13,909
Non-Dermatologic[2]	20,722	10,342	10,380
Total net revenues	$ 85,782	$ 61,493	$ 24,289

(1) Consists of DecisionDx-Melanoma, DecisionDx-SCC and our Diagnostic GEP offering.
(2) Consists of TissueCypher, DecisionDx-UM and IDgenetix.

The following table presents the calculation of gross margin (in thousands, except percentages):

	Three Months Ended September 30,		
	2024	2023	Change
	(unaudited)		
Net revenues	$ 85,782	$ 61,493	$ 24,289
Less: Cost of sales (exclusive of amortization of acquired intangible assets)	15,609	11,319	4,290
Less: Amortization of acquired intangible assets	2,272	2,272	—
Gross margin	$ 67,901	$ 47,902	$ 19,999
Gross margin percentage	79.2 %	77.9 %	1.3 %

Net Revenues

Net revenues for the three months ended September 30, 2024 increased by $24.3 million, or 39.5%, to $85.8 million compared to the three months ended September 30, 2023, due to a $13.9 million increase in revenue from our dermatologic tests and a $10.4 million increase in revenue from our non-dermatologic tests.

The $13.9 million increase in net revenues for our Dermatologic tests was primarily attributable to our DecisionDx-SCC test, which was due to higher test report volumes and a higher realized average selling price (“ASP”), as well our DecisionDx-Melanoma test which had higher test report volumes though a slightly lower ASP. For the three months ended September 30, 2024 compared to the three months ended September 30, 2023, test report volumes for our DecisionDx-SCC and DecisionDx-Melanoma tests increased by 48.8% and 9.4%, respectively. Increases in realized ASP for our DecisionDx-SCC test were primarily attributable to an increase in our Medicare reimbursement rate for this test, beginning in July 2023.

The $10.4 million increase in net revenues from our non-dermatologic tests was largely attributable to a 114.7% increase in test report volumes for our TissueCypher test, and, to a lesser extent, to our IDgenetix test which also had higher test report volumes. Increases in our TissueCypher test report volumes reflect growth through our sales force efforts as well as the impacts of a temporary pause in accepting new orders from July 2023 through September 2023, during which time our lab operations team successfully implemented certain process improvements, automations, and operational enhancements for this test to support future growth. Net revenue from our non-dermatologic tests as a percentage of total net revenue increased from 16.8% for the three months ended September 30, 2023 to 24.2% for the three months ended September 30, 2024.

Cost of Sales (exclusive of amortization of acquired intangible assets)

Cost of sales (exclusive of amortization of acquired intangible assets) for the three months ended September 30, 2024 increased by $4.3 million, or 37.9%, compared to the three months ended September 30, 2023, primarily due to higher personnel costs and higher expense for supplies and lab services. Increases in personnel costs reflect a higher headcount, due to additions made to support business growth in response to growing test report volumes, as well as merit and annual inflationary wage adjustment for existing employees. Higher expense for supplies and lab services also reflects higher test report volumes.

Due to the nature of our business, a significant portion of our cost of sales expenses represents fixed costs associated with our testing operations. Accordingly, our cost of sales expense will not necessarily increase or decrease commensurately with the change in net revenues from period to period. We expect our cost of sales expenses (exclusive of amortization of acquired intangible assets) to continue to increase in future periods as we hire additional laboratory personnel and related resources to support expected operational growth and higher test volumes.

Gross Margin

Our gross margin percentage was 79.2% for the three months ended September 30, 2024, compared to 77.9% for the same period in 2023. The increase was primarily due to higher revenues which were attributable to increases in both test report volumes and average selling prices, partially offset by higher personnel costs, higher expense for supplies, and higher expense incurred through our expanded laboratory capacity and higher test report volumes.

Research and Development

Research and development expenses decreased by $0.6 million, or 4.6%, for the three months ended September 30, 2024, compared to the three months ended September 30, 2023, and primarily reflect slightly lower expense for clinical studies and personnel costs.

We expect to continue incurring research and development expenses through our continued investments in our ongoing pipeline initiatives and as we seek opportunities to build evidentiary support and new tests where commercial opportunities exist.

Selling, General and Administrative

The following table provides a breakdown of SG&A expenses (in thousands):

	Three Months Ended September 30,		
	2024	2023	Change
	(unaudited)		
Sales and marketing	$ 29,835	$ 28,496	$ 1,339
General and administrative	20,664	16,123	4,541
Total selling, general and administrative expense	$ 50,499	$ 44,619	$ 5,880

Sales and marketing expenses increased by $1.3 million, or 4.7%, for the three months ended September 30, 2024, compared to the three months ended September 30, 2023, primarily reflecting higher travel and transportation costs incurred through our business development activities as well as slightly higher marketing costs and relatively consistent personnel costs. Stock-based compensation expense included in sales and marketing was $4.0 million for the three months ended September 30, 2024, compared to $4.4 million for the three months ended September 30, 2023.

General and administrative expenses increased by $4.5 million, or 28.2%, for the three months ended September 30, 2024, compared to the three months ended September 30, 2023, and was primarily due to higher personnel costs, higher professional fees and higher information technology related costs. Higher personnel cost reflects headcount expansions in our administrative support functions as well as merit and annual inflationary wage adjustment for existing employees. Stock-based compensation expense included in general and administrative expense was $5.2 million for the three months ended September 30, 2024, compared to $4.7 million for the three months ended September 30, 2023.

Amortization of Acquired Intangible Assets

Amortization of acquired intangible assets for the three months ended September 30, 2024 was $2.3 million and remains consistent as compared to the three months ended September 30, 2023.

Interest Income

Interest income increased by $0.6 million for the three months ended September 30, 2024, compared to the three months ended September 30, 2023, primarily as a result of higher average balances of marketable investment securities and slightly higher interest rates.

Interest Expense

Interest expense increased by $0.2 million for the three months ended September 30, 2024, compared to the three months ended September 30, 2023, primarily due to interest incurred on our long-term debt where we had no debt outstanding during the comparative period.

Income Tax Expense

Income tax expense was $6.0 million for the three months ended September 30, 2024 and was due to revisions in estimated pre-tax income, reflecting uncertainty in continued Medicare coverage for our DecisionDx-SCC test and updated information, as well as stock-based compensation, permanent differences, changes in valuation allowance, research and development tax credit and state income taxes. We recorded a minimal amount in income tax expense for the three months ended September 30, 2023.

Stock-Based Compensation Expense

Stock-based compensation expense, which is allocated among cost of sales, research and development expense and SG&A expense, was $13.0 million for the three months ended September 30, 2024 and 2023, respectively. We expect material increases in stock-based compensation expense in future periods, attributable to both existing awards outstanding and anticipated additional grants to our current and future employees. As of September 30, 2024, we had 710 employees, compared to 587 as of September 30, 2023. As of September 30, 2024, the total unrecognized stock-based compensation cost related to outstanding awards was $77.6 million, which is expected to be recognized over a weighted-average period of 2.2 years.

Comparison of the Nine Months Ended September 30, 2024 and 2023

The following table summarizes our results of operations for the periods indicated (in thousands, except percentages):

	Nine Months Ended September 30,			
	2024	2023	Change	
	(unaudited)			
Net revenues	$ 245,758	$ 153,668	$ 92,090	59.9 %
Operating expenses				
Cost of sales (exclusive of amortization of acquired intangible assets)	44,022	32,559	11,463	35.2 %
Research and development	40,268	40,624	(356)	(0.9)%
Selling, general and administrative	150,082	136,062	14,020	10.3 %
Amortization of acquired intangible assets	6,766	6,742	24	0.4 %
Total operating expenses, net	241,138	215,987	25,151	11.6 %
Operating income (loss)	4,620	(62,319)	66,939	107.4 %
Interest income	9,544	7,504	2,040	27.2 %
Interest expense	(485)	(9)	(476)	NM
Income (loss) before income taxes	13,679	(54,824)	68,503	125.0 %
Income tax expense	5,024	62	4,962	NM
Net income (loss)	$ 8,655	$ (54,886)	$ 63,541	115.8 %

NM = Not meaningful

The following table indicates the amount of stock-based compensation expense (non-cash) reflected in the line items above (in thousands):

	Nine Months Ended September 30,		
	2024	2023	Change
	(unaudited)		
Cost of sales (exclusive of amortization of acquired intangible assets)	$ 4,179	$ 3,719	$ 460
Research and development	7,611	7,755	(144)
Selling, general and administrative	27,091	27,943	(852)
Total stock-based compensation expense	$ 38,881	$ 39,417	$ (536)

The following table provides a disaggregation of net revenues by type (in thousands):

	Nine Months Ended September 30,		
	2024	2023	Change
	(unaudited)		
Dermatologic[1]	$ 193,223	$ 130,097	$ 63,126
Non-Dermatologic[2]	52,535	23,571	28,964
Total net revenues	$ 245,758	$ 153,668	$ 92,090

(1) Consists of DecisionDx-Melanoma, DecisionDx-SCC and our Diagnostic GEP offering.
(2) Consists of TissueCypher, DecisionDx-UM and IDgenetix.

