
**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

FORM 10-Q

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

For the quarterly period ended **June 30, 2021**

OR

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

Commission File Number: **001-35092**

EXACT SCIENCES CORPORATION

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction of
incorporation or organization)

02-0478229

(I.R.S. Employer
Identification Number)

5505 Endeavor Lane, Madison WI
(Address of principal executive offices)

53719
(Zip Code)

(608) 535-8815 (Registrant's telephone number, including area code)

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, \$0.01 par value per share	EXAS	The Nasdaq Stock Market LLC

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

Indicate by check mark whether the registrant has submitted electronically, if any, 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 checked="" type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input type="checkbox"/>	Smaller reporting company	<input 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 27, 2021, the registrant had 171,948,769 shares of common stock outstanding.

EXACT SCIENCES CORPORATION

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EXACT SCIENCES CORPORATION
Condensed Consolidated Balance Sheets
(Amounts in thousands, except share data - unaudited)

Part I — Financial Information

	June 30, 2021	December 31, 2020
ASSETS		
Current Assets:		
Cash and cash equivalents	\$ 363,715	\$ 1,491,288
Marketable securities	943,864	348,699
Accounts receivable, net	226,539	233,185
Inventory	89,809	92,265
Prepaid expenses and other current assets	45,284	33,157
Total current assets	1,669,211	2,198,594
Long-term Assets:		
Property, plant and equipment, net	501,908	451,986
Operating lease right-of-use assets	166,914	125,947
Goodwill	2,242,535	1,237,672
Intangible assets, net	2,089,108	847,123
Other long-term assets, net	54,658	63,770
Total assets	<u>\$ 6,724,334</u>	<u>\$ 4,925,092</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable	\$ 36,592	\$ 35,709
Accrued liabilities	265,997	233,604
Operating lease liabilities, current portion	16,599	11,483
Debt, current portion	1,319	1,319
Convertible notes, net, current portion	312,961	312,716
Other current liabilities	42,230	38,265
Total current liabilities	675,698	633,096
Long-term Liabilities:		
Convertible notes, net, less current portion	1,864,312	1,861,685
Long-term debt, less current portion	21,740	22,342
Other long-term liabilities	439,175	51,342
Operating lease liabilities, less current portion	164,308	121,075
Total liabilities	3,165,233	2,689,540
Commitments and contingencies (Note 14)		
Stockholders' Equity:		
Preferred stock, \$0.01 par value Authorized—5,000,000 shares issued and outstanding—no shares at June 30, 2021 and December 31, 2020	—	—
Common stock, \$0.01 par value Authorized—400,000,000 shares issued and outstanding—171,855,305 and 159,423,410 shares at June 30, 2021 and December 31, 2020	1,720	1,595
Additional paid-in capital	5,811,286	4,279,327
Accumulated other comprehensive income	67	526
Accumulated deficit	(2,253,972)	(2,045,896)
Total stockholders' equity	3,559,101	2,235,552
Total liabilities and stockholders' equity	<u>\$ 6,724,334</u>	<u>\$ 4,925,092</u>

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

EXACT SCIENCES CORPORATION
Condensed Consolidated Statements of Operations
(Amounts in thousands, except per share data - unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
Revenue	\$ 434,819	\$ 268,868	\$ 836,896	\$ 616,689
Operating expenses				
Cost of sales (exclusive of amortization of acquired intangible assets)	113,968	77,892	223,961	159,498
Research and development	106,235	32,673	221,802	76,182
Sales and marketing	194,827	118,862	380,968	286,611
General and administrative	167,629	106,685	435,356	220,676
Amortization of acquired intangible assets	23,824	23,430	47,014	46,769
Total operating expenses	606,483	359,542	1,309,101	789,736
Other operating income	—	23,665	—	23,665
Loss from operations	(171,664)	(67,009)	(472,205)	(149,382)
Other income (expense)				
Investment income, net	3,429	2,912	34,617	3,009
Interest expense	(4,652)	(4,300)	(9,268)	(58,904)
Total other income (expense)	(1,223)	(1,388)	25,349	(55,895)
Net loss before tax	(172,887)	(68,397)	(446,856)	(205,277)
Income tax benefit (expense)	(4,025)	305	238,780	2,542
Net loss	\$ (176,912)	\$ (68,092)	\$ (208,076)	\$ (202,735)
Net loss per share—basic and diluted	\$ (1.03)	\$ (0.45)	\$ (1.22)	\$ (1.36)
Weighted average common shares outstanding—basic and diluted	171,494	149,727	170,469	148,938

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

EXACT SCIENCES CORPORATION
Condensed Consolidated Statements of Comprehensive Loss
(Amounts in thousands - unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
Net loss	\$ (176,912)	\$ (68,092)	\$ (208,076)	\$ (202,735)
Other comprehensive income (loss), before tax:				
Unrealized gain (loss) on available-for-sale investments	(297)	3,206	(629)	1,564
Foreign currency adjustment	—	—	—	25
Comprehensive loss, before tax	(177,209)	(64,886)	(208,705)	(201,146)
Income tax expense related to items of other comprehensive loss	—	—	170	—
Comprehensive loss, net of tax	<u>\$ (177,209)</u>	<u>\$ (64,886)</u>	<u>\$ (208,535)</u>	<u>\$ (201,146)</u>

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

EXACT SCIENCES CORPORATION
Condensed Consolidated Statements of Stockholders' Equity
(Amounts in thousands, except share data - unaudited)

	Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity
	Number of Shares	\$0.01 Par Value				
Balance, January 1, 2021	159,423,410	\$ 1,595	\$ 4,279,327	\$ 526	\$ (2,045,896)	\$ 2,235,552
Conversion of convertible notes, net of tax	344	—	26	—	—	26
Exercise of common stock options	967,107	10	8,749	—	—	8,759
Issuance of common stock to fund the Company's 2020 401(k) match	162,606	2	22,932	—	—	22,934
Compensation expense related to issuance of stock options and restricted stock awards	1,355,435	13	158,239	—	—	158,252
Issuance of common stock for business combination and asset acquisition	9,384,410	94	1,254,704	—	—	1,254,798
Net loss	—	—	—	—	(31,164)	(31,164)
Other comprehensive loss	—	—	—	(162)	—	(162)
Balance, March 31, 2021	171,293,312	\$ 1,714	\$ 5,723,977	\$ 364	\$ (2,077,060)	\$ 3,648,995
Conversion of convertible notes, net of tax	197	—	14	—	—	14
Exercise of common stock options	140,478	1	2,857	—	—	2,858
Compensation expense related to issuance of stock options and restricted stock awards	121,575	2	56,283	—	—	56,285
Issuance of common stock for business combinations	126,026	1	16,119	—	—	16,120
Purchase of employee stock purchase plan shares	173,717	2	12,036	—	—	12,038
Net loss	—	—	—	—	(176,912)	(176,912)
Other comprehensive loss	—	—	—	(297)	—	(297)
Balance, June 30, 2021	171,855,305	\$ 1,720	5,811,286	\$ 67	(2,253,972)	\$ 3,559,101

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

EXACT SCIENCES CORPORATION
Condensed Consolidated Statements of Stockholders' Equity
(Amounts in thousands, except share data - unaudited)

	Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity
	Number of Shares	\$0.01 Par Value				
Balance, January 1, 2020	147,625,696	\$ 1,477	\$ 3,178,552	\$ (100)	\$ (1,222,290)	\$ 1,957,639
Exercise of common stock options	160,286	2	4,298	—	—	4,300
Issuance of common stock to fund the Company's 2019 401(k) match	136,559	1	12,006	—	—	12,007
Compensation expense related to issuance of stock options and restricted stock awards	1,141,376	11	29,549	—	—	29,560
Issuance of common stock for business combinations	382,947	4	28,593	—	—	28,597
Net loss	—	—	—	—	(134,643)	(134,643)
Other comprehensive loss	—	—	—	(1,617)	—	(1,617)
Balance, March 31, 2020	149,446,864	\$ 1,495	\$ 3,252,998	\$ (1,717)	\$ (1,356,933)	\$ 1,895,843
Exercise of common stock options	208,434	2	6,636	—	—	6,638
Compensation expense related to issuance of stock options and restricted stock awards	157,579	2	40,037	—	—	40,039
Purchase of employee stock purchase plan shares	167,921	2	9,797	—	—	9,799
Net loss	—	—	—	—	(68,092)	(68,092)
Other comprehensive income	—	—	—	3,206	—	3,206
Balance, June 30, 2020	149,980,798	\$ 1,501	\$ 3,309,468	\$ 1,489	\$ (1,425,025)	\$ 1,887,433

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

EXACT SCIENCES CORPORATION
Condensed Consolidated Statements of Cash Flows
(Amounts in thousands - unaudited)

	Six Months Ended June 30,	
	2021	2020
Cash flows from operating activities:		
Net loss	\$ (208,076)	\$ (202,735)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	42,007	33,632
Loss on disposal of property, plant and equipment	639	650
Unrealized gain on equity investments	(2,486)	333
Deferred tax benefit	(244,509)	(3,165)
Stock-based compensation	133,577	69,599
Post-combination expense for acceleration of unvested equity	80,960	—
Realized gain on preferred stock investment	(30,500)	—
Loss on settlement of convertible notes	—	50,819
Amortization of deferred financing costs, convertible note debt discount and issuance costs, and other liabilities	3,282	(32)
Amortization of premium on short-term investments	1,616	503
Amortization of acquired intangible assets	47,014	46,769
Asset acquisition IPR&D expense	85,337	—
Remeasurement of contingent consideration	9,201	—
Non-cash lease expense	11,837	6,860
Changes in assets and liabilities:		
Accounts receivable, net	8,995	(30,644)
Inventory, net	4,267	(20,260)
Operating lease liabilities	(7,095)	(4,997)
Accounts payable and accrued liabilities	27,138	(47,587)
Other assets and liabilities	(94)	43,558
Net cash used in operating activities	(36,890)	(56,697)
Cash flows from investing activities:		
Purchases of marketable securities	(915,289)	(640,085)
Maturities and sales of marketable securities	325,380	268,483
Purchases of property, plant and equipment	(37,504)	(34,244)
Business combination, net of cash acquired	(415,549)	(6,654)
Asset acquisition	(58,073)	—
Investments in privately held companies	(10,000)	—
Other investing activities	(244)	273
Net cash used in investing activities	(1,111,279)	(412,227)
Cash flows from financing activities:		
Proceeds from issuance of convertible notes, net	—	1,125,547
Proceeds from exercise of common stock options	11,617	10,938
Proceeds in connection with the Company's employee stock purchase plan	12,038	9,799
Payments on settlement of convertible notes	—	(150,054)
Other financing activities	(3,068)	(626)
Net cash provided by financing activities	20,587	995,604
Net increase (decrease) in cash, cash equivalents and restricted cash	(1,127,582)	526,680
Cash, cash equivalents and restricted cash, beginning of period	1,491,594	177,528
Cash, cash equivalents and restricted cash, end of period	\$ 364,012	\$ 704,208

EXACT SCIENCES CORPORATION
Condensed Consolidated Statements of Cash Flows
(Amounts in thousands - unaudited)

	Six Months Ended June 30,	
	2021	2020
Supplemental disclosure of non-cash investing and financing activities		
Property, plant and equipment acquired but not paid	\$ 15,139	\$ 8,684
Unrealized gain (loss) on available-for-sale investments, before tax	\$ (629)	\$ 1,564
Issuance of 162,606 and 136,559 shares of common stock to fund the Company's 401(k) matching contribution for 2020 and 2019, respectively	\$ 22,934	\$ 12,007
Issuance of 9,510,436 and 382,947 shares of common stock for business combinations and asset acquisition for 2021 and 2020, respectively	\$ 1,271,022	\$ 28,597
Business combination contingent consideration liability	\$ 350,348	\$ —
Supplemental disclosure of cash flow information:		
Interest paid	\$ 5,414	\$ 3,908

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

EXACT SCIENCES CORPORATION
Notes to Condensed Consolidated Financial Statements
(Unaudited)

(1) SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Business

Exact Sciences Corporation (together with its subsidiaries, “Exact,” or the “Company”) was incorporated in February 1995. Exact is a leading global cancer diagnostics company. It has developed some of the most impactful brands in cancer screening and diagnostics, including Cologuard® and Oncotype DX®. Exact is currently working on the development of additional tests, with the goal of bringing new, innovative cancer tests to patients throughout the world.

Basis of Presentation and Principles of Consolidation

The accompanying condensed consolidated financial statements, which include the accounts of Exact Sciences Corporation and those of its wholly owned subsidiaries and variable interest entities, are unaudited and have been prepared on a basis substantially consistent with the Company’s audited financial statements and notes as of and for the year ended December 31, 2020 included in the Company’s Annual Report on Form 10-K (the “2020 Form 10-K”). All intercompany transactions and balances have been eliminated upon consolidation. These condensed consolidated financial statements are prepared in conformity with accounting principles generally accepted in the United States of America (“GAAP”) and follow the requirements of the Securities and Exchange Commission (“SEC”) for interim reporting. In the opinion of management, the accompanying unaudited condensed financial statements contain all adjustments (consisting only of adjustments of a normal and recurring nature) considered necessary for a fair statement of its financial position, operating results and cash flows for the periods presented. The condensed consolidated balance sheet at December 31, 2020 has been derived from audited financial statements, but does not contain all of the footnote disclosures from the 2020 Form 10-K. The results of the Company’s operations for any interim period are not necessarily indicative of the results of the Company’s operations for any other interim period or for a full fiscal year. The statements should be read in conjunction with the audited financial statements and related notes included in the 2020 Form 10-K.

Use of Estimates

The preparation of the condensed consolidated financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Critical accounting policies are those that affect the Company’s financial statements materially and involve difficult, subjective or complex judgments by management, and actual results could differ from those estimates. These estimates include revenue recognition, valuation of intangible assets and goodwill, and accounting for income taxes among others. The Company’s critical accounting policies and estimates are explained further in the notes to the condensed consolidated financial statements in this Quarterly Report and the 2020 Form 10-K.

The spread of the coronavirus (“COVID-19”) has affected many segments of the global economy, including the cancer screening and diagnostics industry. The Company assessed certain accounting matters that generally require consideration of forecasted financial information in context with the information reasonably available to the Company and the unknown future impacts of COVID-19 as of June 30, 2021 and through the date of the filing of this Quarterly Report on Form 10-Q. The accounting matters assessed included, but were not limited to, the Company’s allowance for doubtful accounts and credit losses, equity investments, software, and the carrying value of the goodwill and other long-lived assets. The Company’s future assessment of the magnitude and duration of COVID-19, as well as other factors, could result in additional material impacts to the Company’s consolidated financial statements in future reporting periods.

The pandemic and related precautionary measures began to materially disrupt the Company’s operations in March 2020 and may continue to disrupt the business for an unknown period of time. As a result, the pandemic impacted the Company’s revenues and operating results for the three and six months ended June 30, 2021.

The ultimate impact of COVID-19 depends on factors beyond the Company’s knowledge or control, including the duration and severity of the outbreak, as well as third-party actions taken to contain its spread and mitigate its public health effects. As a result, the Company is unable to estimate the extent to which COVID-19 will negatively impact its financial results or liquidity.

EXACT SCIENCES CORPORATION
Notes to Condensed Consolidated Financial Statements
(Unaudited)

Significant Accounting Policies

During the six months ended June 30, 2021, there were no changes to the Company's significant accounting policies as described in the Company's Annual Report on Form 10-K for the year ended December 31, 2020, except as described in the Recently Adopted Accounting Pronouncements section below.

Reclassifications

Certain prior year amounts have been reclassified to conform to the current year presentation in the condensed consolidated financial statements and accompanying notes to the condensed consolidated financial statements.

Recent Accounting Pronouncements

Recently Adopted Accounting Pronouncements

In August 2020, The Financial Accounting Standards Board issued Accounting Standards Update ("ASU") No. 2020-06, Debt – Debt with Conversion and Other Options (subtopic 470-20) and Derivatives and Hedging – Contracts in Entity's Own Equity (Subtopic 815-40). This update simplifies the accounting for convertible debt instruments by removing the beneficial conversion and cash conversion separation models for convertible instruments. Under the update, the embedded conversion features are no longer separated from the host contract for convertible instruments with conversion features that are not required to be accounted for as derivatives or that do not result in substantial premiums accounted for as paid-in capital. The update also amends the accounting for certain contracts in an entity's own equity that are currently accounted for as derivatives because of specific settlement provisions. In addition, ASU 2020-06 requires the application of the if-converted method for calculating diluted earnings per share and the treasury stock method will no longer be available. This standard may be adopted through either a modified retrospective method of transition or a full retrospective method of transition. The amendments in this update are effective for fiscal years beginning after December 15, 2021, including interim periods within those fiscal years. Early adoption is permitted, but no earlier than fiscal years beginning after December 15, 2020.

The Company adopted the standard on January 1, 2021 through application of the full retrospective method of transition. This method of adoption was applied to enhance comparability between the periods presented in the Company's financial statements. The Company applied the standard to convertible notes outstanding as of the date of the first offering of the Company's outstanding convertible notes as discussed in Note 9.

The Company's convertible debt instruments will be accounted for as a single liability measured at its amortized cost. The notes are no longer bifurcated between debt and equity, rather accounted for entirely as debt at face value net of any discount or premium and issuance costs. Interest expense is comprised of (1) cash interest payments, (2) amortization of any debt discounts or premiums based on the original offering, and (3) amortization of any debt issuance costs. Gain or loss on extinguishment of convertible notes is calculated as the difference between the (i) fair value of the consideration transferred and (ii) the sum of the carrying value of the debt at the time of repurchase.

EXACT SCIENCES CORPORATION
Notes to Condensed Consolidated Financial Statements
(Unaudited)

As of January 1, 2019, the cumulative effect of adoption resulted in a decrease in additional-paid-in-capital of \$260.2 million, a decrease in accumulated deficit of \$26.6 million, and an increase to net deferred tax assets of \$55.7 million offset by a corresponding increase of \$55.7 million in the valuation allowance. As of January 1, 2020, the cumulative effect of adoption resulted in a decrease in additional-paid-in-capital of \$227.8 million, an increase in accumulated deficit of \$102.6 million, and an increase to the net deferred tax assets of \$83.2 million offset by a corresponding increase of \$74.7 million in the valuation allowance resulting in a net decrease of \$8.5 million in recorded deferred tax liabilities. As of December 31, 2020, the cumulative effect of adoption resulted in an increase in the net carrying amount of convertible notes, net, current portion of \$57.3 million and convertible notes, net, less current portion of \$540.9 million, a decrease in additional-paid-in-capital of \$510.3 million, an increase in accumulated deficit of \$77.7 million, and an increase to net deferred tax assets of \$146.0 million offset by a corresponding increase of \$135.8 million in the valuation allowance resulting in a net decrease of \$10.2 million in recorded deferred tax liabilities. For the three months ended June 30, 2020, interest expense in the condensed consolidated statement of operations decreased by \$18.6 million as a result of a decrease in amortization of debt discounts, premiums, and issuance costs, income tax benefit decreased by \$0.6 million and net loss per share, basic and diluted, decreased by \$0.12 per share. For the six months ended June 30, 2020, interest expense in the condensed consolidated statement of operations increased by \$10.8 million as a result of an increase in loss on extinguishment of \$42.9 million in connection with the extinguishment of \$100.0 million face value of 2025 Notes, which was offset by a decrease in cash interest and amortization of debt discounts, premiums, and issuance costs of \$32.1 million. Income tax benefit decreased by \$0.1 million and net loss per share, basic and diluted, increased by \$0.07 per share.

Net Loss Per Share

Basic net loss per common share was determined by dividing net loss applicable to common stockholders by the weighted average common shares outstanding during the period. Basic and diluted net loss per share is the same because all outstanding common stock equivalents have been excluded, as they are anti-dilutive as a result of the Company's losses.

The following potentially issuable common shares were not included in the computation of diluted net loss per share because they would have an anti-dilutive effect due to net losses for each period:

(In thousands)	June 30,	
	2021	2020
Shares issuable in connection with acquisitions	157	157
Shares issuable upon exercise of stock options	2,486	2,575
Shares issuable upon the release of restricted stock awards	4,334	4,043
Shares issuable upon the release of performance share units	867	619
Shares issuable upon conversion of convertible notes	20,309	20,309
	28,153	27,703

(2) REVENUE

The Company's revenue is primarily generated by its laboratory testing services utilizing its Cologuard, Oncotype DX, and COVID-19 tests. The services are completed upon release of a patient's test result to the ordering healthcare provider.

EXACT SCIENCES CORPORATION
Notes to Condensed Consolidated Financial Statements
(Unaudited)

Disaggregation of Revenue

The following table presents the Company's revenues disaggregated by revenue source:

(In thousands)	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
Screening				
Medicare Parts B & C	\$ 111,387	\$ 59,583	\$ 212,946	\$ 157,742
Commercial	140,149	65,080	268,023	174,449
Other	12,401	6,670	23,296	18,593
Total Screening	263,937	131,333	504,265	350,784
Precision Oncology				
Medicare Parts B & C	\$ 47,705	\$ 33,994	\$ 90,822	\$ 81,028
Commercial	49,722	45,420	102,977	99,810
International	26,848	19,018	52,903	39,980
Other	13,534	4,524	20,514	10,508
Total Precision Oncology	137,809	102,956	267,216	231,326
COVID-19 Testing	\$ 33,073	\$ 34,579	\$ 65,415	\$ 34,579
Total	\$ 434,819	\$ 268,868	\$ 836,896	\$ 616,689

Screening revenue primarily includes laboratory service revenue from the Cologuard test while Precision Oncology revenue primarily includes laboratory service revenue from global Oncotype DX products.

The downward adjustment to revenue from a change in transaction price was \$14.7 million for the three months ended June 30, 2021 and revenue recognized from changes in transaction price was \$3.2 million for the three months ended June 30, 2020. The downward adjustment to revenue from changes in transaction prices was \$13.0 million for the six months ended June 30, 2021 and revenue recognized from changes in transaction price was \$8.6 million for the six months ended June 30, 2020. At each reporting period end, the Company conducts an analysis of the estimates used to calculate the transaction price to determine whether any new information available impacts those estimates made in prior reporting periods. For the period ending June 30, 2021, the Company identified new constraints on variable consideration that had not previously existed resulting in an adjustment to revenue.

