

**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 **June 30, 2023**

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**

(State or other jurisdiction of incorporation or organization)

**505 S. Friendswood Drive, Suite 401,  
Friendswood, Texas**

(Address of principal executive offices)

**77-0701774**

(I.R.S. Employer Identification No.)

**77546**

(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
<b>Common Stock, \$0.001 par value per share</b>	<b>CSTL</b>	<b>The Nasdaq Global Market</b>

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	<input type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input checked="" type="checkbox"/>	Smaller reporting company	<input checked="" type="checkbox"/>
		Emerging growth company	<input type="checkbox"/>

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 July 24, 2023, there were 26,809,728 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	June 30, 2023 (unaudited)	December 31, 2022
<b>Current Assets</b>		
Cash and cash equivalents	\$ 95,874	\$ 122,948
Marketable investment securities	129,634	135,677
Accounts receivable, net	31,314	23,476
Inventory	6,121	3,980
Prepaid expenses and other current assets	6,111	6,207
<b>Total current assets</b>	<b>269,054</b>	<b>292,288</b>
Long-term accounts receivable, net	1,227	1,087
Property and equipment, net	20,511	14,315
Operating lease assets	11,539	12,181
Goodwill and other intangible assets, net	121,879	126,348
Other assets – long-term	1,190	1,110
<b>Total assets</b>	<b>\$ 425,400</b>	<b>\$ 447,329</b>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
<b>Current Liabilities</b>		
Accounts payable	\$ 7,135	\$ 4,731
Accrued compensation	17,298	24,358
Operating lease liabilities	1,966	1,777
Other accrued and current liabilities	7,318	5,262
<b>Total current liabilities</b>	<b>33,717</b>	<b>36,128</b>
Noncurrent operating lease liabilities	12,427	11,533
Deferred tax liability	441	428
Other liabilities	47	90
<b>Total liabilities</b>	<b>46,632</b>	<b>48,179</b>
<b>Commitments and Contingencies (Note 11)</b>		
<b>Stockholders' Equity</b>		
Preferred stock, \$0.001 par value per share; 10,000,000 shares authorized as of June 30, 2023 and December 31, 2022; no shares issued and outstanding as of June 30, 2023 and December 31, 2022	—	—
Common stock, \$0.001 par value per share; 200,000,000 shares authorized as of June 30, 2023 and December 31, 2022; 26,784,008 and 26,553,681 shares issued and outstanding as of June 30, 2023 and December 31, 2022, respectively	27	27
Additional paid-in capital	587,771	560,409
Accumulated deficit	(208,886)	(160,905)
Accumulated other comprehensive loss	(144)	(381)
<b>Total stockholders' equity</b>	<b>378,768</b>	<b>399,150</b>
<b>Total liabilities and stockholders' equity</b>	<b>\$ 425,400</b>	<b>\$ 447,329</b>

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 June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
<b>NET REVENUES</b>	\$ 50,138	\$ 34,838	\$ 92,175	\$ 61,690
<b>OPERATING EXPENSES AND OTHER OPERATING INCOME</b>				
Cost of sales (exclusive of amortization of acquired intangible assets)	11,058	7,686	21,240	13,630
Research and development	13,308	11,926	27,701	22,687
Selling, general and administrative	44,681	37,498	91,443	67,951
Amortization of acquired intangible assets	2,248	2,097	4,470	3,745
Change in fair value of contingent consideration	—	(20,398)	—	(17,836)
Total operating expenses, net	71,295	38,809	144,854	90,177
<b>Operating loss</b>	(21,157)	(3,971)	(52,679)	(28,487)
Interest income	2,399	370	4,735	400
Interest expense	(3)	(4)	(7)	(7)
<b>Loss before income taxes</b>	(18,761)	(3,605)	(47,951)	(28,094)
Income tax expense (benefit)	16	(1,957)	30	(1,823)
<b>Net loss</b>	\$ (18,777)	\$ (1,648)	\$ (47,981)	\$ (26,271)
Loss per share, basic and diluted	\$ (0.70)	\$ (0.06)	\$ (1.80)	\$ (1.02)
Weighted-average shares outstanding, basic and diluted	26,733	26,064	26,670	25,746

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

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
<b>Net loss</b>	\$ (18,777)	\$ (1,648)	\$ (47,981)	\$ (26,271)
<b>Other comprehensive (loss) income:</b>				
Net unrealized (loss) gain on marketable investment securities	(8)	—	237	—
<b>Comprehensive loss</b>	<u>\$ (18,785)</u>	<u>\$ (1,648)</u>	<u>\$ (47,744)</u>	<u>\$ (26,271)</u>

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)**

	Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive Loss	Total Stockholders' Equity
	Shares	Amount	Shares	Amount				
<b>BALANCE, JANUARY 1, 2022</b>	—	\$ —	25,378,520	\$ 25	\$ 505,482	\$ (93,767)	\$ —	\$ 411,740
Stock-based compensation expense	—	—	—	—	8,419	—	—	8,419
Exercise of common stock options	—	—	62,102	—	399	—	—	399
Issuance of common stock from vested restricted stock units and payment of employees' taxes	—	—	2,466	—	(56)	—	—	(56)
Issuance of common stock under the employee stock purchase plan	—	—	42,332	—	1,457	—	—	1,457
Net loss	—	—	—	—	—	(24,623)	—	(24,623)
<b>BALANCE, MARCH 31, 2022</b>	—	\$ —	25,485,420	\$ 25	\$ 515,701	\$ (118,390)	\$ —	\$ 397,336
Stock-based compensation expense	—	—	—	—	8,783	—	—	8,783
Exercise of common stock options	—	—	36,634	—	110	—	—	110
Issuance of common stock from vested restricted stock units and payment of employees' taxes	—	—	6,358	—	(32)	—	—	(32)
Issuance of common stock in acquisition of business	—	—	763,887	1	17,110	—	—	17,111
Net loss	—	—	—	—	—	(1,648)	—	(1,648)
<b>BALANCE, JUNE 30, 2022</b>	—	\$ —	26,292,299	\$ 26	\$ 541,672	\$ (120,038)	\$ —	\$ 421,660

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)**

	Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive Loss	Total Stockholders' Equity
	Shares	Amount	Shares	Amount				
<b>BALANCE, JANUARY 1, 2023</b>	—	\$ —	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)
<b>BALANCE, MARCH 31, 2023</b>	—	\$ —	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)
<b>BALANCE, JUNE 30, 2023</b>	—	\$ —	26,784,008	\$ 27	\$ 587,771	\$ (208,886)	\$ (144)	\$ 378,768

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)**

	Six Months Ended June 30,	
	2023	2022
<b>OPERATING ACTIVITIES</b>		
Net loss	\$ (47,981)	\$ (26,271)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	5,932	4,779
Stock-based compensation expense	26,374	17,202
Change in fair value of contingent consideration	—	(17,836)
Deferred income taxes	13	(1,839)
Accretion of discounts on marketable investment securities	(2,282)	—
Other	213	39
Change in operating assets and liabilities:		
Accounts receivable	(7,978)	(5,628)
Prepaid expenses and other current assets	158	(707)
Inventory	(2,141)	(1,066)
Operating lease assets	(469)	437
Other assets	(80)	504
Accounts payable	3,071	302
Operating lease liabilities	958	(445)
Accrued compensation	(7,060)	(1,013)
Other accrued and current liabilities	2,047	1,111
Net cash used in operating activities	<u>(29,225)</u>	<u>(30,431)</u>
<b>INVESTING ACTIVITIES</b>		
Purchases of property and equipment	(7,373)	(1,807)
Asset acquisition, adjustment to purchase price	—	547
Acquisition of business, net of cash and cash equivalents acquired	—	(26,661)
Proceeds from sale of property and equipment	8	8
Purchases of marketable investment securities	(86,438)	—
Proceeds from maturities of marketable investment securities	95,000	—
Net cash provided by (used in) investing activities	<u>1,197</u>	<u>(27,913)</u>
<b>FINANCING ACTIVITIES</b>		
Proceeds from exercise of common stock options	184	509
Payment of employees' taxes on vested restricted stock units	(848)	(88)
Proceeds from contributions to the employee stock purchase plan	1,688	1,511
Repayment of principal portion of finance lease liabilities	(70)	(55)
Net cash provided by financing activities	<u>954</u>	<u>1,877</u>
<b>NET CHANGE IN CASH AND CASH EQUIVALENTS</b>	<b>(27,074)</b>	<b>(56,467)</b>
Beginning of period	122,948	329,633
End of period	<u>\$ 95,874</u>	<u>\$ 273,166</u>

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)**

	Six Months Ended June 30,	
	2023	2022
<b>DISCLOSURE OF NON-CASH INVESTING AND FINANCING ACTIVITIES:</b>		
Accrued purchases of property and equipment	\$ 728	\$ 696
Common stock issued in acquisition of business	\$ —	\$ 17,111
Contingent consideration in acquisition of business	\$ —	\$ 1,528
Consideration payable in acquisition of business	\$ —	\$ 313
Operating lease assets obtained in exchange for lease obligations	\$ 485	\$ —
Property and equipment acquired with tenant improvement allowance	\$ 1,236	\$ —

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.

We have a history of recurring net losses and negative cash flows and as of June 30, 2023, we had an accumulated deficit of \$208.9 million. We believe our \$95.9 million of cash and cash equivalents and \$129.6 million of marketable investment securities as of June 30, 2023, 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.

**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.

***Unaudited Interim Financial Information***

The accompanying condensed consolidated balance sheet as of June 30, 2023; the condensed consolidated statements of operations, the condensed consolidated statements of comprehensive loss and the condensed consolidated statements of stockholders’ equity, each for the three and six months ended June 30, 2023 and 2022; and the condensed consolidated statements of cash flows for the six months ended June 30, 2023 and 2022 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 June 30, 2023, the results of our consolidated operations for the three and six months ended June 30, 2023 and 2022 and our consolidated cash flows for the six months ended June 30, 2023 and 2022. The financial data and other information disclosed in these notes related to the three and six months ended June 30, 2023 and 2022 are also unaudited. The results for the three and six months ended June 30, 2023 are not necessarily indicative of results to be expected for the year ending December 31, 2023, any other interim periods, or any future year or period. The balance sheet as of December 31, 2022 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, 2022 filed with the Securities and Exchange Commission (“SEC”) on February 28, 2023 (the “2022 Form 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.

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

**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 10 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. The allowance for credit losses was zero as of June 30, 2023 and December 31, 2022. 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.

**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

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

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.

On June 2, 2023, a Medicare administrative contractor (“MAC”) finalized a local coverage determination (“LCD”) pursuant to which the DecisionDx-SCC test would no longer be covered by Medicare effective July 17, 2023. On June 5, 2023, our stock price decreased significantly and did not recover before June 30, 2023. In response to this trigger, we tested goodwill for impairment at June 30, 2023. We elected to bypass the optional qualitative assessment and proceeded directly to the quantitative assessment. In conducting our interim test, we concluded that our business consists of a single reporting unit. To measure the fair value of our reporting unit, we used a market approach whereby we calculated our total market capitalization on the impairment test date, based on the closing price of our common stock as reported on the Nasdaq Global Market, and applied a reasonable control premium. The control premium was based on an analysis of control premiums paid in recent acquisitions of companies in the same or similar industry as us. Our impairment test indicated that the fair value of our reporting unit exceeded its carrying value by 13% and therefore no impairment was indicated. In July 2023, the MAC suspended the LCD and then posted a new draft LCD for comment that is substantially the same as the LCD that was to become effective.