The following table presents the calculation of gross margin (in thousands, except percentages):

	Nine Months Ended September 30,		
	2024	2023	Change
	(unaudited)		
Net revenues	$ 245,758	$ 153,668	$ 92,090
Less: Cost of sales (exclusive of amortization of acquired intangible assets)	44,022	32,559	11,463
Less: Amortization of acquired intangible assets	6,766	6,742	24
Gross margin	$ 194,970	$ 114,367	$ 80,603
Gross margin percentage	79.3 %	74.4 %	4.9 %

Net Revenues

Net revenues for the nine months ended September 30, 2024 increased by $92.1 million, or 59.9%, to $245.8 million compared to the nine months ended September 30, 2023, due to a $63.1 million increase in revenue from our dermatologic tests and a $29.0 million increase in revenue from our non-dermatologic tests.

The $63.1 million increase from our dermatologic tests was primarily due to a higher ASP for DecisionDx-SCC test, where we began receiving Medicare reimbursement at a higher rate beginning in July 2023, a 52.3% increase in DecisionDx-SCC test report volumes, and a 10.5% increase in DecisionDx-Melanoma test report volumes.

The $29.0 million increase in revenue from our non-dermatologic tests was largely attributable to a 152% increase in tests report volumes for our TissueCypher test, and, to a much lesser extent, a higher realized ASP. Increases in our TissueCypher test report volumes reflect growth through our sales force efforts as well as the impacts of a temporary pause in accepting new orders from July 2023 through September 2023, during which time our lab operations team successfully implemented certain process improvements, automations, and operational enhancements for this test to support future growth. Our IDgenetix and DecisionDx-UM tests also contributed to the increase in non-dermatologic revenues, with both tests having higher test report volumes as well as higher ASPs. Net revenue from our non-dermatologic tests as a percentage of total net revenue increased from 15.3% for the nine months ended September 30, 2023 to 21.4% for the nine months ended September 30, 2024.

Cost of Sales (exclusive of amortization of acquired intangible assets)

Cost of sales (exclusive of amortization of acquired intangible assets) for the nine months ended September 30, 2024 increased by $11.5 million, or 35.2%, compared to the nine months ended September 30, 2023, primarily due to higher personnel costs and expense for supplies and lab services. Increases in personnel costs reflect a higher headcount, due to additions made to support business growth in response to growing test report volumes, as well as merit and annual inflationary wage adjustment for existing employees. Higher expense for supplies and lab services also reflects higher test report volumes.

Due to the nature of our business, a significant portion of our cost of sales expenses represents fixed costs associated with our testing operations. Accordingly, our cost of sales expense will not necessarily increase or decrease commensurately with the change in net revenues from period to period. We expect our cost of sales expenses (exclusive of amortization of acquired intangible assets) to continue to increase in future periods as we

hire additional laboratory personnel and related resources to support our expected operational growth and higher test volumes.

Gross Margin

Our gross margin percentage was 79.3% for the nine months ended September 30, 2024, compared to 74.4% for the nine months ended September 30, 2023. The increase was primarily due to higher revenues, partially offset by higher personnel costs, higher expense for supplies and lab services and higher expense incurred through our expanded laboratory capacity and higher test report volumes.

Research and Development

Research and development expenses decreased by $0.4 million, or 0.9%, for the nine months ended September 30, 2024, compared to the nine months ended September 30, 2023, primarily reflecting lower clinical studies costs, lower organizational development costs, and lower expense for laboratory supplies, partially offset by higher personnel costs.

We expect to continue incurring research and development expenses through our continued investments in our ongoing pipeline initiatives and as we seek opportunities to build evidentiary support and new tests where commercial opportunities exist.

Selling, General and Administrative

The following table provides a breakdown of SG&A expenses (in thousands):

	Nine Months Ended September 30,		
	2024	2023	Change
	(unaudited)		
Sales and marketing	$ 93,054	$ 86,693	$ 6,361
General and administrative	57,028	49,369	7,659
Total selling, general and administrative expense	$ 150,082	$ 136,062	$ 14,020

Sales and marketing expenses increased by $6.4 million, or 7.3%, for the nine months ended September 30, 2024, compared to the nine months ended September 30, 2023. The increase is primarily due to higher personnel costs, higher expense incurred through organizational and business development activities and higher marketing expense. Increases in personnel costs reflect a higher headcount as well as merit and annual inflationary wage adjustment for existing employees. Higher test report volumes is a result of our continued investments in human capital for our sales organization. Stock-based compensation expense included in sales and marketing expense was $13.5 million for the nine months ended September 30, 2024, compared to $14.0 million for the nine months ended September 30, 2023.

General and administrative expenses increased by $7.7 million, or 15.5%, for the nine months ended September 30, 2024, compared to the nine months ended September 30, 2023. The increase is primarily due to higher personnel costs, professional fees and information technology-related costs. Increases in personnel costs reflect headcount expansions in our administrative support functions as well as merit and annual inflationary wage adjustment for existing employees. Stock-based compensation expense included in general and administrative expense was $13.6 million for the nine months ended September 30, 2024, compared to $13.9 million for the nine months ended September 30, 2023.

Amortization of Acquired Intangible Assets

Amortization of acquired intangible assets for the nine months ended September 30, 2024 was $6.8 million and remains consistent as compared to the nine months ended September 30, 2023.

Interest Income

Interest income increased by $2.0 million for the nine months ended September 30, 2024, compared to the nine months ended September 30, 2023, primarily as a result of higher average balances of marketable investment securities and slightly higher interest rates.

Interest Expense

Interest expense increased by $0.5 million for the nine months ended September 30, 2024, compared to the nine months ended September 30, 2023, primarily due to interest incurred on our long-term debt where we had no debt outstanding during the comparative period.

Income Tax Expense

Income tax expense was $5.0 million for the nine months ended September 30, 2024 and was due to revisions in estimated pre-tax income, reflecting uncertainty in continued Medicare coverage for our DecisionDx-SCC test and updated information, as well as stock-based compensation, permanent differences, changes in valuation allowance, research and development tax credit and state income taxes. We recorded a minimal amount in income tax expense for the nine months ended September 30, 2023.

Stock-Based Compensation Expense

Stock-based compensation expense, which is allocated among cost of sales, research and development expense and SG&A expense, totaled $38.9 million for the nine months ended September 30, 2024, compared to $39.4 million for the nine months ended September 30, 2023. We expect material increases in stock-based compensation expense in future periods, attributable to both existing awards outstanding and anticipated additional grants to our current and future employees. As of September 30, 2024, we had 710 employees compared to 587 as of September 30, 2023. As of September 30, 2024, the total unrecognized stock-based compensation cost related to outstanding awards was $77.6 million, which is expected to be recognized over a weighted-average period of 2.2 years.

Liquidity and Capital Resources

Sources of Liquidity

Our principal sources of liquidity are our cash and cash equivalents, marketable investment securities, cash generated from the sale of our products and our line-of-credit under the 2024 Loan and Security Agreement (the “2024 LSA”). All of our marketable investment securities are considered investment grade, are readily available for use in current operations and have contractual maturities of one year or less. As of September 30, 2024 and December 31, 2023, we had marketable investment securities of $184.8 million and $144.3 million, respectively. As of September 30, 2024 and December 31, 2023, we had cash and cash equivalents of $95.0 million and $98.8 million, respectively. As of September 30, 2024, we had a $25 million credit-line available under the 2024 LSA.