Deferred revenue balances are reported in other current liabilities in the Company's condensed consolidated balance sheets and were \$28.7 million and \$25.0 million as of June 30, 2021 and December 31, 2020, respectively. As of June 30, 2021, \$27.6 million of the Company's deferred revenue balance is a result of the billing terms pursuant to the existing COVID-19 laboratory service agreements ("LSAs") with customers.

Revenue recognized for the three months ended June 30, 2021 and 2020, which was included in the deferred revenue balance at the beginning of each period was \$10.4 million and \$19,000, respectively. Of the \$10.4 million of revenue recognized for the three months ended June 30, 2021, which was included in the deferred revenue balance at the beginning of the period, \$10.3 million related to COVID-19 testing. Revenue recognized for the six months ended June 30, 2021 and 2020, which was included in the deferred revenue balance at the beginning of each period was \$24.4 million and \$0.2 million, respectively. Of the \$24.4 million of revenue recognized for the six months ended June 30, 2021, which was included in the deferred revenue balance at the beginning of the period, \$24.1 million related to COVID-19 testing.

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(3) MARKETABLE SECURITIES

The following table sets forth the Company's cash, cash equivalents, restricted cash, and marketable securities at June 30, 2021 and December 31, 2020:

(In thousands)	June 30, 2021	December 31, 2020
Cash, cash equivalents, and restricted cash		
Cash and money market	\$ 360,797	\$ 901,294
Cash equivalents	2,918	589,994
Restricted cash	297	306
Total cash, cash equivalents, and restricted cash	364,012	1,491,594
Marketable securities		
Available-for-sale debt securities	936,331	347,178
Equity securities	7,533	1,521
Total marketable securities	943,864	348,699
Total cash and cash equivalents, restricted cash and marketable securities	<u>\$ 1,307,876</u>	<u>\$ 1,840,293</u>

Available-for-sale debt securities at June 30, 2021 consisted of the following:

(In thousands)	Amortized Cost	Gains in Accumulated Other Comprehensive Income (Loss) (1)	Losses in Accumulated Other Comprehensive Income (Loss) (1)	Estimated Fair Value
Cash equivalents				
Corporate bonds	\$ 2,917	\$ 1	\$ —	\$ 2,918
Total cash equivalents	2,917	1	—	2,918
Marketable securities				
Corporate bonds	376,516	262	(80)	376,698
U.S. government agency securities	276,227	29	(186)	276,070
Certificates of deposit	212,863	41	(1)	212,903
Commercial paper	14,999	1	—	15,000
Asset backed securities	55,660	9	(9)	55,660
Total marketable securities	936,265	342	(276)	936,331
Total available-for-sale securities	<u>\$ 939,182</u>	<u>\$ 343</u>	<u>\$ (276)</u>	<u>\$ 939,249</u>

(1) Gains and losses in accumulated other comprehensive income (loss) ("AOCI") are reported before tax impact.

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Available-for-sale debt securities at December 31, 2020 consisted of the following:

(In thousands)	Amortized Cost	Gains in Accumulated Other Comprehensive Income (Loss) (1)	Losses in Accumulated Other Comprehensive Income (Loss) (1)	Estimated Fair Value
Cash equivalents				
U.S. government agency securities	\$ 589,986	\$ 8	\$ —	\$ 589,994
Total cash equivalents	589,986	8	—	589,994
Marketable securities				
U.S. government agency securities	207,119	52	—	207,171
Asset backed securities	7,070	24	—	7,094
Corporate bonds	132,301	612	—	132,913
Total marketable securities	346,490	688	—	347,178
Total available-for-sale securities	\$ 936,476	\$ 696	\$ —	\$ 937,172

(1) Gains and losses in AOCI are reported before tax impact.

The following table summarizes contractual underlying maturities of the Company's available-for-sale debt securities at June 30, 2021:

(In thousands)	Due one year or less		Due after one year through five years	
	Cost	Fair Value	Cost	Fair Value
Cash equivalents				
Corporate bonds	\$ 2,917	\$ 2,918	\$ —	\$ —
Total cash equivalents	2,917	2,918	—	—
Marketable securities				
U.S. government agency securities	7,077	7,106	269,150	268,964
Corporate bonds	184,601	184,799	191,915	191,899
Certificates of deposit	212,863	212,903	—	—
Asset backed securities	—	—	55,660	55,660
Commercial paper	14,999	15,000	—	—
Total marketable securities	419,540	419,808	516,725	516,523
Total	\$ 422,457	\$ 422,726	\$ 516,725	\$ 516,523

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The following table summarizes the gross unrealized losses and fair values of available-for-sale debt securities in an unrealized loss position as of June 30, 2021, aggregated by investment category and length of time that individual securities have been in a continuous unrealized loss position:

(In thousands)	Less than one year		One year or greater		Total	
	Fair Value	Gross Unrealized Loss	Fair Value	Gross Unrealized Loss	Fair Value	Gross Unrealized Loss
Marketable securities						
Corporate bonds	\$ 219,054	\$ (80)	\$ —	\$ —	\$ 219,054	\$ (80)
Certificates of deposit	10,501	(1)	—	—	10,501	(1)
Asset backed securities	40,335	(9)	—	—	40,335	(9)
U.S. government agency securities	268,964	(186)	—	—	268,964	(186)
Total marketable securities	538,854	(276)	—	—	538,854	(276)
Total available-for-sale securities	\$ 538,854	\$ (276)	\$ —	\$ —	\$ 538,854	\$ (276)

The Company evaluates investments, including investments in privately-held companies, that are in an unrealized loss position for impairment as a result of credit loss. It was determined that no credit losses exist as of June 30, 2021 and December 31, 2020, because the change in market value for those securities in an unrealized loss position has resulted from fluctuating interest rates rather than a deterioration of the credit worthiness of the issuers. The realized gain recorded on available-for-sale debt securities was not material to the condensed consolidated statements of income for the three and six months ended June 30, 2021 and 2020.

The Company recorded a gain of \$2.5 million and \$2.5 million from its equity securities for the three and six months ended June 30, 2021 as compared to a gain of \$0.4 million and a loss of \$0.3 million for the three and six months ended June 30, 2020.

The gains and losses recorded are included in investment income, net in the Company's condensed consolidated statements of operations.

(4) INVENTORY

Inventory consisted of the following:

(In thousands)	June 30, 2021	December 31, 2020
Raw materials	\$ 44,755	\$ 43,083
Semi-finished and finished goods	45,054	49,182
Total inventory	\$ 89,809	\$ 92,265

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(5) PROPERTY, PLANT AND EQUIPMENT

The estimated useful lives of property, plant and equipment are as follows:

(In thousands)	Estimated Useful Life	June 30, 2021	December 31, 2020
Property, plant and equipment			
Land	n/a	\$ 4,466	\$ 4,466
Leasehold and building improvements	(1)	140,314	117,865
Land improvements	15 years	4,910	4,864
Buildings	30 - 40 years	201,040	200,980
Computer equipment and computer software	3 years	93,912	75,417
Laboratory equipment	3 - 10 years	168,529	142,110
Furniture and fixtures	3 - 10 years	27,383	24,968
Assets under construction	n/a	35,080	18,854
Property, plant and equipment, at cost		675,634	589,524
Accumulated depreciation		(173,726)	(137,538)
Property, plant and equipment, net		<u>\$ 501,908</u>	<u>\$ 451,986</u>

(1) Lesser of remaining lease term, building life, or estimated useful life.

Depreciation expense for the three months ended June 30, 2021 and 2020 was \$21.5 million and \$17.6 million, respectively. Depreciation expense for the six months ended June 30, 2021 and 2020 was \$42.0 million and \$33.6 million, respectively.

At June 30, 2021, the Company had \$35.1 million of assets under construction which consisted of \$8.4 million in laboratory equipment, \$19.6 million related to building and leasehold improvements, and \$7.1 million in capitalized costs related to software projects. Depreciation will begin on these assets once they are placed into service upon completion between 2021 and 2023.

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(6) INTANGIBLE ASSETS AND GOODWILL
Intangible Assets

The following table summarizes the net-book-value and estimated remaining life of the Company's intangible assets as of June 30, 2021:

(In thousands)	Weighted Average Remaining Life (Years)	Cost	Accumulated Amortization	Net Balance at June 30, 2021
Finite-lived intangible assets				
Trade name	14.4	\$ 100,700	\$ (10,406)	\$ 90,294
Customer relationships	12.3	2,700	(494)	2,206
Patents	3.3	10,441	(6,092)	4,349
Acquired developed technology	8.7	853,171	(134,407)	718,764
Supply agreements	5.9	30,000	(6,505)	23,495
Total finite-lived intangible assets		997,012	(157,904)	839,108
In-process research and development	n/a	1,250,000	—	1,250,000
Total intangible assets		\$ 2,247,012	\$ (157,904)	\$ 2,089,108

The following table summarizes the net-book-value and estimated remaining life of the Company's intangible assets as of December 31, 2020:

(In thousands)	Weighted Average Remaining Life (Years)	Cost	Accumulated Amortization	Net Balance at December 31, 2020
Finite-lived intangible assets				
Trade name	14.9	\$ 100,700	\$ (7,258)	\$ 93,442
Customer relationships	12.8	2,700	(404)	2,296
Patents	3.7	10,441	(5,422)	5,019
Acquired developed technology	9.0	814,171	(93,278)	720,893
Supply agreements	6.5	30,000	(4,527)	25,473
Total intangible assets		\$ 958,012	\$ (110,889)	\$ 847,123

As of June 30, 2021, the estimated future amortization expense associated with the Company's finite-lived intangible assets for each of the five succeeding fiscal years is as follows:

(In thousands)	
2021	\$ 47,880
2022	95,758
2023	95,755
2024	95,421
2025	94,373
Thereafter	409,921
	\$ 839,108

The Company's acquired intangible assets are being amortized on a straight-line basis over the estimated useful life.

There were no impairment losses for the three and six months ended June 30, 2021 and 2020.

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Goodwill

The change in the carrying amount of goodwill for the periods ended June 30, 2021 and December 31, 2020 is as follows:

(In thousands)	
Balance, January 1, 2020	\$ 1,203,197
Paradigm & Viomics acquisition	30,431
Genomic Health acquisition adjustment (1)	4,044
Balance, December 31, 2020	\$ 1,237,672
Thrive acquisition	948,105
Ashion Acquisition	56,758
Balance June 30, 2021	\$ 2,242,535

- (1) The Company recognized a measurement period adjustment to goodwill related to an increase in Genomic Health's pre-acquisition deferred tax liability due to finalization of certain income-tax related items.

There were no impairment losses for the three and six months ended June 30, 2021 and 2020.

(7) FAIR VALUE MEASUREMENTS

The three levels of the fair value hierarchy established are as follows:

- Level 1** Quoted prices (unadjusted) in active markets for identical assets or liabilities that the Company has the ability to access as of the reporting date. Active markets are those in which transactions for the asset or liability occur in sufficient frequency and volume to provide pricing information on an ongoing basis.
- Level 2** Pricing inputs other than quoted prices in active markets included in Level 1, which are either directly or indirectly observable as of the reporting date. These include quoted prices for similar assets or liabilities in active markets and quoted prices for identical or similar assets or liabilities in markets that are not active.
- Level 3** Unobservable inputs that reflect the Company's assumptions about the assumptions that market participants would use in pricing the asset or liability. Unobservable inputs shall be used to measure fair value to the extent that observable inputs are not available.

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The following table presents the Company's fair value measurements as of June 30, 2021 along with the level within the fair value hierarchy in which the fair value measurements, in their entirety, fall.

(In thousands)	Fair Value at June 30, 2021	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Cash, cash equivalents, and restricted cash				
Cash and money market	\$ 360,797	\$ 360,797	\$ —	\$ —
Corporate bonds	2,918	2,918	—	—
Restricted cash	297	297	—	—
Marketable securities				
Corporate bonds	376,698	—	376,698	—
Certificates of deposit	212,903	—	212,903	—
Commercial paper	15,000	—	15,000	—
U.S. government agency securities	276,070	—	276,070	—
Asset backed securities	55,660	—	55,660	—
Equity securities (1)	7,533	—	7,533	—
Liabilities				
Contingent consideration	(361,862)	—	—	(361,862)
Total	\$ 946,014	\$ 364,012	\$ 943,864	\$ (361,862)

(1) The equity securities held are classified as Level 2 as they are subject to a short-term lock-up restriction and have been discounted from the observable market prices of the similar unrestricted equity securities.

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The following table presents the Company's fair value measurements as of December 31, 2020 along with the level within the fair value hierarchy in which the fair value measurements, in their entirety, fall.

(In thousands)	Fair Value at December 31, 2020	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Cash and cash equivalents				
Cash and money market	\$ 901,294	\$ 901,294	\$ —	\$ —
U.S. government agency securities	589,994	—	589,994	—
Restricted cash	306	306	—	—
Marketable securities				
U.S. government agency securities	207,171	—	207,171	—
Corporate bonds	132,913	—	132,913	—
Asset backed securities	7,094	—	7,094	—
Equity securities	1,521	1,521	—	—
Liabilities				
Contingent consideration	(2,477)	—	—	(2,477)
Total	<u>\$ 1,837,816</u>	<u>\$ 903,121</u>	<u>\$ 937,172</u>	<u>\$ (2,477)</u>

There have been no changes in valuation techniques or transfers between fair value measurement levels during the periods ended June 30, 2021 and December 31, 2020. The fair value of Level 2 instruments classified as cash equivalents and marketable debt securities are valued using a third-party pricing agency where the valuation is based on observable inputs including pricing for similar assets and other observable market factors. The Company's marketable equity security investment in Biocartis held as of December 31, 2020 was classified as a Level 1 instrument prior to being sold in the first quarter of 2021.

Contingent Consideration

Certain of the Company's business combinations involve potential payment of future consideration that is contingent upon the achievement of certain regulatory and product revenue milestones being achieved. A liability is recorded for the estimated fair value of the contingent consideration on the acquisition date. The fair value of the contingent consideration is remeasured at each reporting period, and the change in fair value is recognized within general and administrative expenses on the Company's condensed consolidated statements of operations.

The fair value of contingent consideration as of June 30, 2021 and December 31, 2020 was \$361.9 million and \$2.5 million, respectively, which was recorded in other long-term liabilities in the condensed consolidated balance sheets.

The following table provides a reconciliation of the beginning and ending balances of contingent consideration:

(In thousands)	Contingent Consideration
Beginning balance, January 1, 2021	\$ 2,477
Purchase price contingent consideration (1)	350,348
Changes in fair value	9,201
Payments	(164)
Ending balance, June 30, 2021	<u>\$ 361,862</u>

(1) The increase in the contingent consideration liability is due to the contingent consideration associated with the acquisitions of Ashion Analytics, LLC ("Ashion") and Thrive Earlier Detection Corporation ("Thrive"). Refer to Note 17 for further information.

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This fair value measurement of contingent consideration is categorized as a Level 3 liability, as the measurement amount is based primarily on significant inputs not observable in the market.

The fair value of the contingent consideration liability recorded related to regulatory and product development milestones associated with the Thrive and Ashion acquisitions was \$359.5 million as of June 30, 2021. The Company evaluates the fair value of the regulatory and product development milestones related expected contingent consideration and the corresponding liability using the probability-weighted scenario based discounted cash flow model, which is consistent with the initial measurement of the expected contingent consideration liabilities. Probabilities of success are applied to each potential scenario and the resulting values are discounted using a rate that considers a present-value factor. The passage of time in addition to changes in projected milestone achievement timing, present-value factor, the degree of achievement if applicable, and probabilities of success may result in adjustments to the fair value measurement. The fair value measurements of contingent consideration for which a liability is recorded include significant unobservable inputs. As of June 30, 2021, the fair value of the contingent consideration liability recorded related to regulatory and product development milestones was determined using a weighted average probability of success of 90.4% and a weighted average present-value factor of 2.2%. The projected fiscal year of payment range is from 2024 to 2027. Unobservable inputs were weighted by the relative fair value of the contingent consideration liability.

The fair value of the contingent consideration earnout liability related to certain revenue milestones associated with the Biomatrix acquisition was \$2.3 million as of June 30, 2021. The revenue milestone associated with the Ashion acquisition is not expected to be achieved and therefore no liability has been recorded for this milestone.

Non-Marketable Equity Investments

As of June 30, 2021 and December 31, 2020, the aggregate carrying amounts of the Company's non-marketable equity securities without readily determinable fair values were \$26.7 million and \$29.1 million, respectively, which are classified as a component of other long-term assets in the Company's condensed consolidated balance sheets. There have been no downward or upward adjustments made on these investments since initial recognition.

Derivative Financial Instruments

As of June 30, 2021 and December 31, 2020, the Company had open foreign currency forward contracts with notional amounts of \$23.8 million and \$22.4 million, respectively. The Company's foreign exchange derivative instruments are classified as Level 2 within the fair value hierarchy as they are valued using inputs that are observable in the market or can be derived principally from or corroborated by observable market data. The fair value of the foreign currency forward contracts was zero at June 30, 2021 and December 31, 2020, and there were no gains or losses recorded for the three and six months ended June 30, 2021 and 2020.

(8) LONG-TERM DEBT

Construction Loan Agreement

During December 2017, the Company entered into a loan agreement with Fifth Third Bank (formerly MB Financial Bank, N.A.) (the "Construction Loan Agreement"), which provides the Company with a non-revolving construction loan (the "Construction Loan") of \$25.6 million. The Company is using the Construction Loan proceeds to finance the construction of an additional clinical laboratory and related facilities in Madison, Wisconsin. The Construction Loan is collateralized by the additional clinical laboratory and related facilities.

Pursuant to the Construction Loan Agreement, funds drawn will bear interest at a rate equal to the sum of the 1-month LIBOR rate plus 2.25 percent. Regular monthly payments are interest-only for the first 24 months, with further payments based on a 20-year amortization schedule. Amounts borrowed pursuant to the Construction Loan Agreement may be prepaid at any time without penalty. The maturity date of the Construction Loan Agreement is December 10, 2022.

In November 2017, Fifth Third Bank, on behalf of the Company, issued an Irrevocable Standby Letter of Credit in the amount of \$0.6 million in favor of the City of Madison, Wisconsin (the "City Letter of Credit"). The City Letter of Credit is deemed to have been issued pursuant to the Construction Loan Agreement. The amount of the City Letter of Credit will reduce, dollar for dollar, the amount available for borrowing under the Construction Loan Agreement.

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As a condition to Fifth Third Bank’s initial advance of loan proceeds under the Construction Loan Agreement, the Company was required to first invest at least \$16.4 million of its own cash into the construction project. The Company fulfilled its required initial investment and made its first draw on the Construction Loan in June 2018. In December 2019, the Company began making monthly payments towards the outstanding principal balance plus accrued interest. As of June 30, 2021 and December 31, 2020, the outstanding balance was \$23.1 million and \$23.8 million, respectively, from the Construction Loan, including \$0.7 million of interest incurred, which is accrued for as an interest reserve and represents a portion of the loan balance. The Company capitalized the \$0.7 million of interest to the construction project. The Company incurred approximately \$0.2 million of debt issuance costs related to the Construction Loan, which are recorded as a direct deduction from the liability. The debt issuance costs are being amortized over the life of the Construction Loan.

The carrying amount of the Construction Loan approximates fair value due to the short maturity of this instrument. The Construction Loan is privately held with no public market for this debt and therefore is classified as a Level 3 fair value measurement. The change in the fair value during the three and six months ended June 30, 2021 was due to payments made on the loan resulting in a decrease in the liability.

The Construction Loan Agreement was amended effective June 30, 2020 to include a financial covenant to maintain a minimum liquidity of \$250 million and remove the minimum tangible net worth covenant. As of June 30, 2021, the Company is in compliance with the covenant included in the amended agreement.

Tax Increment Financing Loan Agreements

The Company entered into two separate Tax Increment Financing Loan Agreements (“TIFs”) in February 2019 and June 2019 with the City of Madison, Wisconsin. The TIFs provide for \$4.6 million of financing in the aggregate. In return for the loans, the Company is obligated to create and maintain 500 full-time jobs over a five-year period, starting on the date of occupancy of the buildings constructed. In the event that the job creation goals are not met, the Company would be required to pay a penalty.

The Company records the earned financial incentives as the full-time equivalent positions are filled. The amount earned is recorded as a liability and amortized as a reduction of operating expenses over a two-year period, which is the timeframe when the TIFs will be repaid through property taxes.

As of December 31, 2019, the Company had earned and received payment of the full \$4.6 million from the City of Madison, and the corresponding liability became fully amortized in October 2020. In May 2021 the City of Madison confirmed that the Company had repaid the TIFs in full and released the Company from the loans and the related property lien.

(9) CONVERTIBLE NOTES

Convertible note obligations included in the condensed consolidated balance sheet consisted of the following as of June 30, 2021:

(In thousands)	Principal Amount	Unamortized Debt Discount and Issuance Costs	Net Carrying Amount	Fair Value (2)	
				Amount	Leveling
2028 Convertible notes - 0.375%	\$ 1,150,000	\$ (20,365)	\$ 1,129,635	\$ 1,460,500	2
2027 Convertible notes - 0.375%	747,500	(12,823)	734,677	1,008,826	2
2025 Convertible notes - 1.000% (1)	315,008	(2,047)	312,961	581,876	2

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Convertible note obligations included in the condensed consolidated balance sheet consisted of the following as of December 31, 2020:

(In thousands)	Principal Amount	Unamortized Debt Discount and Issuance Costs	Net Carrying Amount	Fair Value (2)	
				Amount	Leveling
2028 Convertible notes - 0.375%	\$ 1,150,000	\$ (21,878)	\$ 1,128,122	\$ 1,526,625	2
2027 Convertible notes - 0.375%	747,500	(13,937)	733,563	992,306	2
2025 Convertible notes - 1.000% (1)	315,049	(2,333)	312,716	601,744	2

- (1) Based on the Company's share price on the days leading up to June 30, 2021 and December 31, 2020, holders of the 2025 Convertible Notes have the right to convert their debentures. As a result, the 2025 Convertible Notes are included within convertible notes, net, current portion on the condensed consolidated balance sheets.
- (2) The fair values are based on observable market prices for this debt, which is traded in active markets and therefore is classified as a Level 2 fair value measurement.