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 June 30, 2023 and December 31, 2022, we accrued approximately \$10,350,000 and \$18,209,000, 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 Loss***

Comprehensive loss is defined as a change in equity during a period from transactions and other events and circumstances from non-owner sources. Comprehensive loss is made up of net loss plus net unrealized gain (loss) on marketable investment securities, which is our only other item of other comprehensive income (loss).

**CASTLE BIOSCIENCES, INC.**  
**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)**  
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### 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<sup>®</sup>-Melanoma test for cutaneous melanoma. We also provide a test for patients with cutaneous squamous cell carcinoma (“SCC”), DecisionDx<sup>®</sup>-SCC, a test for use in patients with suspicious pigmented lesions, MyPath<sup>®</sup> Melanoma and DiffDx<sup>®</sup>-Melanoma, a test for uveal melanoma (“UM”), DecisionDx<sup>®</sup>-UM and a test for patients diagnosed with Barrett’s esophagus, the TissueCypher<sup>®</sup> Barrett’s Esophagus Test. We also began offering a pharmacogenomics testing service focused on mental health, IDgenetix<sup>®</sup>, following a business combination completed in April 2022. 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 LCD 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 June 30, 2023 and 2022 were \$88,000 of net negative revenue adjustments and \$578,000 of net positive revenue adjustments, respectively, associated with changes in estimated variable consideration related to performance obligations satisfied in previous periods. Such amounts of variable consideration for the six months ended June 30, 2023 and 2022 were \$1,705,000 and \$300,000 of net negative revenue adjustments, respectively. 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.

**CASTLE BIOSCIENCES, INC.**  
**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)**  
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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 June 30, 2023 and December 31, 2022.

**Disaggregation of Revenues**

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
Dermatologic <sup>(1)</sup>	\$ 43,030	\$ 31,897	\$ 78,941	\$ 56,236
Non-Dermatologic <sup>(2)</sup>	7,108	2,941	13,234	5,454
<b>Total net revenues</b>	<b>\$ 50,138</b>	<b>\$ 34,838</b>	<b>\$ 92,175</b>	<b>\$ 61,690</b>

(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		Percentage of Accounts Receivable (current) as of		Percentage of Accounts Receivable (noncurrent) as of	
	Six Months Ended June 30,		June 30, 2023		December 31, 2022	
	2023	2022	June 30, 2023	December 31, 2022	June 30, 2023	December 31, 2022
Medicare	49 %	52 %	23 %	28 %	*	*
Payor A	14 %	11 %	15 %	14 %	15 %	16 %
Payor B	*	*	10 %	*	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. Loss Per Share**

Basic loss per share is computed by dividing net loss for the period by the weighted-average number of common shares outstanding during the period. Diluted 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 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.

Because we reported a net loss for all periods presented, all potentially dilutive securities are antidilutive and are excluded from the computation of diluted loss per share for such periods.

**CASTLE BIOSCIENCES, INC.**  
**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)**  
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The table below provides the weighted-average number of potential common shares associated with outstanding securities not included in our calculation of diluted loss per share for the three and six months ended June 30, 2023 and 2022 because to do so would be antidilutive or, in the case of PSUs, the applicable performance conditions have not yet been met (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
Stock options	3,326	3,530	3,357	3,535
RSUs and PSUs	3,562	1,444	3,589	1,293
ESPP	309	111	294	101
Total	7,197	5,085	7,240	4,929

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 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 10 for additional information.

### 5. Marketable Investment Securities

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

	June 30, 2023			
	Amortized Cost	Unrealized		Estimated Fair Value
		Gains	Losses	
U.S. government securities	\$ 129,778	\$ —	\$ (144)	\$ 129,634
Total	\$ 129,778	\$ —	\$ (144)	\$ 129,634

	December 31, 2022			
	Amortized Cost	Unrealized		Estimated Fair Value
		Gains	Losses	
U.S. government securities	\$ 136,058	\$ —	\$ (381)	\$ 135,677
Total	\$ 136,058	\$ —	\$ (381)	\$ 135,677

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 six months ended June 30, 2023 and 2022.

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 June 30, 2023, 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 six months ended June 30, 2023 and 2022. The allowance for credit losses was zero as of June 30, 2023 and December 31, 2022.

As of June 30, 2023, 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 June 30, 2023 and December 31, 2022 the accrued interest receivable balance was immaterial.

**CASTLE BIOSCIENCES, INC.**  
**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)**  
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Additional information relating to the fair value of marketable investment securities can be found in Note 10.

## 6. Acquisition

On April 26, 2022, we completed the acquisition of 100% of the equity interests in AltheaDx which offers the IDgenetix test that focuses on mental health. We acquired AltheaDx for \$30.5 million in cash and \$17.1 million in common stock issued, for total consideration of \$47.6 million. The fair value of assets acquired and liabilities assumed primarily consisted of finite-lived intangible assets of \$35.0 million, goodwill of \$10.7 million, cash and cash equivalents of \$3.5 million and deferred tax liabilities of \$1.7 million. We have concluded that the transaction represents a business combination under ASC Topic 805, *Business Combinations*. The financial results of AltheaDx have been included in our unaudited condensed consolidated financial statements since the date of the acquisition. For further details refer to our consolidated financial statements included in our 2022 Form 10-K. The amount of revenue attributable to AltheaDx included in the unaudited consolidated statements of operations from the acquisition date was not material for the three and six months ended June 30, 2022. The loss attributable to AltheaDx included in the unaudited consolidated statements of operations from the acquisition date was approximately \$3,383,000 for the three and six months ended June 30, 2022. This amount does not reflect transaction costs from the acquisition or the effects of the valuation allowance reduction discussed in Note 13. Transaction costs associated with the acquisition were \$1,711,000 for both the three and six months ended June 30, 2022 and were recognized as expenses in the unaudited condensed consolidated statements of operations.

### *Unaudited Pro Forma Financial Information*

The following unaudited pro forma financial information for the three and six months ended June 30, 2022 combines our historical financial results and the results of AltheaDx, assuming that the companies were combined as of January 1, 2021, and includes adjustments for amortization expense from the acquired intangible assets and additional stock-based compensation expense. Non-recurring pro forma adjustments consist of acquisition-related transaction costs of \$1,711,000 and an income tax benefit of \$1,769,000, both assumed to have been recognized during the year ended December 31, 2021 and therefore removed from the three and six months ended June 30, 2022. The following unaudited pro forma financial information (in thousands) is for informational purposes only and is not necessarily indicative of (i) the results of operations that would have been achieved if the acquisition had taken place as of January 1, 2021 or (ii) the results of operations that are expected in future periods:

	<b>Pro Forma Data</b>	
	<b>Three Months Ended June 30, 2022</b>	<b>Six Months Ended June 30, 2022</b>
Net revenues	\$ 35,243	\$ 62,242
Net loss	\$ (4,062)	\$ (31,945)

### ***Related Parties***

Derek J. Maetzold, our President and Chief Executive Officer, and a member of our board of directors, and Daniel M. Bradbury, the Chairperson of our board of directors, each served on the board of directors of AltheaDx until the acquisition of AltheaDx was completed, were direct or indirect beneficial owners of AltheaDx securities and received consideration in connection with our acquisition of AltheaDx. Further, Frank Stokes, our Chief Financial Officer; Tobin W. Juvenal, our Chief Commercial Officer; Kristen Oelschlager, our Chief Operating Officer and certain immediate family members of Mr. Maetzold and Ms. Oelschlager were direct or indirect beneficial owners of AltheaDx securities and received consideration in the transaction. These individuals may receive additional contingent consideration based on the achievement of certain commercial milestones relating to the 2022, 2023, and 2024 commercial milestones ("AltheaDx Earnout Payments") if the relevant commercial and regulatory milestone events occur. As of June 30, 2023 and December 31, 2022, our contingent consideration liability for the AltheaDx Earnout Payments was zero. See Note 10 for additional information. Our entry into the definitive agreement to acquire AltheaDx was approved by our board of directors based upon the unanimous recommendation of a special transaction committee comprised entirely of independent members of our board of directors without any financial interest in AltheaDx or any conflict of interest with respect to the acquisition of AltheaDx.

**CASTLE BIOSCIENCES, INC.**  
**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)**  
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## 7. Property and Equipment, Net

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

	June 30, 2023	December 31, 2022
Lab equipment <sup>(1)</sup>	\$ 10,929	\$ 9,721
Leasehold improvements	9,306	5,171
Computer equipment	3,853	4,336
Furniture and fixtures	2,332	1,660
Construction-in-progress	383	1,275
Total	26,803	22,163
Less accumulated depreciation <sup>(1)</sup>	(6,292)	(7,848)
Property and equipment, net	\$ 20,511	\$ 14,315

(1) As of June 30, 2023 and December 31, 2022, includes lab equipment under finance lease of \$369 thousand and \$369 thousand, respectively, and accumulated depreciation of \$207 thousand and \$137 thousand, respectively.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
Cost of sales (exclusive of amortization of acquired intangible assets)	\$ 405	\$ 185	\$ 700	\$ 354
Research and development	83	80	162	170
Selling, general and administrative	304	266	600	510
Total	\$ 792	\$ 531	\$ 1,462	\$ 1,034

## 8. Goodwill and Other Intangible Assets, Net

### Goodwill

The balance of our goodwill was \$10.7 million as of June 30, 2023 and December 31, 2022. There were no accumulated impairments of goodwill as of June 30, 2023 or December 31, 2022.

### Other Intangible Assets, Net

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

	June 30, 2023			Weighted-Average Remaining Life (in years)
	Gross carrying value	Accumulated amortization	Net	
Developed technology	\$ 125,317	\$ (14,516)	\$ 110,801	12.5
Assembled workforce	563	(177)	386	3.6
Total other intangible assets, net	\$ 125,880	\$ (14,693)	\$ 111,187	

**CASTLE BIOSCIENCES, INC.**  
**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)**  
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	December 31, 2022			
	Gross carrying value	Accumulated amortization	Net	Weighted-Average Remaining Life (in years)
Developed technology	\$ 125,317	\$ (10,102)	\$ 115,215	12.9
Assembled workforce	563	(122)	441	4.0
<b>Total other intangible assets, net</b>	<b>\$ 125,880</b>	<b>\$ (10,224)</b>	<b>\$ 115,656</b>	

Amortization expense of intangible assets was \$2.2 million and \$4.5 million for the three and six months ended June 30, 2023, respectively, and \$2.1 million and \$3.7 million for the three and six months ended June 30, 2022, respectively.