Our liquidity has been primarily derived from the revenue generated from the sale of our products and proceeds from our initial public offering of common stock in July 29, 2019 (the “IPO”) and our follow-on public offerings of common stock in June and December of 2020. We believe that our existing cash and cash equivalents, marketable investment securities and anticipated cash generated from sales of our products will be sufficient to fund our operations for at least the next 12 months. However, we have based these estimates on assumptions that may prove to be wrong, and could result in us depleting our capital resources sooner than expected.

As mentioned above, we expect to use a portion of our cash and cash equivalents and marketable investment securities to further support and accelerate our research and development activities, including the clinical studies noted above in “—Components of the Results of Operations—Research and Development.”

Material Cash Requirements

Our primary uses of capital are, and we expect will continue to be, compensation and related expenses, clinical research and development services, laboratory operations, equipment and related supplies, legal and other regulatory expenses, general administrative costs and, from time to time, expansion of our laboratory and office facilities in support of our growth, such as the construction of our future corporate headquarters. We anticipate that a substantial portion of our cash requirements in the foreseeable future will relate to the further commercialization of our currently marketed products, the development of our future product candidates in our pipeline and the potential commercialization of these pipeline products, should their development be successful, and the construction of our future corporate headquarters.

In July 2023, following approval by our board of directors, we entered into a definitive agreement to purchase a plot of land located in Friendswood, Texas for a purchase price of $7.6 million, subject to certain adjustments, for the purpose of developing a commercial office building to be used as our future corporate headquarters. In February 2024, we closed on the purchase of the land for cash consideration of $7.2 million. The development project will include a four-story headquarters building, which will encompass approximately 80,000 square feet of Class A office space. Construction began in May 2024 and is expected to continue through early 2026, at which time the building

is expected to be ready for occupancy and use. Over the duration of this project, we expect to make significant capital expenditures in form of payments to the developer under a percentage of completion basis. As of September 30, 2024, the development project is expected to cost a total of approximately $40 million. During the nine months ended September 30, 2024, we have made minimal capital expenditures in the planning and early development phases of this project. We intend to use the proceeds from the 2024 Term Loan, the 2024 Credit Line and our existing cash and cash equivalents to pay for this project.

In connection with our acquisition of AltheaDx, we agreed to pay contingent consideration of up $75.0 million, payable 50% in cash and 50% in common stock, based on the achievement of certain commercial milestones relating to the years ending December 31, 2022, 2023 and 2024. The portion of the AltheaDx Earnout Payments associated with the commercial milestones for the year ended December 31, 2023 was $37.5 million and was not paid since the applicable commercial milestones were not met. The AltheaDx Earnout Payments included a 2022 catch-up provision for additional payment of up to $17.5 million that expired in 2023. Therefore, as of September 30, 2024, we have a potential payment obligation of up to $20.0 million with respect to the remaining commercial milestones for 2024. The number of shares of our common stock that may be issued in connection with the commercial milestone payment for 2024 is subject to limitations. As of September 30, 2024, we believe it to be unlikely that the remaining commercial milestones will be met and that future payments will be due.

Since our inception, we have generally incurred significant losses and negative operating cash flows. For the year ended December 31, 2023, we had a net loss of $57.5 million, used $5.6 million in operating cash flows, and had an accumulated deficit of $218.4 million. For the nine months ended September 30, 2024, we had net income of $8.7 million and positive operating cash flows of $40.5 million. Our ability to maintain profitability will heavily depend on us maintaining Medicare coverage for our currently marketed products, on the successful commercialization of the products we plan to launch in the future, and our ability to manage operating expenses. We expect to incur additional expenses in the future as we invest in the commercialization of our existing products and the development and commercialization of our current pipeline products and future product candidates. We believe that our existing cash and cash equivalents, marketable investment securities and anticipated cash generated from the sale of our commercial products will be sufficient to fund our operations for at least the next 12 months. We believe we will meet longer-term expected cash requirements and obligations through a combination of existing cash and cash equivalents, marketable investment securities and anticipated cash generated from sales of our products and issuances of equity securities or debt offerings. However, we have based these estimates on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we expect. There are numerous risks and uncertainties associated with developing genomic tests, including, among others, the uncertainty of:

- successful commencement and completion of clinical study protocols;
- successful identification and acquisition of tissue samples;
- the development and validation of genomic classifiers; and
- acceptance of new genomic tests by clinicians, patients and third-party payors including competitor actions.

Because of the numerous risks and uncertainties associated with research, development and commercialization of product candidates, we are unable to estimate our exact working capital requirements. Our future funding requirements will depend on and could increase significantly as a result of, many factors, including those listed above as well as those listed in Part I, Item 1A, “Risk Factors” in the 2023 10-K and Part II, Item 1A, “Risk Factors” in this Quarterly Report on Form 10-Q and in our other filings with the SEC.

In the event additional funding is required, we expect that we would use a combination of equity and debt financings, which may not be available to us when needed, on terms that we deem to be favorable or at all. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interest of our stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of common stockholders. Debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making acquisitions or capital expenditures or declaring dividends. Any disruptions to, or volatility in, the credit and financial markets or any deterioration in overall economic conditions may make any necessary debt or equity financing more difficult to obtain, more costly and/or more dilutive. If we are unable to raise additional funds through debt or equity financing or other arrangements when needed, we may be required to delay, limit, reduce or terminate our product discovery and development activities or future commercialization efforts.

Long-Term Debt

We had no debt as of December 31, 2023. Our long-term debt as of September 30, 2024 is presented in the table below (in thousands):

	September 30, 2024 (Unaudited)
Term debt	$ 10,200
Unamortized discount	(185)
Total long-term debt	10,015
Less: Current portion of long-term debt	—
Total	$ 10,015

2024 Loan and Security Agreement

On March 26, 2024 (the ‘‘Closing Date’’), we entered into the ‘2024 LSA, by and between the Company, its wholly owned subsidiary, Castle Narnia Real Estate Holding 1, LLC and Silicon Valley Bank, a division of First-Citizens Bank & Trust Company (the “Lender’’). The 2024 LSA provides for (i) on the Closing Date, $10.0 million aggregate principal amount of term loans (discussed in the ‘‘2024 Term Loan’’ section below), and (ii) from the Closing Date until March 31, 2025, an additional line of credit of $25.0 million with the same interest rate and maturity as the term debt available (discussed in ‘‘—2024 Credit Line” below) at our option.

The obligations under the 2024 LSA are secured by substantially all of our assets, excluding intellectual property, the real property held by the Company, and are subject to certain other exceptions and limitations. We have the right to prepay the 2024 LSA in whole, subject to a prepayment fee of approximately 1.50% if paid prior to March 26, 2026. Amounts repaid under the 2024 LSA may not be reborrowed.

In addition, the 2024 LSA contains customary conditions of borrowing, events of default and covenants, including covenants that restrict our ability to dispose of assets, merge with or acquire other entities, incur indebtedness and make distributions to holders of our capital stock. Should an event of default occur, including the occurrence of a material adverse change, we could be liable for immediate repayment of all obligations under the 2024 LSA. Should we seek to amend the terms of the 2024 LSA, the consent of the Lender would be required. As of September 30, 2024, we were in compliance with this covenant.

The 2024 LSA bears interest at a floating rate equal to the greater of (a) the WSJ Prime Rate plus 0.25% or (b) 6.00% per annum. The Term Loans are interest only from the Closing Date through November 30, 2025, which may be extended at our option through November 30, 2026 as long as no event of default under the 2024 LSA has occurred. After the end of the interest only period, we are required to pay equal monthly installments of principal through the maturity date of November 1, 2028.

We are also obligated to make an additional final payment of 2.00% of the aggregate original principal amounts of Term Loans advanced by the Lender, due at the earlier of the maturity date or date the Term Loans are repaid in full.

2024 Term Loan

On March 26, 2024, we drew $10.0 million in Term Loans under the terms and provisions of the 2024 LSA. We are obligated to make a final payment of $0.2 million under the terms of the 2024 LSA final payment provisions. A discount on debt equal to this obligation was recorded on the draw date and is being amortized as additional interest expense using the effective interest method over the term of the debt. As of September 30, 2024, the effective interest rate for all outstanding debt under the 2024 Term Loan was 8.60%.