Issuances and Settlements

In January 2018, the Company issued and sold \$690.0 million in aggregate principal amount of 1.0% Convertible Notes (the "January 2025 Notes") with a maturity date of January 15, 2025. The January 2025 Notes accrue interest at a fixed rate of 1.0% per year, payable semi-annually in arrears on January 15 and July 15 of each year, beginning on July 15, 2018. The net proceeds from the issuance of the January 2025 Notes were approximately \$671.1 million, after deducting underwriting discounts and commissions and the offering expenses payable by the Company.

In June 2018, the Company issued and sold an additional \$218.5 million in aggregate principal amount of 1.0% Convertible Notes (the "June 2025 Notes"). The June 2025 Notes were issued under the same indenture pursuant to which the Company previously issued the January 2025 Notes (the "Indenture"). The January 2025 Notes and the June 2025 Notes (collectively, the "2025 Notes") have identical terms (including the same January 15, 2025 maturity date) and are treated as a single series of securities. The net proceeds from the issuance of the June 2025 Notes were approximately \$225.3 million, after deducting underwriting discounts and commissions and the offering expenses payable by the Company.

In March 2019, the Company issued and sold \$747.5 million in aggregate principal amount of 0.375% Convertible Notes (the "2027 Notes") with a maturity date of March 15, 2027. The 2027 Notes accrue interest at a fixed rate of 0.375% per year, payable semi-annually in arrears on March 15 and September 15 of each year, beginning on September 15, 2019. The net proceeds from the issuance of the 2027 Notes were approximately \$729.5 million, after deducting underwriting discounts and commissions and the offering expenses payable by the Company.

The Company utilized a portion of the proceeds from the issuance of the 2027 Notes to settle a portion of the 2025 Notes in privately negotiated transactions. In March 2019, the Company used cash of \$494.1 million and an aggregate of 2.2 million shares of the Company's common stock valued at \$182.4 million for total consideration of \$676.5 million to settle \$493.4 million of the 2025 Notes, of which \$0.7 million was used to pay off interest accrued on the 2025 Notes. The transaction resulted in a loss on settlement of convertible notes of \$187.7 million, which is reflected in accumulated deficit in the Company's condensed consolidated balance sheets. The loss represents the difference between (i) the fair value of the consideration transferred and (ii) the carrying value of the debt at the time of repurchase.

In February 2020, the Company issued and sold \$1.15 billion in aggregate principal amount of 0.375% Convertible Notes (the "2028 Notes" and, collectively with the 2025 Notes and the 2027 Notes, the "Notes") with a maturity date of March 1, 2028. The 2028 Notes accrue interest at a fixed rate of 0.375% per year, payable semi-annually in arrears on March 1 and September 1 of each year, beginning on September 1, 2020. The net proceeds from the issuance of the 2028 Notes were approximately \$1.13 billion, after deducting underwriting discounts and commissions and the offering expenses payable by the Company.

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In February 2020, the Company used \$150.1 million of the proceeds from the issuance of the 2028 Notes to settle \$100.0 million of the 2025 Notes, of which \$0.1 million was used to pay off interest accrued on the 2025 Notes. The transaction resulted in a loss on settlement of convertible notes of \$50.8 million, which is recorded in interest expense in the Company's condensed consolidated statement of operations. The loss represents the difference between (i) the fair value of the consideration transferred and (ii) the carrying value of the debt at the time of repurchase.

Summary of Conversion Features

Until the six-months immediately preceding the maturity date of the applicable series of Notes, each series of Notes is convertible only upon the occurrence of certain events and during certain periods, as set forth in the Indentures filed at the time of the original offerings. On or after the date that is six-months immediately preceding the maturity date of the applicable series of Notes until the close of business on the second scheduled trading day immediately preceding the maturity date, holders may convert such Notes at any time. The Notes will be convertible into cash, shares of the Company's common stock (plus, if applicable, cash in lieu of any fractional share), or a combination of cash and shares of the Company's common stock, at the Company's election.

It is the Company's intent and policy to settle all conversions through combination settlement. The initial conversion rate is 13.26, 8.96, and 8.21 shares of common stock per \$1,000 principal amount for the 2025 Notes, 2027 Notes, and 2028 Notes, respectively, which is equivalent to an initial conversion price of approximately \$75.43, \$111.66, and \$121.84 per share of the Company's common stock for the 2025 Notes, 2027 Notes, and 2028 Notes, respectively. The 2025 Notes, 2027 Notes, and 2028 Notes may be convertible in up to 4.2 million, 6.7 million, and 9.4 million shares, respectively. The conversion rate is subject to adjustment upon the occurrence of certain specified events as set forth in the Indentures filed at the time of the original offerings but will not be adjusted for accrued and unpaid interest. In addition, holders of the Notes who convert their Notes in connection with a "make-whole fundamental change" (as defined in the Indenture), will, under certain circumstances, be entitled to an increase in the conversion rate.

If the Company undergoes a "fundamental change" (as defined in the Indenture), holders of the Notes may require the Company to repurchase for cash all or part of their Notes at a repurchase price equal to 100% of the principal amount of the Notes to be repurchased, plus accrued and unpaid interest.

Based on the closing price of the Company's common stock of \$124.31 on June 30, 2021, the if-converted values exceed the principal amount by \$204.1 million, \$84.7 million, and \$23.3 million for the 2025 Notes, 2027 Notes, and 2028 Notes, respectively.

Ranking of Convertible Notes

The Notes are the Company's senior unsecured obligations and (i) rank senior in right of payment to all of its future indebtedness that is expressly subordinated in right of payment to the Notes; (ii) rank equal in right of payment to each outstanding series thereof and to all of the Company's future liabilities that are not so subordinated, unsecured indebtedness; (iii) are effectively junior to all of the Company's existing and future secured indebtedness and other secured obligations, to the extent of the value of the assets securing that indebtedness and other secured obligations; and (iv) are structurally subordinated to all indebtedness and other liabilities of the Company's subsidiaries.

Issuance costs are amortized to interest expense over the term of the Notes. The following table summarizes the original issuance costs at the time of issuance for each set of Notes:

(In thousands)	
January 2025 Notes	\$ 10,284
June 2025 Notes	7,363
2027 Notes	14,285
2028 Notes	24,453

The Notes do not contain any financial or operating covenants or any restrictions on the payment of dividends, the issuance of other indebtedness or the issuance or repurchase of securities by the Company.

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Interest expense includes the following:

(In thousands)	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
Debt issuance costs amortization	\$ 1,428	\$ 1,428	\$ 2,840	\$ 2,416
Debt discount amortization	37	37	73	57
Loss on settlement of convertible notes	—	—	—	50,819
Coupon interest expense	2,566	2,567	5,133	4,498
Total interest expense on convertible notes	4,031	4,032	8,046	57,790
Other interest expense	621	268	1,222	1,114
Total interest expense	\$ 4,652	\$ 4,300	\$ 9,268	\$ 58,904

The effective interest rates on the 2025 Notes, 2027 Notes, and 2028 Notes for the three months ended June 30, 2021 and 2020 were 1.18%, 0.67%, and 0.64% and 1.18%, 0.67%, and 0.63%, respectively. The effective interest rates on the 2025 Notes, 2027 Notes, and 2028 Notes for the six months ended June 30, 2021 and 2020 were 1.18%, 0.67%, and 0.64% and 1.22%, 0.67%, and 0.64%, respectively. The remaining period over which the unamortized debt discount will be recognized as non-cash interest expense is 3.55, 5.71, and 6.67 years for the 2025 Notes, 2027 Notes, and 2028 Notes, respectively.

(10) LICENSE AND COLLABORATION AGREEMENTS

The Company licenses certain technologies that are, or may be, incorporated into its technology under several license agreements, as well as the rights to commercialize certain diagnostic tests through collaboration agreements. Generally, the license agreements require the Company to pay royalties based on net revenues received using the technologies and may require minimum royalty amounts or maintenance fees.

Mayo

In June 2009 the Company entered into a license agreement with Mayo Foundation for Medical Education and Research (“Mayo”). The Company’s license agreement with Mayo was most recently amended and restated in September 2020. Under the license agreement, Mayo granted the Company an exclusive, worldwide license to certain Mayo patents and patent applications, as well as a non-exclusive, worldwide license with regard to certain Mayo know-how. The scope of the license covers any screening, surveillance or diagnostic test or tool for use in connection with any type of cancer, pre-cancer, disease or condition.

The licensed Mayo patents and patent applications contain both method and composition claims that relate to sample processing, analytical testing and data analysis associated with nucleic acid screening for cancers and other diseases. The jurisdictions covered by these patents and patent applications include the U.S., Australia, Canada, the European Union, China, Japan and Korea. Under the license agreement, the Company assumed the obligation and expense of prosecuting and maintaining the licensed Mayo patents and is obligated to make commercially reasonable efforts to bring to market products using the licensed Mayo intellectual property.

Pursuant to the Company’s agreement with Mayo, the Company is required to pay Mayo a low-single-digit royalty on the Company’s net sales of current and future products using the licensed Mayo intellectual property each year during the term of the Mayo agreement.

As part of the most recent amendment, the Company agreed to pay Mayo an additional \$6.3 million, payable in five equal annual installments through 2024. The annual installments are recorded in research and development expenses in the Company’s condensed consolidated statements of operations.

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The license agreement will remain in effect, unless earlier terminated by the parties in accordance with the agreement, until the last of the licensed patents expires in 2038 (or later, if certain licensed patent applications are issued). However, if the Company is still using the licensed Mayo know-how or certain Mayo-provided biological specimens or their derivatives on such expiration date, the term shall continue until the earlier of the date the Company stops using such know-how and materials and the date that is five years after the last licensed patent expires. The license agreement contains customary termination provisions and permits Mayo to terminate the license agreement if the Company sues Mayo or its affiliates, other than any such suit claiming an uncured material breach by Mayo of the license agreement.

In addition to granting the Company a license to the covered Mayo intellectual property, Mayo provides the Company with product development and research and development assistance pursuant to the license agreement and other collaborative arrangements. In September 2020, Mayo also agreed to make available certain personnel to provide such assistance through January 2025. In connection with this collaboration, the Company incurred charges of \$1.0 million and \$1.0 million for the three months ended June 30, 2021 and 2020, respectively. The Company incurred charges of \$2.2 million and \$1.9 million for the six months ended June 30, 2021 and 2020, respectively. The charges incurred in connection with this collaboration are recorded in research and development expenses in the Company's condensed consolidated statements of operations.

Johns Hopkins University (“JHU”)

Through the acquisition of Thrive, the Company acquired a worldwide exclusive license agreement with JHU for use of several JHU patents and licensed know-how. The license is designed to enable the Company to leverage JHU proprietary data in the development and commercialization of a blood-based, multi-cancer screening test. The agreement terms include single-digit sales-based royalties and sales-based milestone payments of \$10.0 million, \$15.0 million, \$20.0 million and upon achieving calendar year licensed product revenue using JHU proprietary data of \$0.50 billion, \$1.00 billion, and \$1.50 billion, respectively.

(11) PFIZER PROMOTION AGREEMENT

In August 2018, the Company entered into a Promotion Agreement (the “Original Promotion Agreement”) with Pfizer Inc. (“Pfizer”), which was amended and restated in October 2020 (the “Restated Promotion Agreement”). The Restated Promotion Agreement extends the relationship between the Company and Pfizer and restructures the manner in which the Company compensates Pfizer for promotion of the Cologuard test through a service fee, and provision of certain other sales and marketing services related to the Cologuard test. The Restated Promotion Agreement includes fixed and performance-related fees, some of which retroactively went into effect on April 1, 2020. All payments to Pfizer are recorded in sales and marketing expenses in the Company's condensed consolidated statements of operations.

Under the Original Promotion Agreement, the service fee was calculated based on incremental gross profits over specified baselines during the term. Under the Restated Promotion Agreement, the service fee provides a fee-for-service model that includes certain fixed fees and performance-related bonuses. The performance-related bonuses are contingent upon the achievement of certain annual performance criteria with any applicable expense being recognized ratably upon achievement of the payment becoming probable. The Company incurred charges of \$24.1 million and \$2.1 million for the service fee for the three months ended June 30, 2021 and 2020, respectively. The Company incurred charges of \$46.8 million and \$21.7 million for the service fee for the six months ended June 30, 2021 and 2020, respectively. The Company incurred charges of \$31.1 million and \$21.1 million for promotion, sales and marketing services performed by Pfizer on behalf of the Company during the three months ended June 30, 2021 and 2020, respectively. The Company incurred charges of \$57.7 million and \$40.5 million for promotion, sales and marketing services performed by Pfizer on behalf of the Company during the six months ended June 30, 2021 and 2020, respectively. During 2022, and contingent upon the achievement of certain Cologuard test revenue metrics during 2021, the Company will pay Pfizer a royalty based on a low single-digit royalty rate applied to actual 2022 Cologuard test revenues. The term of the Restated Promotion Agreement runs through December 31, 2022.

(12) STOCKHOLDERS' EQUITY

Ashion Acquisition Stock Issuance

In April 2021 the Company completed its acquisition of Ashion. In connection with the acquisition, which is further described in Note 17, the Company issued 0.1 million common shares that had a fair value of \$16.2 million.

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Thrive Acquisition Stock Issuance

In January 2021, the Company completed its acquisition of Thrive. In connection with the acquisition, which is further described in Note 17, the Company issued 9.3 million common shares that had a fair value of \$1.19 billion.

Targeted Digital Sequencing (“TARDIS”) License Acquisition Stock Issuance

In January 2021, the Company acquired a worldwide exclusive license to the TARDIS technology from The Translational Genomics Research Institute (“TGen”), which is further described in Note 17. As part of the consideration transferred, the Company issued 0.2 million shares that had a fair value of \$27.3 million.

Paradigm Diagnostics, Inc. (“Paradigm”) and Viomics, Inc. (“Viomics”) Acquisition Stock Issuance

In March 2020, the Company completed the acquisitions of Paradigm and Viomics. The purchase price for these acquisitions consisted of cash and stock with a fair value of \$40.4 million. Of the \$40.4 million purchase price, \$32.2 million is expected to be settled through the issuance of 0.4 million shares of common stock. Of the \$32.2 million that will be settled through the issuance of common stock, \$28.8 million was issued as of June 30, 2021, and the remainder was withheld and may become issuable as additional merger consideration subject to the terms and conditions of the acquisition agreements.

Changes in Accumulated Other Comprehensive Income (Loss)

The amount recognized in AOCI for the six months ended June 30, 2021 were as follows:

(In thousands)	Unrealized Gain (Loss) on Marketable Securities	Accumulated Other Comprehensive Income (Loss)
Balance at December 31, 2020	\$ 526	\$ 526
Other comprehensive loss before reclassifications	(399)	(399)
Amounts reclassified from accumulated other comprehensive loss	(230)	(230)
Net current period change in accumulated other comprehensive loss, before tax	(629)	(629)
Income tax expense related to items of other comprehensive income	170	170
Balance at June 30, 2021	<u>\$ 67</u>	<u>\$ 67</u>

The amounts recognized in AOCI for the six months ended June 30, 2020 were as follows:

(In thousands)	Foreign Currency Translation Adjustments	Unrealized Gain (Loss) on Marketable Securities (1)	Accumulated Other Comprehensive Income (Loss)
Balance at December 31, 2019	\$ (25)	\$ (75)	\$ (100)
Other comprehensive loss before reclassifications	—	1,564	1,564
Amounts reclassified from accumulated other comprehensive loss	25	—	25
Net current period change in accumulated other comprehensive loss	25	1,564	1,589
Balance at June 30, 2020	<u>\$ —</u>	<u>\$ 1,489</u>	<u>\$ 1,489</u>

(1) There was no tax impact from the amounts recognized in AOCI for the three and six months ended June 30, 2020.

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Amounts reclassified from AOCI for the six months ended June 30, 2021 and 2020 were as follows:

Details about AOCI Components (In thousands)	Affected Line Item in the Statements of Operations	Six Months Ended June 30,	
		2021	2020
Change in value of available-for-sale investments			
Sales and maturities of available-for-sale investments	Investment income, net	\$ (230)	\$ —
Foreign currency adjustment	General and administrative	—	25
Total reclassifications		<u>\$ (230)</u>	<u>\$ 25</u>

(13) STOCK-BASED COMPENSATION

Stock-Based Compensation Plans

The Company maintains the 2010 Omnibus Long-Term Incentive Plan (As Amended and Restated Effective July 27, 2017), the 2019 Omnibus Long-Term Incentive Plan, the 2010 Employee Stock Purchase Plan, and the 2016 Inducement Award Plan (collectively, the “Stock Plans”).

Stock-Based Compensation Expense

The Company records stock-based compensation expense in connection with the amortization of restricted stock and restricted stock unit awards (“RSUs”), stock purchase rights granted under the Company’s employee stock purchase plan and stock options granted to employees, non-employee consultants and non-employee directors. The Company recorded \$56.3 million and \$40.0 million in stock-based compensation expense during the three months ended June 30, 2021 and 2020, respectively. The Company recorded \$219.7 million and \$69.6 million in stock-based compensation expense during the six months ended June 30, 2021 and 2020, respectively.

As of June 30, 2021, there was \$433.2 million of expected total unrecognized compensation cost related to non-vested share-based compensation arrangements granted under all equity compensation plans. The Company expects to recognize that cost over a weighted average period of 2.9 years.

In connection with the acquisition of Thrive, the Company accelerated the vesting of shares of previously unvested stock options and restricted stock units for employees with qualifying termination events. During the three months ended June 30, 2021, the Company accelerated 4,982 shares of previously unvested stock options and 5,827 shares of previously unvested restricted stock awards and restricted stock units and recorded \$1.0 million of non-cash stock-based compensation for the accelerated awards. During the six months ended June 30, 2021, the Company accelerated 103,996 shares of previously unvested stock options and 33,306 shares of previously unvested restricted stock awards and restricted stock units and recorded \$14.5 million of non-cash stock-based compensation for the accelerated awards. As further discussed in Note 17, the Company also recorded \$86.2 million in stock-based compensation related to accelerated vesting of awards held by Thrive employees in connection with the acquisition.

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Stock Options

The Company determines the fair value of each service-based option award on the date of grant using the Black-Scholes option-pricing model, which utilizes several key assumptions which are disclosed in the following table:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
Option Plan Shares				
Risk-free interest rates	(1)	(1)	(1)	0.98% - 1.47%
Expected term (in years)	(1)	(1)	(1)	4.68 - 6.15
Expected volatility	(1)	(1)	(1)	65.67% - 77.51%
Dividend yield	(1)	(1)	(1)	—%

(1) The Company did not grant stock options under its 2010 Omnibus Long-Term Incentive Plan or 2019 Omnibus Long-Term Incentive Plan during the period.

A summary of stock option activity under the Stock Plans is as follows:

Options	Shares	Weighted Average Exercise Price (1)	Weighted Average Remaining Contractual Term(Years)	Aggregate Intrinsic Value(2)
<i>(Aggregate intrinsic value in thousands)</i>				
Outstanding, January 1, 2021	2,231,059	\$ 39.67	6.0	
Granted	—	—		
Assumed through acquisition	1,393,748	5.51		
Exercised	(1,107,613)	10.51		
Forfeited	(31,234)	64.77		
Outstanding, June 30, 2021	2,485,960	\$ 33.20	6.2	\$ 226,506
Vested and expected to vest, June 30, 2021	2,485,960	\$ 33.20	6.2	\$ 226,506
Exercisable, June 30, 2021	1,825,975	\$ 25.29	5.5	\$ 180,809

(1) The weighted average grant date fair value of options granted during the three and six months ended June 30, 2020 was \$58.77.

(2) The total intrinsic value of options exercised during the six months ended June 30, 2021 and 2020 was \$140.2 million and \$20.4 million, respectively, determined as of the date of exercise.

The Company received approximately \$11.6 million and \$10.9 million from stock option exercises during the six months ended June 30, 2021 and 2020, respectively.

Restricted Stock and Restricted Stock Units

The fair value of restricted stock and restricted stock units is determined on the date of grant using the closing stock price on that day.

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A summary of restricted stock and restricted stock unit activity during the six months ended June 30, 2021 is as follows:

Restricted stock and restricted stock units	Shares	Weighted Average Grant Date Fair Value (2)
Outstanding, January 1, 2021	3,968,214	\$ 79.46
Granted	1,680,182	140.63
Assumed through acquisition	242,123	127.79
Released (1)	(1,308,929)	71.15
Forfeited	(247,183)	95.88
Outstanding, June 30, 2021	<u>4,334,407</u>	<u>\$ 107.44</u>

(1) The fair value of restricted stock units vested and converted to shares of the Company's common stock was \$93.1 million and \$63.5 million during the six months ended June 30, 2021 and 2020, respectively.

(2) The weighted average grant date fair value of the restricted stock units granted during the six months ended June 30, 2020 was \$92.29.

Performance Share Units

The Company has issued performance-based equity awards to certain employees which vest upon the achievement of certain performance goals, including financial performance targets and operational milestones.

In February 2021, the Company issued additional performance-based equity awards to certain employees which vest upon the achievement of certain performance goals, including financial performance targets and operational milestones.

A summary of performance share-based compensation arrangements granted under all equity compensation unit activity is as follows:

Performance share units	Shares (1)	Weighted Average Grant Date Fair Value (2)
Outstanding, January 1, 2021	618,515	\$ 93.22
Granted	253,120	140.96
Released	—	—
Forfeited	(4,150)	147.81
Outstanding, June 30, 2021	<u>867,485</u>	<u>\$ 106.89</u>

(1) The performance share units listed above assumes attainment of maximum payout rates as set forth in the performance criteria. Applying actual or expected payout rates, the number of outstanding performance share units as of June 30, 2021 was 174,904.

(2) The weighted average grant date fair value of the performance share units granted during the six months ended June 30, 2020 was \$90.17.