### 9. Other Accrued and Current Liabilities

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

	June 30, 2023	December 31, 2022
Clinical studies	\$ 3,601	\$ 1,822
Accrued service fees	2,333	2,125
ESPP contributions	936	900
Other	448	415
<b>Total</b>	<b>\$ 7,318</b>	<b>\$ 5,262</b>

### 10. 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.

**CASTLE BIOSCIENCES, INC.**  
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The table below provides 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 June 30, 2023 and December 31, 2022 (in thousands):

	As of June 30, 2023			Total
	Quoted Prices in Active Markets for Identical Items (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	
<b>Assets</b>				
Money market funds <sup>(1)</sup>	\$ 77,828	\$ —	\$ —	\$ 77,828
U.S. government securities <sup>(2)</sup>	\$ 129,634	\$ —	\$ —	\$ 129,634
<b>Liabilities</b>				
Contingent consideration <sup>(3)</sup>	\$ —	\$ —	\$ —	\$ —
	As of December 31, 2022			Total
	Quoted Prices in Active Markets for Identical Items (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	
<b>Assets</b>				
Money market funds <sup>(1)</sup>	\$ 108,673	\$ —	\$ —	\$ 108,673
U.S. government securities <sup>(2)</sup>	\$ 135,677	\$ —	\$ —	\$ 135,677
<b>Liabilities</b>				
Contingent consideration <sup>(3)</sup>	\$ —	\$ —	\$ —	\$ —

(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 Cernostics, Inc. (“Cernostics”) in December 2021, we recorded a liability for contingent consideration of up to \$50.0 million that could have been payable based on the achievement of certain commercial milestones relating to the year ending December 31, 2022 (“Cernostics Earnout Payments”). At our sole discretion, we could have settled Cernostics Earnout Payments in cash or shares of our common stock, subject to certain limitations. There were no Cernostics Earnout Payments that became payable because the commercial milestones were not achieved during the earnout period and the final valuation of the contingent consideration was assessed to be zero as of December 31, 2022. The fair value of the contingent consideration associated with our acquisition of Cernostics decreased by \$20.8 million and \$18.2 million for the three and six months ended June 30, 2022, respectively, with no similar activity for the same periods in 2023.

In connection with our acquisition of AltheaDx, we agreed to pay contingent consideration of up to \$75.0 million relating to the AltheaDx Earnout Payments. The portion of the AltheaDx Earnout Payments associated with the commercial milestones for the year ended December 31, 2022 was not paid since the applicable commercial milestones were not met. This portion represented \$35.0 million of the \$75.0 million total potential payment obligation, exclusive of the catch-up payment in 2023 of \$17.5 million, which will become payable if all 2023 commercial milestones are fully met. Therefore, as of June 30, 2023, we have a potential payment obligation of up to \$57.5 million with respect to the remaining commercial milestones for 2023 and 2024. If the settlement of the remaining portion of the AltheaDx Earnout Payments would have occurred on June 30, 2023, no amounts would have been due because no commercial milestones had been achieved as of such date.

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**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)**  
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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. We recognized a loss of \$0.4 million during the three and six months ended June 30, 2022 associated with the change in fair value of the preliminary AltheaDx contingent consideration. The valuation of the AltheaDx contingent consideration was zero as of June 30, 2023 and December 31, 2022, and no gains or losses were recorded associated with changes in fair value during the three and six months ended June 30, 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.

### 11. 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.

### 12. Stock Incentive Plans and Stock-Based Compensation

#### *Stock Incentive Plans*

Effective January 1, 2023, an additional 1,327,684 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 June 30, 2023, we have granted awards with an aggregate of 9,930 shares of underlying common stock in excess of the number of shares authorized for issuance 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 June 30, 2023, there were 161,264 shares available for grant under the Inducement Plan.

#### *Stock Options*

Stock option activity under our stock plans for the six months ended June 30, 2023 is set forth below:

	Stock Options Outstanding	Weighted-Average		Aggregate Intrinsic Value (in thousands)
		Exercise Price	Remaining Contractual Term (Years)	
Balance as of December 31, 2022	3,419,840	\$ 35.11		
Granted	170	\$ 25.06		
Exercised	(46,101)	\$ 4.01		
Forfeited/Cancelled	(63,670)	\$ 45.73		
Balance as of June 30, 2023	3,310,239	\$ 35.34	7.0	\$ 5,450
Exercisable at June 30, 2023	2,374,351	\$ 31.51	6.7	\$ 5,450

**CASTLE BIOSCIENCES, INC.**  
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**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 six months ended June 30, 2023:

	Restricted Stock Units Outstanding	Weighted-Average Grant Date Fair Value
Balance as of December 31, 2022	3,477,922	\$ 27.56
Granted	307,131	\$ 17.63
Vested <sup>(1)</sup>	(144,592)	\$ 26.76
Forfeited/Cancelled	(153,613)	\$ 26.17
Balance as of June 30, 2023	3,486,848	\$ 26.78

(1) The aggregate number of shares withheld upon vesting for employee tax obligations was 37,556 for the six months ended June 30, 2023.

**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.

The following table summarizes our PSU activity for the six months ended June 30, 2023:

	Performance-Based Restricted Stock Units Outstanding	Weighted-Average Grant Date Fair Value
Balance as of December 31, 2022	196,033	\$ 23.23
Granted	—	\$ —
Vested	—	\$ —
Forfeited/Cancelled	—	\$ —
Balance as of June 30, 2023	196,033	\$ 23.23

**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 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 \$1.1 million during the three and six months ended June 30, 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 265,536 shares becoming available under the ESPP effective January 1, 2023. During the six months ended June 30, 2023, we issued 77,190 of common stock pursuant to scheduled purchases under the ESPP. As of June 30, 2023, 1,002,945 shares remained available for issuance under the ESPP.

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

**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:

	Six Months Ended June 30,	
	2023	2022
Average expected term (years)	5.0	5.8
Expected stock price volatility	75.57% - 76.01%	68.34% - 71.58%
Risk-free interest rate	3.57% - 3.57%	1.54% - 2.91%
Dividend yield	—%	—%

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

	Six Months Ended June 30,	
	2023	2022
Average expected term (years)	1.3	1.3
Expected stock price volatility	72.80% - 82.61%	62.98% - 66.75%
Risk-free interest rate	4.77% - 5.07%	0.60% - 1.30%
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 June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
Cost of sales (exclusive of amortization of acquired intangible assets)	\$ 1,202	\$ 897	\$ 2,474	\$ 1,750
Research and development	2,486	1,831	5,073	3,659
Selling, general and administrative	9,161	6,055	18,827	11,793
Total stock-based compensation expense	<u>\$ 12,849</u>	<u>\$ 8,783</u>	<u>\$ 26,374</u>	<u>\$ 17,202</u>

For the six months ended June 30, 2023 and 2022, the weighted-average grant date fair value of stock options was \$15.99 and \$14.07 per option, respectively, and the weighted-average grant date fair value of the purchase rights granted under the ESPP was \$11.00 and \$19.91 per share, respectively. As of June 30, 2023, the total unrecognized stock-based compensation cost related to outstanding awards was \$108,870,000, which is expected to be recognized over a weighted-average period of 2.6 years. The total unrecognized compensation cost will be adjusted for forfeitures in future periods as they occur.

**13. Income Taxes**

In connection with our acquisition of AltheaDx in 2022, we recorded deferred tax liabilities based on our allocation of the fair values of assets acquired and liabilities assumed. As a result of these additional deferred tax liabilities, we recorded a \$1,769,000 reduction to our existing valuation allowance on deferred tax assets, which was reflected in our income tax benefit on the condensed consolidated statements of operations for the three and six months ended June 30, 2022 as a discrete item.

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

**14. Subsequent Event**

On July 10, 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. We have the option to terminate the contract within 90 days, for any reason, and will use this time to complete initial suitability diligence. Closing, if it should occur, is expected in late 2023.

## **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 and our audited financial statements and notes thereto as of and for the years ended December 31, 2022 and 2021 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, 2022, as filed with the Securities and Exchange Commission (the “SEC”) on February 28, 2023. 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 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 applying innovative diagnostics to inform disease management and improve patient outcomes. For the diseases that our portfolio of tests cover, we believe the traditional approach to developing a treatment plan for cancers and other diseases using clinical and pathology factors alone is inadequate and can be improved by incorporating the personalized information our tests provide.

### **Our Test Portfolio**

We currently offer five proprietary multi-analyte assays with algorithmic analysis (“MAAA”) tests for use in the dermatologic, ocular and gastroenterology fields. We also offer a proprietary pharmacogenomics (“PGx”) test to guide optimal drug treatment for patients suffering from depression, anxiety and other mental health conditions following our acquisition of AltheaDx, Inc. (“AltheaDx”) in April 2022, as discussed below.

Currently, our revenue is primarily generated by our DecisionDx-Melanoma risk stratification gene expression profile (“GEP”) test for cutaneous melanoma, 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 Barrett’s esophagus (“BE”) and our DecisionDx-UM risk stratification test for uveal melanoma (“UM”).

All five of our MAAA tests have been granted Advanced Diagnostic Laboratory (“ADLT”) test 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**

Our lead product is DecisionDx-Melanoma, a proprietary risk stratification GEP test that predicts the risk of metastasis or recurrence for patients diagnosed with invasive cutaneous melanoma. In a typical year, we estimate approximately 130,000 patients are diagnosed with invasive cutaneous melanoma in the United States, representing an estimated U.S. total addressable market (“TAM”) of approximately \$540 million. We launched DecisionDx-Melanoma in May 2013.

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 200,000 SCC patients are annually diagnosed and classified at high risk in the United States, are classified as high risk, representing an estimated U.S. TAM of approximately \$820 million. We launched DecisionDx-SCC in August 2020.

Initially, we offered both our MyPath Melanoma test and our DiffDx-Melanoma test under an offering that we referred to as our Diagnostic GEP offering for use in patients with a melanocytic lesion and uncertainty related to the malignancy of the lesion representing an estimated U.S. TAM of approximately \$600 million. 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**

The TissueCypher Barrett’s Esophagus Test (sometimes referred to as “TissueCypher”) is the world’s first precision medicine 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 Barrett’s Esophagus. We estimate a U.S. TAM of approximately \$1 billion. We began offering the TissueCypher Barrett’s Esophagus Test following our acquisition of Cernostics, Inc. (“Cernostics”) in December 2021.

In the second quarter of 2023, we opened a new laboratory in Pittsburgh, Pennsylvania where we process our TissueCypher Barrett’s Esophagus Test. We have seen such a strong adoption of the test from the gastrointestinal community that our orders have outpaced our forecasts as well as our process improvements and automation efforts. In July 2023, in response to significant demand, we elected to temporarily pause accepting additional orders for the TissueCypher Barrett’s Esophagus Test in order to bring our process improvements and additional instrumentation and personnel on line. We are currently working through these efforts and believe that we will be able to begin accepting new orders prior to the end of third quarter of 2023.