2024 Credit Line

We have a $25.0 million line of credit under the terms and provisions of the 2024 LSA available from the Closing Date until March 31, 2025. Amounts repaid under the 2024 Credit Line may not be reborrowed. As of September 30, 2024, no draws had been made on the line of credit.

Leases

We have entered into various operating and finance leases, which are primarily associated with our laboratory facilities and office space.

Total undiscounted future minimum payment obligations under our operating leases and finance leases as of September 30, 2024 totaled approximately $24.0 million, of which $0.8 million is payable through the remainder of 2024 and $23.2 million is payable through early 2034. The leases expire on various dates through 2034 and provide certain options to renew for additional periods.

We expect our lease obligations may increase in the future as we expand our facilities, operations and headcount in support of the anticipated growth in our portfolio of commercial products and pipeline tests.

Cash Flows

The following table summarizes our sources and uses of cash and cash equivalents for each of the periods presented (in thousands):

	Nine Months Ended September 30,	
	2024	2023
	(unaudited)	
Net cash provided by (used in) operating activities	$ 40,501	$ (24,213)
Net cash used in investing activities	(55,907)	(8,511)
Net cash provided by financing activities	11,524	999
Net change in cash and cash equivalents	(3,882)	(31,725)
Cash and cash equivalents, beginning of period	98,841	122,948
Cash and cash equivalents, end of period	$ 94,959	$ 91,223

Operating Activities

Net cash provided by operating activities was $40.5 million for the nine months ended September 30, 2024, and was primarily attributable to non-cash stock-based compensation expense of $38.9 million, depreciation and amortization of $10.2 million, net income of $8.7 million, deferred income taxes of $3.7 million and decreases in inventory of $1.4 million, partially offset by increases in accounts receivable of $11.9 million, increases in accretion of discounts on marketable investment securities of $5.1 million, decreases in accounts payable of $3.8 million, increases in prepaid expenses and other current assets of $1.7 million and decreases in accrued compensation of $1.3 million.

Net cash used in operating activities was $24.2 million for the nine months ended September 30, 2023, and was primarily attributable to the net loss of $54.9 million, increases in accounts receivable of $13.8 million, increases in accretion of discounts on marketable investment securities of $3.9 million, decreases in accrued compensation of $2.0 million and increases in inventory of $1.8 million, partially offset by non-cash stock-based compensation expense of $39.4 million, depreciation and amortization of $9.1 million, a change in accounts payable of $2.7 million and a change in other accrued and current liabilities of $1.4 million.

The $64.7 million increase in cash inflows from operating activities for the nine months ended September 30, 2024 compared to the nine months ended September 30, 2023 is primarily due to increases in collections from customers attributable to higher net revenues partially offset by increases in operating expenditures. During the nine months ended September 30, 2024 net revenues increased by 59.9% compared to the nine months ended September 30, 2023 which outpaced the 11.6% increase in net operating expenses for the same period. In part, the cash provided during the nine months ended September 30, 2024 reflects the payment of annual cash bonuses to our employees as well as certain health care benefit payments totaling $20.8 million, that are not expected to recur during the remainder of 2024. In comparison, we paid $17.7 million during the same period in 2023 towards annual cash bonuses and certain health care benefits.

Investing Activities

Net cash used in investing activities was $55.9 million for the nine months ended September 30, 2024 and consisted primarily of purchases of marketable investment securities of $158.4 million and purchases of property and equipment of $20.8 million, partially offset by the maturity of marketable investment securities of $123.3 million. Net cash used in investing activities was $8.5 million for the nine months ended September 30, 2023 and consisted primarily of purchases of marketable investment securities of $136.7 million and purchases of property and equipment of $9.8 million, partially offset by the maturity of marketable investment securities of $138.0 million.

The $47.4 million increase in cash used in investing activities for the nine months ended September 30, 2024 compared to the nine months ended September 30, 2023 was primarily due to purchasing $21.7 million more in marketable investment securities and collecting $14.7 million fewer proceeds from maturing marketable investment securities. We also increased our purchases of property and equipment by $10.9 million for the nine months ended September 30, 2024 compared to the nine months ended September 30, 2023, primarily due to our purchase of land for cash consideration of $7.2 million on February 9, 2024.

Financing Activities

Net cash provided by financing activities was $11.5 million for the nine months ended September 30, 2024, and consisted primarily of $10.0 million of proceeds from issuance of long-term debt and $2.3 million of proceeds from contributions to our 2019 Employee Stock Purchase Plan (the "ESPP") and $1.6 million of proceeds from the exercise of stock options, partially offset by the $2.4 million payment of employee taxes attributable to the vesting of Restricted Stock Units ("RSUs").

Net cash provided by financing activities was $1.0 million for the nine months ended September 30, 2023, and primarily consisted of $2.0 million of proceeds from contributions to the ESPP and $0.2 million of proceeds from the exercise of stock options, partially offset by the $1.1 million payment of employee taxes attributable to the vesting of RSUs.

Inflation

In 2021, the rate of inflation in the United States began to increase but has continued to subside since the second half of 2022. We do not believe that inflation has had a material impact on our financial results during the three and nine months ended September 30, 2024. We are unable to predict if the rate of inflation will increase in future periods.

Critical Accounting Estimates

During the nine months ended September 30, 2024, there were no significant changes to the information discussed under "Critical Accounting Estimates" included in the Management's Discussion and Analysis of Financial Condition and Results of Operations section of our 2023 10-K.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

Interest Rate Risk

We are exposed to market risks in the ordinary course of our business. These risks primarily relate to interest rates fluctuations. We had cash and cash equivalents of $95.0 million as of September 30, 2024, which include bank deposits and money market funds. We had marketable investment securities of $184.8 million as of September 30, 2024, which include U.S. government securities. Due to the nature of these instruments, we believe that we have no material exposure to interest rate risk.

We had long-term debt of $10.0 million as of September 30, 2024, consisting of an outstanding term loan which bears interest at a floating rate that fluctuates with the WSJ Prime Rate, subject to an interest rate floor of 6.00%. In September 2024, the U.S. Federal Reserve lowered interest rates by 50 basis points, lowering the target for key lending rates by half a percent and the WSJ Prime Rate decreased by 50 basis points thereafter.

A hypothetical 10% change in interest rates during any of the periods presented would not have had a material impact on our financial statements.

Inflation Risk

Our exposure to inflationary pressures is primarily in personnel and related costs. The extent of any future impacts from inflation on our business and our results of operations will be dependent upon how long the elevated inflation levels persist and if the rate of inflation were to further increase, neither of which we are able to predict. If elevated levels of inflation were to persist or if the rate of inflation were to accelerate, the purchasing power of our cash and cash equivalents may be eroded, our expenses could increase faster than anticipated and we may utilize our capital resources sooner than expected. Further, given the complexities of the reimbursement landscape in which we operate, our payors may be unwilling or unable to increase reimbursement rates to compensate for inflationary impacts.

Item 4. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

We maintain “disclosure controls and procedures,” as defined in Rules 13a-15(e) or 15d-15(e) under the Exchange Act, that are designed to ensure that information required to be disclosed in the reports that we file or submit under the Exchange Act is (1) recorded, processed, summarized and reported, within the time periods specified in the SEC’s rules and forms and (2) accumulated and communicated to our management, including our principal executive officer and principal financial officer, to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures as of September 30, 2024. Based upon the evaluation, our Chief Executive Officer and Chief Financial Officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

Changes in Internal Control over Financial Reporting

There have been no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) or 15d-15(f) under the Exchange Act) that occurred during the third quarter of 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.