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Employee Stock Purchase Plan (“ESPP”)

The fair value of ESPP shares is based on the assumptions in the following table:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
ESPP Shares				
Risk-free interest rates	0.04% - 0.16%	0.12% - 0.20%	0.04% - 0.16%	0.12% - 0.20%
Expected term (in years)	0.5 - 2	0.5 - 2	0.5 - 2	0.5 - 2
Expected volatility	48.38% - 68.51%	63.67% - 89.04%	48.38% - 68.51%	63.67% - 89.04%
Dividend yield	—%	—%	—%	—%

(14) COMMITMENTS AND CONTINGENCIES
Leases

Supplemental disclosure of cash flow information related to the Company’s cash and non-cash activities with its leases are as follows:

(In thousands)	Six Months Ended June 30, 2021			
	2021		2020	
Cash paid for amounts included in the measurement of lease liabilities:				
Operating cash flows from operating leases	\$	12,309	\$	12,289
Operating cash flows from finance leases		480		27
Finance cash flows from finance leases		2,443		182
Non-cash investing and financing activities:				
Right-of-use assets obtained in exchange for new operating lease liabilities (1)		54,451		13,024
Right-of-use assets obtained in exchange for new finance lease liabilities		2,308		1,471
Weighted-average remaining lease term - operating leases (in years)		8.43		9.20
Weighted-average remaining lease term - finance leases (in years)		3.28		3.81
Weighted-average discount rate - operating leases	6.32	%	6.83	%
Weighted-average discount rate - finance leases	5.54	%	6.33	%

(1) For the six months ended June 30, 2021, this includes right-of-use assets acquired as part of the business combinations described in Note 17 of \$39.6 million.

As of June 30, 2021 and December 31, 2020, the Company’s right-of-use assets from operating leases are \$166.9 million and \$125.9 million, respectively, which are reported in operating lease right-of-use assets in the Company’s condensed consolidated balance sheets. As of June 30, 2021, the Company has outstanding operating lease obligations of \$180.9 million, of which \$16.6 million is reported in operating lease liabilities, current portion and \$164.3 million is reported in operating lease liabilities, less current portion in the Company’s condensed consolidated balance sheets. As of December 31, 2020, the Company had outstanding operating lease obligations of \$132.6 million, of which \$11.5 million is reported in operating lease liabilities, current portion and \$121.1 million is reported in operating lease liabilities, less current portion in the Company’s condensed consolidated balance sheets. The Company calculates its incremental borrowing rates for specific lease terms, used to discount future lease payments, as a function of the U.S. Treasury rate and an indicative Moody’s rating for operating leases.

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As of June 30, 2021 and December 31, 2020, the Company's right-of-use assets from finance leases are \$18.2 million and \$18.6 million, respectively, which are reported in other long-term assets, net in the Company's condensed consolidated balance sheets. As of June 30, 2021, the Company has outstanding finance lease obligations of \$18.5 million, of which \$5.4 million is reported in other current liabilities and \$13.1 million is reported in other long-term liabilities in the Company's condensed consolidated balance sheets. As of December 31, 2020, the Company had outstanding finance lease obligations of \$18.7 million, of which \$4.7 million is reported in other current liabilities and \$14.0 million is reported in other long-term liabilities in the Company's condensed consolidated balance sheets. The Company calculates its incremental borrowing rates for specific lease terms, used to discount future lease payments, as a function of the U.S. Treasury rate and an indicative Moody's rating for finance leases.

The Company executed a lease agreement for a new facility in La Jolla, California that will commence in 2021. The Company anticipates that it will recognize \$22.8 million in operating lease right-of-use assets and \$22.8 million in operating lease liabilities in the condensed consolidated balance sheet, respectively, upon commencement of the lease.

Legal Matters

The Company records reserves and accrues costs for certain legal proceedings and regulatory matters to the extent that it determines an unfavorable outcome is probable and the amount of the loss can be reasonably estimated. While such reserves and accrued costs reflect the Company's best estimate of the probable loss for such matters, the recorded amounts may differ materially from the actual amount of any such losses. In some cases, no estimate of the possible loss or range of loss in excess of amounts accrued, if any, can be made because of the inherently unpredictable nature of legal and regulatory proceedings, which may be exacerbated by various factors, including but not limited to, they may involve indeterminate claims for monetary damages or may involve fines, penalties or punitive damages; present novel legal theories or legal uncertainties; involve disputed facts; represent a shift in regulatory policy; involve a large number of parties, claimants or regulatory bodies; are in the early stages of the proceedings; involve a number of separate proceedings and/or a wide range of potential outcomes; or result in a change of business practices.

As of the date of this Quarterly Report on Form 10-Q, amounts accrued for legal proceedings and regulatory matters were not material. However, it is possible that in a particular quarter or annual period the Company's financial condition, results of operations, cash flow and/or liquidity could be materially adversely affected by an ultimate unfavorable resolution of, or development in, legal and/or regulatory proceedings, including as described below. Except for the proceedings discussed below, the Company believes that the ultimate outcome of any of the regulatory and legal proceedings that are currently pending against it should not have a material adverse effect on financial condition, results of operations, cash flow or liquidity.

The Company is currently responding to civil investigative demands and administrative subpoenas issued pursuant to the Health Insurance Portability and Accountability Act of 1996 by the United States Department of Justice ("DOJ") concerning Genomic Health's compliance with the Medicare Date of Service billing regulations (the "DOS Rule Investigation"). The Company has been cooperating with the DOS Rule Investigation and has produced documents in response thereto.

During the second quarter of 2021, as part of ongoing discussions between the DOJ and the Company regarding the DOS Rule Investigation, the DOJ presented an estimate of civil damages in the amount of \$48.2 million relating to alleged non-compliance with the Medicare Date of Service billing regulations from 2007 to 2020. At the time of this filing, the Company is in the process of evaluating the damages estimate and preparing a response to the DOJ. The civil damages estimate does not include potential treble damages, civil or criminal penalties or other remedies that the DOJ could seek against the Company. Given the early stage of these ongoing discussions, the Company is unable to establish a reasonable estimate or an estimated range of loss related to this matter at this time. As a result, no amounts of loss related to the DOS Rule Investigation have been accrued in the condensed consolidated financial statements.

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On June 24, 2019, Niles Rosen M.D. filed a sealed ex parte qui tam lawsuit against the Company in the United States District Court for the Middle District of Florida, that alleged a violation of the Federal Anti-Kickback Statute and False Claims Act for offering gift cards to patients in exchange for returning the Cologuard screening test (the “Qui Tam Suit”). Dr. Rosen seeks on behalf of the U.S. government and himself an award of civil penalties, treble damages and fees and costs. On February 25, 2020, the Company received a civil investigative demand by the DOJ related to the Company’s gift card program. The Company produced documents in response thereto. On March 25, 2021, the DOJ filed a notice of its election to decline intervention in the Qui Tam Suit. This election does not prevent Dr. Rosen from continuing the Qui Tam Suit. On April 12, 2021, Dr. Rosen filed an amended complaint against the Company, alleging violations of the Federal Anti-Kickback Statute and False Claims Act. The Company first learned of the Qui Tam Suit and the DOJ’s election to decline intervention in July 2021. The Company intends to vigorously defend itself against Dr. Rosen’s claims and seek, among other things, the Company’s attorneys’ fees and costs incurred in defending this action. Although the Company denies Dr. Rosen’s allegations and believes that it has meritorious defenses to his False Claims Act claims, neither the outcome of the litigation nor can a reasonable estimate or an estimated range of loss associated with the litigation be determined at this time.

Adverse outcomes from the DOS Rule Investigation and the Qui Tam Suit could include the Company being required to pay treble damages, incur civil and criminal penalties, paying attorneys’ fees, entering into a corporate integrity agreement, being excluded from participation in government healthcare programs, including Medicare and Medicaid, and other adverse actions that could materially affect the Company’s business, financial condition and results of operation.

In connection with the Company’s combination with Genomic Health, on June 22, 2020, Suzanne Flannery, a purported former stockholder of Genomic Health, filed a Verified Individual and Class Action Complaint in the Delaware Court of Chancery, captioned Flannery v. Genomic Health, Inc., et al., C.A. No. 2020-0492. Flannery amended her complaint on November 23, 2020. The amended complaint asserts individual and class action claims, including: (i) a violation of 8 Del. C. § 203 by Genomic Health, Exact Sciences and a purported controlling group of former Genomic Health stockholders; (ii) conversion by Genomic Health, Exact Sciences and Spring Acquisition Corp.; (iii) breach of fiduciary duty by Genomic Health’s former directors; (iv) breach of fiduciary duty by the purported controlling group; and (v) aiding and abetting breach of fiduciary duty against Exact Sciences, Spring Acquisition and Goldman Sachs & Co. LLC, Genomic Health’s financial advisor in the combination. The amended complaint seeks, among other things, declaratory relief, unspecified monetary damages and attorneys’ fees and costs. All defendants moved to dismiss the amended complaint. Oral argument on defendants’ motions to dismiss the amended complaint occurred in May 2021 and the ruling on the motion to dismiss is pending as of the date of this Quarterly Report on Form 10-Q.

(15) NEW MARKET TAX CREDIT

During the fourth quarter of 2014, the Company received approximately \$2.4 million in net proceeds from financing agreements related to working capital and capital improvements at one of its Madison, Wisconsin facilities. This financing arrangement was structured with an unrelated third-party financial institution (the “Investor”), an investment fund, and its majority owned community development entity in connection with the Company’s participation in transactions qualified under the federal New Markets Tax Credit (“NMTC”) program, pursuant to Section 45D of the Internal Revenue Code of 1986, as amended. The Company is required to be in compliance through December 2021 with various regulations and contractual provisions that apply to the NMTC arrangement. Noncompliance with applicable requirements could result in the Investor’s projected tax benefits not being realized and, therefore, require the Company to indemnify the Investor for any loss or recapture of NMTC related to the financing until such time as the recapture provisions have expired under the applicable statute of limitations. The Company does not anticipate any credit recapture will be required in connection with this financing arrangement.

The Investor and its majority owned community development entity are considered Variable Interest Entities (“VIEs”) and the Company is the primary beneficiary of the VIEs. This conclusion was reached based on the following:

- the ongoing activities of the VIEs — collecting and remitting interest and fees and NMTC compliance — were all considered in the initial design and are not expected to significantly affect performance throughout the life of the VIE;
- contractual arrangements obligate the Company to comply with NMTC rules and regulations and provide various other guarantees to the Investor and community development entity;
- the Investor lacks a material interest in the underlying economics of the project; and
- the Company is obligated to absorb losses of the VIEs.

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Because the Company is the primary beneficiary of the VIEs, they have been included in the consolidated financial statements. There are no other assets, liabilities or transactions in these VIEs outside of the financing transactions executed as part of the NMTC arrangement.

(16) WISCONSIN ECONOMIC DEVELOPMENT TAX CREDITS

During the first quarter of 2015, the Company entered into an agreement with the Wisconsin Economic Development Corporation (“WEDC”) to earn \$9.0 million in refundable tax credits on the condition that the Company expends \$26.3 million in capital investments and establishes and maintains 758 full-time positions over a seven-year period. The tax credits earned are first applied against the tax liability otherwise due, and if there is no such liability present, the claim for tax credits will be reimbursed in cash to the Company. The maximum amount of the refundable tax credit to be earned for each year is fixed, and the Company earns the credits by meeting certain capital investment and job creation thresholds over the seven-year period. Should the Company earn and receive the job creation tax credits but not maintain those full-time positions through the end of the agreement, the Company may be required to pay those credits back to the WEDC.

The Company records the earned tax credits as job creation and capital investments occur. The amount of tax credits earned is recorded as a liability and amortized as a reduction of operating expenses over the expected period of benefit. The tax credits earned from capital investment are recognized as an offset to depreciation expense over the expected life of the acquired capital assets. The tax credits earned related to job creation are recognized as an offset to operational expenses over the life of the agreement, as the Company is required to maintain the minimum level of full-time positions through the seven-year period.

As of June 30, 2021, the Company has earned all \$9.0 million of the refundable tax credits and has received payment of \$7.5 million from the WEDC. The unpaid portion is \$1.5 million, which is reported in prepaid expenses and other current assets, reflecting when collection of the refundable tax credits is expected to occur. As of June 30, 2021 and December 31, 2020, the corresponding liability, which reflected when the expected benefit of tax credit amortization would reduce future operating expenses, has been fully amortized.

During the three and six months ended June 30, 2020, the Company amortized \$0.6 million and \$1.2 million, respectively, of the tax credits earned as a reduction of operating expenses.

(17) BUSINESS COMBINATIONS AND ASSET ACQUISITIONS

Business Combinations

Ashion Analytics, LLC

On April 14, 2021, the Company completed the acquisition (“Ashion Acquisition”) of all of the outstanding equity interests of Ashion from PMed Management, LLC (“PMed”), which is a subsidiary of TGen. The Ashion Acquisition provided the Company a Clinical Laboratory Improvement Amendments (“CLIA”) certified and College of American Pathologists (“CAP”) accredited sequencing lab based in Phoenix, Arizona. Ashion developed GEMExTra®, a comprehensive genomic cancer test, and provides access to whole exome, matched germline, and transcriptome sequencing capabilities. The Company has included the financial results of Ashion in the consolidated financial statements from the date of the combination.

The combination date fair value of the consideration transferred for Ashion was approximately \$110.0 million, which consisted of the following:

(In thousands)	
Cash	\$ 74,775
Common stock issued	16,224
Contingent consideration	19,000
Total purchase price	<u>\$ 109,999</u>

The fair value of the 125,444 common shares issued as part of consideration transferred was determined on the basis of the average of the high and low market price of the Company's shares on the acquisition date, which was \$129.33.

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The contingent consideration arrangement requires the Company to pay \$20.0 million of additional cash consideration to PMed upon the Company's commercial launch, on or before the tenth anniversary of the Ashion Acquisition, of a test for minimal residual disease ("MRD") detection and/or treatment (the "Commercial Launch Milestone"). The fair value of the Commercial Launch Milestone at the acquisition date was \$19.0 million. The contingent consideration arrangement also requires the Company to pay \$30.0 million of additional cash upon the Company's achievement, on or before the fifth anniversary of the Ashion Acquisition, of cumulative revenues from MRD products of \$500.0 million (the "MRD Product Revenue Milestone"). No value was ascribed to the MRD Product Revenue Milestone based on probability assessments as of the acquisition date. The fair value of the Commercial Launch Milestone and MRD Product Revenue Milestone was estimated using a probability-weighted scenario based discounted cash flow model. This fair value measurement is based on significant inputs not observable in the market and thus represents a Level 3 measurement as defined in Accounting Standards Codification ("ASC") 820. The key assumptions are described in Note 7.

The following table summarizes the estimated fair values of the assets acquired and liabilities assumed at the acquisition date.

(In thousands)	
Cash and cash equivalents	\$ 2,474
Accounts receivable	2,349
Inventory	1,811
Prepaid expenses and other current assets	425
Property, plant and equipment	9,947
Operating lease right-of-use assets	548
Developed technology	39,000
Total identifiable assets acquired	\$ 56,554
Accounts payable	(1,477)
Accrued liabilities	(1,190)
Operating lease liabilities, current portion	(343)
Other current liabilities	(98)
Operating lease liabilities, less current portion	(205)
Total liabilities assumed	\$ (3,313)
Net identifiable assets acquired	\$ 53,241
Goodwill	56,758
Net assets acquired	\$ 109,999

The company recorded \$39.0 million of identifiable intangible assets related to the developed technology associated with GEMExTra. Developed technology represents purchased technology that had reached technological feasibility and for which Ashion had substantially completed development as of the date of combination. The fair value of the developed technology has been determined using the income approach multi-period excess earnings method, which involves significant unobservable inputs (Level 3 inputs). These inputs include projected sales, margin, and required rate of return and tax rate. Cash flows were discounted to their present value as of the closing date. Developed technology is amortized on a straight-line basis over its estimated useful life of 13 years.

The calculation of the excess of the purchase price over the estimated fair value of the tangible net assets and intangible assets acquired was recorded to goodwill, which is primarily attributed to the acquired workforce expertise, the capabilities in the advancement of creating and launching new products, including an MRD product, and expected salesforce synergies related to the developed technology. The total goodwill related to this combination is deductible for tax purposes.

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The total purchase price allocation is preliminary and based upon estimates and assumptions that are subject to change within the measurement period as additional information for the estimates is obtained. The measurement period remains open pending the completion of valuation procedures related to certain acquired assets and liabilities assumed, primarily in connection with the developed technology intangible asset.

Pro forma impact and results of operations disclosures have not been included due to immateriality.

During the three and six months ended June 30, 2021, the Company incurred \$0.7 million and \$1.6 million of acquisition-related costs recorded in general and administrative expenses in the condensed consolidated statement of operations, respectively. These costs include fees associated with financial, legal, accounting and other advisors incurred to complete the merger.

Thrive Earlier Detection Corporation

On January 5, 2021, the Company completed the acquisition (“Thrive Merger”) of all of the outstanding capital stock of Thrive. Thrive, headquartered in Cambridge, Massachusetts, is a healthcare company dedicated to incorporating earlier cancer detection into routine medical care. The Company expects that combining Thrive’s early-stage screening test, CancerSEEK, with the Company’s scientific platform, clinical organization and commercial infrastructure will establish the Company as a leading competitor in blood-based, multi-cancer screening. The Company has included the financial results of Thrive in the consolidated financial statements from the date of the combination.

The combination date fair value of the consideration transferred for Thrive was approximately \$2.19 billion, which consisted of the following:

(In thousands)	
Common stock issued	\$ 1,175,431
Cash	584,996
Contingent consideration	331,348
Fair value of replaced equity awards	52,245
Previously held equity investment fair value	43,034
Total purchase price	<u>\$ 2,187,054</u>

The Company issued 9,323,266 common shares that had a fair value of \$1.19 billion based on the average of the high and low market price of the Company’s shares on the acquisition date, which was \$127.79. Of the total consideration for common stock issued, \$1.18 billion was allocated to the purchase consideration and \$16.0 million was recorded as compensation within general and administrative expenses in the condensed consolidated statement of operations on the acquisition date due to accelerated vesting of legacy Thrive restricted stock awards (“RSA”) and RSU awards in connection with the acquisition.

The Company paid \$590.2 million in cash on the acquisition date. Of the total consideration for cash, \$585.0 million was allocated to the purchase consideration and \$5.2 million was recorded as compensation within general and administrative expenses on the acquisition date due to accelerated vesting of legacy Thrive RSU and RSA awards that were cash-settled in connection with the acquisition.

The contingent consideration arrangement requires the Company to pay up to \$450.0 million of additional cash consideration to Thrive’s former shareholders upon the achievement of two discrete events, U.S. Food and Drug Administration (“FDA”) approval and Centers for Medicare & Medicaid Services (“CMS”) coverage, for \$150.0 million and up to \$300.0 million, respectively. The fair value of the contingent consideration arrangement at the acquisition date was \$352.0 million. The fair value of the contingent consideration was estimated using a probability-weighted scenario based discounted cash flow model. This fair value measurement is based on significant inputs not observable in the market and thus represents a Level 3 measurement as defined in ASC 820. The key assumptions are described in Note 7. Of the total fair value of the contingent consideration, \$331.3 million was allocated to the consideration transferred, \$6.4 million was allocated to the Company’s previous ownership interest in Thrive, and \$14.3 million was deemed compensatory as participation is dependent on replaced unvested equity awards vesting which requires future service. Compensation expense related to the milestones could be up to \$18.2 million undiscounted and will be recognized in the future once probable and payable.

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The Company replaced unvested stock options, RSUs, and RSAs and vested stock options with a combination-date fair value of \$197.0 million. Of the total consideration for replaced equity awards, \$52.2 million was allocated to the consideration transferred and \$144.8 million was deemed compensatory as it was attributable to post acquisition vesting. Of the total compensation related to replaced awards, \$65.0 million was expensed on the acquisition date due to accelerated vesting of stock options in connection with the acquisition and \$79.8 million relates to future services and will be expensed over the remaining service periods of the unvested stock options, RSUs, and RSAs on a straight-line basis. Including expense recognized for accelerated vesting of RSUs and RSAs described above, total expected stock-based compensation expense is \$166.0 million, of which \$86.2 million was recognized immediately to general and administrative expenses in the condensed consolidated statement of operations due to accelerated vesting.

The fair value of the stock options assumed by the Company was determined using the Black-Scholes option pricing model. The fair value of the RSA and RSUs assumed by the Company was determined based on the average of the high and low market price of the Company's shares on the acquisition date. The share conversion ratio of 0.06216 was applied to convert Thrive's outstanding equity awards for Thrive's common stock into equity awards for shares of the Company's common stock.

The fair value of options assumed were based on the assumptions in the following table:

Option Plan Shares Assumed	
Risk-free interest rates	0.11% - 0.12%
Expected term (in years)	1.26 - 1.57
Expected volatility	65.54% - 71.00%
Dividend yield	—%
Weighted average fair value per share of options assumed	\$109.74 - \$124.89

The Company previously held a preferred stock investment of \$12.5 million in Thrive and recognized a gain of approximately \$30.5 million on the transaction within investment income, net on the Company's consolidated statement of operations, which represented the adjustment of the Company's historical investment to the acquisition date fair value. The fair value of the Company's previous ownership in Thrive was determined based on the pro-rata share payout applied to the Company's interest combined with the fair value of the Company's share of the contingent consideration arrangement, as discussed above.