### **Our Uveal Melanoma Test**

DecisionDx-UM is a proprietary, risk stratification GEP test that predicts 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 for depression, anxiety and other mental health conditions. We estimate a U.S. TAM of approximately \$5 billion associated with this test. We began offering the IDgenetix test following our acquisition of AltheaDx in April 2022.

### **Commercial Expansion Efforts**

In late April 2022, we acquired AltheaDx and a commercial team covering approximately 20 outside sales territories. In September 2022, we added additional outside territories for our TissueCypher Barrett’s Esophagus Test and established a new commercial sales team dedicated to our Diagnostic GEP offering, with the current dermatologic commercial team shifting to focus primarily on DecisionDx-Melanoma and DecisionDx-SCC. The new sales teams were fully integrated into our commercial operations by the end of the second quarter of 2023.

We will continue to assess market response in determining further commercial expansions.

### **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. *De novo* coverage by government and third-party payors for our pipeline tests will be important over time.

We bill third-party payors and patients for the tests we perform. The majority of our revenue collections is paid by third-party insurers, including Medicare. 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, representing approximately 60 million covered lives. A “covered life” means a subscriber, or a dependent of a subscriber, who is insured under an insurance carrier’s policy.

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 our Annual Report on Form 10-K for the year ended December 31, 2022.

### **DecisionDx-Melanoma**

#### *LCD*

Palmetto GBA MoIDX (“Palmetto”), the Medicare Administrative Contractor (“MAC”) responsible for administering MoIDX, the program that assesses molecular diagnostic technologies, issued a final expanded local coverage determination (“LCD”) for DecisionDx-Melanoma, effective November 22, 2020. With this expanded LCD and the accompanying billing and coding articles, we estimate that a significant majority of the DecisionDx-Melanoma tests performed for Medicare patients will meet the coverage criteria. Noridian Healthcare Solutions, LLC (“Noridian”), the MAC responsible for administering claims for laboratory services performed in our Arizona laboratory, has adopted the same coverage policy as Palmetto and also issued an expanded final LCD for DecisionDx-Melanoma, effective December 6, 2020. More recently, Palmetto converted the DecisionDx-Melanoma test-specific LCD to a “foundational” LCD. This LCD was issued as final May 19, 2022 with Noridian issuing the same on June 16, 2022. The final LCDs did not result in any changes in coverage.

#### *ADLT*

On May 17, 2019, CMS determined that DecisionDx-Melanoma meets the criteria for ADLT status. 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. The rate for 2022 was \$7,193 per test and continues to be \$7,193 per test for 2023.

### **DecisionDx-UM**

#### *LCD*

Palmetto issued a final LCD for DecisionDx-UM, which became effective in July 2017. Noridian, the MAC responsible for administering claims for laboratory services performed in our Arizona laboratory, has adopted the same coverage policy as Palmetto.

#### *ADLT*

On May 17, 2019, CMS determined that DecisionDx-UM meets the criteria for “existing advanced diagnostic laboratory test” status, also referred to as “existing ADLT” status. 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. The rate for 2022 was \$7,776 per test and the rate for 2023 remains at \$7,776 per test.

### **Diagnostic GEP Offering**

#### *MyPath Melanoma*

MyPath Melanoma is currently covered under a MoIDX LCD policy through Noridian that first became effective in June 2019.

#### *ADLT*

MyPath Melanoma was approved as a new ADLT in September 2019. The rate for 2022 was \$1,950 per test. Our 2023 rate is 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. Rates for our MyPath Melanoma test continues to be set annually based upon the median private payor rate for the first half of the second preceding calendar year.

### *DiffDx-Melanoma*

In early 2021, we submitted our technical assessment dossier for DiffDx-Melanoma. The dossier was accepted as complete in the first quarter of 2021. In June 2022, Palmetto and Noridian each posted a proposed LCD that would convert the MyPath Melanoma test-specific LCD to a “foundational” LCD and provide coverage for both MyPath Melanoma and DiffDx-Melanoma. On June 22, 2023, Palmetto and Noridian issued final foundational LCDs that will provide coverage for both MyPath Melanoma and DiffDx-Melanoma effective August 6, 2023.

In the second quarter of 2022, we obtained a Proprietary Laboratory Analyses (“PLA”) code for DiffDx-Melanoma. DiffDx-Melanoma is going through CMS’s gapfill pricing process in 2023, which we expect to conclude in late 2023 and to be effective January 1, 2024. The gapfill process consists of several steps throughout the calendar year. First, individual MACs develop gapfill rates and report them to CMS. Using this information, CMS then posts preliminary rates and commences a public comment period. After evaluating public comments, CMS posts updated rates and begins accepting requests to reconsider these rates, known as reconsideration requests. After CMS processes any reconsideration requests, the gapfill rates are considered final. In April 2023, CMS posted a preliminary determination of a gapfill rate for DiffDx-Melanoma of \$1,950 per test, which is subject to a public comment period and any reconsideration requests. We cannot predict at this time what the final gapfill rate will be.

### **DecisionDx-SCC**

In the first quarter of 2022, we requested that Novitas Solutions, Inc. (“Novitas”), the MAC that manages the Medicare jurisdiction covering our Pittsburgh, Pennsylvania laboratory, conduct a medical review of our DecisionDx-SCC test. That review was completed towards the end of that quarter. In the second quarter of 2022, following the completion of a requested medical review and pricing of our DecisionDx-SCC test by Novitas, we obtained a PLA code and began receiving reimbursement from Novitas for DecisionDx-SCC at a rate of \$3,873 per test.

### *LCD*

On June 2, 2023, Novitas finalized the 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 ends on September 9, 2023. We cannot predict whether this LCD will be finalized as proposed or what the timing of any final LCD might be.

In the second quarter of 2020, we submitted our technical assessment dossier for DecisionDx-SCC to Palmetto and Noridian. The dossier was accepted as complete in the third quarter of 2020. On June 8, 2023, both Palmetto and Noridian posted their draft LCD recommending no coverage for DecisionDx-SCC. The comment period for the draft LCDs ended on July 22, 2023.

### *ADLT*

On June 30, 2023, 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. Effective April 1, 2024 and through December 31, 2025, the published Clinical Laboratory Fee Schedule (“CLFS”) rate for DecisionDx-SCC will be based on the median private payor rates received between July 1, 2023 and November 30, 2023. Thereafter, the rate 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, Pennsylvania laboratory and falls under the Medicare jurisdiction managed by Novitas which previously reviewed TissueCypher. We receive payments for claims according to the published CLFS rate. For 2022, the published CLFS payment rate was \$2,513 for the test.

On March 24, 2022, CMS determined that TissueCypher meets the criteria for “new ADLT” status. From April 1, 2022 through December 31, 2022, CMS has set the initial period rate equal to the original list price of \$2,350. Effective January 1, 2023, the published CLFS rate for TissueCypher is \$4,950, 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 an LCD policy through MoIDX and an accompanying billing and coding article through Noridian. The Medicare coverage includes depression and the following seven additional mental health conditions beyond major depressive disorder: schizophrenia, bipolar disorder, anxiety disorders, social phobia, obsessive-compulsive personality disorder, post-traumatic stress disorder and attention deficit hyperactivity disorder. IDgenetix has historically been billed to Medicare using an unspecified Current Procedural Terminology (“CPT”) code along with the IDgenetix test-specific MoIDX Z-code (the “IDgenetix Z-Code”). In February 2023, MoIDX 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 is currently contractor priced at \$917 while it undergoes CMS’s gapfill pricing process in 2023. Accordingly, as a result of this change, the Medicare reimbursement rate for the IDgenetix multi-gene panel decreased from approximately \$1,500 per test to \$917 per test. The New CPT Code does not describe all of the components of the IDgenetix test. We subsequently obtained a test-specific PLA CPT code. The new PLA code becomes effective October 1, 2023 and is currently undergoing the 2024 CLFS pricing process.

**Delivered Test Reports**

The number of test reports we generate 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 sent to the clinician who ordered the test.

The number of test reports delivered by us during the six months ended June 30, 2023 and 2022 and for the year ended December 31, 2022 are presented in the table below:

	Proprietary Dermatologic GEP Tests					DecisionDx-UM	TissueCypher Barrett's Esophagus Test	IDgenetix <sup>(2)</sup>	Grand Total
	DecisionDx-Melanoma	DecisionDx-SCC	Diagnostic GEP offering <sup>(1)</sup>	Dermatologic Total					
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	
<b>For the six months ended June 30, 2023</b>	<b>16,180</b>	<b>5,092</b>	<b>1,933</b>	<b>23,205</b>	<b>870</b>	<b>2,830</b>	<b>4,831</b>	<b>31,736</b>	
Q1 2022	6,023	1,142	950	8,115	456	56	—	8,627	
Q2 2022	7,125	1,344	955	9,424	431	352	827	11,034	
<b>For the six months ended June 30, 2022</b>	<b>13,148</b>	<b>2,486</b>	<b>1,905</b>	<b>17,539</b>	<b>887</b>	<b>408</b>	<b>827</b>	<b>19,661</b>	
Q3 2022	7,354	1,636	834	9,824	392	690	1,208	12,114	
Q4 2022	7,301	1,845	822	9,968	432	1,030	1,214	12,644	
<b>For year ended December 31, 2022</b>	<b>27,803</b>	<b>5,967</b>	<b>3,561</b>	<b>37,331</b>	<b>1,711</b>	<b>2,128</b>	<b>3,249</b>	<b>44,419</b>	

(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 began offering the IDgenetix test on April 26, 2022, following our acquisition of AltheaDx. Includes both single-gene and multi-gene tests.

For the three and six months ended June 30, 2023, our test report volume increased by 52.4% and 61.4% respectively, compared to the same periods of 2022. Our dermatologic test report volume increased by 29.8% and 32.3% for the three and six months ended June 30, 2023, respectively, compared to the prior periods in 2022,

largely driven by continued growth from our DecisionDx-Melanoma and DecisionDx-SCC tests. Increases from our other tests (non-dermatologic), primarily TissueCypher and IDgenetix, also contributed to the overall volume increase. For a discussion of how we recognize revenue derived from our tests, refer to “Net Revenues” under “Components of Results of Operations” below.

We continue to see new clinicians order our dermatologic tests for the first time. For the three months ended June 30, 2023, we saw approximately 567 new ordering clinicians for our dermatologic tests compared to 608 during the same period of 2022. For the six months ended June 30, 2023 and 2022, we saw approximately 1,106 and 1,200, respectively, new ordering clinicians for our dermatologic tests. Total ordering clinicians for our dermatologic tests were approximately 2,067 and 2,032 for the three months ended June 30, 2023 and 2022, respectively, and 6,592 and 5,661 for the six months ended June 30, 2023 and 2022, respectively.

For additional information on the metrics we disclose, refer to “Information About Certain Metrics” below.

In developing our DecisionDx-SCC test, we believed that in addition to addressing significant unmet clinical needs, we would see opportunities for leverage, as many of the clinicians currently ordering DecisionDx-Melanoma would likely be the same clinicians who would find value in our DecisionDx-SCC test. For example, we found that during the six months ended June 30, 2023, approximately 69% 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 Operation.