From time to time, we may be involved in legal proceedings arising in the ordinary course of business. Legal proceedings, including litigation, government investigations and enforcement actions could result in material costs, occupy significant management resources and entail civil and criminal penalties, even if we ultimately prevail. On February 1, 2024, we received a Subpoena from the Department of Health and Human Services, Office of Inspector General, seeking documents and information concerning claims submitted for payment under federal healthcare programs. The Subpoena requested that we produce documents relating primarily to interactions with medical providers and billing to government-funded healthcare programs for our tests. The time period covered by the Subpoena is January 1, 2015 through February 1, 2024. We are continuing to cooperate with the government's request and is in the process of responding to the Subpoena. We are unable to predict what action, if any, might be taken in the future by the Department of Health and Human Services, Office of Inspector General, or any other governmental authority as a result of the matters related to this Subpoena. No claims have been made against us at this time. This inquiry, and any potential resulting claim asserted against us, with or without merit, could be time-consuming, expensive to address and divert management's attention and other resources. Any potential claims could subject us to significant liability for damages and harm our reputation. Our insurance and indemnities may not cover all claims that may be asserted against us. We are unable to predict the outcome and are unable to make a meaningful estimate of the amount or range of loss, if any, that could result from any unfavorable outcome.

Item 1A. Risk Factors.

In addition to the other information set forth in this Quarterly Report on Form 10-Q, you should carefully consider the risk factors and other cautionary statements described under the heading "Item 1A. Risk Factors" included in our Annual Report on Form 10-K for the year ended December 31, 2023 filed with the SEC on February 28, 2024, which could materially affect our business, financial condition or future results. Additional risks and uncertainties not currently known to us or that we currently deem to be immaterial also may materially and adversely affect our business, financial condition or future results. There have been no material changes in our risk factors from those described in our Annual Report on Form 10-K for the year ended December 31, 2023 other than the updates to the risk factors or new risk factors set forth below. New risk factors that were not included in our Annual Report on Form 10-K for the year ended December 31, 2023 have been marked with an asterisk (*).

We may disclose changes to risk factors or additional risk factors from time to time in our future filings with the SEC.

Risks Related to Our Financial Position

We may need to raise additional capital to fund our existing operations, commercialize new products or expand our operations.

We believe our existing cash and cash equivalents, marketable investment securities and anticipated cash generated from sales of our products will be sufficient to fund our operations for at least the next 12 months. If our available cash and cash equivalents, marketable investment securities and anticipated cash generated from sales of our products are insufficient to satisfy our liquidity requirements including because of lower demand for our products, lower than currently expected rates of reimbursement from third-party payors or other risks described in this Annual Report on Form 10-K, we may finance our cash needs through a combination of equity offerings, debt financings, collaborations, strategic alliances and marketing, distribution or licensing arrangements. In March 2024, we entered into the 2024 LSA, by and between us, our wholly owned subsidiary, Castle Narnia Real Estate Holding 1, LLC and the Lender. The 2024 LSA provides for (i) on the Closing Date, $10.0 million aggregate principal amount of term loans, and (ii) from the Closing Date until March 31, 2025, an additional $25.0 million available at our option. We drew $10.0 million in Term Loans on the Closing Date. We expect to use the proceeds for the purpose of developing a commercial office building to be used as our future corporate headquarters, and the remainder for working capital and other general corporate purposes.

We may consider raising additional capital in the future to expand our business, to pursue strategic investments, to take advantage of financing opportunities or for other reasons, including to:

- increase our sales and marketing efforts for the DecisionDx-Melanoma, DecisionDx-SCC, MyPath Melanoma, DecisionDx-UM, TissueCypher and IDgenetix tests and address competitive developments among these or future commercial products;
- fund ongoing evidence development for our existing products as well as additional pipeline programs;
- expand our laboratory testing facility and related testing capacity;

- expand our technologies into other types of dermatological, ocular, gastrointestinal or mental health disorders;
- acquire, license or invest in technologies;
- acquire or invest in complementary businesses or assets; and
- finance capital expenditures and general and administrative expenses.

Our present and future funding requirements will depend on many factors, including:

- our ability to achieve revenue growth;
- our rate of progress in establishing payor coverage and reimbursement arrangements with third-party payors;
- our rate of progress in, and cost of the sales, marketing, coverage and reimbursement activities associated with, establishing adoption of our lead product, DecisionDx-Melanoma, among our other products;
- the cost of expanding our laboratory operations and offerings, including our sales, marketing, coverage and reimbursement efforts;
- our rate of progress in, and cost of research and development activities associated with, diagnostic products in research and early development;
- the potential cost of, and delays in, the development of new products as a result of changes in regulatory oversight applicable to our products;
- acquisitions of businesses, assets, products or technologies;
- the duration and effects of elevated inflation;
- the effects on our operations of general political and economic conditions and evolving macroeconomic developments, including geopolitical and macroeconomic developments, such as the ongoing conflict between Ukraine by Russia and related sanctions or the Israel-Hamas war, public health crises, economic slowdowns, labor shortages, recessions or market corrections, supply chain disruptions, inflation and monetary policy shifts, bank failures or other disruptions in the banking system or financing markets, rising interest rates and tightening of credit markets resulting from the conflict or other evolving macroeconomic developments; and
- the effect of competing technological and market developments.

To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a common stockholder. Debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making acquisitions or capital expenditures or declaring dividends.

If we raise additional funds through collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or products, or grant licenses on terms that may not be favorable to us.

Any disruptions to, or volatility in, the credit and financial markets or any deterioration in overall economic conditions may make any necessary debt or equity financing more difficult to obtain, more costly and/or more dilutive. If we are unable to raise additional funds through equity or debt financings or other arrangements when needed, we may be required to delay, limit, reduce or terminate our commercialization, research and development efforts or grant rights to third parties to market and/or develop products that we would otherwise prefer to market and develop ourselves.

The terms of the Loan and Security Agreement place restrictions on our operating and financial flexibility. If we raise additional capital through debt financing, the terms of any new debt could further restrict our operating and financial flexibility.*

In March 2024, we entered into the 2024 LSA with the Lender, which provides for (i) on the Closing Date, $10.0 million aggregate principal amount of term loans, and (ii) from the Closing Date until March 31, 2025, an additional $25.0 million available at our option. The 2024 LSA includes customary affirmative and negative covenants, as well as standard events of default, including an event of default based on the occurrence of a material adverse event. The negative covenants include, among others, restrictions on us transferring collateral, incurring additional indebtedness, engaging in mergers or acquisitions, paying cash dividends or making other distributions, making investments, creating liens, selling assets and making any payment on subordinated debt, in each case subject to certain exceptions. These restrictive covenants could limit our flexibility in operating our business and our ability to pursue business opportunities that we or our stockholders may consider beneficial. In addition, the Lender could declare a default upon the occurrence of any event that it interprets could have a material adverse effect, as defined in the 2024 LSA. Upon the occurrence and continuance of an event of default, the Lender may declare all outstanding obligations immediately due and payable and take such other actions as set forth in the 2024 LSA. Any declaration by the Lender of an event of default could significantly harm our business and prospects and could cause the price of our common stock to decline. We may not have enough available cash or be able to raise additional funds through equity or debt financings to repay these outstanding obligations at the time any event of default occurs. Further, if we raise any additional capital through debt financing, the terms of such additional debt could further restrict our operating and financial flexibility.

Risks Related to Our Business

Our products are currently marketed as LDTs, and any changes in regulations or the FDA's enforcement discretion for LDTs, or violations of regulations by us, could adversely affect our business, prospects, results of operations or financial condition.

The diagnostics industry is highly regulated, and we cannot assure you that the regulatory environment in which we operate will not change significantly and adversely in the future. In many instances, there are no significant regulatory or judicial interpretations of these laws and regulations. Although the FDA has statutory authority to assure that medical devices are safe and effective for their intended uses, the FDA has generally exercised its enforcement discretion and not enforced applicable regulations with respect to in vitro diagnostics ("IVD") that are designed, manufactured and used within a single laboratory. These tests are referred to as LDTs. We currently market our products as LDTs.