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The following table summarizes the estimated fair values of the assets acquired and liabilities assumed at the acquisition date:

(In thousands)	Preliminary Allocation January 5, 2021	Measurement Period Adjustments	Allocation as of June 30, 2021
Cash and cash equivalents	\$ 241,748	\$ —	\$ 241,748
Prepaid expenses and other current assets	3,939	—	3,939
Property, plant and equipment	29,977	—	29,977
Operating lease right-of-use assets	39,027	—	39,027
Other long-term assets	67	—	67
In-process research and development (IPR&D)	1,250,000	—	1,250,000
Total identifiable assets acquired	\$ 1,564,758	\$ —	\$ 1,564,758
Accounts payable	(3,222)	—	(3,222)
Accrued liabilities	(6,218)	(1,862)	(8,080)
Operating lease liabilities, current portion	(2,980)	—	(2,980)
Operating lease liabilities, less current portion	(38,622)	—	(38,622)
Deferred tax liability	(272,905)	—	(272,905)
Total liabilities assumed	\$ (323,947)	\$ (1,862)	\$ (325,809)
Net identifiable assets acquired	\$ 1,240,811	\$ (1,862)	\$ 1,238,949
Goodwill	946,243	1,862	948,105
Net assets acquired	\$ 2,187,054	\$ —	\$ 2,187,054

IPR&D represents the fair value assigned to research and development assets that have not reached technological feasibility. The primary basis for determining technological feasibility of these projects is obtaining regulatory approval to market the underlying product and expected commercial release. The amounts capitalized are accounted for as indefinite-lived intangible assets, subject to impairment testing, until completion or abandonment of the research and development efforts associated with the projects. The company recorded \$1.25 billion of IPR&D related to a project associated with the development of an FDA approved blood-based, multi cancer screening test. The IPR&D asset was valued using the multiple-period excess earnings method approach, which involves significant unobservable inputs (Level 3 inputs). These inputs include projected sales, margin, required rate of return and tax rate, as well as estimates of achievement probability and timing related to the royalty and milestone obligations due to JHU, as described in Note 10.

The calculation of the excess of the purchase price over the estimated fair value of the tangible net assets and intangible assets acquired was recorded to goodwill, which is primarily attributed to the research and development workforce expertise, next generation sequencing capabilities and expected synergies. The total goodwill related to this combination is not deductible for tax purposes.

The total purchase price allocation is preliminary and based upon estimates and assumptions that are subject to change within the measurement period as additional information for the estimates is obtained. The measurement period remains open pending the completion of valuation procedures related to certain acquired assets and liabilities assumed, primarily in connection with the IPR&D asset, as well as finalization of the pre-combination income tax returns.

The net loss before tax of Thrive included in the Company's condensed consolidated statement of operations from the combination date of January 5, 2021 to June 30, 2021 was \$180.0 million. The net loss before tax of Thrive included in the Company's condensed consolidated statement of operations for the three months ended June 30, 2021 was \$37.2 million.

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The following unaudited pro forma financial information summarizes the combined results of operations for the Company and Thrive, as though the companies were combined as of the beginning of January 1, 2020.

(In thousands)	Three Months Ended June 30,		Six Months Ended June 30, 2021	
	2021	2020	2021	2020
Total revenues	\$ 434,819	\$ 268,868	\$ 836,896	\$ 616,689
Net loss before tax	(172,887)	(91,376)	(365,456)	(351,122)

The unaudited pro forma financial information for all periods presented above has been calculated after adjusting the results of Thrive to reflect the business combination accounting effects resulting from this combination. The Company incurred \$86.2 million of stock-based compensation expense related to accelerated vesting in connection with the acquisition, \$13.5 million of stock-based compensation expense related to accelerated vesting for employees with qualifying termination events, and \$10.3 million of transaction costs incurred to execute the acquisition during the first quarter of 2021. These expenses are included in general and administrative expenses on the condensed consolidated statement of operations for the six months ended June 30, 2021 and are reflected in pro forma earnings for the six months ended June 30, 2020 in the table above. The Company recorded a realized gain of \$30.5 million during the first quarter of 2021 in investment income, net on the Company's condensed consolidated statement of operations relating to the Company's pre-acquisition investment in Thrive. This gain has been reduced to \$7.6 million due to the Company's smaller ownership interest in Thrive on January 1, 2020, and is reflected in pro forma earnings for the six months ended June 30, 2020 in the table above. The Company recorded a remeasurement of contingent consideration of \$9.0 million related to Thrive in general and administrative expenses in the consolidated statement of operations for the six months ended June 30, 2021. This expense is reflected in the six months ended June 30, 2020 in the table above. The historical consolidated financial statements have been adjusted in the unaudited pro forma combined financial information to give effect to pro forma events that are directly attributable to the business combination and factually supportable. The unaudited pro forma financial information is for informational purposes only and is not indicative of the results of operations that would have been achieved if the combination had taken place as of January 1, 2020.

During 2021, the Company incurred \$10.3 million of acquisition-related costs recorded in general and administrative expenses in the condensed consolidated statement of operations. These costs include fees associated with financial, legal, accounting and other advisors incurred to complete the merger.

In connection with acquisition-related severances, the Company recorded \$1.0 million of expense related to vesting of previously unvested equity awards and \$0.7 million of additional benefit charges for the three months ended June 30, 2021. The Company recorded \$14.5 million of expense related to vesting of previously unvested equity awards and \$2.7 million of additional benefit charges for the six months ended June 30, 2021.

Paradigm Diagnostics, Inc. and Viomics, Inc.

On March 3, 2020, the Company acquired all of the outstanding capital stock of Paradigm and Viomics, two related party companies of one another headquartered in Phoenix, Arizona, in transactions that were deemed to be a single business combination in accordance with ASC 805, Business Combinations, ("the Paradigm Acquisition"). Paradigm provides comprehensive genomic-based profiling tests that assist in the diagnosis and therapy recommendations for late-stage cancer. Viomics provides a platform for identification of biomarkers.

The Company entered into this acquisition to enhance its product portfolio in cancer diagnostics and to enhance its capabilities for biomarker identification.

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The acquisition date fair value of the consideration to be transferred for Paradigm and Viomics was \$40.4 million, which consists of \$32.2 million payable in shares of the Company's common stock and \$8.2 million which was settled through a cash payment. Of the \$32.2 million to be settled through the issuance of common stock, \$28.8 million was issued as of June 30, 2021, and the remaining \$3.4 million, which was withheld and may become payable as additional merger consideration, is included in other current liabilities in the condensed consolidated balance sheet as of June 30, 2021. The purchase price was allocated to the underlying assets acquired and liabilities assumed based upon their estimated fair values as follows:

(In thousands)	Preliminary Allocation March 3, 2020	Measurement Period Adjustments	Final Allocation March 3, 2021
Net operating assets	\$ 6,133	\$ (760)	\$ 5,373
Goodwill	29,695	736	30,431
Developed technology	7,800	—	7,800
Net operating liabilities	(3,123)	(80)	(3,203)
Total purchase price	<u>\$ 40,505</u>	<u>\$ (104)</u>	<u>\$ 40,401</u>

The measurement period adjustments primarily related to accounts receivable valuation and working capital adjustments.

The fair value of identifiable intangible assets has been determined using the income approach, which involves significant unobservable inputs (Level 3 inputs). These inputs include projected sales, margin, weighted average cost of capital and tax rate.

Developed technology represents purchased technology that had reached technological feasibility and for which development had been completed as of the acquisition date. Fair value was determined using future discounted cash flows related to the projected income stream of the developed technology for a discrete projection period. Cash flows were discounted to their present value as of the closing date. Developed technology is amortized on a straight-line basis over its estimated useful life of 15 years.

The calculation of the excess of the purchase price over the estimated fair value of the tangible net assets and intangible assets acquired was recorded to goodwill, which is primarily attributed to the assembled workforce, and expected synergies. The total goodwill related to this acquisition is not deductible for tax purposes.

The Company agreed to issue to the previous investors in Viomics equity interests with an acquisition-date fair value of up to \$8.4 million in Viomics, vesting over 4 years based on certain retention arrangements. Payment is contingent upon continued employment with the Company over the four year vesting period and is recognized as stock-based compensation expense in general and administrative expense in the condensed consolidated statement of operations.

Asset Acquisitions

PFS Genomics Inc.

On May 3, 2021, the Company acquired 90% of the outstanding capital stock of PFS Genomics Inc. ("PFS"). On June 23, 2021, the Company completed the acquisition of the remaining 10% interest in PFS. The Company paid cash of \$33.6 million for 100% of the outstanding capital stock in PFS. PFS is a healthcare company focused on personalizing treatment for breast cancer patients to improve outcomes and reduce unnecessary treatment. The Company expects this acquisition to expand its ability to help guide early-stage breast cancer treatment through individualized radiotherapy treatment decisions.

The transaction was treated as an asset acquisition under GAAP because substantially all of the fair value of the gross assets acquired were deemed to be associated with the acquired technology.

The assets acquired and liabilities assumed were substantially comprised of the In-process research and development ("IPR&D") asset as shown in the table below. The IPR&D asset acquired was recorded to research and development expense in the consolidated statement of operations immediately after acquisition as the asset was deemed to be incomplete and had no alternative future use at the time of acquisition.

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The Company accounted for the acquisition in accordance with the accounting standards codification guidance for business combinations, whereby the total purchase price was allocated to the acquired net tangible and intangible assets based on their estimated fair values as of the closing date.

Acquisition related costs were not material in this asset acquisition.

The following table summarizes the allocation of the purchase price to the fair values assigned to the assets acquired and liabilities assumed:

(In thousands)	
Consideration	
Cash paid for acquisition of PFS Genomics outstanding shares	\$ 33,569
Assets acquired and liabilities assumed	
Cash	496
IPR&D asset	33,074
Other assets and liabilities	(1)
Net assets acquired	\$ 33,569

TARDIS License Agreement

On January 11, 2021, the Company entered into a worldwide exclusive license to the proprietary TARDIS technology from TGen, an affiliate of City of Hope. Under the agreement, the Company acquired a royalty-free, worldwide exclusive license to proprietary TARDIS patents and know-how. The Company intends to develop and commercialize the TARDIS technology as a minimal residual disease test. The Company accounted for this transaction as an asset acquisition. In connection with the asset acquisition, the Company paid upfront fair value consideration of \$52.3 million comprised of \$25.0 million in cash and issuance of 0.2 million shares of common stock valued at \$27.3 million based on the average of the high and low market price of the Company's shares on the acquisition date. In addition, the Company is obligated to make milestone payments to TGen of \$10.0 million and \$35.0 million upon achieving cumulative product revenue related to MRD detection and/or treatment totaling \$100.0 million and \$250.0 million, respectively. These payments are contingent upon achievement of these cumulative revenues on or before December 31, 2030. The upfront consideration was recorded to research and development expense in the condensed consolidated statement of operations immediately after acquisition as the asset was deemed to be incomplete and had no alternative future use at the time of acquisition. The Company will record the sales milestones once achievement is deemed probable. No acquisition related costs were incurred in this asset acquisition during the three and six months ended June 30, 2021.

(18) SEGMENT INFORMATION

Management determined that the Company functions as a single operating segment, and thus reports as a single reportable segment. This operating segment is focused on the development and global commercialization of clinical laboratory services allowing healthcare providers and patients to make individualized treatment decisions. Management assessed the discrete financial information routinely reviewed by the Company's Chief Operating Decision Maker, its President and Chief Executive Officer, to monitor the Company's operating performance and support decisions regarding allocation of resources to its operations. Performance is continuously monitored at the consolidated level to timely identify deviations from expected results.

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The following table summarizes total revenue from customers by geographic region. Product revenues are attributed to countries based on ship-to location.

(In thousands)	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
United States	\$ 407,971	\$ 249,850	\$ 783,993	\$ 576,709
Outside of United States	26,848	19,018	52,903	39,980
Total revenues	\$ 434,819	\$ 268,868	\$ 836,896	\$ 616,689

Long-lived assets located in countries outside of the United States are not significant.

(19) INCOME TAXES

The Company recorded an income tax expense of \$4.0 million and a benefit of \$0.3 million for the three months ended June 30, 2021 and 2020, respectively. The Company recorded an income tax benefit of \$238.8 million and a benefit of \$2.5 million for the six months ended June 30, 2021 and 2020, respectively. The Company's income tax expense recorded during the three months ended June 30, 2021 is primarily related to foreign tax expense, as well as the future limitations on and expiration of certain Federal and State deferred tax assets. The Company's income tax benefit recorded during the six months ended June 30, 2021 is primarily related to an income tax benefit of \$239.2 million recorded as a result of the change in the deferred tax asset valuation allowance resulting from the Thrive Merger. A deferred tax liability of approximately \$37.5 million was recorded as of June 30, 2021, which is included in other long-term liabilities on the Company's condensed consolidated balance sheet. The Company continues to maintain a full valuation allowance against its deferred tax assets based on management's determination that it is more likely than not the benefit will not be realized.

The Company had \$18.6 million and \$16.6 million of unrecognized tax benefits at June 30, 2021 and December 31, 2020, respectively. These amounts have been recorded as a reduction to the Company's deferred tax asset, if recognized they would not have an impact on the effective tax rate due to the existing valuation allowance. Certain of the Company's unrecognized tax benefits could change due to activities of various tax authorities, including possible settlement of audits, or through normal expiration of various statutes of limitations. The Company does not expect a material change in unrecognized tax benefits in the next twelve months.

As of June 30, 2021, due to the carryforward of unutilized net operating losses and research and development credits, the Company is subject to U.S. federal income tax examinations for the tax years 2001 through 2021, and to state income tax examinations for the tax years 2001 through 2021. No interest or penalties related to income taxes have been accrued or recognized as of June 30, 2021.

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

The following discussion of our financial condition and results of operations should be read in conjunction with the condensed consolidated financial statements and the related notes thereto included elsewhere in this Quarterly Report on Form 10-Q and the audited financial statements and notes thereto and Management’s Discussion and Analysis of Financial Condition and Results of Operations included in our Annual Report on Form 10-K for the year ended December 31, 2020, which has been filed with the SEC (the “2020 Form 10-K”).

Forward-Looking Statements

This Quarterly Report on Form 10-Q contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, that are intended to be covered by the “safe harbor” created by those sections. Forward-looking statements, which are based on certain assumptions and describe our future plans, strategies and expectations, can generally be identified by the use of forward-looking terms such as “believe,” “expect,” “may,” “will,” “should,” “would,” “could,” “seek,” “intend,” “plan,” “goal,” “project,” “estimate,” “anticipate” or other comparable terms. All statements other than statements of historical facts included in this Quarterly Report on Form 10-Q regarding our strategies, prospects, expectations, financial condition, operations, costs, plans and objectives are forward-looking statements. Examples of forward-looking statements include, among others, statements we make regarding expected future operating results; our strategies, positioning, resources, capabilities and expectations for future events or performance; and the anticipated benefits of our acquisitions, including estimated synergies and other financial impacts. Forward-looking statements are neither historical facts nor assurances of future performance or events. Instead, they are based only on current beliefs, expectations and assumptions regarding the future of our business, future plans and strategies, projections, anticipated events and trends, the economy and other future conditions. Because forward-looking statements relate to the future, they are subject to inherent uncertainties, risks and changes in circumstances that are difficult to predict and many of which are outside of our control. Actual results, conditions and events may differ materially from those indicated in the forward-looking statements. Therefore, you should not rely on any of these forward-looking statements. Important factors that could cause actual results, conditions and events to differ materially from those indicated in the forward-looking statements include, among others, the following: uncertainties associated with the coronavirus (“COVID-19”) pandemic, including its possible effects on our operations, including our supply chain and clinical studies, and the demand for our cancer and COVID-19 testing products and services; our ability to efficiently and flexibly manage our business amid uncertainties related to COVID-19; our ability to successfully and profitably market our products and services; the acceptance of our products and services by patients and healthcare providers; our ability to meet demand for our products and services; the willingness of health insurance companies and other payers to cover our products and services and adequately reimburse us for such products and services; the amount and nature of competition for our products and services; the effects of any judicial, executive or legislative action affecting us or the healthcare system; recommendations, guidelines and quality metrics issued by various organizations regarding cancer screening or our products and services; our ability to successfully develop new products and services and assess potential market opportunities; our ability to effectively enter into and utilize strategic partnerships and acquisitions; our success establishing and maintaining collaborative, licensing and supplier arrangements; our ability to obtain and maintain regulatory approvals and comply with applicable regulations; our ability to manage an international business and our expectations regarding our international expansion and opportunities; the potential effects of foreign currency exchange rate fluctuations and our efforts to hedge such effects; the possibility that the anticipated benefits from our business acquisitions will not be realized in full or at all or may take longer to realize than expected; the possibility that costs or difficulties related to the integration of acquired businesses’ operations will be greater than expected and the possibility that integration efforts will disrupt our business and strain management time and resources; the outcome of any litigation, government investigations, enforcement actions or other legal proceedings, including in connection with acquisitions; our ability to retain and hire key personnel, including employees at businesses we acquire. The risks included above are not exhaustive. Other important risks and uncertainties are described in the Risk Factors and in Management’s Discussion and Analysis of Financial Condition and Results of Operations sections of the 2020 Form 10-K and subsequently filed Quarterly Reports on Form 10-Q. You are further cautioned not to place undue reliance upon any such forward-looking statements, which speak only as of the date made. Except as otherwise required by the federal securities laws, we undertake no obligation to publicly update any forward-looking statement, whether written or oral, that may be made from time to time, whether as a result of new information, future developments or otherwise.

Overview

Exact Sciences Corporation (together with its subsidiaries, “Exact,” “we,” “us,” “our” or the “Company”) is a leading global cancer diagnostics company. We have developed some of the most impactful brands in cancer diagnostics, and we are currently working on the development of additional tests, with the goal of bringing new innovative cancer tests to patients throughout the world.

Acquisitions

On April 14, 2021, we completed the acquisition of all of the outstanding equity interests of Ashion Analytics, LLC (“Ashion”; such transaction the “Ashion Acquisition”) from PMed Management, LLC (“PMed”), which is a subsidiary of The Translational Genomics Research Institute (“TGen”). Ashion is a Clinical Laboratory Improvement Amendments (“CLIA”) certified and College of American Pathologists (“CAP”) accredited sequencing lab based in Phoenix, Arizona and developed GEMExTra[®], a comprehensive genomic cancer test, and provides access to the whole exome, matched germline, and transcriptome sequencing capabilities.

On May 3, 2021, we acquired 90% of the outstanding capital stock of PFS Genomics Inc. (“PFS”; such transaction, the “PFS Acquisition”), pursuant to a share purchase agreement. On June 23, 2021, we completed the acquisition of the remaining 10% interest in PFS. PFS is a healthcare company focused on personalizing treatment for breast cancer patients to improve outcomes and reduce unnecessary treatment. We expect this acquisition to expand our ability to help guide early stage breast cancer treatment through individualized radiotherapy treatment decisions.

Refer to Note 17 of our condensed consolidated financial statements included in this Quarterly Report on Form 10-Q for full discussion of acquisitions completed during the year.

Our Cologuard Test

Colorectal cancer is the second leading cause of cancer deaths in the United States and the leading cause of cancer deaths in the United States among non-smokers. In 2020 in the United States there was estimated to be approximately 148,000 new cases of colorectal cancer and 53,000 deaths from colorectal cancer. It is widely accepted that colorectal cancer is among the most preventable, yet least prevented cancers.

Our Cologuard[®] test is a non-invasive stool-based DNA (“sDNA”) screening test that utilizes a multi-target approach to detect DNA and hemoglobin biomarkers associated with colorectal cancer and pre-cancer. Upon approval by the U.S. Food and Drug Administration (“FDA”) in August 2014, our Cologuard test became the first and only FDA-approved sDNA non-invasive colorectal cancer screening test. Our Cologuard test is now indicated for average risk adults 45 years of age and older.

Our Oncotype IQ Tests

With our Oncotype IQ Genomic Intelligence Platform we are applying our world-class scientific and commercial expertise and infrastructure to lead the translation of clinical and genomic data into clinically actionable results for treatment planning throughout the cancer patient’s journey, from diagnosis to treatment selection and monitoring. Our Oncotype IQ Genomic Intelligence Platform is currently comprised of our flagship line of Oncotype DX[®] gene expression tests for breast, prostate and colon cancer, as well as Oncotype DX AR-V7 Nucleus Detect[®] test, a liquid-based test for advanced stage prostate cancer.

In October 2020, we announced the introduction of the Oncotype MAP[™] Pan-Cancer Tissue test, which is a rapid, comprehensive tumor profiling panel that aids therapy selection for patients with advanced, metastatic, refractory, or recurrent cancer.

International Business Background and Products

We commercialize our Oncotype IQ tests internationally through employees in Canada, Japan and six European countries, as well as through exclusive distribution agreements. We have provided our Oncotype IQ tests in more than 90 countries outside of the United States. We do not offer our Cologuard test or COVID-19 testing outside of the United States. Inclusion of our products in guidelines and quality measures will be critical to our international success.

Pipeline Research and Development

Our research and development efforts are focused on developing new products and enhancing existing products to address new cancer areas and expand the clinical utility and addressable patient populations for our existing tests. We expect to advance liquid biopsy through biomarker discovery and validation in tissue, blood, or other fluids and to leverage recent business development activities to accelerate our leadership in earlier cancer detection and treatment guidance. We are pursuing the following opportunities:

- *Colon Cancer Screening.* We are seeking opportunities to improve upon our Cologuard test's performance characteristics. In October 2019, we and Mayo presented at the American College of Gastroenterology's 2019 Annual Scientific Meeting findings from a blinded-case control study showing enhanced colorectal cancer and advanced adenoma detection using newly discovered methylation biomarkers. To establish the performance of an enhanced multi-target stool DNA test, we expect to enroll more than 10,000 patients 40 years of age and older in our multi-center, prospective BLUE-C study. The timing of any such enhancements to our Cologuard test is unknown and would be subject to FDA approval. We are also working to develop a blood-based screening test for colorectal cancer.
- *Multi-Cancer Screening Test Development.* We are currently seeking to develop a blood-based, multi-cancer screening test. In January 2021, we completed the acquisition of Thrive Earlier Detection Corporation ("Thrive"), a healthcare company dedicated to developing a blood-based, multi-cancer screening test. An early version of Thrive's test has achieved promising results in a 10,000-patient, prospective, interventional study detecting 10 different types of cancer, including seven with no current recommended screening guidelines, with very few false positives. We intend to combine Thrive's expertise with our scientific capabilities, clinical organization and commercial infrastructure to establish us as a leading competitor in blood-based, multi-cancer screening.
- *Hepatocellular Carcinoma ("HCC") Test Development.* We are currently developing a blood-based biomarker test to serve as an alternative to ultrasound and alpha-fetoprotein ("AFP") for use in HCC testing. HCC is the most common type of liver cancer. Our goal is to provide a patient-friendly test that performs better than the current guideline-recommended testing options. In November 2019, we released the results of a 450-patient study which demonstrated 80% overall sensitivity for HCC at 90% specificity with a novel combination of six blood-based biomarkers for HCC. The study also showed 71% sensitivity for early-stage HCC at 90% specificity. The study compared performance to the AFP test, which demonstrated 45% sensitivity at 90% specificity for early stage HCC. Our test was made available on a limited basis in the second quarter of 2021.
- *Minimal Residual Disease ("MRD") Test Development.* In January 2021 we acquired an exclusive license to the TGen proprietary Targeted Digital Sequencing ("TARDIS") technology. We are currently seeking to utilize this compelling and technically distinct approach to develop a test to detect small amounts of tumor DNA that may remain in patients' blood after they have undergone initial treatment. In a study published in Science Translational Medicine, TARDIS demonstrated high accuracy in assessing molecular response and residual disease during neoadjuvant therapy to treat breast cancer. TARDIS achieved up to 100-fold improvement beyond the current limit of circulating tumor DNA detection. We intend to expand our precision oncology business to become a leader in minimal residual disease testing, which will leverage our existing foundation to deliver better solutions to patients navigating cancer.
- *Development Studies for Oncotype DX Products.* We may also conduct or fund clinical studies that could support additional opportunities for our Oncotype DX products. For example, we are exploring clinical studies to expand the use of genomic testing to address additional populations, including higher-risk patients.