#### ***Test Reports Delivered***

Test reports delivered represents 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 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.

#### ***New Ordering Clinicians***

New ordering clinicians for our dermatologic tests represents the number of clinicians who ordered a dermatologic test from us for the first time during the reporting period specified. Our dermatologic tests currently consist of DecisionDx-Melanoma, DecisionDx-SCC and MyPath Melanoma. We believe this metric is useful in evaluating the effectiveness of our sales and marketing efforts in establishing new relationships with clinicians and increasing the adoption of our suite of dermatologic tests. We also believe this metric provides useful information to investors in assessing our ability to expand the use of our dermatologic tests. Since this metric is based upon the reporting period in which an order is placed, it does not necessarily correspond to the reporting period in which a test report was delivered or revenue was recognized.

### **Other Events**

#### ***Impact of Macroeconomic Conditions***

Macroeconomic conditions, including uncertainties associated with COVID-19, the ongoing conflict between Ukraine and Russia, economic slowdowns, 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, rising interest rates and financial and credit market fluctuations, volatility in the capital markets or 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 (loss) 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, 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 new expanded laboratory facility in Pittsburgh, Pennsylvania in the second quarter of 2023.

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 June 30, 2023 and 2022” and “Results of Operations—Comparison of the Six Months ended June 30, 2023 and 2022” 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 two important studies that are underway to support our DecisionDx-Melanoma test. The first is the CONNECTION study, which is collecting long-term outcomes for up to 10,000 patients who have been tested with DecisionDx-Melanoma. The second is the DECIDE study, which is designed to determine the association of GEP test results with sentinel lymph node biopsy (“SLNB”) surgical decisions in patients eligible for SLNB as well as to track outcomes for patients who did and did not undergo SLNB. 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 IDENTITY Study, a 4,800 patient, prospective, multi-center clinical study to develop, validate and bring to market a pipeline test aimed at predicting response to systemic therapy in patients with moderate to severe psoriasis, atopic dermatitis and related inflammatory skin conditions. As of June 30, 2023, we have 57 committed sites and 759 patients enrolled in our IDENTITY study. We expect to obtain early developmental data from this study in the second half of 2023 and to launch this test in 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 the Myriad MyPath Laboratory in May 2021, Cernostics in December 2021 and AltheaDx in April 2022.

***Change in Fair Value of Contingent Consideration***

Change in fair value of contingent consideration is associated with our acquisitions of Cernostics and AltheaDx and the related contingent consideration of up to \$50.0 million and \$75.0 million, respectively, payable based on the achievement of certain commercial milestones relating to the year ended December 31, 2022 in the case of Cernostics, and the years ending December 31, 2022, 2023 and 2024, in the case of AltheaDx (the “Earnout Payments”). No Earnout Payments were paid relating to the year ended December 31, 2022 in connection with our acquisitions of Cernostics and AltheaDx since the applicable commercial milestones were not achieved. As of June 30, 2023 and December 31, 2022, our contingent consideration liability for AltheaDx was zero.

***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 finance leases.

***Income Tax Expense (Benefit)***

In connection with our acquisition of AltheaDx in April 2022, and taking into consideration the additional deferred tax liabilities resulting from such acquisition, we determined that a portion of our valuation allowance should be reduced, which is reflected in our income tax benefit for the three and six months ended June 30, 2022. Our consolidated financial statements do not reflect any federal or state income tax benefits attributable to the pre-tax losses we have incurred, due to the uncertainty of realizing a benefit from those items. As of December 31, 2022, we had federal net operating loss (“NOL”) carryforwards of \$207.2 million, of which \$106.1 million will begin to expire in 2029 if not utilized to offset federal taxable income, and \$101.1 million may be carried forward indefinitely. Also, as of December 31, 2022, we had state NOL carryforwards of \$114.0 million, which begin to expire in 2028 if not utilized to offset state taxable income.

## Results of Operations

### Comparison of the Three Months Ended June 30, 2023 and 2022

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

	Three Months Ended June 30,		Change	
	2023	2022		
	(unaudited)			
<b>Net revenues</b>	\$ 50,138	\$ 34,838	\$ 15,300	43.9 %
<b>Operating expenses and other operating income</b>				
Cost of sales (exclusive of amortization of acquired intangible assets)	11,058	7,686	3,372	43.9 %
Research and development	13,308	11,926	1,382	11.6 %
Selling, general and administrative	44,681	37,498	7,183	19.2 %
Amortization of acquired intangible assets	2,248	2,097	151	7.2 %
Change in fair value of contingent consideration	—	(20,398)	20,398	100.0 %
Total operating expenses, net	71,295	38,809	32,486	83.7 %
<b>Operating loss</b>	(21,157)	(3,971)	(17,186)	(432.8)%
Interest income	2,399	370	2,029	548.4 %
Interest expense	(3)	(4)	1	25.0 %
<b>Loss before income taxes</b>	(18,761)	(3,605)	(15,156)	(420.4)%
Income tax expense (benefit)	16	(1,957)	1,973	100.8 %
<b>Net loss</b>	\$ (18,777)	\$ (1,648)	\$ (17,129)	NM

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 June 30,		Change	
	2023	2022		
	(unaudited)			
Cost of sales (exclusive of amortization of acquired intangible assets)	\$ 1,202	\$ 897	\$ 305	
Research and development	2,486	1,831	655	
Selling, general and administrative	9,161	6,055	3,106	
Total stock-based compensation expense	\$ 12,849	\$ 8,783	\$ 4,066	

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

	Three Months Ended June 30,		Change	
	2023	2022		
	(unaudited)			
Dermatologic <sup>(1)</sup>	\$ 43,030	\$ 31,897	\$ 11,133	
Non-Dermatologic <sup>(2)</sup>	7,108	2,941	4,167	
Total net revenues	\$ 50,138	\$ 34,838	\$ 15,300	

(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 June 30,		Change
	2023	2022	
	(unaudited)		
Net revenues	\$ 50,138	\$ 34,838	\$ 15,300
Less: Cost of sales (exclusive of amortization of acquired intangible assets)	11,058	7,686	3,372
Less: Amortization of acquired intangible assets	2,248	2,097	151
Gross margin	\$ 36,832	\$ 25,055	\$ 11,777
Gross margin percentage	73.5 %	71.9 %	1.6 %

### **Net Revenues**

Net revenues for the three months ended June 30, 2023 increased by \$15.3 million, or 43.9%, to \$50.1 million compared to the three months ended June 30, 2022, due to a \$11.1 million increase in revenue from our dermatologic tests and a \$4.2 million increase in revenue from our non-dermatologic tests.

The increase from our dermatologic tests was primarily due to increases in test report volume of 20.7% for DecisionDx-Melanoma and 99.5% for DecisionDx-SCC, and a slightly higher average selling price for DecisionDx-Melanoma.

The increase in revenue from our non-dermatologic tests of \$4.2 million was primarily attributable to the effect of the increase in the Medicare reimbursement rate for our TissueCypher test and higher test report volume during the second quarter of 2023 compared to the second quarter of 2022.

The increases in total net revenues were partially offset by the effect of variations in revenue adjustments related to tests delivered in previous periods, associated with changes in estimated variable consideration, which were \$0.1 million of net negative revenue adjustments for the three months ended June 30, 2023, compared to \$0.6 million of net positive revenue adjustments for the three months ended June 30, 2022. 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.

### **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 June 30, 2023 increased by \$3.4 million, or 43.9%, compared to the three months ended June 30, 2022, primarily due to increased expenditures on supplies, higher personnel costs, third-party services and rent. Supply and service expenses increased largely due to our higher test volumes. The increase in personnel costs consists of higher salaries and wages, stock-based compensation expense and benefits related to headcount additions as well as existing employees.

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 growth in volume for our dermatologic, gastrointestinal, mental health and pipeline tests.

### **Gross Margin**

Our gross margin percentage was 73.5% for the three months ended June 30, 2023, compared to 71.9% for the same period in 2022. 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 supplies expenditures and higher personnel costs, both of which have increased due to our expanded laboratory capacity and higher test report volumes.

### **Research and Development**

Research and development expenses increased by \$1.4 million, or 11.6%, for the three months ended June 30, 2023, compared to the three months ended June 30, 2022. A majority of the increase was attributable to higher personnel costs, primarily due to expansions in headcount in support of our growth, higher salaries and wages and

higher stock-based compensation expense. Additionally, 20.0% of the increase is due to higher costs for clinical studies, most of which relates to our IDENTITY study and our inflammatory skin disease pipeline test. Increases in personnel and clinical studies expenses were partially offset by slightly lower advisory costs. We expect to continue to increase our research and development expenses as we fund ongoing evidence development related to our existing products as well as additional pipeline programs.

### **Selling, General and Administrative**

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

	Three Months Ended June 30,		Change
	2023	2022	
	(unaudited)		
Sales and marketing	\$ 28,252	\$ 21,581	\$ 6,671
General and administrative	16,429	15,917	512
Total selling, general and administrative expense	<u>\$ 44,681</u>	<u>\$ 37,498</u>	<u>\$ 7,183</u>

Sales and marketing expenses increased by \$6.7 million, or 30.9%, for the three months ended June 30, 2023, compared to the three months ended June 30, 2022. Of the increase, 68.4% is attributable to higher personnel costs, including salaries, stock-based compensation and bonuses. Personnel costs have increased through the expansions of our dermatology-facing and non-dermatology-facing commercial teams and outside sales forces, as described above. In addition, higher personnel costs also reflect salary increases for members of our existing sales force. The remainder of the increase in sales and marketing expenses was primarily associated with travel, conferences and other marketing costs, attributable to our expanded commercial operations and headcount. Stock-based compensation expense included in sales and marketing was \$4.7 million for the three months ended June 30, 2023, compared to \$2.9 million for the three months ended June 30, 2022.

General and administrative expenses increased by \$0.5 million, or 3.2%, for the three months ended June 30, 2023, compared to the three months ended June 30, 2022. The increase is primarily attributable to \$1.0 million in higher personnel costs and \$1.0 million in higher information technology-related costs. Increases in personnel costs reflect higher stock-based compensation and salaries, partially offset by lower bonus expense and employee benefits. Higher personnel costs reflect expanded headcount in our administrative support functions, as well as higher rates of salaries and wages. Increases in personnel costs and information technology-related costs were partially offset by a reduction of professional fees of \$1.5 million, primarily due to transaction costs incurred in connection with our acquisition of AltheaDx during the three months ended June 30, 2022. Stock-based compensation expense included in general and administrative expense was \$4.5 million for the three months ended June 30, 2023, compared to \$3.2 million for the three months ended June 30, 2022.

### **Change in Fair Value of Contingent Consideration**

The change in fair value of contingent consideration for the three months ended June 30, 2022 of \$20.4 million, a net gain, was primarily related to the remeasurement of the Earnout Payments associated with our acquisition of Cernostics with no similar activity occurring in the second quarter of 2023.

### **Interest Income**

Interest income increased by \$2.0 million for the three months ended June 30, 2023, compared to the three months ended June 30, 2022, primarily as a result of higher interest rates and our purchases of marketable investment securities beginning in the third quarter of 2022.