On April 29, 2024, the FDA published final regulations under 21 CFR Part 809 under the Federal Food, Drug, and Cosmetic Act (the "FD&C Act") to make explicit that IVD products are devices under the FD&C Act, removing much of the FDA's historical enforcement discretion for most LDTs. In conjunction with this final rule, the FDA proposed to phase out its general enforcement discretion approach for LDTs so that IVDs manufactured by a laboratory would generally fall under the same enforcement approach as other IVDs. This final rule also provides that FDA intends to exercise enforcement discretion and generally not enforce premarket review and quality system requirements (except for requirements under Part 820, subpart M (records)) for currently marketed IVDs offered as LDTs that were first marketed prior to April 29, 2024 and intends to exercise enforcement discretion and generally not enforce premarket review requirements for LDTs approved by the NYS CLEP. We believe that our tests will continue to be subject to FDA enforcement discretion in their current forms. Additionally, pursuant to the final rule, the FDA will gradually end its general enforcement discretion approach in five stages over a four-year period for other LDTs not approved by NYS CLEP or not already on market. Each stage of the proposed phaseout period would subject LDTs to a set of regulatory requirements. For example, the first stage of the phaseout would require LDT developers to comply with medical device reporting requirements and correction and removal reporting requirements by May 6, 2025. LDTs that are considered higher risk IVDs would be subject to premarket review requirements within three and a half years, and LDTs that are considered moderate or low risk IVDs would be subject to premarket submission requirements within four years after the FDA publishes the final rule. While the enforcement policy is phased out, the FDA could still decide to pursue enforcement action at any time against LDTs that it deems to be violative of its regulations when appropriate.

All of our existing tests were marketed prior to April 29, 2024 and are conducted in labs licensed by the New York State Department of Health. If the FDA were to determine that our tests, or modifications thereof, are not within the scope of the FDA's enforcement discretion policy for LDTs for any reason, including based on these final rules or new rules, regulations, policies or guidance, or due to changes in statute, our existing tests may become subject to extensive FDA requirements, or our business may otherwise be adversely affected and lead to potential adverse

effects on our business, prospects, results of operations and financial condition. Furthermore, under the terms of this FDA final rule, any future Castle tests developed and commercialized are likely to be subject to extensive FDA requirements which may adversely impact our business, prospects, results of operations and financial conditions. In addition, we would be required to obtain 510(k) or premarket approval ("PMA") for certain of our tests by October 1, 2027. We would also be subject to device registration and listing requirements, medical device reporting requirements and the requirements of the FDA's Quality System Regulation. We may be required to conduct clinical trials prior to continuing to sell our existing products or launching any other products we may develop. This may increase the cost of conducting, or otherwise harm, our business.

Even if the FDA does not modify its policy of enforcement discretion, the FDA may disagree that we are marketing our LDTs within the scope of its policy of enforcement discretion and may impose significant regulatory requirements. While we believe that we are currently in material compliance with applicable laws and regulations as historically enforced by the FDA, we cannot assure you that the FDA will agree with our determination. A determination that we have violated these laws and regulations, or a public announcement that we are being investigated for possible violations, could adversely affect our business, prospects, results of operations or financial condition.

We may be required to obtain premarket clearance under Section 510(k) of the FDCA or a PMA for any future test we wish to offer. The process for submitting a 510(k) premarket notification and receiving FDA clearance usually takes from three to 12 months, but it can take significantly longer and clearance is never guaranteed. The process for submitting and obtaining FDA approval of a PMA is much more costly, lengthy and uncertain. It generally takes from one to three years or even longer, and approval is not guaranteed. PMA approval typically requires extensive clinical data and can be significantly longer, more expensive and more uncertain than the 510(k) clearance process. Despite the time, effort and expense expended, there can be no assurance that a particular device ultimately will be cleared or approved by the FDA through either the 510(k) clearance process or the PMA process on a timely basis, or at all. Moreover, there can be no assurance that any cleared or approved labeling claims will be consistent with our current claims or adequate to support continued adoption of and reimbursement for our products. If premarket review is required for some or all of our products, the FDA may require that we stop selling our products pending clearance or approval, which would negatively impact our business. Even if our products are allowed to remain on the market prior to clearance or approval, demand or reimbursement for our products may decline if there is uncertainty about our products, if we are required to label our products as investigational by the FDA, or if the FDA limits the labeling claims we are permitted to make for our products. As a result, we could experience significantly increased development costs and a delay in generating additional revenue from our products, or from other pipeline products. Furthermore, it could reduce our revenues or increase our operating costs and adversely affect our business, prospects, results of operations or financial condition.

Risks Related to Reimbursement and Government Regulation

We generally have limited reimbursement coverage for our products, and if third-party payors, including government and commercial payors, do not provide sufficient coverage of, or adequate reimbursement for, our products, our commercial success, including revenue, will be negatively affected.

Our revenue depends on achieving broad coverage and adequate reimbursement for our products from third-party payors, including both government and commercial third-party payors. If third-party payors do not provide coverage of, or do not provide adequate reimbursement for, a substantial portion of the list price of our products, we may need to seek additional payment from the patient beyond any co-payments and deductibles, which may adversely affect demand for our products. Coverage determinations by a third-party payor may depend on a number of factors, including, but not limited to, a third-party payor's determination of whether our products are appropriate, medically necessary or cost-effective. If we are unable to provide third-party payors with sufficient evidence of the clinical utility and validity of our products, they may not provide coverage, or may provide limited coverage, which will adversely affect our revenues and our ability to succeed. To the extent that more competitors enter our markets, the availability of coverage and the reimbursement rate for our products may decrease as we encounter pricing pressure from these competitors.

Since each third-party payor makes its own decision as to whether to establish a policy to cover our products, enter into a contract with us and set the amount it will reimburse for a product, these negotiations are a time-consuming and costly process, and they do not guarantee that the third-party payor will provide coverage or adequate reimbursement for our products. In addition, the determinations by a third-party payor whether to cover our products and the amount it will reimburse for them are often made on an indication-by-indication basis.

In cases where there is no coverage policy or we do not have a contracted rate for reimbursement as a participating provider, the patient is typically responsible for a greater share of the cost of the product, which may result in further delay of our revenue, increase our collection costs or decrease the likelihood of collection.

Our claims for reimbursement from third-party payors may be denied upon submission, and we may need to take additional steps to receive payment, such as appealing the denials. Such appeals and other processes are time-consuming and expensive and may not result in payment. Third-party payors may perform audits of historically paid claims and attempt to recoup funds years after the funds were initially distributed if the third-party payors believe the funds were paid in error or determine that our products were medically unnecessary. If a third-party payor audits our claims and issues a negative audit finding, and we are not able to overturn the audit findings through appeal, the recoupment may result in a material adverse effect on our revenue. Additionally, in some cases commercial third-party payors for whom we are not a participating provider may elect at any time to review claims previously paid and determine the amount they paid was too much. In these situations, the third-party payor will typically notify us of their decision and then offset whatever amount they determine they overpaid against amounts they owe us on current claims. We cannot predict when, or how often, a third-party payor might engage in these reviews and we may not be able to dispute these retroactive adjustments.

Under ASC 606, we recognize revenue at the amount we expect to be entitled, subject to a constraint for variable consideration, in the period in which our tests are delivered to the treating clinician. We have determined that our contracts contain variable consideration under ASC 606 because the amounts paid by third-party payors may be paid at less than our standard rates or not paid at all, with such differences considered implicit price concessions. Variable consideration is recognized only to the extent it is probable that a significant reversal of revenue will not occur in future periods when the uncertainties are resolved.

Variable consideration is evaluated each reporting period and adjustments are recorded as increases or decreases in revenues. Variable consideration for Medicare claims that are not covered by Medicare, including those claims undergoing appeal, is deemed to be fully constrained due to factors outside our influence (e.g., judgment or actions of third parties) and the uncertainty of the amount to be received is not expected to be resolved for a long period of time. For these fully constrained claims, we generally recognize revenue in the period the uncertainties are resolved, if favorable. Due to potential future changes in Medicare coverage policies and appeal cycles, insurance coverage policies, contractual rates and other trends in the reimbursement of our tests, our revenues may fluctuate significantly from period to period.

Although we are an in-network participating provider with some commercial third-party payors, including several Blue Cross Blue Shield plans, and certain large, national commercial third-party payors, including Aetna, other commercial third-party payors have issued non-coverage policies that currently categorize our tests as experimental or investigational. If we are not successful in obtaining coverage from third-party payors, in reversing existing non-coverage policies, or if other third-party payors issue similar non-coverage policies, this could have a material adverse effect on our business and operations.