We may also use a number of other technologies across various development programs and product implementations. While early-stage cancer continues to be our main focus, we believe we also have an opportunity to expand our business further along the patient's cancer journey, both through our research and development process and strategic collaborations.

Research and development, which includes our clinical study programs, accounts for a material portion of our operating expenses. As we seek to enhance our current product portfolio and expand our product pipeline by developing additional cancer screening and diagnostic tests, we expect that our research and development expenditures will continue to increase.

COVID-19 Testing Business

In late March 2020, we began providing COVID-19 testing. We have partnered with various customers, including the State of Wisconsin Department of Health Services, to administer testing. Customers are responsible for employing trained personnel to collect specimens. Specimens are sent to our laboratory in Madison, Wisconsin, where we run the assay in our laboratories and provide test results to ordering providers. In light of the uncertainty surrounding the COVID-19 pandemic, we intend to periodically reassess our COVID-19 testing business. As the pandemic abates and more people receive vaccinations, we expect demand for our COVID-19 testing services to decline.

2021 Priorities

Our top priorities for 2021 are to (1) get more people tested, (2) advance new solutions, and (3) enhance our customer experience.

Get More People Tested

We are committed to delivering critical answers to patients by getting more people tested with our Cologuard and Oncotype IQ tests. Depending on the course of the COVID-19 pandemic, we expect to continue to provide COVID-19 testing.

Advance New Solutions

In 2021, we are focused on advancing new solutions to provide answers to patients throughout their cancer journeys. We plan to continue investing in ongoing and additional clinical trials to support our product development efforts in enhancing existing products. We also plan to bring new products to patients and providers as further discussed in the Pipeline Research and Development section above.

Enhance Our Customer Experience

Another priority for 2021 is to enhance our customer experience. To establish long-term relationships with patients and providers, we plan to improve customer communications and create new ways to personalize their experiences. Our goal is to become the cancer diagnostic provider of choice for providers and patients.

Results of Operations

The spread of COVID-19 has affected many segments of the global economy, including the cancer screening and diagnostics industry. The pandemic and related precautionary measures have materially disrupted our business since March 2020 and has significantly impacted, and may continue to impact, our testing volumes, revenues, margins and cash utilization, among other measures. The level and nature of the disruption caused by COVID-19 is unpredictable, may be cyclical and long-lasting and may vary from location to location. As a result of the pandemic, we continue to provide COVID-19 testing, the revenue from which has partially offset the pandemic's impact on our Screening and Precision Oncology testing revenue.

Due to social distancing, stay-at-home orders, and other actions taken in response to COVID-19, there was a significant and widespread decline in standard wellness visits and preventive services beginning at the end of the first quarter of 2020. We took steps to limit exposure to COVID-19 based on recommendations from government and health agencies, including limiting field-based, face-to-face interactions by our sales force. The decline in field-based, face-to-face interactions with health care providers negatively impacted Cologuard test orders beginning in March 2020 in our Screening business, notwithstanding the availability of alternative ordering channels such as telehealth. Order volumes recovered over the course of 2020 and by the first quarter of 2021 exceeded pre-pandemic levels. Our Precision Oncology business started to see weakening underlying conditions in April 2020 because of COVID-19. The widespread decrease in preventive services, including mammograms and prostate cancer screenings, negatively impacted Precision Oncology test volumes beginning in May 2020 and continuing throughout the third quarter of 2020 due to the typical lag between cancer screening and genomic test ordering. We began to see orders recovering in the fourth quarter of 2020 to near pre-pandemic levels, and that recovery continued in the first half of 2021. Reduced well-patient access to healthcare providers has contributed to, and may continue to contribute to, delays to clinical studies that are critical to the launch of future products and services.

Although health and safety precautions loosened in many jurisdictions over the past several months as the number of COVID-19 cases began to decline and vaccination rates increased, beginning in early July 2021, COVID-19 cases, including cases associated with the highly contagious delta variant, have increased significantly in the United States. Public health officials and medical professionals have warned that COVID-19 cases may continue to spike, particularly if vaccination rates do not quickly increase or if additional, potent disease variants emerge. It is unclear how long the resurgence will last, how severe it will be, and what safety measures governments will impose in response to it. As cases rise, mask mandates, social-distancing, travel restrictions and stay-at-home orders could be reinstated. Even before the recent increases in cases, many individuals remained cautious about resuming activities such as preventive-care medical visits and many medical practices remained cautious about allowing individuals, such as sales representatives, into their offices.

Both our and Pfizer Inc.'s ("Pfizer") sales teams have recommenced some field-based interactions, but portions of those interactions are primarily telephone and other electronic interactions. Sales representatives' access to healthcare providers remains limited and uneven across the country and could further tighten depending on the course of the pandemic, including the spread of new virus variants like the delta variant. Even after the pandemic subsides, some healthcare providers and health systems may limit the extent and type of sales representatives' access to their facilities and personnel.

We are uncertain how many or what type of sales details Pfizer's sales representatives will contribute during the second half of 2021 and beyond. In October 2020, we amended and restated our promotion agreement with Pfizer (the "Promotion Agreement") to, among other things, address changes to the operational landscape resulting from the COVID-19 pandemic, and we are in the process of negotiating further amendments to the Promotion Agreement. Those negotiations could result in material changes to the Promotion Agreement and how we and Pfizer promote our Cologuard test. If we are unable to manage our relationships with Pfizer and Pfizer's sales representatives, or if we or Pfizer fail to optimally or effectively promote, market and sell our Cologuard test, our results of operation could be adversely affected.

We have adjusted, and expect to continue to adjust, our COVID-19 precautionary measures at our various locations based on local recovery levels and applicable governmental regulations. For example, we have authorized more employees to work on-site and have rolled-back certain precautionary measures for vaccinated employees. Our business could be negatively affected if we take excessive, ineffective or inadequate precautions.

We continue to plan for future growth through investing in our existing operations and through the acquisitions further discussed above.

We have generated significant losses since inception and, as of June 30, 2021, we had an accumulated deficit of approximately \$2.25 billion. We expect to continue to incur losses for the near future, and it is possible we may never achieve profitability.

Revenue. Our revenue is primarily generated by our laboratory testing services from our Cologuard, Oncotype IQ, and COVID-19 tests. Our Screening revenue, which primarily includes laboratory service revenue from our Cologuard test, was \$263.9 million and \$131.3 million for the three months ended June 30, 2021 and 2020, respectively. Screening revenue was \$504.3 million and \$350.8 million for six months ended June 30, 2021 and 2020, respectively. The increase for the three and six months ended June 30, 2021 was primarily due to an increase in the number of completed Cologuard tests. Our Precision Oncology revenue, which primarily includes laboratory service revenue from our global Oncotype IQ products, was \$137.8 million and \$103.0 million for the three months ended June 30, 2021 and 2020, respectively. Precision Oncology revenue was \$267.2 million and \$231.3 million for the six months ended June 30, 2021 and 2020, respectively. The increase for the three and six months ended June 30, 2021 was primarily due to an increase in the number of completed Oncotype IQ tests. For the three months ended June 30, 2021 and 2020, we also generated revenue from our COVID-19 testing of \$33.1 million and \$34.6 million, respectively. For the six months ended June 30, 2021 and 2020, we generated revenue from our COVID-19 testing of \$65.4 million and \$34.6 million, respectively.

During the three and six months ended June 30, 2021, we recorded a downward adjustment to revenue of \$14.7 million and \$13.0 million, respectively, on completed tests from the prior year after identifying a lower realized reimbursement rate on a portion of our laboratory testing services. This change in transaction price is primarily driven by certain prior claims not being submitted to insurance timely. We are working to address these issues, and are more broadly working on improvements to our billing systems to prevent recurrence. Pursuant to our contracts with payers and standards within the industry, claims submitted outside of specified timeframes may not be reimbursed. Successful reimbursement for our laboratory testing services will continue to depend on our ability to execute our order to cash operations efficiently. At each reporting period-end, we monitor our estimates of transaction price to ensure reflection of conditions that exist at each reporting date, and while we strive to restrict volatility in our realized reimbursement rates, changes in transaction price can occur.

Our cost structure. Our selling, general and administrative expenses consist primarily of non-research personnel salaries, office expenses, professional fees, sales and marketing expenses incurred in support of our commercialization efforts and non-cash stock-based compensation.

Cost of sales includes costs related to inventory production and usage, shipment of collection kits and tissue samples, royalties and the cost of services to process tests and provide results to healthcare providers.

We expect that revenue and cost of sales for our services will continue to fluctuate and be affected by the test volume of our products, our operating efficiencies, patient adherence rates, payer mix, the levels of reimbursement, and payment patterns of payers and patients.

Cost of sales (exclusive of amortization of acquired intangible assets). Cost of sales increased to \$114.0 million for the three months ended June 30, 2021 compared to \$77.9 million for the three months ended June 30, 2020. Cost of sales increased to \$224.0 million for the six months ended June 30, 2021 compared to \$159.5 million for the six months ended June 30, 2020. The increase in cost of sales is primarily due to an increase in production costs from an increase in completed Cologuard and Oncotype IQ tests and costs incurred from our COVID-19 testing including a charge of \$3.5 million and \$9.5 million for a reserve of excess inventory related to our COVID-19 testing during the three and six months ended June 30, 2021. We also incurred an increase in personnel expenses to support the increase in volume and future growth of our tests.

Amounts in millions	Three Months Ended June 30,		
	2021	2020	Change
Production costs	\$ 64.2	\$ 38.8	\$ 25.4
Personnel expenses	29.7	22.9	6.8
Facility and support services	15.0	13.0	2.0
Stock-based compensation	4.4	3.3	1.1
Other cost of sales expenses	0.7	(0.1)	0.8
Total cost of sales expense	<u>\$ 114.0</u>	<u>\$ 77.9</u>	<u>\$ 36.1</u>

Amounts in millions	Six Months Ended June 30,		
	2021	2020	Change
Production costs	\$ 124.8	\$ 83.0	\$ 41.8
Personnel expenses	60.7	45.2	15.5
Facility and support services	29.2	25.3	3.9
Stock-based compensation	8.5	5.8	2.7
Other cost of sales expenses	0.8	0.2	0.6
Total cost of sales expense	<u>\$ 224.0</u>	<u>\$ 159.5</u>	<u>\$ 64.5</u>

Research and development expenses. Research and development expenses increased to \$106.2 million for the three months ended June 30, 2021 compared to \$32.7 million for the three months ended June 30, 2020. Research and development expenses increased to \$221.8 million for the six months ended June 30, 2021 compared to \$76.2 million for the six months ended June 30, 2020. The increase in research and development expenses was primarily due to our acquisition of the license to the TARDIS technology in January 2021 and our acquisition of PFS Genomics in May 2021, which resulted in an expense of \$52.3 million and \$33.1 million upon acquisition, respectively. The acquisitions are further described in Note 17 of our

condensed consolidated financial statements included in this Quarterly Report on Form 10-Q. The increase is also due to increased direct research and development expenses incurred as a result of our acquisition of Thrive in January 2021 and lower direct research and development costs during the three months ended June 30, 2020 due to the cost saving measures taken as a result of the COVID-19 pandemic. In addition, there was an increase in stock-based compensation and personnel expenses incurred primarily due to our acquisition of Thrive in January 2021.

Amounts in millions	Three Months Ended June 30,		
	2021	2020	Change
Technology acquisition	\$ 33.1	\$ —	\$ 33.1
Personnel expenses	22.9	15.4	7.5
Direct research and development	27.6	6.8	20.8
Stock-based compensation	12.4	5.6	6.8
Facility and support services	6.4	3.5	2.9
Professional fees	1.7	0.7	1.0
Other research and development	2.1	0.7	1.4
Total research and development expenses	\$ 106.2	\$ 32.7	\$ 73.5

Amounts in millions	Six Months Ended June 30,		
	2021	2020	Change
Technology acquisition	\$ 85.3	\$ —	\$ 85.3
Personnel expenses	44.6	31.8	12.8
Direct research and development	46.6	25.1	21.5
Stock-based compensation	27.2	9.6	17.6
Facility and support services	12.4	6.4	6.0
Professional fees	2.7	1.8	0.9
Other research and development	3.0	1.5	1.5
Total research and development expenses	\$ 221.8	\$ 76.2	\$ 145.6

General and administrative expenses. General and administrative expenses increased to \$167.6 million for the three months ended June 30, 2021 compared to \$106.7 million for the three months ended June 30, 2020. General and administrative expenses increased to \$435.4 million for the six months ended June 30, 2021 compared to \$220.7 million for the six months ended June 30, 2020. The increase in general and administrative expenses was in part due to \$12.9 million and \$131.3 million in acquisition and integration related costs incurred during the three and six months ended June 30, 2021 as part of our acquisitions completed during the year, which primarily consists of integration related stock-based compensation and professional and legal fees incurred. The acquisition and integration related costs also include the remeasurement of the contingent consideration liabilities recorded from our acquisitions, which are included in other general and administrative expenses. The contingent consideration liability is further discussed in Note 7 of our condensed consolidated financial statements included in this Quarterly Report on Form 10-Q. Personnel expenses and stock-based compensation also increased due to an increase in headcount to prepare for future growth in our operations and from our recent acquisitions.

Amounts in millions	Three Months Ended June 30,		
	2021	2020	Change
Stock-based compensation	\$ 25.8	\$ 19.0	\$ 6.8
Personnel expenses	73.7	51.9	21.8
Professional and legal fees	29.8	15.2	14.6
Facility and support services	19.9	14.0	5.9
Other general and administrative	18.4	6.6	11.8
Total general and administrative expenses	\$ 167.6	\$ 106.7	\$ 60.9

Amounts in millions	Six Months Ended June 30,		
	2021	2020	Change
Stock-based compensation	\$ 157.2	\$ 33.4	\$ 123.8
Personnel expenses	146.3	105.1	41.2
Professional and legal fees	65.1	37.0	28.1
Facility and support services	35.1	29.4	5.7
Other general and administrative	31.7	15.8	15.9
Total general and administrative expenses	\$ 435.4	\$ 220.7	\$ 214.7

Sales and marketing expenses. Sales and marketing expenses increased to \$194.8 million for the three months ended June 30, 2021 compared to \$118.9 million for the three months ended June 30, 2020. Sales and marketing expenses increased to \$381.0 million for the six months ended June 30, 2021 compared to \$286.6 million for the six months ended June 30, 2020. The increase in sales and marketing expenses was primarily due to an increase in direct marketing spend to support the future growth of our products and increased personnel expenses and stock-based compensation as a result of an increase in headcount. In addition, professional fees increased during the three and six months ended June 30, 2021 primarily due to a reduction of costs incurred related to our promotion agreement with Pfizer during the second quarter of 2020 due to the COVID-19 pandemic.

Amounts in millions	Three Months Ended June 30,		
	2021	2020	Change
Personnel expenses	\$ 87.0	\$ 60.4	\$ 26.6
Direct marketing costs	47.2	29.7	17.5
Professional and legal fees	30.8	5.4	25.4
Facility and support services	15.6	10.9	4.7
Stock-based compensation	13.7	12.1	1.6
Other sales and marketing expenses	0.5	0.4	0.1
Total sales and marketing expenses	\$ 194.8	\$ 118.9	\$ 75.9

Amounts in millions	Six Months Ended June 30,		
	2021	2020	Change
Personnel expenses	\$ 172.0	\$ 141.3	\$ 30.7
Direct marketing costs	88.6	63.1	25.5
Professional and legal fees	58.5	37.5	21.0
Facility and support services	33.4	23.2	10.2
Stock-based compensation	26.8	20.8	6.0
Other sales and marketing expenses	1.7	0.7	1.0
Total sales and marketing expenses	\$ 381.0	\$ 286.6	\$ 94.4

Amortization of acquired intangible assets. Amortization of acquired intangible assets increased to \$23.8 million for the three months ended June 30, 2021 compared to \$23.4 million for the three months ended June 30, 2020. Amortization of acquired intangible assets increased to \$47.0 million for the six months ended June 30, 2021 compared to \$46.8 million for the six months ended June 30, 2020. The increase in amortization of acquired intangible assets was primarily due to the amortization of intangible assets acquired as part of our acquisition of Ashion.

Other operating income. Other operating income decreased to zero for the three and six months ended June 30, 2021 compared to \$23.7 million for the three and six months ended June 30, 2020. The income generated during the three and six months ended June 30, 2020 represents the funding received under the Coronavirus Aid, Relief, and Economic Security Act (“CARES Act”) Provider Relief Fund, which was accepted from the Department of Health & Human Services in May 2020.

Investment income, net. Investment income, net increased to \$3.4 million for the three months ended June 30, 2021 compared to \$2.9 million for the three months ended June 30, 2020. Investment income, net increased to \$34.6 million for the six months ended June 30, 2021 compared to \$3.0 million for the six months ended June 30, 2020. The increase in investment income, net was primarily due to the realized gain of \$30.5 million that was recorded on our preferred stock investment in Thrive, which represented the adjustment to our historical investment to its fair value prior to our acquisition of Thrive. Our acquisition of Thrive is further described in Note 17 of our condensed consolidated financial statements included in this Quarterly Report on Form 10-Q.

Interest expense. Interest expense increased to \$4.7 million for the three months ended June 30, 2021 compared to \$4.3 million for the three months ended June 30, 2020. Interest expense recorded from our outstanding convertible notes totaled \$4.0 million during each of the three months ended June 30, 2021 and 2020. Interest expense decreased to \$9.3 million for the six months ended June 30, 2021 compared to \$58.9 million for the six months ended June 30, 2020. Interest expense recorded from our outstanding convertible notes totaled \$8.0 million and \$57.8 million during the six months ended June 30, 2021 and 2020, respectively. Of the interest expense recorded on our outstanding convertible notes for the six months ended June 30, 2020, \$50.8 million is due to the loss on settlement of convertible notes. The convertible notes are further described in Note 9 of our condensed consolidated financial statements included in this Quarterly Report on Form 10-Q. In addition, we recognized an immaterial amount of interest expense relating to stated interest expense on our construction loan for the three and six months ended June 30, 2021 and 2020.

Income tax benefit. Income tax expense was \$4.0 million for the three months ended June 30, 2021 compared to a benefit of \$0.3 million for the three months ended June 30, 2020. Income tax benefit increased to \$238.8 million for the six months ended June 30, 2021 compared to \$2.5 million for the six months ended June 30, 2020. This increase in income tax benefit is primarily due to an income tax benefit of \$239.2 million recorded during the six months ended June 30, 2021, as a result of the change in the deferred tax asset valuation allowance resulting from the acquisition of Thrive.

Liquidity and Capital Resources

We have financed our operations since inception primarily through public offerings of our common stock and convertible debt and through revenue generated by the sale of our Cologuard test, and since the completion of our Genomic Health combination, of Oncotype IQ tests. As of June 30, 2021, we had approximately \$363.7 million in unrestricted cash and cash equivalents and approximately \$943.9 million in marketable securities.

The majority of our investments in marketable securities consist of fixed income investments, and all are deemed available-for-sale. The objectives of this portfolio are to provide liquidity and safety of principal while striving to achieve the highest rate of return. Our investment policy limits investments to certain types of instruments issued by institutions with investment grade credit ratings and places restrictions on maturities and concentration by type and issuer.

Net cash used in operating activities was \$36.9 million for the six months ended June 30, 2021 compared to cash use of \$56.7 million for the six months ended June 30, 2020. The decrease in cash used in operating activities for the six months ended June 30, 2021 was primarily due to the increase in cash receipts as a result of an increase in revenue. The increase in revenue was driven by an increase in completed Cologuard, Oncotype IQ, and COVID-19 tests. This was partially offset by an increase in cash payments made related to expenses necessary to process our tests and an increase in operating expenses to prepare for future growth of our operations.

Net cash used in investing activities was \$1.11 billion for the six months ended June 30, 2021 compared to cash use of \$412.2 million for the six months ended June 30, 2020. The increase in cash used in investing activities for the six months ended June 30, 2021 compared to the same period in 2020 was primarily the result of the timing of purchases, sales, and maturities of marketable securities. Excluding the impact of purchases, sales, and maturities of marketable securities, net cash used in investing activities was \$521.4 million for the six months ended June 30, 2021 compared to \$40.6 million for the six months ended June 30, 2020. Cash use consisted primarily of our acquisition of Thrive of \$343.2 million, our acquisition of Ashion of \$72.3 million, our asset acquisition of PFS Genomics of \$33.1 million, and our TARDIS license asset acquisition of \$25.0 million, purchases of property and equipment of \$37.5 million, and investments in privately held companies of \$10.0 million for the six months ended June 30, 2021. Cash use primarily consisted of purchase of property and equipment of \$34.2 million and business combinations of \$6.7 million for the six months ended June 30, 2020.