### **Income Tax Expense (Benefit)**

We recorded a minimal amount in income tax expense for the three months ended June 30, 2023. Our income tax benefit was \$2.0 million for the three months ended June 30, 2022 and was primarily attributable to a reduction of \$1.8 million in our valuation allowance on net deferred tax assets resulting from our acquisition of AltheaDx in April 2022. Specifically, we took into consideration the additional deferred tax liabilities resulting from the acquisition and determined that a portion of our existing valuation allowance should be reduced.

### **Stock-Based Compensation Expense**

Stock-based compensation expense, which is allocated among cost of sales, research and development expense and SG&A expense, totaled \$12.8 million for the three months ended June 30, 2023, compared to \$8.8 million for

the three months ended June 30, 2022. The increase is primarily due to our annual grant of equity awards in December 2022. 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 June 30, 2023, we had 582 employees compared to 482 as of June 30, 2022. As of June 30, 2023, the total unrecognized stock-based compensation cost related to outstanding awards was \$108.9 million, which is expected to be recognized over a weighted-average period of 2.6 years.

### Comparison of the Six Months Ended June 30, 2023 and 2022

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

	Six Months Ended June 30,		Change	
	2023	2022		
	(unaudited)			
<b>Net revenues</b>	\$ 92,175	\$ 61,690	\$ 30,485	49.4 %
<b>Operating expenses and other operating income</b>				
Cost of sales (exclusive of amortization of acquired intangible assets)	21,240	13,630	7,610	55.8 %
Research and development	27,701	22,687	5,014	22.1 %
Selling, general and administrative	91,443	67,951	23,492	34.6 %
Amortization of acquired intangible assets	4,470	3,745	725	19.4 %
Change in fair value of contingent consideration	—	(17,836)	17,836	100.0 %
Total operating expenses, net	144,854	90,177	54,677	60.6 %
<b>Operating loss</b>	(52,679)	(28,487)	(24,192)	(84.9)%
Interest income	4,735	400	4,335	NM
Interest expense	(7)	(7)	—	— %
<b>Loss before income taxes</b>	(47,951)	(28,094)	(19,857)	(70.7)%
Income tax expense (benefit)	30	(1,823)	1,853	101.6 %
<b>Net loss</b>	\$ (47,981)	\$ (26,271)	\$ (21,710)	(82.6)%

NM = Not meaningful

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

	Six Months Ended June 30,		Change	
	2023	2022		
	(unaudited)			
Cost of sales (exclusive of amortization of acquired intangible assets)	\$ 2,474	\$ 1,750	\$ 724	
Research and development	5,073	3,659	1,414	
Selling, general and administrative	18,827	11,793	7,034	
Total stock-based compensation expense	\$ 26,374	\$ 17,202	\$ 9,172	

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

	Six Months Ended June 30,		Change
	2023	2022	
	(unaudited)		
Dermatologic <sup>(1)</sup>	\$ 78,941	\$ 56,236	\$ 22,705
Non-Dermatologic <sup>(2)</sup>	13,234	5,454	7,780
<b>Total net revenues</b>	<b>\$ 92,175</b>	<b>\$ 61,690</b>	<b>\$ 30,485</b>

(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):

	Six Months Ended June 30,		Change
	2023	2022	
	(unaudited)		
Net revenues	\$ 92,175	\$ 61,690	\$ 30,485
Less: Cost of sales (exclusive of amortization of acquired intangible assets)	21,240	13,630	7,610
Less: Amortization of acquired intangible assets	4,470	3,745	725
Gross margin	<b>\$ 66,465</b>	<b>\$ 44,315</b>	<b>\$ 22,150</b>
Gross margin percentage	72.1 %	71.8 %	0.3 %

### Net Revenues

Net revenues for the six months ended June 30, 2023 increased by \$30.5 million, or 49.4%, to \$92.2 million compared to the six months ended June 30, 2022, due to a \$22.7 million increase in revenue from our dermatologic tests and a \$7.8 million increase in revenue from our non-dermatologic tests.

The increase from our dermatologic tests was primarily due to increases in test report volume of 23.1% for DecisionDx-Melanoma and 104.8% for DecisionDx-SCC. We began receiving Medicare coverage for DecisionDx-SCC tests in the second quarter of 2022, which also contributed to the increase in revenue.

The increase in revenue from our non-dermatologic tests of \$7.8 million was primarily attributable to higher test report volume and the effect of the increase in the Medicare reimbursement rate for our TissueCypher test during the six months ended June 30, 2023 compared to the same period of 2022. Our IDgenetix test, which we acquired in connection with our acquisition of AltheaDx in April 2022, also contributed to the increase in non-dermatologic revenues during the period.

The increases in total net revenues were partially offset by the effect of variations in revenue adjustments related to tests delivered in previous periods, associated with changes in estimated variable consideration, which were \$1.7 million of net negative revenue adjustments for the six months ended June 30, 2023, compared to \$0.3 million of net negative revenue adjustments for the same period in 2022. 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.

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

Cost of sales (exclusive of amortization of acquired intangible assets) for the six months ended June 30, 2023 increased by \$7.6 million, or 55.8%, compared to the six months ended June 30, 2022, primarily due to increased expenditures on supplies, higher personnel costs, third-party services and rent. Supply and service expenses have increased due to higher laboratory activity, which is attributable to higher test report volume. The increase in personnel costs, including increases in salaries and wages, stock-based compensation expense and benefits, was primarily due to increased headcount driven by our expanded laboratory capacity. The increased personnel costs also reflect higher salaries and wages for existing employees. 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 growth in volume for our dermatologic, gastrointestinal, mental health and pipeline tests.

### **Gross Margin**

Our gross margin percentage was 72.1% for the six months ended June 30, 2023, compared to 71.8% for the six months ended June 30, 2022. The increase was primarily due to higher revenues, partially offset by higher supplies expenditures, personnel costs, attributable to increases in laboratory headcount as well as higher rates of pay, and variations in revenue adjustments related to tests delivered in previous periods.

### **Research and Development**

Research and development expenses increased by \$5.0 million, or 22.1%, for the six months ended June 30, 2023, compared to the six months ended June 30, 2022. Higher personnel costs comprise 79.8% of the increase and were primarily due to expansions in headcount in support of our growth, higher salaries and wages, higher stock-based compensation expense and employee benefits. Additionally, 24.2% is attributable to higher costs for clinical studies, most of which was attributable to our IDENTITY study and our inflammatory skin disease pipeline test. Increases in personnel and clinical studies expenses were partially offset by slightly lower advisory costs. We expect to continue to increase our research and development expenses as we fund ongoing evidence development related to our existing products as well as additional pipeline programs.

### **Selling, General and Administrative**

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

	Six Months Ended June 30,		Change
	2023	2022	
	(unaudited)		
Sales and marketing	\$ 58,197	\$ 39,802	\$ 18,395
General and administrative	33,246	28,149	5,097
Total selling, general and administrative expense	<u>\$ 91,443</u>	<u>\$ 67,951</u>	<u>\$ 23,492</u>

Sales and marketing expenses increased by \$18.4 million, or 46.2%, for the six months ended June 30, 2023, compared to the six months ended June 30, 2022. Of the increase, 62.9% is attributable to higher personnel costs, including salaries, stock-based compensation and bonuses. Personnel costs have increased through the expansions of our dermatology-facing and non-dermatology-facing commercial teams and outside sales forces. In addition, higher personnel costs also reflect salary increases for members of our existing sales force. The remainder of the increase in sales and marketing expenses was primarily associated with travel, training events, conference fees and other marketing costs, attributable to our expanded commercial operations and headcount. Stock-based compensation expense included in sales and marketing expense was \$9.6 million for the six months ended June 30, 2023, compared to \$5.7 million for the six months ended June 30, 2022.

General and administrative expenses increased by \$5.1 million, or 18.1%, for the six months ended June 30, 2023, compared to the six months ended June 30, 2022. The increase is primarily attributable to \$4.4 million in higher personnel costs and \$1.0 million in higher information technology-related costs. Increases in personnel costs reflect higher stock-based compensation and salaries. The higher personnel costs reflect expanded headcount in our administrative support functions as well as higher rates of salaries and wages. Increases in personnel costs and information technology-related costs were partially offset by a decrease in professional fees, primarily due to transaction costs incurred in connection with our acquisition of AltheaDx during the six months ended June 30, 2022. Stock-based compensation expense included in general and administrative expense was \$9.2 million for the six months ended June 30, 2023, compared to \$6.1 million for the six months ended June 30, 2022. The remainder of the increase in general and administrative expenses was primarily associated with general increases across various categories.

### ***Amortization of Acquired Intangible Assets***

Amortization of acquired intangible assets increased by \$0.7 million for the six months ended June 30, 2023, compared to the six months ended June 30, 2022. The increase is primarily associated with amortization of developed technology attributable to the acquisition of AltheaDx in April 2022.

### ***Change in Fair Value of Contingent Consideration***

The change in fair value of contingent consideration for the six months ended June 30, 2022 of \$17.8 million, a net gain, was primarily related to the remeasurement of the Earnout Payments associated with our acquisition of Cernostics. There was no such activity during the six months ended June 30, 2023.

### ***Interest Income***

Interest income increased by \$4.3 million for the six months ended June 30, 2023, compared to the six months ended June 30, 2022, primarily as a result of higher interest rates and our purchases of marketable investment securities beginning in the third quarter of 2022.

### ***Income Tax Expense (Benefit)***

We recorded a minimal amount in income tax expense for the six months ended June 30, 2023. Our income tax benefit was \$1.8 million for the six months ended June 30, 2022, and was primarily attributable to a reduction of \$1.8 million in our valuation allowance on net deferred tax assets resulting from our acquisition of AltheaDx in April 2022. Specifically, we took into consideration the additional deferred tax liabilities resulting from the acquisition and determined that a portion of our existing valuation allowance should be reduced.

### ***Stock-Based Compensation Expense***

Stock-based compensation expense, which is allocated among cost of sales, research and development expense and SG&A expense, totaled \$26.4 million for the six months ended June 30, 2023, compared to \$17.2 million for the six months ended June 30, 2022. The increase is primarily due to our annual grant of equity awards in December 2022. 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 June 30, 2023, we had 582 employees compared to 482 as of June 30, 2022. As of June 30, 2023, the total unrecognized stock-based compensation cost related to outstanding awards was \$108.9 million, which is expected to be recognized over a weighted-average period of 2.6 years.

## **Liquidity and Capital Resources**

### ***Sources of Liquidity***

Our principal sources of liquidity are our cash and cash equivalents, marketable investment securities and cash generated from the sale of our products. 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 June 30, 2023 and December 31, 2022, we had marketable investment securities of \$129.6 million and \$135.7 million, respectively. As of June 30, 2023 and December 31, 2022, we had cash and cash equivalents of \$95.9 million and \$122.9 million, respectively.