The process to obtain Medicare coverage is lengthy, time-consuming, has changed over time, may change in the future and requires significant dedication of resources, and as we develop or acquire new products, we may be unsuccessful in receiving Medicare coverage for those products or in maintaining our current Medicare coverage. On a periodic basis, CMS requests bids for its MAC services, and MAC jurisdictions have changed in the past. A change in our MAC, or future changes in the MolDX program, the elimination of the program, or a change in the administrator of that program, may affect our ability to maintain Medicare coverage and reimbursement for products for which we have coverage, obtain Medicare coverage for products for which we do not yet have coverage, or obtain Medicare coverage for any products we may launch in the future, or delay payments for our tests. Additionally, MACs that currently provide coverage for our products may periodically reevaluate their coverage decisions and decide to withdraw coverage based on a number of factors that we may not be able to predict or control. Accordingly, current Medicare coverage of our tests or a history of coverage by Medicare is no guarantee of future Medicare coverage. We have received positive coverage decisions and receive Medicare reimbursement for our DecisionDx-Melanoma, DecisionDx-UM, MyPath Melanoma tests, and IDgenetix. Our DecisionDx-SCC and TissueCypher tests receive Medicare reimbursement as well. If coverage for one or more of our products is withdrawn, our business could be adversely impacted.

On June 2, 2023, Novitas the MAC responsible for administering claims for test reports issued by our Pittsburgh laboratory, posted a finalized oncology biomarker LCD pursuant to which the DecisionDx-SCC test would no longer be covered by Medicare effective July 17, 2023. However, on July 6, 2023, Novitas suspended the final version of the LCD and announced its intent to post a new proposed LCD for comment and presentation at an open meeting. On July 27, 2023, Novitas posted a nearly identical proposed oncology biomarker LCD that continues to intend to

rely upon evidentiary reviews sourced from three databases: ClinGen, OncoKB and NCCN. The proposed LCD also recommends non-coverage for our DecisionDx-SCC test. The comment period for the proposed LCD ended on September 9, 2023. On July 26, 2024, Novitas posted a note that it had been granted an extension by CMS. We cannot predict whether this LCD will be finalized as proposed or what the timing of any final LCD might be.

Palmetto's MolDX program oversees MAAA tests that are reported from our Phoenix laboratory and Noridian is the MAC responsible for administering claims for test reports issued by our Phoenix laboratory. On June 8, 2023, both Palmetto and Noridian posted a preliminary draft LCD recommending no coverage for DecisionDx-SCC. The comment period for the draft LCDs ended on July 22, 2023. On July 4, 2024, the LCD was finalized as proposed with a future effective date of August 18, 2024.

Under Medicare, payment for products like ours is generally made under the CLFS with payment amounts assigned to specific procedure billing codes. Medicare reimbursement rates for our tests are subject to change and may decrease from those currently in effect. For example, in February 2023, MolDX notified us that IDgenetix should shift billing to a different multi-test generic gene sequencing CPT code and continue using the IDgenetix Z-Code beginning in March 2023. As a result of this change, the Medicare reimbursement rate for the IDgenetix multi-gene panel decreased from approximately $1,500 to $917 per test. We subsequently obtained a test-specific PLA CPT code which became effective October 1, 2023. In November 2023, CMS posted its final CLFS determination which crosswalks our PLA CPT code to an existing PLA code at a rate of $1,336 per test effective January 1, 2024.

In April 2014, Congress passed the Protecting Access to Medicare Act ("PAMA") which included substantial changes to the way in which clinical laboratory services are paid under Medicare. Under PAMA, certain laboratories are required to report to CMS commercial third-party payor payment rates and volumes for each test they perform. CMS uses this data to calculate a weighted median payment rate for each test, which will be used to establish revised Medicare CLFS reimbursement rates for the test. Laboratories that fail to report the required payment information may be subject to substantial civil monetary penalties. We bill Medicare for our products, and therefore we are subject to reporting requirements under PAMA.

If we are unable to obtain and maintain adequate reimbursement rates from commercial third-party payors, this may adversely affect our Medicare rate. It is unclear what impact new pricing structures, such as those adopted under PAMA, may have on our business, financial condition, results of operations or cash flows.

The U.S. federal government continues to show significant interest in pursuing healthcare reform and reducing healthcare costs. Similarly, commercial third-party payors may seek to reduce costs by limiting coverage or reducing reimbursement for our products. Any government-adopted reform measures or changes to commercial third-party payor coverage and reimbursement policies could cause significant pressure on the pricing of, and reimbursement for, healthcare products and services, including our products, which could decrease demand for our products, and adversely affect our sales and revenue.

In addition, some third-party payors have implemented, or are in the process of implementing, laboratory benefit management programs, often using third-party benefit managers to manage these programs. The stated goals of these programs are to help improve the quality of outpatient laboratory services, support evidence-based guidelines for patient care and lower costs. The impact on laboratories, such as ours, of active laboratory benefit management by third parties is unclear, and we expect that it could have a negative impact on our revenue in the short term. It is possible that third-party payors will resist reimbursement for the products that we offer, in favor of less expensive products, may require pre-approval for our products or may impose additional pricing pressure on and substantial administrative burden for reimbursement for our products.

We expect to continue to focus substantial resources on increasing coverage and reimbursement for our current products and any future products we may develop. We believe it may take several years to achieve broad coverage and adequate contracted reimbursement with a majority of third-party payors for our products.

However, we cannot predict whether, under what circumstances, or at what payment levels third-party payors will cover and reimburse our products. If we fail to establish and maintain broad adoption of, and coverage and reimbursement for, our products, our ability to generate revenue could be harmed and our future prospects and our business could suffer.

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

Use of Proceeds from IPO of Common Stock

On July 29, 2019, we completed our IPO, pursuant to which we issued and sold 4,600,000 shares of our common stock, including 600,000 shares associated with the full exercise of the underwriters' option to purchase additional shares, at a price to the public of $16.00 per share.

The offer and sale of all of the shares of our common stock in the IPO were registered under the Securities Act pursuant to our Registration Statements on Form S-1, as amended (File Nos. 333-232369 and 333-232796), which were declared or became effective on July 24, 2019.

There has been no material change in our planned use of the net proceeds from the IPO as described in the final prospectus filed with the SEC on July 26, 2019 relating to our Registration Statements on Form S-1 (File Nos. 333-232369 and 333-232796).

Since the effective date of our registration statement through September 30, 2024, we have not used any of the net proceeds from the IPO. Pending such uses, we have invested, and plan to continue to invest, the balance of the net proceeds from the IPO in cash and cash equivalent securities or highly liquid investment securities.

Item 3. Defaults Upon Senior Securities.

None.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

On August 13, 2024, Frank Stokes, Chief Financial Officer, adopted a Rule 10b5-1 trading arrangement providing for the sale from time to time of an aggregate of up to 6,923 shares of our common stock plus any additional shares that remain unsold under his previous arrangement. The new trading arrangement is intended to satisfy the affirmative defense in Rule 10b5-1(c). The duration of the trading arrangement is estimated to be from November 15, 2024 until the earlier of all transaction under the trading arrangement being completed or the termination of the plan.

On September 11, 2024, Tobin Juvenal, our Chief Commercial Officer, adopted a Rule 10b5-1 trading arrangement providing for the sale from time to time of an aggregate of up to 2,230 shares of our common stock plus any additional shares that remain unsold under his previous arrangement. The trading arrangement is intended to satisfy the affirmative defense in Rule 10b5-1(c). The duration of the trading arrangement will be from January 2, 2025 through December 31, 2025.

No other officers or directors, as defined in Rule 16a-1(f), adopted and/or terminated a Rule 10b5-1 trading arrangement or a non-Rule 10b5-1 trading arrangement, as defined in Regulation S-K Item 408, during the last fiscal quarter.

Item 6. Exhibits.