Net cash provided by financing activities was \$20.6 million for the six months ended June 30, 2021 compared to \$995.6 million for the six months ended June 30, 2020. The cash provided by financing activities during the six months ended June 30, 2021 consisted of proceeds of \$11.6 million from the exercise of stock options and \$12.0 million in connection with our employee stock purchase plan, which was partially offset with cash outflows of \$3.1 million for other financing activities. The cash provided by financing activities for the six months ended June 30, 2020 was primarily the result of proceeds of \$1.13 billion from our issuance of Convertible Notes with a maturity date of March 1, 2028 (the “2028 Notes”), and we used \$150.1 million of cash to settle a portion of the 2025 Notes. In addition, during the six months ended June 30, 2020 we received proceeds of \$10.9 million from the exercise of stock options and \$9.8 million in connection with our employee stock purchase plan.

We expect that cash and cash equivalents and marketable securities on hand at June 30, 2021 will be sufficient to fund our current operations for at least the next twelve months based on current operating plans. However, we may need to raise additional capital to fully fund our current strategic plan, which includes successfully commercializing our Cologuard test and Oncotype IQ products and developing a pipeline of future products. Additionally, we may enter into transactions to acquire other businesses, products, services, or technologies as part of our strategic plan. If we are unable to obtain sufficient additional funds to enable us to fund our operations through the completion of such plan, our results of operations and financial condition would be materially adversely affected, and we may be required to delay the implementation of our plan and otherwise scale back our operations. Even if we successfully raise sufficient funds to complete our plan, there is no certainty that we will be successful in generating sufficient cash flow from operations or achieving and maintaining profitable operations in the future to enable us to meet our obligations as they come due.

A table reflecting certain of our specified contractual obligations as of December 31, 2020 was provided in the Management’s Discussion and Analysis of Financial Condition and Results of Operation of our 2020 Form 10-K. There were no material changes outside the ordinary course of our business in our specified contractual obligations during the six months ended June 30, 2021.

Critical Accounting Policies and Estimates

Management’s discussion and analysis of our financial condition and results of operations is based on our condensed consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the U.S. (“GAAP”). The preparation of these financial statements requires us to make estimates and assumptions that affect the amounts reported in our condensed consolidated financial statements and accompanying notes. On an ongoing basis, we evaluate our estimates and judgments. We base our estimates on historical experience and on various other factors that are believed to be appropriate under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

While our significant accounting policies are more fully described in Note 1 of our financial statements included in our 2020 Form 10-K, as well as our Management’s Discussion and Analysis of Financial Condition and Results of Operations on our 2020 Form 10-K, we believe that the following accounting policies and judgments are most critical to aid in fully understanding and evaluating our reported financial results. Other than the adoption of Accounting Standards Update 2020-06 fully discussed in Note 9 of our condensed consolidated financial statements in this Quarterly Report on Form 10-Q, there have not been any significant changes to our critical accounting policies and estimates during the six months ended June 30, 2021.

Revenue Recognition. Revenues are recognized when we release a result to the ordering healthcare provider, in an amount that reflects the consideration we expect to collect in exchange for those services. The amount of revenue we recognize is based on the established billing rates less contractual and other adjustments, which yields the unconstrained amount that we expect to ultimately collect. We determine the amount we expect to ultimately collect, using historical collections, established reimbursement rates and other adjustments. The expected amount is typically lower than, if applicable, the agreed-upon reimbursement amount due to several factors, such as the amount of any patient co-payments, out-of-network payers, the existence of secondary payers and claim denials. The consideration derived from our contracts is fixed when we contract with a direct bill payer. Our ability to collect is not contingent on the customer’s ability to collect through their downstream billing efforts.

In the case of some of our laboratory service agreements (“LSAs”) with various organizations, the right to bill and collect exists prior to the receipt of a specimen and release of a test result to the ordering healthcare provider, which results in deferred revenue. The deferred revenue balance is generally relieved upon the release of the applicable patient’s test result to the ordering healthcare provider or as of the date the customer has surpassed the window of time in which they are able to exercise their rights for testing services. We believe these points in time represent our fulfillment of our obligations to the customer.

The quality of our billing operations, most notably those activities that relate to obtaining the correct information in order to bill effectively for services provided, directly impacts the collectability of our receivables and revenue estimates. As such, we continually assess the state of our order to cash operations in order to identify areas of risk and opportunity that allow us to appropriately estimate receivables and revenue. Upon ultimate collection, the aggregate amount received from payers and patients where reimbursement was estimated is compared to previous collection estimates and, if necessary, the transaction price is adjusted. Finally, should we later determine the judgments underlying estimated collections change, our financial results could be negatively impacted in future quarters.

Business Combinations and Asset Acquisitions. Business Combinations are accounted for under the acquisition method in accordance with Accounting Standards Codification (“ASC”) 805, Business Combinations. The acquisition method requires identifiable assets acquired and liabilities assumed and any non-controlling interest in the business acquired be recognized and measured at fair value on the acquisition date, which is the date that the acquirer obtains control of the acquired business. The amount by which the fair value of consideration transferred as the purchase price exceeds the net fair value of assets acquired and liabilities assumed is recorded as goodwill. Acquisitions that do not meet the definition of a business combination under the ASC are accounted for as asset acquisitions. Asset acquisitions are accounted for by allocating the cost of the acquisition to the individual assets acquired and liabilities assumed on a relative fair value basis. Goodwill is not recognized in an asset acquisition with any consideration in excess of net assets acquired allocated to acquired assets on a relative fair value basis. Transaction costs are expensed in a business combination and are considered a component of the cost of the acquisition in an asset acquisition.

Impairment of Long-Lived Assets. We evaluate the fair value of long-lived assets, which include property, plant and equipment, intangible assets, and investments in privately held companies, for impairment whenever events or changes in circumstances indicate that the carrying amounts of the assets may not be fully recoverable. Recoverability of assets to be held and used is measured by a comparison of the carrying amount of an asset to future undiscounted net cash flows expected to be generated by the asset. If such assets are considered to be impaired, the impairment to be recognized is measured by the amount by which the carrying amount of the assets exceeds the fair value of the assets. Assets to be disposed of are reported at the lower of the carrying amount or fair value less costs to sell.

Recent Accounting Pronouncements

See Note 1 in the Notes to Condensed Consolidated Financial Statements for the discussion of Recent Accounting Pronouncements.

Off-Balance Sheet Arrangements

As of June 30, 2021, we had no off-balance sheet arrangements.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

Interest Rate Risk

Our exposure to market risk is principally confined to our cash, cash equivalents and marketable securities. We invest our cash, cash equivalents, and marketable securities in securities of the U.S. governments and its agencies and in investment-grade, highly liquid investments consisting of commercial paper, bank certificates of deposit, and corporate bonds, which as of June 30, 2021 and December 31, 2020 were classified as available-for-sale. We place our cash, cash equivalents, restricted cash, and marketable securities with high-quality financial institutions, limit the amount of credit exposure to any one institution, and have established investment guidelines relative to diversification and maturities designed to maintain safety and liquidity.

Based on a hypothetical ten percent adverse movement in interest rates, the potential losses in future earnings, fair value of risk-sensitive financial instruments, and cash flows are immaterial, although the actual effects may differ materially from the

hypothetical analysis. While we believe our cash, cash equivalents, restricted cash, and marketable securities do not contain excessive risk, we cannot provide absolute assurance that, in the future, our investments will not be subject to adverse changes in market value. In addition, we maintain significant amounts of cash, cash equivalents, restricted cash, and marketable securities at one or more financial institutions that are in excess of federally insured limits. Given the potential instability of financial institutions, we cannot provide assurance that we will not experience losses on these deposits. We do not utilize interest rate hedging agreements or other interest rate derivative instruments.

A hypothetical ten percent change in interest rates would not have a material adverse impact on our future operating results or cash flows. All of our significant interest-bearing liabilities bear interest at fixed rates and therefore are not subject to fluctuations in market interest rates; however, because these interest rates are fixed, we may be paying a higher interest rate, relative to market, in the future if circumstances change.

Foreign Currency Risk

Substantially all of our revenues are recognized in U.S. dollars, although a small portion is denominated in foreign currency as we continue to expand into markets outside of the U.S. Certain expenses related to our international activities are payable in foreign currencies. As a result, factors such as changes in foreign currency exchange rates or weak economic conditions in foreign markets will affect our financial results.

We enter into forward contracts to mitigate the impact of adverse movements in foreign exchange rates related to the re-measurement of monetary assets and liabilities and hedge our foreign currency exchange rate exposure. As of June 30, 2021, we had open foreign currency forward contracts with notional amounts of \$23.8 million. Although the impact of currency fluctuations on our financial results has been immaterial in the past, there can be no guarantee that the impact of currency fluctuations related to our international activities will not be material in the future.

Item 4. Controls and Procedures

As of the end of the period covered by this report, we carried out an evaluation, under the supervision and with the participation of our management, including our principal executive officer and our principal financial officer, of the effectiveness of our disclosure controls and procedures, as defined in Rule 13a-15(e) promulgated under the Securities Exchange Act of 1934, as amended (the “Exchange Act”). Based upon that evaluation, our principal executive officer and our principal financial officer concluded that, as of June 30, 2021, our disclosure controls and procedures were effective. Disclosure controls and procedures enable us to record, process, summarize and report information required to be included in our Exchange Act filings within the required time period. Our disclosure controls and procedures include controls and procedures designed to ensure that information required to be disclosed by us in the periodic reports filed with the SEC is accumulated and communicated to our management, including our principal executive, financial and accounting officers, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure.

In January 2021, we acquired all of the outstanding capital stock of Thrive (see Note 17 of the accompanying condensed consolidated financial statements for additional information). As of June 30, 2021, management is in the process of evaluating and integrating the internal controls of Thrive into the Company’s existing operations. Other than the controls enhanced or implemented to integrate the Thrive business, there have been no significant changes in internal control over financial reporting during the quarter ended June 30, 2021 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 are a party to various legal proceedings arising in the ordinary course of our business. Legal proceedings, including litigation, government investigations and enforcement actions could result in material costs, occupy significant management resources and entail civil and criminal penalties. The information called for by this item is incorporated by reference to the information in Note 14 of the Notes to Condensed Consolidated Financial Statements included in Part I of this Quarterly Report on Form 10-Q.

Item 1A. Risk Factors

We operate in a rapidly changing environment that involves a number of risks that could materially affect our business, financial condition or future results, some of which are beyond our control. In addition to the other information set forth in this report, the risks and uncertainties that we believe are most important for you to consider are discussed in Part I, “Item 1A. Risk Factors” in the 2020 Form 10-K and in Part II, “Item 1A. Risk Factors” in our subsequently filed Quarterly Reports on Form 10-Q. Other than the factors set forth below, there have been no material changes to the risk factors described in the 2020 Form 10-K.

The COVID-19 outbreak has and may further materially and adversely affect our business and financial results.

The COVID-19 pandemic, together with related precautionary measures, has materially disrupted our business since March 2020 and may continue to disrupt our business for an unknown period of time. COVID-19 has significantly impacted, and may continue to significantly impact, our operating results including our revenues, margins, and cash utilization, among other measures. The territories in which we market, sell, distribute and perform our tests have attempted to address the COVID-19 pandemic in varying ways, including stay-at-home orders, temporarily closing businesses, restricting gatherings, restricting travel, and mandating social distancing and face coverings. Certain jurisdictions have begun re-opening only to return to restrictions due to increases in new COVID-19 cases. Although health and safety precautions loosened in many jurisdictions over the past several months as the number of COVID-19 cases declined and vaccination rates increased, beginning in early July 2021, COVID-19 cases, including cases associated with the highly contagious delta variant, have increased significantly in the United States. Public health officials and medical professionals have warned that COVID-19 cases may continue to spike, particularly if vaccination rates do not quickly increase or if additional, potent disease variants emerge. It is unclear how long the resurgence will last, how severe it will be, and what safety measures governments will impose in response to it. As cases rise, mask mandates, social-distancing, travel restrictions and stay-at-home orders could be reinstated. Even before the recent increase in cases, many individuals remained cautious about resuming activities such as preventive-care medical visits and many medical practices remained cautious about allowing individuals, such as sales representatives, into their offices. The level and nature of the disruption caused by COVID-19 is unpredictable, may be cyclical and long-lasting and may vary from location to location.

The COVID-19 pandemic has materially impacted our business, and may continue to impact our business for an unknown period of time. Such impacts may include the following:

- Both our and Pfizer’s sales teams have been, and for an extended period of time may continue to be, limited in their in-person interactions with healthcare providers, and therefore, also limited in their ability to engage in various types of healthcare provider education activities as contemplated by our and Pfizer’s Cologuard promotion agreement;
- We are uncertain how many or what type of sales details Pfizer’s sales representatives will contribute during the second half of 2021 and beyond; although in October 2020 we amended and restated the promotion agreement to, among other things, address changes to the operational landscape resulting from the COVID-19 pandemic, we are in the process of negotiating further amendments that could result in material changes to our relationship with Pfizer and how we and Pfizer promote our Cologuard test, and we may fail to realize the expected benefits from the agreement;
- Healthcare providers or patients have canceled or delayed scheduling, and for an extended period of time may continue to cancel or delay scheduling, standard wellness visits and other non-emergency appointments and procedures (including mammograms and prostate cancer screenings), contributing to a decline in orders for our products or services;

- Restrictions on travel, commerce and shipping may prevent patients and pathologists from shipping samples to our clinical laboratories;
- Pandemic-related supply chain disruptions (whether caused by restrictions, congestion, or slowdowns in shipping or logistics, increases in demand for certain goods used on our operations, or otherwise) may hinder, or even force us to suspend, operations at some or all of our clinical laboratories;
- Illnesses, quarantines, financial hardships, restrictions on travel, commerce and shipping, or other consequences of the pandemic, may disrupt our business relationships, and we or other parties may assert rights under force majeure clauses to excuse performance;
- We have experienced, and for an extended period of time may continue to experience, reduced volumes at our clinical laboratories and we may need to suspend operations at some or all of our clinical laboratories;
- Our efforts to manage our operations through a volatile and cyclical pandemic, which efforts may include cost cutting measures, may hinder our efforts to commercialize our products or delay the development of future products and services;
- We and our partners have postponed or cancelled clinical studies, which may delay or prevent our launch of future products and services and increase the opportunity for competitors to develop products and services that compete with ours;
- Our workforce may be infected by the virus or otherwise distracted;
- A combination of factors, including infection from the virus, supply shortfalls or disruptions, and inability to obtain or maintain equipment, could increase our operating expenses and adversely affect our lab capacity and our ability to meet the demand for our testing services;
- We have adjusted, and expect to continue to adjust, our precautionary measures at our various locations based on our perception of local recovery levels and applicable governmental regulations; our business could be negatively affected if we take excessive, ineffective or inadequate precautions; and
- We may inaccurately estimate the duration or severity of the COVID-19 pandemic, which could cause us to misalign our staffing, spending, activities and precautionary measures with current or future market conditions.

Despite our efforts, the ultimate impact of COVID-19 depends on factors beyond our knowledge or control, including the duration and severity of the outbreak, third-party actions taken to contain its spread and mitigate its public health effects and short- and long-term changes in the behaviors of medical professionals and patients resulting from the pandemic.

If payers, including managed care organizations, do not approve and maintain reimbursement for our tests at adequate reimbursement rates, our commercial success could be compromised.

Our commercial success depends, in large part, on the availability of adequate reimbursement for our tests, including our flagship Cologuard and Oncotype IQ tests, from government insurance plans, managed care organizations and private insurance plans. Although we received a positive coverage decision and what we believe is an adequate reimbursement rate from Centers for Medicare & Medicaid Services (“CMS”) for our Cologuard test, it is also critical that other third-party payers approve and maintain reimbursement for our Cologuard test at adequate reimbursement rates. Healthcare providers may be reluctant to prescribe, and patients may be reluctant to complete, our tests if they are not confident that patients will be reimbursed for our tests.

Third-party payers, both in the United States and internationally, are increasingly attempting to contain healthcare costs by limiting both coverage and the level of reimbursement for healthcare products and services. As a result, there is uncertainty surrounding the future level of reimbursement, if any, for our current tests and any new tests we may develop. Reimbursement by a third-party payer may depend on a number of factors, including a payer’s determination that tests using our technologies are: sufficiently sensitive and specific; not experimental or investigational; approved or recommended by the major guidelines organizations; subject to applicable federal or state coverage mandates; reliable, safe and effective; medically necessary; appropriate for the specific patient; and cost-effective.

Our Oncotype DX Breast Recurrence Score test has received certain negative assessments in the past relating to technology criteria for clinical effectiveness and appropriateness for use in certain patients, and our tests may receive similar negative assessments in the future. Since each payer makes its own decision as to whether to establish a policy to reimburse our tests, seeking these approvals is a time-consuming and costly process. Although we have positive coverage determinations for our Oncotype DX breast cancer test for N-, ER+ and N+ patients from most third party payers in the United States through contracts, agreements or policy decisions, we cannot be certain that coverage for this test will be provided in the future by additional third party payers or that existing contracts, agreements or policy decisions or reimbursement levels, including tests processed as out of network, will remain in place or be fulfilled within existing terms and provisions.

We have obtained limited reimbursement from private third-party payers in the U.S. for our Oncotype DX colon cancer test and for our Oncotype DX breast cancer test for ductal carcinoma in situ (“DCIS”) patients. Unless and until further clinical data is presented, our DCIS indication for our breast cancer test and our colon cancer test may be considered investigational by payers and therefore may not be covered under their reimbursement policies.

We have obtained Medicare reimbursement coverage for our Oncotype DX GPS prostate cancer test for low and very-low risk patients, unfavorable and favorable intermediate risk patients, and high risk patients. However, we may not be able to obtain other third-party payer reimbursement for our tests for patients with colon or prostate cancer or DCIS that is similar to the coverage we have obtained for our invasive breast cancer test for N-, ER+ and N+ patients.

Under the terms of the coverage determinations for our Oncotype DX GPS prostate cancer test, coverage for the test for patients with certain risk profiles is limited to tests ordered by healthcare providers who agree to participate in a Certification and Training Registry, or CTR, and to provide certain information about Medicare beneficiaries who receive our test. If healthcare providers do not timely submit necessary information as part of participating in the CTR, the timeframe in which we are reimbursed and recognize revenue for those tests may be accordingly delayed.

From time to time payers change processes that may affect timely payment. These changes may result in uneven cash flow or impact the timing of revenue recognized with these payers. Additionally, on a five-year rotational basis, Medicare requests bids for its regional Medicare Administrative Contractor, or MAC, services. Effective January 2021, CMS renewed its contract with Noridian Healthcare Solutions for the jurisdiction in which we process our Oncotype IQ tests. However, Palmetto, another MAC, makes coverage determinations for our Oncotype IQ tests through the MoDx Program. Future changes in the MAC with jurisdiction over our tests may affect our ability to obtain Medicare coverage and reimbursement for tests for which we have or may seek coverage.

Successful commercialization of our newly developed products and products in development will also depend on our ability to obtain adequate coverage from government insurance plans, managed care organizations and private insurance plans for such products.

Moreover, coverage determinations and reimbursement rates are subject to change, and we cannot guarantee that even if we initially achieve adequate coverage and reimbursement rates for our Cologuard and Oncotype IQ tests, they will continue to apply in the future. As noted above, under the Protecting Access to Medicare Act (“PAMA”), our Medicare reimbursement rates will be subject to adjustment based on our volume-weighted median commercial reimbursement rate. Any reduction in our Medicare reimbursement rates could significantly and adversely affect our business prospects, financial condition and results of operations.

Even where a third-party payer agrees to cover one of our tests, other factors may have a significant impact on the actual reimbursement we receive from that payer. For example, if we do not have a contract with a given payer, we may be deemed an “out-of-network” provider by that payer, which could result in the payer allocating a portion of the cost of the test to the patient, notwithstanding any applicable coverage mandate. We may be unsuccessful in our efforts to enter into, or maintain, a network contract with a given payer, and we expect that our network status with a given payer may change from time to time for a variety of reasons, many of which may be outside our control. To the extent one of our tests is out of network for a given payer, healthcare providers may be less likely to prescribe that test for their patients and their patients may be less likely to comply with those prescriptions that are written. Also, some payers may require that they give prior authorization for a test before they are willing to pay for it or review claims post-service to ensure the service was medically appropriate for specific patients. Prior authorization and other medical management practices may require that we, patients or healthcare providers provide the payer with extensive medical records and other information. Prior authorization and other medical management practices impose a significant additional cost on us, may be difficult to comply with given our position as a laboratory that generally does not have direct access to patient medical records, may make healthcare providers less likely to prescribe our tests for their patients, and may make patients less likely to comply with healthcare provider orders for our tests, all or any of which may have an adverse effect on our revenues.

Other companies or institutions may develop and market novel or improved technologies, which may make our technologies less competitive or obsolete.

We operate in a rapidly evolving and highly competitive industry. There are a number of private and public companies that offer products or have announced that they are developing products that compete with ours. Some of our current and potential competitors possess greater brand recognition, financial and other resources and development capabilities than us. As more

information regarding cancer genomics becomes available to the public, we anticipate that competition will further increase. We expect to compete with a broad range of organizations in the U.S. and other countries that are engaged in the development, production and commercialization of cancer screening and diagnostic products and services. These competitors include:

- biotechnology, diagnostic, diagnostic tools, and other life science companies;
- academic and scientific institutions;
- governmental agencies; and
- public and private research organizations.

The U.S. market for colorectal cancer and pre-cancer screening is large, consisting of nearly 110 million individuals between the ages of 45 and 85, and has attracted numerous competitors. Our Cologuard test faces competition from procedure-based detection technologies such as colonoscopy, flexible sigmoidoscopy, and “virtual” colonoscopy, a radiological imaging approach that visualizes the inside of the bowel by CT scan (spiral computerized axial tomography), as well as other common screening tests, such as the fecal occult blood test and the fecal immunochemical test, and newer screening technologies. Some payers and health systems promote the fecal immunochemical test as a lower-cost screening alternative. Newer screening technologies include liquid biopsy tests, such as Epi proColon, approved by the FDA in April 2016, and pill-based imaging solutions like PillCam COLON, cleared by the FDA in February 2014, and C-Scan, which obtained a CE Mark in early 2019. A number of companies, including Freenome, Inc. and Guardant Health, Inc., are developing blood-based liquid biopsy tests for colorectal cancer screening, as well as other applications.