Since becoming a public company, our liquidity has been primarily derived from the revenue generated from the sale of our products, proceeds from our initial public offering of common stock on July 29, 2019 (the "IPO"), follow-on public offerings of common stock in June 2020 and December 2020 and bank debt, which has since been repaid in full. 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 through 2025. 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. 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.

In April 2022, we acquired AltheaDx, for \$30.5 million in cash and \$17.1 million in shares of our common stock. We agreed to pay contingent consideration of up to \$75.0 million, 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 associated with the commercial milestones for the year ended December 31, 2022 was not paid since the applicable commercial milestones were not met. This portion represented \$35.0 million of the \$75.0 million total potential payment obligation, exclusive of a potential catch-up payment in 2023 of \$17.5 million which will become payable if all 2023 commercial milestones are fully met. Therefore, as of June 30, 2023, we have a potential payment obligation of up to \$57.5 million with respect to the remaining commercial milestones for 2023 and 2024. In each case, the number of shares of our common stock that may be issued in connection with the commercial milestone payments is subject to limitations. Our actual liability with respect to these commercial milestone payments from our acquisition will depend, in part, on our ability to successfully integrate IDgenetix (acquired from AltheaDx) into our suite of commercial product offerings and the timing thereof. See Note 6 of the unaudited condensed consolidated financial statements for additional information on the acquisition of AltheaDx.

On July 10, 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 which may be used as our future corporate headquarters. We have the option to terminate the contract within 90 days, for any reason, and will use this time to complete initial suitability diligence. Closing, if it should occur, is expected in late 2023.

Since our inception, we have generally incurred significant losses and negative cash flows. For the year ended December 31, 2022 we had a net loss of \$67.1 million and an accumulated deficit of \$160.9 million as of December 31, 2022. For the six months ended June 30, 2023, we had a net loss of \$48.0 million and an accumulated deficit of \$208.9 million as of June 30, 2023. Our ability to generate revenue sufficient to achieve profitability will depend heavily on the successful commercialization of our currently marketed products and the products we plan to launch in the future as well as our spending on research and development activities. We expect to incur additional expenses and losses 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. Further, we expect that any acquisitions of businesses, products, assets or technologies will also increase our expenses. 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 and for the foreseeable future. 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.

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 II, Item 1A., "Risk Factors" in this Quarterly Report on Form 10-Q.

We do not currently have any committed external source of funds. 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.

### 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 June 30, 2023 totaled approximately \$23.7 million, of which \$1.1 million is payable through the remainder of 2023 and \$22.6 million is payable through the end of 2033. The leases expire on various dates through 2033 and provide certain options to renew for additional periods. On April 18, 2023, we amended an existing lease agreement to lease additional laboratory space in Phoenix, Arizona. Upon taking possession of the additional laboratory space, we expect our undiscounted future minimum payment obligations to increase by approximately \$1.7 million.

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):

	Six Months Ended June 30,	
	2023	2022
	(unaudited)	
Net cash used in operating activities	\$ (29,225)	\$ (30,431)
Net cash provided by (used in) investing activities	1,197	(27,913)
Net cash provided by financing activities	954	1,877
Net change in cash and cash equivalents	(27,074)	(56,467)
Cash and cash equivalents, beginning of period	122,948	329,633
Cash and cash equivalents, end of period	\$ 95,874	\$ 273,166

### Operating Activities

Net cash used in operating activities was \$29.2 million for the six months ended June 30, 2023, and was primarily attributable to the net loss of \$48.0 million, increases in accounts receivable of \$8.0 million, decreases in accrued compensation of \$7.1 million, increases in accretion of discounts on marketable investment securities of \$2.3 million and increases in inventory of \$2.1 million, partially offset by non-cash stock-based compensation expense of \$26.4 million, depreciation and amortization of \$5.9 million, a change in accounts payable of \$3.1 million and a change in other accrued and current liabilities of \$2.0 million.

Net cash used in operating activities was \$30.4 million for the six months ended June 30, 2022, and was primarily attributable to the net loss of \$26.3 million, the change in fair value of contingent consideration of \$17.8 million, increases in accounts receivable of \$5.6 million and deferred income taxes of \$1.8 million, partially offset by non-cash stock-based compensation expense of \$17.2 million and depreciation and amortization of \$4.8 million.

The \$1.2 million decrease in net cash used in operating activities for the six months ended June 30, 2023 compared to the six months ended June 30, 2022 is primarily due to increases in collections from customers attributable to higher net revenues partially offset by increases in operating expenditures. In part, the cash used during the first half of 2023 reflects the payment of annual cash bonuses to our employees as well as certain health care benefit payments totaling \$17.7 million, that are not expected to recur during the remainder of 2023. In comparison, we paid \$11.6 million during the same period in 2022 towards annual cash bonuses and certain health care benefits.

### Investing Activities

Net cash provided by investing activities was \$1.2 million for the six months ended June 30, 2023 and consisted primarily of the maturity of marketable investment securities of \$95.0 million, partially offset by purchases of marketable investment securities of \$86.4 million and purchases of property and equipment of \$7.4 million. Net cash

used in investing activities was \$27.9 million for the six months ended June 30, 2022 and consisted primarily of the cash portion of the purchase price of \$26.7 million (net of cash and cash equivalents acquired) paid for our acquisition of AltheaDx and the purchase of property and equipment of \$1.8 million.

The \$5.6 million increase in cash used for the purchase of property and equipment for the six months ended June 30, 2023 compared to the six months ended June 30, 2022 was primarily due to the build out and completion of our new laboratory and office facilities located in Pittsburgh, Pennsylvania. Fixed asset purchases for this build out included those made for leasehold improvements, furniture and fixtures, new laboratory equipment and information technology infrastructure.

#### *Financing Activities*

Net cash provided by financing activities was \$1.0 million for the six months ended June 30, 2023, and consisted primarily of \$1.7 million of proceeds from contributions to our 2019 Employee Stock Purchase Plan (the “ESPP”), \$0.2 million of proceeds from exercise of common stock options, partially offset by the \$0.8 million payment of employee taxes attributable to the vesting of Restricted Stock Units (“RSUs”).

Net cash provided by financing activities was \$1.9 million for the six months ended June 30, 2022, and primarily consisted of \$1.5 million in proceeds from contributions to the ESPP and \$0.5 million in proceeds from the exercise of stock options.

#### **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 six months ended June 30, 2023. We are unable to predict if the rate of inflation will increase in future periods.

#### **Critical Accounting Estimates**

During the six months ended June 30, 2023, except as noted below, 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 Annual Report on Form 10-K for the year ended December 31, 2022.

The following is an updated discussion of our critical accounting estimates related to goodwill impairment testing and requisite service period for stock-based compensation. This information should be read in conjunction with our other information on critical accounting estimates included in our Annual Report on Form 10-K for the year ended December 31, 2022.

#### ***Goodwill—Impairment Testing***

On June 2, 2023, a MAC finalized an LCD pursuant to which the DecisionDx-SCC test would no longer be covered by Medicare effective July 17, 2023. On June 5, 2023, our stock price decreased significantly and did not recover before June 30, 2023. In response to this trigger, we tested goodwill for impairment at June 30, 2023. We elected to bypass the optional qualitative assessment and proceeded directly to the quantitative assessment. In conducting our interim test, we concluded that our business consists of a single reporting unit. To measure the fair value of our reporting unit, we used a market approach whereby we calculated our total market capitalization on the impairment test date, based on the closing price of our common stock as reported on the Nasdaq Global Market, and applied a reasonable control premium. The control premium was based on an analysis of control premiums paid in recent acquisitions of companies in the same or similar industry as us. Our impairment test indicated that the fair value of our reporting unit exceeded its carrying value by 13% and therefore no impairment was indicated. In July 2023, the MAC suspended the LCD and then posted a new draft LCD for comment that is substantially the same as the LCD that was to become effective.

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.

#### ***Stock-Based Compensation—Requisite Service Period***

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 awards’ vesting period (typically four years). Performance-based restricted stock units (“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.

**Item 3. Quantitative and Qualitative Disclosures About Market Risk.**

As a smaller reporting company, we are not required to provide the information required by this Item.

**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 June 30, 2023. 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 second quarter of 2023 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. We believe there is no pending or threatened litigation that could have, individually or in the aggregate, a material adverse effect on our financial position, results of operations or cash flows.

### **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, 2022 filed with the SEC on February 28, 2023, 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, 2022 and our Quarterly Report on Form 10-Q for the three months ended March 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, 2022 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 Business**

#### ***The failure of financial institutions or transactional counterparties could adversely affect our current and projected business operations, financial condition, results of operations or cash flows.\****

The recent closures of Silicon Valley Bank, Signature Bank and First Republic Bank have resulted in broader financial institution liquidity risk and concerns. Although we have not experienced an adverse impact to our liquidity or to our current and projected business operations, financial condition, results of operations or cash flows, future adverse developments with respect to specific financial institutions or the broader financial services industry may lead to market-wide liquidity shortages that could materially harm our business and financial condition. In this regard, we continue to maintain our cash deposits with banking institutions, often in balances that exceed the current Federal Deposit Insurance Corporation insurance limits, and the failure of any bank in which we deposit our funds could reduce the amount of cash we have available for our operations or delay our ability to access such funds or collect receivables. Any such failure may increase the possibility of a sustained deterioration of financial market liquidity, or illiquidity at clearing, cash management and/or custodial financial institutions. In the event we have a commercial relationship with a bank that has failed or is otherwise distressed, we may experience delays or other issues in meeting our financial obligations. If other banks and financial institutions fail or become insolvent in the future in response to financial conditions affecting the banking system and financial markets, our ability to access our cash, cash equivalents and investments, including transferring funds, making payments or receiving funds may be threatened and our ability to raise additional capital could be substantially impaired, any of which could materially and adversely affect our business and financial condition. In any event, if the financial market disruptions and economic slowdown deepen or persist, we may not be able to access additional capital on favorable terms, or at all, which could negatively affect our financial condition and our ability to pursue our business strategy.

#### ***Impairment of our goodwill or other intangible assets could have a material adverse effect on our operating results and financial condition.\****

Goodwill represents the excess of amounts paid for acquiring businesses over the fair value of the net assets acquired, and intangible assets are measured at fair value upon the acquisition of a business for purposes of such calculations. As of December 31, 2022, our goodwill and other intangible assets balances were \$10.7 million and \$115.7 million, respectively. Goodwill is evaluated for impairment annually, or more frequently if conditions warrant, by comparing the carrying value of a reporting unit to its estimated fair value. Intangible assets with finite lives are reviewed for impairment when events or circumstances indicate that their carrying value may not be recoverable. Declines in operating results, divestitures, sustained market declines and other factors could result in an impairment of goodwill or other intangible assets and, in turn, a charge to net income or loss. Any future charges could have a material adverse effect on our results of operations or financial condition.