Exhibit Number	Description of document
2.1#+	Agreement and Plan of Merger, dated October 18, 2021, by and among the Registrant, Space Merger Sub, Inc., Cernostics, Inc., and Shareholder Representative Services LLC, incorporated by reference to Exhibit 2.1 of the Registrant's Current Report on Form 8-K, as amended, originally filed with the SEC on December 6, 2021.
2.2#+	Agreement and Plan of Merger, dated April 4, 2022, by and among the Registrant, AltheaDx, Inc., Acorn Merger Sub, Inc. and Fortis Advisors LLC, incorporated by reference to Exhibit 2.1 of the Registrant's Current Report on Form 8-K filed with the SEC on April 4, 2022.
3.1	Amended and Restated Certificate of Incorporation of the Registrant, incorporated by reference to Exhibit 3.1 of the Registrant's Current Report on Form 8-K filed with the SEC on July 29, 2019.
3.2	Amended and Restated Bylaws of the Registrant, incorporated by reference to Exhibit 3.2 of the Registrant's Current Report on Form 8-K filed with the SEC on July 29, 2019.
4.1	Form of Common Stock Certificate of the Registrant, incorporated by reference to Exhibit 4.1 of the Registrant's Registration Statement on Form S-1 (File No. 333-232369), as amended, originally filed with the SEC on June 26, 2019.
4.2	Sixth Amended and Restated Investors' Rights Agreement, dated July 12, 2019, by and among the Registrant and certain of its stockholders, incorporated by reference to Exhibit 4.2 of the Registrant's Registration Statement on Form S-1 (File No. 333-232369), as amended, originally filed with the SEC on June 26, 2019.
10.1*	Confirmation of Amendment Provisions, dated as of August 8, 2024, to the Lease Agreement, dated April 1, 2022, by and between the Registrant and ACA Concourse East Unit 3 LLC.

Exhibit Number	Description of document
31.1*	Certification of Principal Executive Officer pursuant to Rules 13a-14(a) and 15d-14(a) of the Exchange Act.
31.2*	Certification of Principal Financial Officer pursuant to Rules 13a-14(a) and 15d-14(a) of the Exchange Act.
32.1**	Certification of Principal Executive Officer and Principal Financial Officer pursuant to Rules 13a-14(b) or 15d-14(b) of the Exchange Act, and 18 U.S.C. Section 1350.
101.INS*	Inline XBRL Instance Document—the instance document does not appear in the Interactive Data File as its XBRL tags are embedded within the Inline XBRL document.
101.SCH*	Inline XBRL Taxonomy Extension Schema.
101.CAL*	Inline XBRL Taxonomy Extension Calculation Linkbase.
101.DEF*	Inline XBRL Taxonomy Extension Definition Linkbase.
101.LAB*	Inline XBRL Taxonomy Extension Label Linkbase.
101.PRE*	Inline XBRL Taxonomy Extension Presentation Linkbase.
104*	Cover Page Interactive Data File (embedded within the Inline XBRL and contained in Exhibit 101).

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* Filed herewith

** Furnished herewith

\+ Indicates management contract or compensatory plan.

\# Certain schedules or exhibits have been omitted pursuant to Item 601(a)(5) of Regulation S-K. A copy of any omitted schedule or exhibit will be furnished to the SEC upon request; provided, however, that we may request confidential treatment pursuant to Rule 24b-2 of the Exchange Act for any schedule or exhibit so furnished.

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.

CASTLE BIOSCIENCES, INC.

Date: November 4, 2024

By: /s/ Derek J. Maetzold

Derek J. Maetzold
President and Chief Executive Officer
(Principal Executive Officer)

Date: November 4, 2024

By: /s/ Frank Stokes

Frank Stokes
Chief Financial Officer
(Principal Financial and Accounting Officer)

CONFIRMATION OF AMENDMENT PROVISIONS

THIS CONFIRMATION OF AMENDMENT PROVISIONS (the"**Agreement**"), made and agreed as of the date of the last party to sign below by and between **CASTLE BIOSCIENCES, INC.** ("**Tenant**") and **ACA CONCOURSE EAST UNIT 3 LLC** ("**Landlord**").

WITNESSETH:

WHEREAS, Landlord and Tenant entered into a certain Lease Agreement dated April 1, 2022 as amended by the First Amendment to Lease Agreement dated March 26, 2024 (collectively, the "**Lease**") covering certain Premises in Unit 3 of the Nova Place Condominium located in Pittsburgh, Pennsylvania, as more particularly described in said Lease. Capitalized terms used herein and not otherwise defined shall have the meanings ascribed to them in the Lease.

NOW, THEREFORE, in consideration of the foregoing, the parties hereto agree as follows:

1. The Expansion Date of the Lease is August 1, 2024. Any improvements required by the terms of the Lease to be made by Landlord, including the Landlord's Work (as defined in the Lease) regarding the Expansion Space, have been completed to the satisfaction of Tenant in all respects in accordance with any plans and specifications approved by Tenant, and Landlord has fulfilled all of its duties under the Lease regarding such improvements.

2. As of the Expansion Date, the Basic Rent Table set forth in Section 2.3 of the Lease shall be deleted in its entirety and replaced with the following:

Basic Rent Period	Basic Rent (per Basic Rent Period)	Monthly Basic Rent	Rate per r.s.f
4/5/23-10/31/23	$37,800.00	$6,300.00	$3.62
11/1/23-7/31/24	$447,750.00	$49,750.00	$28.62
8/1/24-10/31/24	$319,281.25	$106,427.08	$28.59
11/1/24-10/31/25	$1,302,667.50	$108,555.63	$29.16
11/1/25-10/31/26	$1,328,720.85	$110,726.74	$29.74
11/1/26-10/31/27	$1,355,295.27	$112,941.27	$30.34
11/1/27-10/31/28	$1,382,401.17	$115,200.10	$30.94
11/1/28-10/31/29	$1,410,049.20	$117,504.10	$31.56
11/1/29-10/31/30	$1,438,250.18	$119,854.18	$32.19
11/1/30-10/31/31	$1,467,015.18	$122,251.27	$32.84
11/1/31-10/31/32	$1,496,355.49	$124,696.29	$33.49
11/1/32-10/31/33	$1,526,282.60	$127,190.22	$34.16

3. The Lease is in full force and effect and has not been modified, altered or amended except as follows: none.

4. This Agreement, and each and all of the provisions hereof, shall inure to the benefit, or bind, as the case may require, the parties hereto and their respective heirs, successors and assigns. A scanned signature hereon shall have the same force and effect as an original signature.

IN WITNESS WHEREOF, the parties hereto have executed this Agreement on the day and year of the last party to sign below.

"Landlord":		**"Tenant":**	
ACA CONCOURSE EAST UNIT 3 LLC,		**CASTLE BIOSCIENCES, INC.,**	
a Delaware limited liability company		a Delaware corporation	
By:	/s/ Elliot Gould	By:	Kristen Oelschalger
Name:	Elliot Gould	Name:	/s/ Kristen Oelschalger
Title:	a Manager	Title:	Chief Operating Officer
Date:	8/8/24	Date:	8/08/2024

Exhibit 31.1

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER
PURSUANT TO EXCHANGE ACT RULE 13a-14(a)/15d-14(a),
AS ADOPTED PURSUANT TO SECTION 302
OF THE SARBANES-OXLEY ACT OF 2002

I, Derek J. Maetzold, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Castle Biosciences, 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(s) 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 period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize, and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 4, 2024

/s/ Derek J. Maetzold

Derek J. Maetzold
President and Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER
PURSUANT TO EXCHANGE ACT RULE 13a-14(a)/15d-14(a),
AS ADOPTED PURSUANT TO SECTION 302
OF THE SARBANES-OXLEY ACT OF 2002

I, Frank Stokes, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Castle Biosciences, 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(s) 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 period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize, and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 4, 2024

/s/ Frank Stokes

Frank Stokes
Chief Financial Officer
(Principal Financial and Accounting Officer)

Exhibit 32.1

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

In connection with the Quarterly Report on Form 10-Q for the quarterly period ended September 30, 2024 of Castle Biosciences, Inc. (the "Company"), as filed with the Securities and Exchange Commission on the date hereof (the "Report"), Derek J. Maetzold, President and Chief Executive Officer of the Company, and Frank Stokes, Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to their knowledge:

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

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

Date: November 4, 2024

/s/ Derek J. Maetzold
Derek J. Maetzold
President and Chief Executive Officer
(Principal Executive Officer)

/s/ Frank Stokes
Frank Stokes
Chief Financial Officer
(Principal Financial and Accounting Officer)

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 Castle Biosciences, Inc. under the Securities Act of 1933, as amended, or the Exchange Act (whether made before or after the date of the Form 10-Q), irrespective of any general incorporation language contained in such filing.