We also are aware of at least three companies, DiaTech Pharmacogenetics, Prescient Metabionics, and Geneoscopy, that are seeking to develop, stool-based colorectal cancer tests in the U.S. Our competitors may also be developing additional methods of detecting colorectal cancer and pre-cancer that have not yet been announced.

While we believe that our Cologuard test compares favorably to other available products and services, our success depends on our ability to successfully market and sell our Cologuard test, build acceptance of our Cologuard test in the medical community, obtain and maintain positive reimbursement determinations and inclusion in healthcare guidelines, recommendations and quality measures, effectively and efficiently operate our clinical laboratories, and ensure positive patient and healthcare provider experience. We also need to innovate and adopt emerging technologies to develop and commercialize improved versions of our Cologuard test or new colorectal cancer screening tests. We are seeking opportunities to improve upon our Cologuard test’s performance characteristics and plan to enroll more than 10,000 patients in a multi-center, prospective BLUE-C study to establish the performance of an enhanced multi-target stool DNA test. We are also working to develop a blood-based screening test. If we are unable to successfully develop new colorectal cancer screening tests, if our competitors deliver new or improved tests before we do, or if healthcare providers, patients or payers perceive our future tests as less attractive than our competitors’ tests, then we may lose market share and our operating results and financial condition may be materially and adversely affected.

Similarly, our Oncotype IQ products compete against a number of companies that offer products or have conducted research to profile genes and gene expression in breast, colon and prostate cancer. These companies include Agendia Inc., BioTheragnostics, Guardant Health, Inc., Hologic Inc., Myriad Genetics Inc. (and its Sividon Diagnostics subsidiary), NeoGenomics, Inc., OPKO Health, Inc. (and its Bio-Reference Laboratories, Inc. subsidiary), Pacific Edge Limited, Qiagen N.V. and Veracyte, Inc. Historically, our principal competition for our Oncotype IQ tests has come from existing diagnostic methods used by pathologists and oncologists, and such traditional diagnostic methods can be difficult to change or supplement. Our Oncotype IQ tests also face competition from commercial laboratories with strong distribution networks for diagnostic tests, such as Laboratory Corporation of America Holdings and Quest Diagnostics Incorporated. Other potential competitors include companies that develop diagnostic tests such as Roche Diagnostics, a division of Roche Holding, Ltd, and Siemens AG, as well as other companies and academic and research institutions.

For our prostate cancer tests, we face comparatively greater competition than for our breast cancer tests, including competition from products that were on the market prior to our product launch and that are supported by clinical studies and published data. This existing direct and indirect competition for tests and procedures may make it difficult to gain market share, impact our ability to obtain reimbursement or result in a substantial increase in resources necessary for us to successfully continue to commercialize our Oncotype DX GPS prostate test and the Oncotype DX AR-V7 Nucleus Detect test.

We believe that our Oncotype IQ tests compete primarily on the basis of the value of the quantitative information they provide, the clinical validation of the utility of our tests, the level of adoption and reimbursement coverage for our tests, the inclusion of our tests in clinical practice guidelines, our ability to commercialize products through our clinical development

platform, our ability to expand our sales efforts into new areas of medical practice as we launch new products, our collaborations with clinical study groups, the quality of our clinical laboratory, and the level of customer service we provide. While we believe that our Oncotype IQ tests compete favorably with respect to these factors, to continue to do so we must innovate and adopt advanced technology, successfully market, sell and enhance our tests, obtain peer-reviewed publications of our clinical studies in a timely manner, continue to obtain positive reimbursement determinations, continue to expand in countries outside of the U.S., continue to develop our technological and clinical operations, encourage healthcare provider participation in Medicare-required information collection efforts, and successfully expand our reach into additional product markets including through collaborations with third parties.

We recently began offering our Oncoguard Liver test, a blood test to detect hepatocellular carcinoma (“HCC”), and we intend to offer additional liquid biopsy tests that:

- screen for colorectal cancer,
- screen for multiple types of cancers using a single test,
- provide prognostic information, guide therapy selection, or measure minimal residual disease or cancer recurrence.

We are aware of a number of companies — including Bioprognos, Bluestar Genomics, Burning Rock, Caris Life Sciences, CellMax, Inc., Clinical Genomics, DiaCarta, EarlyDx, Epigenomics AG, Foundation Medicine, Freenome Inc., Genetron Health, Glycotest, GRAIL, Inc., Guardant Health, Inc., Helio Health, Immunovia AB, Inivata, Invitae, JBS Science, Natera Inc., Nucleix Ltd., Singlera Genomics, Sysmex Inostics, and Tempus — that have developed, or are developing, liquid biopsy tests for the detection of cancer, based on the detection of proteins, tumor cells, nucleic acids, epigenetic markers, or other biomarkers. Other companies, hospitals, and academic and research institutions may also develop liquid biopsy tests. Many proposed liquid biopsy tests rely on next-generation sequencing platforms, such as those provided by Illumina, Inc. and Thermo Fisher Scientific Inc. It appears that certain of our competitors have entered into long-term supply agreements with vendors of next generation sequencing equipment, reagents and other consumables. We may be competitively disadvantaged if we are unable to secure next-generation sequencing equipment and supplies on favorable terms and pricing.

Other companies’ liquid biopsy tests could represent significant competition for our current tests, including our Cologuard and Oncotype IQ tests, as well as other tests we may develop. Freenome Inc., Geneoscopy and Guardant Health are conducting prospective colorectal cancer screening clinical trials intended to support FDA approval, and other companies may do so in the future.

Our liquid biopsy tests may also compete with other types of diagnostic technologies, including imaging solutions, as well as more established and potentially less expensive alternatives. For example, our Oncoguard Liver test faces competition from alpha fetoprotein testing, which has been practiced since the 1960s, and ultrasound, MRI and CT imaging. We are also aware of companies and other researchers that are advancing new imaging approaches and technologies.

Our industry is experiencing increasing levels of merger and acquisition activity as companies attempt to strengthen or hold their market positions in an evolving industry and as companies are acquired or are unable to continue operations. In addition to consolidations among competitive molecular diagnostic companies, critical suppliers have sought to acquire molecular diagnostics companies. For example, in September 2020 Illumina announced an agreement to acquire GRAIL; however that acquisition remains subject to challenges by the Federal Trade Commission and review by the European Commission’s Directorate-General of Competition. Industry consolidation may result in companies that have competitive advantages over us in terms of access to capabilities, technology, equipment, supplies, intellectual property, talent and other resources and that are better able to rapidly and cost-effectively develop, commercialize and perform new tests.

Competitors may develop their own versions of our tests in countries where we did not apply for patents, where our patents have not issued or where our intellectual property rights are not recognized and compete with us in those countries, including encouraging the use of their test by healthcare providers or patients in other countries.

We may be unable to compete effectively against our competitors either because their products and services are superior or because they are more effective in developing or commercializing competing products and services. These competitors may have broader product lines and greater name recognition than we do. Furthermore, even if we do develop new marketable products or services, our current and future competitors may develop products and services that are more clinically or commercially attractive than ours, and they may bring those products and services to market earlier or more effectively than us. If we are unable to compete successfully against current or future competitors, we may be unable to increase market acceptance for and sales of our tests, which could prevent us from increasing or sustaining our revenues or achieving sustained profitability and could cause the market price of our common stock to decline.

We heavily rely upon certain suppliers, including suppliers that are the sole source of certain products; the loss or interruption of supply from our suppliers could have a disruptive effect on our business.

We purchase certain supplies from third-party suppliers and manufacturers. In some cases, due to the unique attributes of products that are incorporated into our tests, we maintain either a single-source supplier relationship or a very limited set of supplier relationships. Certain of our third-party suppliers possess exclusive intellectual property or otherwise may be the only party with the rights or expertise to provide us critical supplies. These third parties are independent entities subject to their own unique operational, regulatory compliance, and financial risks that are outside our control. These third parties may not be willing to enter or renew long-term supply arrangements with us or continue to supply us at all. Additionally, they may not perform their obligations in a timely and cost-effective manner and they may be unwilling or unable to increase production capacity commensurate with demand for our tests or future products or services. Our relationships with suppliers may also be negatively affected by general supply chain material shortages worldwide, as suppliers struggle to keep pace with demand and manage their own supply chains.

We may become dependent on additional single- or limited-source suppliers, or become increasingly dependent on existing suppliers, as we expand and develop our product and service pipeline. For example, our Oncotype MAP and GEM ExTra tests are currently only validated to be performed on Illumina's sequencing platform and we are not aware of any other platform that we could use in the near future as a commercially viable alternative. Further, Illumina may become the sole supplier of certain equipment and reagents necessary for future tests we may develop, including multi-cancer screening, minimal residual disease, and recurrence monitoring tests. We currently procure Illumina equipment and reagents on a purchase order basis, without any long-term supply agreement. Illumina has entered into an agreement to acquire GRAIL, which is commercializing a multi-cancer screening test against which our planned tests would compete. Illumina's ownership of GRAIL could incentivize Illumina to offer its sequencing products in a manner that advantages GRAIL over us and other competitors. The Federal Trade Commission has taken action to seek to block Illumina's proposed acquisition of GRAIL, and the transaction is still under review by the European Commission. We, along with certain other diagnostic companies, have been called by the Federal Trade Commission to testify in its administrative trial to block Illumina's acquisition of Grail currently scheduled to commence on August 24, 2021. Although Illumina has made an irrevocable standing offer to supply any customer with its sequencing products on certain terms, that offer is contingent upon the closing of Illumina's acquisition of GRAIL and may not provide pricing or other terms necessary for us or others to successfully compete against GRAIL, including outside of the U.S. Even if Illumina's acquisition is unsuccessful, Illumina may be unwilling or unable to supply, or commit to supplying, us with sequencing equipment and reagents on commercially acceptable terms, if at all. Although we expect to continue our efforts to validate alternative sequencing platforms on which we could run our Oncotype MAP or GEM ExTra tests or other future tests in a commercially viable manner, we may expend considerable time and efforts, endure delays to our test development and commercialization timelines, and be ultimately unsuccessful in our efforts to validate alternatives. Even if we validate an alternative sequencing platform, we may become substantially dependent on the supplier of that platform.

Similarly, as an additional example, we rely on Hamilton Company to provide us laboratory equipment and related supplies (such as racking and pipette tips) necessary to perform certain critical DNA analysis steps in our clinical laboratory tests, including our Cologuard, Oncotype DX and COVID-19 tests. Although other companies may offer viable alternative platforms, we have invested significant capital, time and expertise to procure Hamilton machines and to optimize their use in our tests. Industry demand for Hamilton supplies has increased significantly since the onset of the COVID-19 pandemic, and although we have a long-term supply agreement with Hamilton, it is possible that Hamilton could become unable or unwilling to continue to provide us with certain equipment and supplies on commercially acceptable terms, if at all. Hamilton may require us to exclusively use Hamilton consumables and components in connection with certain Hamilton laboratory equipment. Therefore, if our access to certain Hamilton consumables and components became impacted, we may need to completely replace the Hamilton platform. Validating alternative vendors' offerings could be expensive, time-consuming, and unsuccessful. Further, because our Cologuard test is regulated by the FDA, we may also need FDA clearance or approval to replace certain Hamilton equipment and supplies with another vendor's offerings. FDA approval or clearance may entail extensive new clinical and material costs and delays and may be ultimately unsuccessful.

The loss of a critical supplier, the failure to perform by a critical supplier, the deterioration of our relationship with a critical supplier or any unilateral modification to the contractual terms under which we are supplied materials could have a disruptive effect on our business, and could adversely affect our results of operations for an extended period of time, particularly if we are required to validate an alternative supplier.

We expect to make significant investments to research and develop new cancer tests, which may not be successful.

We are seeking to increase our Cologuard test's specificity by substituting new biomarkers and to develop a pipeline for future products and services, including multi-cancer screening, minimal residual disease and recurrence monitoring tests. We expect to incur significant expenses on these development efforts, but they may not be successful.

Developing new or improved cancer tests is a speculative and risky endeavor. Candidate products and services that may initially show promise may fail to achieve the desired results in larger clinical studies or may not achieve acceptable levels of clinical accuracy. Results from early studies or trials are not necessarily predictive of future clinical trial results, and interim results of a trial are not necessarily indicative of final results. From time to time, we may publicly disclose then-available data from clinical studies before the studies are complete, and the results and related findings and conclusions may be subject to change following the final analysis of the data related to the particular study or trial. As a result, such data should be viewed with caution until the final data are available. Additionally, such data from clinical trials are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment and/or follow-up continues and more patient data become available. Significant adverse differences between initial or interim data and final data could significantly harm our reputation and business prospects.

Any cancer screening test we develop will need to demonstrate in clinical studies a high level of accuracy. Because cancer screening tests seek to identify relatively rare occurrences, if in a clinical study a candidate product or service fails to identify even a small number of cancer cases, the sensitivity rate may be materially and adversely affected and we may have to abandon the candidate product or service. Any cancer diagnostic test we develop will need to address an unmet medical need with accurate performance and utility.

We may need to explore a number of different biomarker combinations, alter our candidate products or platform technologies and repeat clinical studies before we identify a potentially successful candidate. We may need to acquire, whether through purchase, license or otherwise, technologies owned by third parties, and we may not be able to acquire such technologies on commercially reasonable terms or at all. Product development is expensive, may take years to complete and can have uncertain outcomes. Failure can occur at any stage of the development. If, after development, a candidate product or service appears successful, we may, depending on the nature of the product or service, still need to obtain FDA and other regulatory clearances or approvals before we can market it. The FDA's clearance or approval pathways are likely to involve significant time, as well as additional research, development and clinical study expenditures. There can be no guarantee that the FDA would clear or approve any future product or service we may develop.

Even if the FDA clears or approves a new product or service we develop, we would need to commit substantial resources to commercialize, sell and market it before it could be profitable, and the product or service may never be commercially viable. In developing a test, we must make numerous assumptions regarding the commercial viability of a test, including with respect to healthcare providers' and patients' interest in a test, payers' willingness to pay for a test, our costs to perform a test, and availability and attractiveness of competing offerings. Frequently, we must make those assumptions many years before a test is ready for clinical use. If we determine that any of our current or future development programs is unlikely to succeed, we may abandon it without any return on our investment into the program. We may need to raise significant additional capital to bring any new products or services to market, which may not be available on acceptable terms, if at all.

Delays in obtaining regulatory clearances or approvals for new medical devices, or improvements to or expanded indications for our current offerings, could prevent, delay or adversely impact future product commercialization.

Although the FDA has historically exercised enforcement discretion with regard to certain types of tests – commonly referred to as lab developed tests or LDTs – that are developed by laboratories certified pursuant to federal Clinical Laboratory Improvement Amendments, we may develop new tests that are regulated by the FDA as medical devices. Unless otherwise exempted, medical devices must receive either FDA regulatory approval or clearance before being marketed in the U.S. The FDA determines whether a medical device will require either regulatory approval or clearance based on statutory criteria that include the risk associated with the device and whether the device is similar to an existing, legally marketed product. The process to obtain either regulatory approval or clearance will likely be costly, time-consuming and uncertain. However, we believe the regulatory approval process is generally more challenging than the clearance process. Even if we design a product that we expect to be eligible for the regulatory clearance process, the FDA may require that the product undergo the regulatory approval process. There can be no assurance that the FDA will ever permit us to market any new product that we develop. Even if regulatory approval or clearance is granted, such approval may include significant limitations on indicated uses, which could materially and adversely affect the prospects of any new medical device.

FDA regulatory approval or clearance is not just required for new medical devices we develop, but would also be required for certain enhancements or other changes we may seek to make to our Cologuard test or future FDA-approved or -cleared tests. For example, FDA approval or clearance may be required to make changes to the processes, equipment, reagents and other consumables used in connection with a test. The FDA's pathway to approve or clear changes to tests can be time-consuming and costly and the FDA could ultimately reject our proposed changes. For example, if we develop a multi-cancer test that utilizes Illumina's sequencing platform, we may subsequently determine that it is necessary or preferable to switch sequencing platforms, whether due to potential lack of access (on acceptable terms or at all) to Illumina supplies, the development of a superior sequencing platform, or other reasons. However, switching sequencing platforms would likely require FDA approval or clearance, a process that may entail extensive new clinical trials and material costs and delays and may be ultimately unsuccessful.

Delays in receipt of, or failure to obtain, clearances or approvals could materially delay or prevent us from commercializing our products or result in substantial additional costs that could decrease our profitability. In addition, even if we receive FDA clearance or approval for a new or enhanced product, the FDA may condition, withdraw or materially modify its clearance or approval.

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

In order to settle a potential dispute in the connection with the termination of a former employee (the "Grantee"), in May 2021, we issued 6,007 shares of restricted stock to the Grantee. We believe that the offer and sale of the securities referenced were exempt from registration under the Securities Act of 1933 (the "Securities Act") by virtue of Section 4(a)(2) of the Securities Act and/or Regulation D promulgated thereunder as transactions not involving any public offering. Use of this exemption is based on the following facts:

- Neither we nor any person acting on our behalf solicited any offer to buy or sell securities by any form of general solicitation or advertising.
- The Grantee has had access to information regarding Exact and is knowledgeable about us and our business affairs.
- The shares were issued with a restrictive legend.

Item 3. Defaults Upon Senior Securities

Not applicable.

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information

Not applicable.

Item 6. Exhibits

The following documents are filed as part of this Form 10-Q.

Exhibit Number	Exhibit Description	Filed with This Report	Incorporated by Reference herein from Form or Schedule	Filing Date	SEC File / Registration Number
3.1	Sixth Amended and Restated Certificate of Incorporation of the Registrant		S-1 (Exhibit 3.3)	12/4/2000	333-48812
3.2	Amendment to Sixth Amended and Restated Certificate of Incorporation of the Registrant		8-K (Exhibit 3.1)	7/24/2020	001-35092
3.3	Fifth Amended and Restated By-Laws of the Registrant		8-K (Exhibit 3.1)	3/3/2021	001-35092
31.1	Certification Pursuant to Rule 13(a)-14(a) or Rule 15d-14(a) of Securities Exchange Act of 1934	X			
31.2	Certification Pursuant to Rule 13(a)-14(a) or Rule 15d-14(a) of Securities Exchange Act of 1934	X			
32.1	Certification Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002	X			
101	The following materials from the Quarterly Report on Form 10-Q of Exact Sciences Corporation for the quarter ended June 30, 2021 filed on July 28, 2021, formatted in Inline eXtensible Business Reporting Language (“iXBRL”): (i) Condensed Consolidated Balance Sheets, (ii) Condensed Consolidated Statements of Operations, (iii) Condensed Consolidated Statement of Changes in Stockholders’ Equity, (iv) Condensed Consolidated Statements of Cash Flows and (v) related notes to these financial statements	X			
104	The cover page from our Quarterly Report for the period ended June 30, 2021, filed with the Securities and Exchange Commission on July 28, 2021, is formatted in Inline Extensible Business Reporting Language (“iXBRL”)	X			

SIGNATURES

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

EXACT SCIENCES CORPORATION

Date: July 28, 2021

By: /s/ Kevin T. Conroy

Kevin T. Conroy
President and Chief Executive Officer
(Principal Executive Officer)

Date: July 28, 2021

By: /s/ Jeffrey T. Elliott

Jeffrey T. Elliott
Executive Vice President, Chief Financial Officer and Chief
Operating Officer
(Principal Financial and Accounting Officer)

Certification pursuant to Section 302 of the Sarbanes-Oxley Act of 2002

I, Kevin T. Conroy, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Exact Sciences Corporation (the “registrant”);
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant’s other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - c) Evaluated the effectiveness of the registrant’s disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d) Disclosed in this report any change in the registrant’s internal control over financial reporting that occurred during the registrant’s most recent fiscal quarter (the registrant’s fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant’s internal control over financial reporting; and
5. The registrant’s other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant’s auditors and the audit committee of the registrant’s board of directors (or persons performing the equivalent functions):
 - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant’s ability to record, process, summarize and report financial information; and
 - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant’s internal control over financial reporting.

Date: July 28, 2021

By: /s/ Kevin T. Conroy

Kevin T. Conroy
President and Chief Executive Officer
(Principal Executive Officer)

Certification pursuant to Section 302 of the Sarbanes-Oxley Act of 2002

I, Jeffrey T. Elliott, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Exact Sciences Corporation (the “registrant”);
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant’s other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - c) Evaluated the effectiveness of the registrant’s disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d) Disclosed in this report any change in the registrant’s internal control over financial reporting that occurred during the registrant’s most recent fiscal quarter (the registrant’s fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant’s internal control over financial reporting; and
5. The registrant’s other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant’s auditors and the audit committee of the registrant’s board of directors (or persons performing the equivalent functions):
 - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant’s ability to record, process, summarize and report financial information; and
 - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant’s internal control over financial reporting.

Date: July 28, 2021

By: /s/ Jeffrey T. Elliott

Jeffrey T. Elliott
Executive Vice President, Chief Financial Officer and Chief Operating Officer
(Principal Financial and Accounting Officer)

**CERTIFICATION 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 of Exact Sciences Corporation (the "Company") on Form 10-Q for the quarter ended June 30, 2021 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), we, Kevin T. Conroy, President and Chief Executive Officer of the Company and Jeffrey T. Elliott, 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, to our knowledge, that:

- (1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: July 28, 2021

/s/ Kevin T. Conroy

Name: Kevin T. Conroy
Title: President and Chief Executive Officer
(Principal Executive Officer)

Dated: July 28, 2021

/s/ Jeffrey T. Elliott

Name: Jeffrey T. Elliott
Title: Executive Vice President, Chief Financial Officer and Chief Operating Officer
(Principal Financial Officer and Principal Accounting Officer)