On June 2, 2023, a MAC finalized an LCD pursuant to which the DecisionDx-SCC test would no longer be covered by Medicare effective July 17, 2023. On June 5, 2023, our stock price decreased significantly and did not recover before June 30, 2023. In response to this trigger, we tested goodwill for impairment at June 30, 2023. We elected to bypass the optional qualitative assessment and proceeded directly to the quantitative assessment. In conducting

our interim test, we concluded that our business consists of a single reporting unit. To measure the fair value of our reporting unit, we used a market approach whereby we calculated our total market capitalization on the impairment test date, based on the closing price of our common stock as reported on the Nasdaq Global Market, and applied a reasonable control premium. The control premium was based on an analysis of control premiums paid in recent acquisitions of companies in the same or similar industry as us. Our impairment test indicated that the fair value of our reporting unit exceeded its carrying value by 13% and therefore no impairment was indicated. In July 2023, the MAC suspended the LCD and then posted a new draft LCD for comment that is substantially the same as the LCD that was to become effective.

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.

#### **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.

Palmetto issued a final LCD for DecisionDx-Melanoma, which became effective on December 3, 2018, and issued a final expanded LCD for DecisionDx-Melanoma, effective November 22, 2020. Noridian has adopted the same coverage policy as Palmetto and also issued an expanded final LCD for DecisionDx-Melanoma, effective December 6, 2020. More recently, Palmetto converted the DecisionDx-Melanoma test-specific LCD to a “foundational” LCD. This LCD was issued as final May 19, 2022 with Noridian issuing the same on June 16, 2022. The final LCDs did not result in any change in coverage.

Palmetto issued a final LCD for DecisionDx-UM effective July 10, 2017. Noridian has adopted the same coverage policy as Palmetto for DecisionDx-UM.

We worked with Palmetto to obtain these positive coverage decisions through the submission of a detailed dossier of analytical and clinical data to substantiate that the tests meet Medicare’s medical necessity requirements. Per their joint operating agreement, Noridian, the MAC responsible for administering claims for laboratory services performed in Arizona, adopts the same coverage policy as Palmetto.

Separately, we also have received Medicare coverage for our MyPath Melanoma, DecisionDx-SCC, TissueCypher and IDgenetix tests.

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 MoIDX 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. If coverage for one or more of our products is withdrawn, our business could be adversely impacted.

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, MoIDX notified us that as part of its annual CPT code updates IDgenetix should shift billing to a different generic gene sequencing CPT code and continue using the IDgenetix Z-Code beginning in March 2023. The New CPT Code is currently contractor priced at \$917 while it undergoes CMS’s gapfill pricing process in 2023. Accordingly, 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. The New CPT Code does not describe all of the components of the IDgenetix test. We subsequently obtained a test-specific PLA CPT code. The new PLA code becomes effective October 1, 2023 and is currently undergoing the 2024 CLFS pricing process.

In April 2014, Congress passed the Protecting Access to Medicare Act of 2014 (“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.

In early 2021, we submitted our technical assessment dossier for DiffDx-Melanoma. The dossier was accepted as complete in the first quarter of 2021. In June 2022, Palmetto and Noridian each posted a proposed LCD that would convert the MyPath Melanoma test-specific LCD to a “foundational” LCD and provide coverage for both MyPath Melanoma and DiffDx-Melanoma. On June 22, 2023, Palmetto and Noridian issued final foundational LCDs that will provide coverage for both MyPath Melanoma and DiffDx-Melanoma effective August 6, 2023.

In the second quarter of 2022, we obtained a PLA code for DiffDx-Melanoma. DiffDx-Melanoma is going through CMS’s gapfill pricing process in 2023, which we expect to conclude in late 2023 and to be effective January 1, 2024. The gapfill process consists of several steps throughout the calendar year. First, individual MACs develop gapfill rates and report them to CMS. Using this information, CMS then posts preliminary rates and commences a public comment period. After evaluating public comments, CMS posts updated rates and begins accepting requests to reconsider these rates, known as reconsideration requests. After CMS processes any reconsideration requests, the gapfill rates are considered final. In April 2023, CMS posted a preliminary determination of a gapfill rate for DiffDx-Melanoma of \$1,950 per test, which is subject to a public comment period and any reconsideration requests. We cannot predict at this time what the final gapfill rate will be.

On June 2, 2023, Novitas finalized the 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 ends on September 9, 2023. We cannot predict whether this LCD will be finalized as proposed or what the timing of any final LCD might be.

In the second quarter of 2020, we submitted our technical assessment dossier for DecisionDx-SCC to Palmetto and Noridian. The dossier was accepted as complete in the third quarter of 2020. On June 8, 2023, both Palmetto and Noridian posted their draft LCD recommending no coverage for DecisionDx-SCC. The comment period for the draft LCDs ended on July 22, 2023.

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.

## **Risks Related to Employee Matters and Managing Growth and Other Risks Related to Our Business**

### ***We may be unable to manage our future growth effectively, which could make it difficult to execute our business strategy.***

We have experienced significant revenue growth in a short period of time. We may not achieve similar growth rates in future periods. You should not rely on our operating results for any prior periods as an indication of our future operating performance. To effectively manage our anticipated future growth, we must continue to maintain and enhance our financial, accounting, human resources, laboratory operations, customer support and sales administration systems, processes and controls. Failure to effectively manage our anticipated growth could lead us to over-invest or under-invest in development, operational and administrative infrastructure, result in weaknesses in our infrastructure, systems, or internal controls, give rise to operational mistakes, losses, loss of customers, productivity or business opportunities, and result in loss of employees and reduced productivity of remaining employees.

We also anticipate further growth in our business operations. For example, since May 2021, we have completed the acquisitions of Myriad MyPath Laboratory, Cernostics and AltheaDx, each of which we expect will contribute to our future growth. These acquisitions and other future growth could create strain on our organizational, administrative and operational infrastructure, including laboratory operations, quality control, customer service and sales organization management. We expect to continue increasing our headcount and hire more specialized personnel in the future as we grow our business and expand our product offerings. We will need to continue to hire, train and manage additional qualified scientists, laboratory personnel, client and account services personnel, and sales and marketing staff and improve and maintain our technology to effectively manage our growth. If our new hires perform poorly, if we are unsuccessful in hiring, training, managing and integrating these new employees or if we are not successful in retaining our existing employees, our business may be harmed.

In addition, our anticipated growth could require significant capital expenditures and might divert financial resources from other projects such as the development of new diagnostic tests and services. As we commercialize additional tests, we may need to incorporate new equipment, implement new technology systems, automate or otherwise improve the efficiency of our operational processes or hire new personnel with different qualifications. Failure to manage this growth or transition could result in turnaround time delays, higher costs, declining quality, deteriorating customer service, and slower responses to competitive challenges. A failure in any one of these areas could make it difficult for us to meet market expectations for our products and could damage our reputation and the prospects for our business.

In July 2023, in response to significant demand, we elected to temporarily pause accepting additional orders for the TissueCypher Barrett's Esophagus Test in order to bring our process improvements and additional instrumentation and personnel on line. We are currently working through these efforts and believe that we will be able to begin accepting new orders prior to the end of third quarter of 2023. However, there can be no assurance that our efforts will be successful.

We may not be able to maintain the quality or expected turnaround times of our products, or satisfy customer demand as it grows. Our ability to manage our growth properly will require us to continue to improve our operational, financial and management controls, as well as our reporting systems and procedures. The time and resources required to implement these new systems and procedures is uncertain, and failure to complete this in a timely and efficient manner could adversely affect our operations. If our management is unable to effectively manage our anticipated growth, our expenses may increase more than expected, our revenue could decline or grow more slowly than expected and we may be unable to implement our business strategy. The quality of our products and services may suffer, which could negatively affect our reputation and harm our ability to retain and attract customers.

### **Risks Related to Ownership of Our Common Stock**

#### ***The price of our common stock may be volatile or may decline regardless of our operating performance, and you may lose all or part of your investment.***

The market price of our common stock may fluctuate significantly in response to numerous factors, many of which are beyond our control, including:

- our operating performance and the performance of other similar companies;
- our success in marketing and selling our products;
- our ability to achieve guideline inclusion for our products;

- reimbursement determinations by third-party payors, including MACs, and reimbursement rates for our products;
- changes in our projected operating results that we provide to the public, our failure to meet these projections or changes in recommendations by securities analysts that elect to follow our common stock;
- regulatory or legal developments in the United States and other countries;
- the level of expenses related to product development and clinical studies for our products;
- our ability to achieve product development goals in the timeframes we announce;
- announcements of clinical study results, regulatory developments, acquisitions, strategic alliances or significant agreements by us or by our competitors;
- the success or failure of our efforts to acquire, license or develop additional tests;
- recruitment or departure of key personnel;
- general economic conditions and market conditions specific to our industry;
- interest rates and the rate of inflation;
- the extent and duration of the impacts on our operations of general political and economic conditions, including COVID-19, the ongoing conflict between Ukraine and Russia, economic slowdowns, recessions or market corrections, the duration and effects of elevated inflation, rising interest rates and tightening of credit markets resulting from the conflict or other evolving macroeconomic developments;
- trading activity by a limited number of stockholders who together beneficially own a significant percentage of our outstanding common stock;
- general investor interest in emerging growth stocks;
- the size of our market float; and
- any other factors discussed in this Quarterly Report on Form 10-Q.

For example, on June 5, 2023, our stock price decreased 49% after Novitas published a final LCD that would have impacted Medicare coverage for our DecisionDx-SCC test. In addition, the stock market in general, and diagnostic and life sciences companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. Broad market and industry factors may negatively affect the market price of our securities, regardless of our actual operating performance. In the past, stockholders of other companies have filed securities class action litigation following periods of market volatility. If we were to become involved in securities litigation, it could subject us to substantial costs, divert resources and the attention of management from our business and adversely affect our business.

## **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 June 30, 2023, 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.**

None.

**Item 6. Exhibits.**

<b>Exhibit Number</b>	<b>Description of document</b>
2.1#+	<a href="#">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.</a>
2.2#+	<a href="#">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.</a>
3.1	<a href="#">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.</a>
3.2	<a href="#">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.</a>
4.1	<a href="#">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.</a>
4.2	<a href="#">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.</a>
10.1	<a href="#">Fourth Amendment to Standard Office Lease, dated April 18, 2023, by and between the Registrant and Alturas Siete II, LLC, incorporated by reference to Exhibit 10.4 of the Registrant's Quarterly Report on Form 10-Q filed with the SEC on May 3, 2023.</a>
31.1*	<a href="#">Certification of Principal Executive Officer pursuant to Rules 13a-14(a) and 15d-14(a) of the Exchange Act.</a>
31.2*	<a href="#">Certification of Principal Financial Officer pursuant to Rules 13a-14(a) and 15d-14(a) of the Exchange Act.</a>
32.1**	<a href="#">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.</a>
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).

\* Filed herewith

\*\* Furnished herewith.

# 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.

+ Pursuant to Item 601(b)(2) of Regulation S-K, certain portions of this exhibit have been omitted (indicated by "[\*\*\*]") because the Company has determined that the information is not material and is the type that the Company treats as private or confidential.



**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: August 2, 2023

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

**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: August 2, 2023

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

**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 June 30, 2023 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: August 2, 2023

/s/ Derek J. Maetzold

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

/s/ Frank Stokes

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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.